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DRUG ABUSE: THE PHARMACIST

HEARING

BEFORE THE

SUBCOMMITTEE TO INVESTIGATE JUVENILE DELINQUENCY

OF THE

COMMITTEE ON THE JUDICIARY

UNITED STATES SENATE

NINETY-THIRD CONGRESS

SECOND SESSION

PURSUANT TO

S. Res. 255, Section 12

INVESTIGATION OF JUVENILE DELINQUENCY IN THE UNITED STATES

THE COMPREHENSIVE DRUG ABUSE PREVENTION AND CONTROL ACT OF 1970 (P.L. 91-513) AND ITS RELATIONSHIP TO THE PHARMACIST

MARCH 28, 1974

Printed for the use of the Committee on the Judiciary

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DRUG ABUSE: THE PHARMACIST

THURSDAY, MARCH 28, 1974

U.S. SENATE,
SUBCOMMITTEE TO INVESTIGATE JUVENILE DELINQUENCY,
OF THE COMMITTEE ON THE JUDICIARY,
Washington, D.C.

The subcommittee [composed of Senators Bayh, Hart, Burdick, Kennedy, Tunney, Cook, Hruska, Fong and Mathias] met, pursuant to notice, at 10:40 a.m., in room 457, Russell Senate Office Building, Senator Birch Bayh [Chairman of the subcommittee] presiding.

Present: Senator Bayh.

Also present: John M. Rector, staff director and chief counsel; Mary K. Jolly, editorial director and chief clerk; Alice Petrovich, assistant to the chief counsel; Catherine van de Velde, secretary; Peter DiLeo, asistant clerk; Chuck Bruce, Legislative assistant to Senator Hruska; and Pat DeSousa, asistant to Senator Mathias.

Senator BAYH. Our hearing will come to order, with apologies to all of you who are in close proximity to one another here this morning.

We had a different, more ample hearing room guaranteed until yesterday afternoon when one of the other subcommittees decided to meet. Technicalities of the Senate being what they are, that particular room we had belonged to another parent committee rather than our Judiciary Committee, so we got bumped. Because we got bumped yesterday you are rubbing elbows today. I appreciate the tolerance and I am sorry for the inconvenience that some of you are suffering by not having seats.

OPENING STATEMENT OF SENATOR BIRCH BAYH

Today's hearing is the first in a series which we have scheduled to assess the effectiveness of the Nation's drug control laws. In 1969, after conducting hearings on the adequacy of Federal drug control legislation, the subcommittee to investigate juvenile delinquency, with the assistance of many who will testify today, developed a measure which in an amended form became the Comprehensive Drug Abuse Prevention and Control Act of 1970 [Public Law 91-513]. Since 1970 this subcommittee has monitored the implementation of the act and sought to assure that the Federal agencies responsible for its enforcement acted appropriately to curb the illegal importation,

manufacture, distribution, possession and improper use of controlled drugs. This is the oversight function which Senate Committees felt is certainly an important part of our constitutional duties.

We have made considerable progress in the last several years. We have obtained a drastic, but necessary reduction in amphetamine production. We have secured more appropriate control over the production and distribution of other drugs with high abuse potential, including the barbituates and methaqualone.

Although one of the goals we hope to continue this year is to continue the controls of barbituates.

In short, these and similar important steps have effectively reduced illicit traffic and clandestine manufacture of controlled drugs. As a consequence, however, pushers and abusers alike are concentrating their attention on legitimate sources of these drugs, particularly pharmacies.

Pharmacists have always had a special role to fill in the battle against drug traffic and abuse. Through educational efforts they have helped to promote the legitimate use of medicine which when abused presents a danger to the abuser and the community. Through efforts of police carelessness and occasionally unethical colleagues and physicians they have combated the illegitimate use of these drugs. These professionals in the pharmacy business however, urban and rural alike, are today on the frontline of defense.

Department of Justice statistics are alarming. The number of thefts of controlled drugs reported by registrants during the first half of fiscal year 1974 totaled over 3,500 and resulted in the loss of over 14.2 million dosage units of drugs; 85 percent—it is difficult to believe—of all the thefts were from pharmacies and 89 percent of all drugs taken were from pharmacies. Compared to the first half of fiscal year 1973, this constitutes an 18 percent increase—557—in total thefts and a startling 65 percent—up from 57 percent—increase in the percent of all thefts which were from pharmacies. Almost half of the total volume of drugs stolen during these 6 months were amphetamines and barbituates. By far the preferred method of theft, utilized in 2,539—72 percent—of the 3,531 theft incidents, was the night break-in. Armed robbery was the second choice, accounting for an additional 525 thefts. Night break-ins and armed robberies of pharmacies accounted for 89 percent—2,279—and 96 percent—504—respectively of the total incidents of break-ins, burglaries and thefts.

I am particularly concerned about escalating levels of violent crime—burglary, assault, robbery and even murder—committed by criminals attempting to obtain controlled drugs.

Similarly, I am concerned about the far less visible problems of prescription fraud and mail order diversion which both contribute to illicit traffic and abuse of controlled drugs.

We in this committee and I as the chairman of it are interested in an assessment of the 1970 act and its impact on these and related

matters. We are especially interested in learning, from those who are confronted daily with these problems, what we can do to improve the act so that pharmacists can function more fully in their role as a vital link in the health care delivery system while simultaneously fulfilling an equally vital role in the battle to curb drug abuse.

I am appreciative of the cooperation of the organized pharmacy who are scheduled to testify today. Their appearances indicate a willingness to once again work with the subcommittee to meet the challenge of ever-changing and increasingly complex patterns of illegal drug traffic and abuse. These witnesses are uniquely qualified to discuss the impact of the 1970 act and its relationship to the practicing pharmacists. I look forward to a productive and informative session.

I should say, as the committee has studied the entire drug problem, we found that really getting on top of drug abuse and stopping addiction and all that means to our society is very much like trying to deal with the air and pollution. If you stick to one place it moves on to someplace else. So we have had the initial approach to heroin and similarly imported illicit drugs, traffic moving to the legally produced yet illicitly acquired and used drugs which are produced by some of those reputable pharmacies, pharmaceutical firms and dispensed by pharmacists. So our effort has to be, as we try to control production now with some success, to find out from those of you who are in the business of distributing these worthwhile products, when used properly, what we can do to help you, our law enforcement officers, and doctors to stop that one particular part of the problem, which, as I mentioned earlier, has shown a large increase.

We have today a very prestigious panel, led by Mr. Harold Shinnick, president, National Association of Retail Druggists, Chicago, accompanied by William E. Woods, associate general counsel, NARD, David Clark, the executive director of the Indiana Pharmaceutical Association who I should welcome personally to the committee I had a chance to visit Mr. Clark earlier.

Mr. Ivan Rose of Arkansas, the past president. I should say publicly on the record that Senator McClellan offered to be here and unfortunately for all of us the Appropriations Committee has a hearing which he will Chair. Mr. Johnsen, the first vice president and president-elect of the Nebraska Pharmaceutical Association.

Gentlemen, you have the floor. We appreciate very much your courtesy in being here and look forward to your testimony.

At this point in the record I would like to insert the text of the subcommittee's enabling resolution, S.Res. 255, section 12 and the text of Public Law 91-513, the Comprehensive Drug Abuse Prevention and Control Act of 1970.

[The documents were marked "Exhibit No. 1 and 2" respectively and are as follows:]

EXHIBIT NO. 1

93D CONGRESS
2D SESSION

S. RES. 255

[Report No. 93–714]

IN THE SENATE OF THE UNITED STATES

JANUARY 30, 1974

Mr. EASTLAND, from the Committee on the Judiciary, reported the following resolution; which was referred to the Committee on Rules and Administration

FEBRUARY 28, 1974

Reported by Mr. CANNON, with amendments

MARCH 1, 1974

Considered, amended, and agreed to

RESOLUTION

Authorizing additional expenditures by the Committee on the Judiciary for inquiries and investigations.

Resolved, That in holding hearings, reporting such hearings, and making investigations as authorized by sections 134(a) and 136 of the Legislative Reorganization Act of 1946, as amended, and in accordance with its jurisdiction under rule XXV of the Standing Rules of the Senate so far as applicable, the Committee on the Judiciary, or any subcommittee thereof, is authorized from March 1, 1974, through February 28, 1975, for the purposes stated and within the limitations imposed by the following sections, in its discretion (1) to make expenditures from the contingent

fund of the Senate, (2) to employ personnel, and (3) with the prior consent of the Government department or agency concerned and the Committee on Rules and Administration, to use on a reimbursable basis the services or personnel of any such department or agency.

SEC. 2. The Committee on the Judiciary, or any subcommittee thereof, is authorized from March 1, 1974, through February 28, 1975, to expend not to exceed $4,073,000 to examine, investigate, and make a complete study of any and all matters pertaining to each of the subjects set forth below in succeeding sections of this resolution, said funds to be allocated to the respective specific inquiries and to the procurement of the services of individual consultants or organizations thereof (as authorized by section 202 (i) of the Legislative Reorganization Act of 1946, as amended) in accordance with succeeding sections of this resolution.

SEC. 3. Not to exceed $377,800 shall be available for a study or investigation of administrative practice and procedure, of which amount not to exceed $5,000 may be expended for the procurement of individual consultants or organizations thereof.

SEC. 4. Not to exceed $767,000 shall be available for a study or investigation of antitrust and monopoly, of which amount not to exceed $10,000 may be expended for the procurement of individual consultants or organizations thereof.

SEC. 5. Not to exceed $252,000 shall be available for a study or investigation of constitutional amendments, of which amount not to exceed $12,000 may be expended for the procurement of individual consultants or organizations thereof.

SEC. 6. Not to exceed $299,900 shall be available for a study or investigation of constitutional rights, of which amount not to exceed $10,000 may be expended for the procurement of individual consultants or organizations thereof.

SEC. 7. Not to exceed $221,000 shall be available for a study or investigation of criminal laws and procedures, of which amount not to exceed $5,000 may be expended for the procurement of individual consultants or organizations thereof.

SEC. 8. Not to exceed $16,500 shall be available for a study or investigation of Federal charters, holidays, and celebrations.

SEC. 9. Not to exceed $205,000 shall be available for a study or investigation of immigration and naturalization.

SEC. 10. Not to exceed $35,000 shall be available for a study or investigation of improvements in judicial machinery, of which amount not to exceed $10,000 may be expended for the procurement of individual consultants or organizations thereof.

SEC. 11. Not to exceed $400,000 shall be available for a complete and continuing study and investigation of (1) the administration, operation, and enforcement of the Internal Security Act of 1950, as amended, (2) the administration, operation, and enforcement of other laws relating to espionage, sabotage, and the protection of the internal security of the United States, and (3) the extent, nature, and effect of subversive activities in the United States, its territories and possessions, including, but not limited to, espionage, sabotage, and infiltration by persons who are or may be under the domination of the foreign government or organization controlling the world Communist movement or any other movement seeking to overthrow the Government of the United States by force and violence or otherwise threatening the internal security of the United States.

SEC. 12. Not to exceed $353,000 shall be available for a study or investigation of juvenile delinquency, of which amount not to exceed $14,000 may be expended for the procurement of individual consultants or organizations thereof.

SEC. 13. Not to exceed $178,000 shall be available for a study or investigation of patents, trademarks, and copyrights.

SEC. 14. Not to exceed $88,000 shall be available for a study or investigation of national penitentiaries, of which

amount not to exceed $500 may be expended for the procurement of individual consultants or organizations thereof.

SEC. 15. Not to exceed $182,000 shall be available for a study or investigation of refugees and escapees, of which amount not to exceed $2,000 may be expended for the procurement of individual consultants or organizations thereof.

SEC. 16. Not to exceed $64,800 shall be available for a study or investigation of revision and codification.

SEC. 17. Not to exceed $263,000 shall be available for a study or investigation of separation of powers between the executive, judicial, and legislative branches of Government, of which amount not to exceed $12,000 may be expended for the procurement of individual consultants or organizations thereof.

SEC. 18. Not to exceed $150,000 shall be available for a study or investigation of citizens' interests, of which amount not to exceed $5,000 may be expended for the procurement of individual consultants or organizations thereof.

SEC. 19. Not to exceed $20,000 shall be available for a study or investigation of Federal Bureau of Investigation oversight.

SEC. 20. The committee shall report its findings, together with such recommendations for legislation as it deems advisable with respect to each study or investigation for

which expenditure is authorized by this resolution, to the Senate at the earliest practicable date, but not later than February 28, 1975.

SEC. 21. Expenses of the committee under this resolution shall be paid from the contingent fund of the Senate upon vouchers approved by the chairman of the committee.

EXHIBIT No. 2

Public Law 91-513
91st Congress, H. R. 18583
October 27, 1970

An Act

84 STAT. 1236

To amend the Public Health Service Act and other laws to provide increased research into, and prevention of, drug abuse and drug dependence; to provide for treatment and rehabilitation of drug abusers and drug dependent persons; and to strengthen existing law enforcement authority in the field of drug abuse.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Comprehensive Drug Abuse Prevention and Control Act of 1970". Comprehensive Drug Abuse Prevention and Control Act of 1970.

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84 STAT. 1237

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TITLE I—REHABILITATION PROGRAMS RELATING TO DRUG ABUSE

PROGRAMS UNDER COMMUNITY MENTAL HEALTH CENTERS ACT RELATING TO DRUG ABUSE

SECTION 1. (a) Part D of the Community Mental Health Centers Act is amended as follows:

(1) Sections 251, 252, and 253 of such part (42 U.S.C. 2688k, 2688l, and 2688m) are each amended by inserting "and other persons with drug abuse and drug dependence problems" immediately after "narcotic addicts" each place those words appear in those sections. 82 Stat. 1009.

(2) Clauses (A) and (C) of section 252 of such part are each amended by inserting ", drug abuse, and drug dependence" immediately after "narcotic addiction".

(3) The heading for such part is amended to read as follows:

"PART D—NARCOTIC ADDICTION, DRUG ABUSE, AND DRUG DEPENDENCE PREVENTION AND REHABILITATION".

(b) Part E of such Act is amended as follows:

(1) Section 261(a) of such part (42 U.S.C. 2688o) is amended by striking out "$30,000,000 for the fiscal year ending June 30, 1971, $35,000,000 for the fiscal year ending June 30, 1972, and $40,000,000 for the fiscal year ending June 30, 1973" and inserting in lieu thereof "$40,000,000 for the fiscal year ending June 30, 1971, $60,000,000 for the fiscal year ending June 30, 1972, and $80,000,000 for the fiscal year ending June 30, 1973". 82 Stat. 1010; Ante, p. 57.

(2) Section 261(a) of such part is further amended by inserting ", drug abuse, and drug dependence" immediately after "narcotic addiction".

(3) Sections 261(c) and 264 are each amended by inserting "and other persons with drug abuse and drug dependence problems" immediately after "narcotic addicts". Ante, pp. 58, 61.

(4) The section headings for sections 261 and 263 are each amended by striking out "AND NARCOTIC ADDICTS" and inserting in lieu thereof ", NARCOTIC ADDICTS, AND OTHER PERSONS WITH DRUG ABUSE AND DRUG DEPENDENCE PROBLEMS".

(c) Part D of such Act is further amended by redesignating sections 253 and 254 as sections 254 and 255, respectively, and by adding after section 252 the following new section: 42 USC 2688n.

"DRUG ABUSE EDUCATION

"SEC. 253. (a) The Secretary is authorized to make grants to States and political subdivisions thereof and to public or nonprofit private agencies and organizations, and to enter into contracts with other private agencies and organizations, for— Grants. Contract authority.

"(1) the collection, preparation, and dissemination of educational materials dealing with the use and abuse of drugs and the prevention of drug abuse, and

"(2) the development and evaluation of programs of drug abuse education directed at the general public, school-age children, and special high-risk groups.

"(b) The Secretary, acting through the National Institute of Mental Health, shall (1) serve as a focal point for the collection and dissemination of information related to drug abuse; (2) collect, prepare, and disseminate materials (including films and other educational devices) dealing with the abuse of drugs and the prevention of drug abuse; (3) provide for the preparation, production, and conduct of programs of public education (including those using films and other educational devices); (4) train professional and other persons to organize and participate in programs of public education in relation to drug abuse; (5) coordinate activities carried on by such departments, agencies, and instrumentalities of the Federal Government as he shall designate with respect to health education aspects of drug abuse; (6) provide technical assistance to State and local health and educational agencies with respect to the establishment and implementation of programs and procedures for public education on drug abuse; and (7) undertake other activities essential to a national program for drug abuse education. 77 Stat. 291; 81 Stat. 79. 42 USC 2684.

Personnel training.

"(c) The Secretary, acting through the National Institute of Mental Health, is authorized to develop and conduct workshops, institutes, and other activities for the training of professional and other personnel to work in the area of drug abuse education.

Appropriation.

"(d) To carry out the purposes of this section, there are authorized to be appropriated $3,000,000 for the fiscal year ending June 30, 1971, $12,000,000 for the fiscal year ending June 30, 1972, and $14,000,000 for the fiscal year ending June 30, 1973."

(d) Such part D is further amended by adding at the end thereof the following new section: 82 Stat. 1009; Ante, p.1238. 42 USC 2688k.

"SPECIAL PROJECTS FOR NARCOTIC ADDICTS AND DRUG DEPENDENT PERSONS

Grants, treatment and rehabilitation.

"SEC. 256. (a) The Secretary is authorized to make grants to public or nonprofit private agencies and organizations to cover a portion of the costs of programs for treatment and rehabilitation of narcotic addicts or drug dependent persons which include one or more of the following: (1) Detoxification services or (2) institutional services (including medical, psychological, educational, or counseling services) or (3) community-based aftercare services.

Conditions.

"(b) Grants under this section for the costs of any treatment and rehabilitation program—

"(1) may be made only for the period beginning with the first day of the first month for which such a grant is made and ending with the close of eight years after such first day; and

Limitation.

"(2)(A) except as provided in subparagraph (B), may not exceed 80 per centum of such costs for each of the first two years after such first day, 75 per centum of such costs for the third year after such first day, 60 per centum of such costs for the fourth year after such first day, 45 per centum of such costs for the fifth year after such first day, and 30 per centum of such costs for each of the next three years after such first day; and

"(B) in the case of any such program providing services for persons in an area designated by the Secretary as an urban or rural poverty area, such grants may not exceed 90 per centum of such costs for each of the first two years after such first day, 80 per centum of such costs for the third year after such first day, 75 per centum of such costs for the fourth and fifth years after such first day, and 70 per centum of such costs for each of the next three years after such first day.

"(c) No application for a grant authorized by this section shall be approved by the Secretary unless such application is forwarded through the State agency responsible for administering the plan submitted pursuant to section 204 of this Act or, if there be a separate State agency, designated by the Governor as responsible for planning, coordinating, and executing the State's efforts in the treatment and

rehabilitation of narcotic addicts and drug dependent persons, through such latter agency, which shall submit to the Secretary such comments as it deems appropriate. No application for a grant under this section for a program to provide services for persons in an area in which is located a facility constructed as a new facility after the date of enactment of this section with funds provided under a grant under part A or this part shall be approved unless such application contains satisfactory assurance that, to the extent feasible, such program will be included as part of the programs conducted in or through such facility.

"(d) The Secretary shall make grants under this section for projects within the States in accordance with criteria determined by him designed to provide priority for grant applications in States, and in areas within the States, having the higher percentages of population who are narcotic addicts or drug dependent persons. Criteria.

"(e) There are authorized to be appropriated to carry out this section not to exceed $20,000,000 for the fiscal year ending June 30, 1971; $30,000,000 for the fiscal year ending June 30, 1972; and $35,000,000 for the fiscal year ending June 30, 1973." Appropriation.

BROADER TREATMENT AUTHORITY IN PUBLIC HEALTH SERVICE HOSPITALS FOR PERSONS WITH DRUG ABUSE AND OTHER DRUG DEPENDENCE PROBLEMS

SEC. 2. (a) Part E of title III of the Public Health Service Act is amended as follows:

(1) Section 341(a) of such part is amended by adding immediately after "addicts" the second time it appears the following: "and other persons with drug abuse and drug dependence problems". 80 Stat. 1449. 42 USC 257.

(2)(A) Sections 342, 343, 344, and 346 of such part are each amended by inserting "or other persons with drug abuse and drug dependence problems" immediately after "addicts" each place it appears in those sections. 58 Stat. 699; 68 Stat. 79. 42 USC 258-260, 261.

(B) The section heading of section 342 of such part is amended by inserting "OR OTHER PERSONS WITH DRUG ABUSE AND DRUG DEPENDENCE PROBLEMS" after "ADDICTS".

(3) Sections 343 and 344 of such part are each amended by inserting "or other person with a drug abuse or other drug dependence problem" immediately after "addict" each place it appears in those sections.

(4) Sections 343, 344, and 347 of such part are each amended by inserting ", drug abuse, or drug dependence" immediately after "addiction" each place it appears in those sections. 42 USC 261a.

(5) Section 346 of such part is amended by inserting "or substance controlled under the Controlled Substances Act" immediately after "habit-forming narcotic drug". Post, p. 1242.

(6) The heading for such part is amended to read as follows:

"PART E—NARCOTIC ADDICTS AND OTHER DRUG ABUSERS".

(b) Section 2 of the Public Health Service Act (42 U.S.C. 201) is amended by adding after paragraph (p) the following new paragraph: 58 Stat. 682; 74 Stat. 34.

"(q) The term 'drug dependent person' means a person who is using a controlled substance (as defined in section 102 of the Controlled Substances Act) and who is in a state of psychic or physical dependence, or both, arising from the use of that substance on a continuous basis. Drug dependence is characterized by behavioral and other responses which include a strong compulsion to take the substance on a continuous basis in order to experience its psychic effects or to avoid the discomfort caused by its absence." Post, p. 1243.

RESEARCH UNDER THE PUBLIC HEALTH SERVICE ACT IN DRUG USE, ABUSE, AND ADDICTION

Research populations, protection of identity. 70 Stat. 929.

SEC. 3. (a) Section 303(a) of the Public Health Service Act (42 U.S.C. 242a(a)) is amended by adding after and below paragraph (2) the following:

"The Secretary may authorize persons engaged in research on the use and effect of drugs to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."

80 Stat. 1184. 42 USC 246.

(b) Section 314(d)(2) of the Public Health Service Act is amended—

(1) by striking out "and" at the end of subparagraph (I);

(2) by striking out the period at the end of subparagraph (J) and inserting in lieu thereof "; and"; and

(3) by adding after subparagraph (J) the following new subparagraph:

"(K) provide for services for the prevention and treatment of drug abuse and drug dependence, commensurate with the extent of the problem."

81 Stat. 79.

(c) Section 507 of the Public Health Service Act (42 U.S.C. 225a) is amended—

(1) by striking out "available for research, training, or demonstration project grants pursuant to this Act" and inserting in lieu thereof "available under this Act for research, training, or demonstration project grants or for grants to expand existing treatment and research programs and facilities for alcoholism, narcotic addiction, drug abuse, and drug dependence, and appropriations available under the Community Mental Health Centers Act for construction and staffing of community mental health centers and alcoholism and narcotic addiction, drug abuse, and drug dependence facilities", and

77 Stat. 190. 42 USC 2681 note.

(2) by inserting immediately before the period at the end thereof the following: ", except that grants to such Federal institutions may be funded at 100 per centum of the costs".

MEDICAL TREATMENT OF NARCOTIC ADDICTION

SEC. 4. The Secretary of Health, Education, and Welfare, after consultation with the Attorney General and with national organizations representative of persons with knowledge and experience in the treatment of narcotic addicts, shall determine the appropriate methods of professional practice in the medical treatment of the narcotic addiction of various classes of narcotic addicts, and shall report thereon from time to time to the Congress. Report to Congress.

TITLE II—CONTROL AND ENFORCEMENT

PART A—SHORT TITLE; FINDINGS AND DECLARATION; DEFINITIONS

SHORT TITLE

SEC. 100. This title may be cited as the "Controlled Substances Act". Citation of title.

FINDINGS AND DECLARATIONS

SEC. 101. The Congress makes the following findings and declarations:

(1) Many of the drugs included within this title have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people.

(2) The illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people.

(3) A major portion of the traffic in controlled substances flows through interstate and foreign commerce. Incidents of the traffic which are not an integral part of the interstate or foreign flow, such as manufacture, local distribution, and possession, nonetheless have a substantial and direct effect upon interstate commerce because—

(A) after manufacture, many controlled substances are transported in interstate commerce,

(B) controlled substances distributed locally usually have been transported in interstate commerce immediately before their distribution, and

(C) controlled substances possessed commonly flow through interstate commerce immediately prior to such possession.

(4) Local distribution and possession of controlled substances contribute to swelling the interstate traffic in such substances.

(5) Controlled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate. Thus, it is not feasible to distinguish, in terms of controls, between controlled substances manufactured and distributed interstate and controlled substances manufactured and distributed intrastate.

(6) Federal control of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic.

(7) The United States is a party to the Single Convention on Narcotic Drugs, 1961, and other international conventions designed to establish effective control over international and domestic traffic in controlled substances. 18 UST 1407.

DEFINITIONS

SEC. 102. As used in this title:

(1) The term "addict" means any individual who habitually uses any narcotic drug so as to endanger the public morals, health, safety, or welfare, or who is so far addicted to the use of narcotic drugs as to have lost the power of self-control with reference to his addiction.

(2) The term "administer" refers to the direct application of a controlled substance to the body of a patient or research subject by—

(A) a practitioner (or, in his presence, by his authorized agent), or

(B) the patient or research subject at the direction and in the presence of the practitioner,

whether such application be by injection, inhalation, ingestion, or any other means.

(3) The term "agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser; except that such term does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman, when acting in the usual and lawful course of the carrier's or warehouseman's business.

(4) The term "Bureau of Narcotics and Dangerous Drugs" means the Bureau of Narcotics and Dangerous Drugs in the Department of Justice.

(5) The term "control" means to add a drug or other substance, or immediate precursor, to a schedule under part B of this title, whether by transfer from another schedule or otherwise. Post, p. 1247.

(6) The term "controlled substance" means a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of this title. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1954. 68A Stat. 515; 26 USC 5001.

(7) The term "counterfeit substance" means a controlled substance which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number, or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person or persons who in fact manufactured, distributed, or dispensed such substance and which thereby falsely purports or is represented to be the product of, or to have been distributed by, such other manufacturer, distributor, or dispenser.

(8) The terms "deliver" or "delivery" mean the actual, constructive, or attempted transfer of a controlled substance, whether or not there exists an agency relationship.

(9) The term "depressant or stimulant substance" means—

(A) a drug which contains any quantity of (i) barbituric acid or any of the salts of barbituric acid; or (ii) any derivative of barbituric acid which has been designated by the Secretary as habit forming under section 502(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(d)); or 52 Stat. 1050.

(B) a drug which contains any quantity of (i) amphetamine or any of its optical isomers; (ii) any salt of amphetamine or any salt of an optical isomer of amphetamine; or (iii) any substance which the Attorney General, after investigation, has found to be, and by regulation designated as, habit forming because of its stimulant effect on the central nervous system; or

(C) lysergic acid diethylamide; or

(D) any drug which contains any quantity of a substance which the Attorney General, after investigation, has found to have, and by regulation designated as having, a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect.

(10) The term "dispense" means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

(11) The term "distribute" means to deliver (other than by administering or dispensing) a controlled substance. The term "distributor" means a person who so delivers a controlled substance.

(12) The term "drug" has the meaning given that term by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act. 52 Stat. 1041; 76 Stat. 784. 21 USC 321.

(13) The term "felony" means any Federal or State offense classified by applicable Federal or State law as a felony.

(14) The term "manufacture" means the production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of such substance or labeling or relabeling of its container; except that such term does not include the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice. The term "manufacturer" means a person who manufactures a drug or other substance.

(15) The term "marihuana" means all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.

(16) The term "narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(A) Opium, coca leaves, and opiates.

(B) A compound, manufacture, salt, derivative, or preparation of opium, coca leaves, or opiates.

(C) A substance (and any compound, manufacture, salt, derivative, or preparation thereof) which is chemically identical with any of the substances referred to in clause (A) or (B).

Such term does not include decocainized coca leaves or extracts of coca leaves, which extracts do not contain cocaine or ecgonine.

(17) The term "opiate" means any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability.

(18) The term "opium poppy" means the plant of the species Papaver somniferum L., except the seed thereof.

(19) The term "poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

(20) The term "practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

(21) The term "production" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.

(22) The term "immediate precursor" means a substance—

(A) which the Attorney General has found to be and by regulation designated as being the principal compound used, or produced primarily for use, in the manufacture of a controlled substance;

(B) which is an immediate chemical intermediary used or likely to be used in the manufacture of such controlled substance; and

(C) the control of which is necessary to prevent, curtail, or limit the manufacture of such controlled substance.

(23) The term "Secretary", unless the context otherwise indicates, means the Secretary of Health, Education, and Welfare.

(24) The term "State" means any State, territory, or possession of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Trust Territory of the Pacific Islands, and the Canal Zone.

(25) The term "ultimate user" means a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.

(26) The term "United States", when used in a geographic sense, means all places and waters, continental or insular, subject to the jurisdiction of the United States.

INCREASED NUMBERS OF ENFORCEMENT PERSONNEL

SEC. 103. (a) During the fiscal year 1971, the Bureau of Narcotics and Dangerous Drugs is authorized to add at least 300 agents, together with necessary supporting personnel, to the number of enforcement personnel currently available to it.

Appropriation.

(b) There are authorized to be appropriated not to exceed $6,000,000 for the fiscal year 1971 and for each fiscal year thereafter to carry out the provisions of subsection (a).

PART B—AUTHORITY TO CONTROL; STANDARDS AND SCHEDULES

AUTHORITY AND CRITERIA FOR CLASSIFICATION OF SUBSTANCES

SEC. 201. (a) The Attorney General shall apply the provisions of this title to the controlled substances listed in the schedules established by section 202 of this title and to any other drug or other substance added to such schedules under this title. Except as provided in subsections (d) and (e), the Attorney General may by rule—

(1) add to such a schedule or transfer between such schedules any drug or other substance if he—

(A) finds that such drug or other substance has a potential for abuse, and

(B) makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 202 for the schedule in which such drug is to be placed; or

(2) remove any drug or other substance from the schedules if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule.

Hearing opportunity. Rules. 60 Stat. 381. 5 USC 551.

Rules of the Attorney General under this subsection shall be made on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by subchapter II of chapter 5 of title 5 of the United States Code. Proceedings for the issuance, amendment, or

repeal of such rules may be initiated by the Attorney General (1) on his own motion, (2) at the request of the Secretary, or (3) on the petition of any interested party.

Evaluation.

(b) The Attorney General shall, before initiating proceedings under subsection (a) to control a drug or other substance or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance. In making such evaluation and recommendations, the Secretary shall consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of subsection (c) and any scientific or medical considerations involved in paragraphs (1), (4), and (5) of such subsection. The recommendations of the Secretary shall include recommendations with respect to the appropriate schedule, if any, under which such drug or other substance should be listed. The evaluation and the recommendations of the Secretary shall be made in writing and submitted to the Attorney General within a reasonable time. The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance. If the Attorney General determines that these facts and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or substantial evidence that the drug or other substance should be removed entirely from the schedules, he shall initiate proceedings for control or removal, as the case may be, under subsection (a).

(c) In making any finding under subsection (a) of this section or under subsection (b) of section 202, the Attorney General shall consider the following factors with respect to each drug or other substance proposed to be controlled or removed from the schedules:

(1) Its actual or relative potential for abuse.
(2) Scientific evidence of its pharmacological effect, if known.
(3) The state of current scientific knowledge regarding the drug or other substance.
(4) Its history and current pattern of abuse.
(5) The scope, duration, and significance of abuse.
(6) What, if any, risk there is to the public health.
(7) Its psychic or physiological dependence liability.
(8) Whether the substance is an immediate precursor of a substance already controlled under this title.

Order.

(d) If control is required by United States obligations under international treaties, conventions, or protocols in effect on the effective date of this part, the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by subsection (a) of this section or section 202(b) and without regard to the procedures prescribed by subsections (a) and (b) of this section.

(e) The Attorney General may, without regard to the findings required by subsection (a) of this section or section 202(b) and without regard to the procedures prescribed by subsections (a) and (b) of this section, place an immediate precursor in the same schedule in which the controlled substance of which it is an immediate precursor is placed or in any other schedule with a higher numerical designation. If the Attorney General designates a substance as an immediate precursor and places it in a schedule, other substances shall not be placed in a schedule solely because they are its precursors.

(f) If, at the time a new-drug application is submitted to the Secretary for any drug having a stimulant, depressant, or hallucinogenic effect on the central nervous system, it appears that such drug has an abuse potential, such information shall be forwarded by the Secretary to the Attorney General.

52 Stat. 1040. 21 USC 321.

Dextromethorphan, exception.

(g)(1) The Attorney General shall by regulation exclude any nonnarcotic substance from a schedule if such substance may, under the Federal Food, Drug, and Cosmetic Act, be lawfully sold over the counter without a prescription.

(2) Dextromethorphan shall not be deemed to be included in any schedule by reason of enactment of this title unless controlled after the date of such enactment pursuant to the foregoing provisions of this section.

SCHEDULES OF CONTROLLED SUBSTANCES

Establishment.

SEC. 202. (a) There are established five schedules of controlled substances, to be known as schedules I, II, III, IV, and V. Such schedules shall initially consist of the substances listed in this section. The schedules established by this section shall be updated and republished on a semiannual basis during the two-year period beginning one year after the date of enactment of this title and shall be updated and republished on an annual basis thereafter.

Placement on schedules, findings required.

(b) Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on the effective date of this part, and except in the case of an immediate precursor, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance. The findings required for each of the schedules are as follows:

(1) SCHEDULE I.—
(A) The drug or other substance has a high potential for abuse.
(B) The drug or other substance has no currently accepted medical use in treatment in the United States.
(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

(2) SCHEDULE II.—
(A) The drug or other substance has a high potential for abuse.
(B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.
(C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.

(3) SCHEDULE III.—
(A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.
(B) The drug or other substance has a currently accepted medical use in treatment in the United States.
(C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

(4) SCHEDULE IV.—
(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.
(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

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(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

(5) SCHEDULE V.—

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

(c) Schedules I, II, III, IV, and V shall, unless and until amended pursuant to section 201, consist of the following drugs or other substances, by whatever official name, common or usual name, chemical name, or brand name designated:

SCHEDULE I

Opiates.

(a) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Acetylmethadol.
(2) Allylprodine.
(3) Alphacetylmathadol.
(4) Alphameprodine.
(5) Alphamethadol.
(6) Benzethidine.
(7) Betacetylmethadol.
(8) Betameprodine.
(9) Betamethadol.
(10) Betaprodine.
(11) Clonitazene.
(12) Dextromoramide.
(13) Dextrorphan.
(14) Diampromide.
(15) Diethylthiambutene.
(16) Dimenoxadol.
(17) Dimepheptanol.
(18) Dimethylthiambutene.
(19) Dioxaphetyl butyrate.
(20) Dipipanone.
(21) Ethylmethylthiambutene.
(22) Etonitazene.
(23) Etoxeridine.
(24) Furethidine.
(25) Hydroxypethidine.
(26) Ketobemidone.
(27) Levomoramide.
(28) Levophenacylmorphan.
(29) Morpheridine.
(30) Noracymethadol.
(31) Norlevorphanol.
(32) Normethadone.
(33) Norpipanone.
(34) Phenadoxone.
(35) Phenampromide.

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(36) Phenomorphan.
(37) Phenoperidine.
(38) Piritramide.
(39) Proheptazine.
(40) Properidine.
(41) Racemoramide.
(42) Trimeperidine.

Opium derivatives.

(b) Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Acetorphine.
(2) Acetyldihydrocodeine.
(3) Benzylmorphine.
(4) Codeine methylbromide.
(5) Codeine-N-Oxide.
(6) Cyprenorphine.
(7) Desomorphine.
(8) Dihydromorphine.
(9) Etorphine.
(10) Heroin.
(11) Hydromorphinol.
(12) Methyldesorphine.
(13) Methylhydromorphine.
(14) Morphine methylbromide.
(15) Morphine methylsulfonate.
(16) Morphine-N-Oxide.
(17) Myrophine.
(18) Nicocodeine.
(19) Nicomorphine.
(20) Normorphine.
(21) Pholcodine.
(22) Thebacon.

Hallucinogenic substances.

(c) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) 3,4-methylenedioxy amphetamine.
(2) 5-methoxy-3,4-methylenedioxy amphetamine.
(3) 3,4,5-trimethoxy amphetamine.
(4) Bufotenine.
(5) Diethyltryptamine.
(6) Dimethyltryptamine.
(7) 4-methyl-2,5-dimethoxyamphetamine.
(8) Ibogaine.
(9) Lysergic acid diethylamide.
(10) Marihuana.
(11) Mescaline.
(12) Peyote.
(13) N-ethyl-3-piperidyl benzilate.
(14) N-methyl-3-piperidyl benzilate.
(15) Psilocybin.
(16) Psilocyn.
(17) Tetrahydrocannabinols.

SCHEDULE II

Substances, vegetable origin or chemical synthesis.

(a) Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.

(2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (1), except that these substances shall not include the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) Coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine.

Opiates.

(b) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Alphaprodine.
(2) Anileridine.
(3) Bezitramide.
(4) Dihydrocodeine.
(5) Diphenoxylate.
(6) Fentanyl.
(7) Isomethadone.
(8) Levomethorphan.
(9) Levorphanol.
(10) Metazocine.
(11) Methadone.
(12) Methadone-Intermediate, 4-cyano - 2 - dimethylamino-4,4-diphenyl butane.
(13) Moramide-Intermediate, 2 - methyl - 3 - morpholino-1, 1-diphenylpropane-carboxylic acid.
(14) Pethidine.
(15) Pethidine-Intermediate-A, 4 - cyano-1-methyl-4-phenylpiperidine.
(16) Pethidine-Intermediate-B, ethyl - 4-phenylpiperidine-4-carboxylate.
(17) Pethidine-Intermediate-C, 1-methyl - 4 - phenylpiperidine-4-carboxylic acid.
(18) Phenazocine.
(19) Piminodine.
(20) Racemethorphan.
(21) Racemorphan.

Methamphetamine.

(c) Unless specifically excepted or unless listed in another schedule, any injectable liquid which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.

SCHEDULE III

Stimulants.

(a) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers.
(2) Phenmetrazine and its salts.
(3) Any substance (except an injectable liquid) which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.
(4) Methylphenidate.

Depressants.

(b) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid.
(2) Chorhexadol.
(3) Glutethimide.
(4) Lysergic acid.
(5) Lysergic acid amide.
(6) Methyprylon.
(7) Phencyclidine.
(8) Sulfondiethylmethane.
(9) Sulfonethylmethane.
(10) Sulfonmethane.

Nalorphine.

(c) Nalorphine.

Narcotic drugs.

(d) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof:

(1) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.
(2) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
(3) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.
(4) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
(5) Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(6) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(7) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(8) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

SCHEDULE IV

(1) Barbital.
(2) Chloral betaine.
(3) Chloral hydrate.
(4) Ethchlorvynol.
(5) Ethinamate.
(6) Methohexital.
(7) Meprobamate.
(8) Methylphenobarbital.
(9) Paraldehyde.
(10) Petrichloral.
(11) Phenobarbital.

SCHEDULE V

Narcotic drugs containing nonnarcotic active medicinal ingredients.

Any compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

(1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.

(2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.

(3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.

(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.

(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.

Stimulants or depressants containing active medicinal ingredients, exception.

(d) The Attorney General may by regulation except any compound, mixture, or preparation containing any depressant or stimulant substance in paragraph (a) or (b) of schedule III or in schedule IV or V from the application of all or any part of this title if (1) the compound, mixture, or preparation contains one or more active medicinal ingredients not having a depressant or stimulant effect on the central nervous system, and (2) such ingredients are included therein in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse of the substances which do have a depressant or stimulant effect on the central nervous system.

PART C—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

RULES AND REGULATIONS

Rules and regulations.

SEC. 301. The Attorney General is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances.

PERSONS REQUIRED TO REGISTER

Annual registration.

SEC. 302. (a) Every person who manufactures, distributes, or dispenses any controlled substance or who proposes to engage in the manufacture, distribution, or dispensing of any controlled substance, shall obtain annually a registration issued by the Attorney General in accordance with the rules and regulations promulgated by him.

(b) Persons registered by the Attorney General under this title to manufacture, distribute, or dispense controlled substances are authorized to possess, manufacture, distribute, or dispense such substances (including any such activity in the conduct of research) to the extent authorized by their registration and in conformity with the other provisions of this title.

Registration, exceptions.

(c) The following persons shall not be required to register and may lawfully possess any controlled substance under this title:

(1) An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance if such agent or employee is acting in the usual course of his business or employment.

(2) A common or contract carrier or warehouseman, or an employee thereof, whose possession of the controlled substance is in the usual course of his business or employment.

Ante, p. 1245.

(3) An ultimate user who possesses such substance for a purpose specified in section 102(25).

Waiver.

(d) The Attorney General may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and safety.

Separate registration.

(e) A separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances.

Inspection.

(f) The Attorney General is authorized to inspect the establishment of a registrant or applicant for registration in accordance with the rules and regulations promulgated by him.

REGISTRATION REQUIREMENTS

Factors consistent with public interest.

SEC. 303. (a) The Attorney General shall register an applicant to manufacture controlled substances in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on the effective date of this part. In determining the public interest, the following factors shall be considered:

Controls, Importation and bulk manufacture, limitation.

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately com-

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petitive conditions for legitimate medical, scientific, research, and industrial purposes;

(2) compliance with applicable State and local law; Compliance.

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances; Technology.

(4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances; Applicants, prior conviction record.

(5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and Experience.

(6) such other factors as may be relevant to and consistent with the public health and safety.

(b) The Attorney General shall register an applicant to distribute a controlled substance in schedule I or II unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered: Factors consistent to public interest.

(1) maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(c) Registration granted under subsections (a) and (b) of this section shall not entitle a registrant to (1) manufacture or distribute controlled substances in schedule I or II other than those specified in the registration, or (2) manufacture any quantity of those controlled substances in excess of the quota assigned pursuant to section 306. Prohibition.

Post, p. 1257.

(d) The Attorney General shall register an applicant to manufacture controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule III, IV, or V compounded therefrom into other than legitimate medical, scientific, or industrial channels;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture, distribution, and dispensing of controlled substances, and the existence in the establishment of effective controls against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(e) The Attorney General shall register an applicant to distribute controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

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(1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

Research. (f) Practitioners shall be registered to dispense or conduct research with controlled substances in schedule II, III, IV, or V if they are authorized to dispense or conduct research under the law of the State in which they practice. Separate registration under this part for practitioners engaging in research with nonnarcotic controlled substances in schedule II, III, IV, or V, who are already registered under this part in another capacity, shall not be required. Pharmacies (as distinguished from pharmacists) when engaged in commercial activities, shall be registered to dispense controlled substances in schedule II, III, IV, or V if they are authorized to dispense under the law of the State in which they regularly conduct business. Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Secretary, who shall determine qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol. The Secretary, in determining the merits of each research protocol, shall consult with the Attorney General as to effective procedures to adequately safeguard against diversion of such controlled substances from legitimate medical or scientific use. Registration for the purpose of bona fide research with controlled substances in schedule I by a practitioner deemed qualified by the Secretary may be denied by the Attorney General only on a ground specified in section 304(a).

Pharmacies.

Research applications.

DENIAL, REVOCATION, OR SUSPENSION OF REGISTRATION

SEC. 304. (a) A registration pursuant to section 303 to manufacture, distribute, or dispense a controlled substance may be suspended or revoked by the Attorney General upon a finding that the registrant—

(1) has materially falsified any application filed pursuant to or required by this title or title III; Post, p. 1285.

(2) has been convicted of a felony under this title or title III or any other law of the United States, or of any State, relating to any substance defined in this title as a controlled substance; or

(3) has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances.

(b) The Attorney General may limit revocation or suspension of a registration to the particular controlled substance with respect to which grounds for revocation or suspension exist.

Service of order. (c) Before taking action pursuant to this section, or pursuant to a denial of registration under section 303, the Attorney General shall serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended. The order to show cause shall contain a statement of the basis thereof and shall call upon the applicant or registrant to appear before the Attorney

General at a time and place stated in the order, but in no event less than thirty days after the date of receipt of the order. Proceedings to deny, revoke, or suspend shall be conducted pursuant to this section in accordance with subchapter II of chapter 5 of title 5 of the United States Code. Such proceedings shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under this title or any other law of the United States. 80 Stat. 381. 5 USC 551.

Registration, suspension.

(d) The Attorney General may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this section, in cases where he finds that there is an imminent danger to the public health or safety. Such suspension shall continue in effect until the conclusion of such proceedings, including judicial review thereof, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction.

(e) The suspension or revocation of a registration under this section shall operate to suspend or revoke any quota applicable under section 306.

(f) In the event the Attorney General suspends or revokes a registration granted under section 303, all controlled substances owned or possessed by the registrant pursuant to such registration at the time of suspension or the effective date of the revocation order, as the case may be, may, in the discretion of the Attorney General, be placed under seal. No disposition may be made of any controlled substances under seal until the time for taking an appeal has elapsed or until all appeals have been concluded except that a court, upon application therefor, may at any time order the sale of perishable controlled substances. Any such order shall require the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final, all such controlled substances (or proceeds of sale deposited in court) shall be forfeited to the United States; and the Attorney General shall dispose of such controlled substances in accordance with section 511(e). Post, p. 1277.

LABELING AND PACKAGING REQUIREMENTS

Symbol.

SEC. 305. (a) It shall be unlawful to distribute a controlled substance in a commercial container unless such container, when and as required by regulations of the Attorney General, bears a label (as defined in section 201(k) of the Federal Food, Drug, and Cosmetic Act) containing an identifying symbol for such substance in accordance with such regulations. A different symbol shall be required for each schedule of controlled substances. 52 Stat. 1041. 21 USC 321.

(b) It shall be unlawful for the manufacturer of any controlled substance to distribute such substance unless the labeling (as defined in section 201(m) of the Federal Food, Drug, and Cosmetic Act) of such substance contains, when and as required by regulations of the Attorney General, the identifying symbol required under subsection (a).

(c) The Secretary shall prescribe regulations under section 503(b) of the Federal Food, Drug, and Cosmetic Act which shall provide that the label of a drug listed in schedule II, III, or IV shall, when dispensed to or for a patient, contain a clear, concise warning that it is a crime to transfer the drug to any person other than the patient. 65 Stat. 648. 21 USC 353.

Unlawful distribution.

(d) It shall be unlawful to distribute controlled substances in schedule I or II, and narcotic drugs in schedule III or IV, unless the bottle or other container, stopper, covering, or wrapper thereof is securely sealed as required by regulations of the Attorney General.

QUOTAS APPLICABLE TO CERTAIN SUBSTANCES

Production quota.

SEC. 306. (a) The Attorney General shall determine the total quantity and establish production quotas for each basic class of controlled substance in schedules I and II to be manufactured each calendar year to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. Production quotas shall be established in terms of quantities of each basic class of controlled substance and not in terms of individual pharmaceutical dosage forms prepared from or containing such a controlled substance.

(b) The Attorney General shall limit or reduce individual production quotas to the extent necessary to prevent the aggregate of individual quotas from exceeding the amount determined necessary each year by the Attorney General under subsection (a). The quota of each registered manufacturer for each basic class of controlled substance in schedule I or II shall be revised in the same proportion as the limitation or reduction of the aggregate of the quotas. However, if any registrant, before the issuance of a limitation or reduction in quota, has manufactured in excess of his revised quota, the amount of the excess shall be subtracted from his quota for the following year.

Manufacturing quota.

(c) On or before July 1 of each year, upon application therefor by a registered manufacturer, the Attorney General shall fix a manufacturing quota for the basic classes of controlled substances in schedules I and II that the manufacturer seeks to produce. The quota shall be subject to the provisions of subsections (a) and (b) of this section. In fixing such quotas, the Attorney General shall determine the manufacturer's estimated disposal, inventory, and other requirements for the calendar year; and, in making his determination, the Attorney General shall consider the manufacturer's current rate of disposal, the trend of the national disposal rate during the preceding calendar year, the manufacturer's production cycle and inventory position, the economic availability of raw materials, yield and stability problems, emergencies such as strikes and fires, and other factors.

(d) The Attorney General shall, upon application and subject to the provisions of subsections (a) and (b) of this section, fix a quota for a basic class of controlled substance in schedule I or II for any registrant who has not manufactured that basic class of controlled substance during one or more preceding calendar years. In fixing such quota, the Attorney General shall take into account the registrant's reasonably anticipated requirements for the current year; and, in making his determination of such requirements, he shall consider such factors specified in subsection (c) of this section as may be relevant.

Quota, increase.

(e) At any time during the year any registrant who has applied for or received a manufacturing quota for a basic class of controlled substance in schedule I or II may apply for an increase in that quota to meet his estimated disposal, inventory, and other requirements during the remainder of that year. In passing upon the application the Attorney General shall take into consideration any occurrences since the filing of the registrant's initial quota application that may require an increased manufacturing rate by the registrant during the balance of the year. In passing upon the application the Attorney General may also take into account the amount, if any, by which the determination of the Attorney General under subsection (a) of this section exceeds the aggregate of the quotas of all registrants under this section.

Controlled substances, incidental production, exception.

(f) Notwithstanding any other provisions of this title, no registration or quota may be required for the manufacture of such quantities of controlled substances in schedules I and II as incidentally and

necessarily result from the manufacturing process used for the manufacture of a controlled substance with respect to which its manufacturer is duly registered under this title. The Attorney General may, by regulation, prescribe restrictions on the retention and disposal of such incidentally produced substances.

Restrictions.

RECORDS AND REPORTS OF REGISTRANTS

SEC. 307. (a) Except as provided in subsection (c)—

Inventory.

(1) every registrant under this title shall, on the effective date of this section, or as soon thereafter as such registrant first engages in the manufacture, distribution, or dispensing of controlled substances, and every second year thereafter, make a complete and accurate record of all stocks thereof on hand, except that the regulations prescribed under this section shall permit each such biennial inventory (following the initial inventory required by this paragraph) to be prepared on such registrant's regular general physical inventory date (if any) which is nearest to and does not vary by more than six months from the biennial date that would otherwise apply;

(2) on the effective date of each regulation of the Attorney General controlling a substance that immediately prior to such date was not a controlled substance, each registrant under this title manufacturing, distributing, or dispensing such substance shall make a complete and accurate record of all stocks thereof on hand; and

(3) on and after the effective date of this section, every registrant under this title manufacturing, distributing, or dispensing a controlled substance or substances shall maintain, on a current basis, a complete and accurate record of each such substance manufactured, received, sold, delivered, or otherwise disposed of by him, except that this paragraph shall not require the maintenance of a perpetual inventory.

(b) Every inventory or other record required under this section (1) shall be in accordance with, and contain such relevant information as may be required by, regulations of the Attorney General, (2) shall (A) be maintained separately from all other records of the registrant, or (B) alternatively, in the case of nonnarcotic controlled substances, be in such form that information required by the Attorney General is readily retrievable from the ordinary business records of the registrant, and (3) shall be kept and be available, for at least two years, for inspection and copying by officers or employees of the United States authorized by the Attorney General.

Availability.

(c) The foregoing provisions of this section shall not apply—

Nonapplicability.

(1) (A) with respect to narcotic controlled substances in schedule II, III, IV, or V, to the prescribing or administering of such substances by a practitioner in the lawful course of his professional practice; or

(B) with respect to nonnarcotic controlled substances in schedule II, III, IV, or V, to any practitioner who dispenses such substances to his patients, unless the practitioner is regularly engaged in charging his patients, either separately or together with charges for other professional services, for substances so dispensed;

(2) (A) to the use of controlled substances, at establishments registered under this title which keep records with respect to such substances, in research conducted in conformity with an exemption granted under section 505(i) or 512(j) of the Federal Food, Drug, and Cosmetic Act;

52 Stat. 1052; 76 Stat. 783. 82 Stat. 343. 21 USC 355, 360b.

(B) to the use of controlled substances, at establishments registered under this title which keep records with respect to such substances, in preclinical research or in teaching; or

(3) to the extent of any exemption granted to any person, with respect to all or part of such provisions, by the Attorney General by or pursuant to regulation on the basis of a finding that the application of such provisions (or part thereof) to such person is not necessary for carrying out the purposes of this title.

(d) Every manufacturer registered under section 303 shall, at such time or times and in such form as the Attorney General may require, make periodic reports to the Attorney General of every sale, delivery, or other disposal by him of any controlled substance, and each distributor shall make such reports with respect to narcotic controlled substances, identifying by the registration number assigned under this title the person or establishment (unless exempt from registration under section 302(d)) to whom such sale, delivery, or other disposal was made.

(e) Regulations under sections 505(i) and 512(j) of the Federal Food, Drug, and Cosmetic Act, relating to investigational use of drugs, shall include such procedures as the Secretary, after consultation with the Attorney General, determines are necessary to insure the security and accountability of controlled substances used in research to which such regulations apply.

52 Stat. 1052; 76 Stat. 783. 82 Stat. 343. 21 USC 355, 360b.

ORDER FORMS

SEC. 308. (a) It shall be unlawful for any person to distribute a controlled substance in schedule I or II to another except in pursuance of a written order of the person to whom such substance is distributed, made on a form to be issued by the Attorney General in blank in accordance with subsection (d) and regulations prescribed by him pursuant to this section.

Unlawful distribution.

(b) Nothing in subsection (a) shall apply to—

Nonapplicability.

(1) the exportation of such substances from the United States in conformity with title III;

Post, p. 1285.

(2) the delivery of such a substance to or by a common or contract carrier for carriage in the lawful and usual course of its business, or to or by a warehouseman for storage in the lawful and usual course of its business; but where such carriage or storage is in connection with the distribution by the owner of the substance to a third person, this paragraph shall not relieve the distributor from compliance with subsection (a).

(c) (1) Every person who in pursuance of an order required under subsection (a) distributes a controlled substance shall preserve such order for a period of two years, and shall make such order available for inspection and copying by officers and employees of the United States duly authorized for that purpose by the Attorney General, and by officers or employees of States or their political subdivisions who are charged with the enforcement of State or local laws regulating the production, or regulating the distribution or dispensing, of controlled substances and who are authorized under such laws to inspect such orders.

Preservation and availability.

(2) Every person who gives an order required under subsection (a) shall, at or before the time of giving such order, make or cause to be made a duplicate thereof on a form to be issued by the Attorney General in blank in accordance with subsection (d) and regulations prescribed by him pursuant to this section, and shall, if such order is accepted, preserve such duplicate for a period of two years and make it available for inspection and copying by the officers and employees mentioned in paragraph (1) of this subsection.

Duplicate, preservation and availability.

(d)(1) The Attorney General shall issue forms pursuant to subsections (a) and (c)(2) only to persons validly registered under section 303 (or exempted from registration under section 302(d)). Whenever any such form is issued to a person, the Attorney General shall, before delivery thereof, insert therein the name of such person, and it shall be unlawful for any other person (A) to use such form for the purpose of obtaining controlled substances or (B) to furnish such form to any person with intent thereby to procure the distribution of such substances. Forms, issuance.

(2) The Attorney General may charge reasonable fees for the issuance of such forms in such amounts as he may prescribe for the purpose of covering the cost to the United States of issuing such forms, and other necessary activities in connection therewith. Fees.

(e) It shall be unlawful for any person to obtain by means of order forms issued under this section controlled substances for any purpose other than their use, distribution, dispensing, or administration in the conduct of a lawful business in such substances or in the course of his professional practice or research. Unlawful act.

PRESCRIPTIONS

SEC. 309. (a) Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed without the written prescription of a practitioner, except that in emergency situations, as prescribed by the Secretary by regulation after consultation with the Attorney General, such drug may be dispensed upon oral prescription in accordance with section 503(b) of that Act. Prescriptions shall be retained in conformity with the requirements of section 307 of this title. No prescription for a controlled substance in schedule II may be refilled. 52 Stat. 1040. 21 USC 301. 65 Stat. 648. 21 USC 353.

(b) Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed without a written or oral prescription in conformity with section 503(b) of that Act. Such prescriptions may not be filled or refilled more than six months after the date thereof or be refilled more than five times after the date of the prescription unless renewed by the practitioner.

(c) No controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medical purpose.

(d) Whenever it appears to the Attorney General that a drug not considered to be a prescription drug under the Federal Food, Drug, and Cosmetic Act should be so considered because of its abuse potential, he shall so advise the Secretary and furnish to him all available data relevant thereto.

PART D—OFFENSES AND PENALTIES

PROHIBITED ACTS A—PENALTIES

SEC. 401. (a) Except as authorized by this title, it shall be unlawful for any person knowingly or intentionally—

(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance; or

(2) to create, distribute, or dispense, or possess with intent to distribute or dispense, a counterfeit substance.

Post, p. 1265.

Penalties.

Post, p. 1285.

Special parole term.

(b) Except as otherwise provided in section 405, any person who violates subsection (a) of this section shall be sentenced as follows:

(1)(A) In the case of a controlled substance in schedule I or II which is a narcotic drug, such person shall be sentenced to a term of imprisonment of not more than 15 years, a fine of not more than $25,000, or both. If any person commits such a violation after one or more prior convictions of him for an offense punishable under this paragraph, or for a felony under any other provision of this title or title III or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 30 years, a fine of not more than $50,000, or both. Any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a special parole term of at least 3 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a special parole term of at least 6 years in addition to such term of imprisonment.

(B) In the case of a controlled substance in schedule I or II which is not a narcotic drug or in the case of any controlled substance in schedule III, such person shall be sentenced to a term of imprisonment of not more than 5 years, a fine of not more than $15,000, or both. If any person commits such a violation after one or more prior convictions of him for an offense punishable under this paragraph, or for a felony under any other provision of this title or title III or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 10 years, a fine of not more than $30,000, or both. Any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a special parole term of at least 2 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a special parole term of at least 4 years in addition to such term of imprisonment.

(2) In the case of a controlled substance in schedule IV, such person shall be sentenced to a term of imprisonment of not more than 3 years, a fine of not more than $10,000, or both. If any person commits such a violation after one or more prior convictions of him for an offense punishable under this paragraph, or for a felony under any other provision of this title or title III or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 6 years, a fine of not more than $20,000, or both. Any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a special parole term of at least one year in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a special parole term of at least 2 years in addition to such term of imprisonment.

(3) In the case of a controlled substance in schedule V, such person shall be sentenced to a term of imprisonment of not more than one year, a fine of not more than $5,000, or both. If any person commits such a violation after one or more convictions of him for an offense punishable under this paragraph, or for a crime under any other provision of this title or title III or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 2 years, a fine of not more than $10,000, or both.

(4) Notwithstanding paragraph (1)(B) of this subsection, any person who violates subsection (a) of this section by distributing a small amount of marihuana for no remuneration shall be treated as provided in subsections (a) and (b) of section 404. Marihuana, simple possession.

(c) A special parole term imposed under this section or section 405 may be revoked if its terms and conditions are violated. In such circumstances the original term of imprisonment shall be increased by the period of the special parole term and the resulting new term of imprisonment shall not be diminished by the time which was spent on special parole. A person whose special parole term has been revoked may be required to serve all or part of the remainder of the new term of imprisonment. A special parole term provided for in this section or section 405 shall be in addition to, and not in lieu of, any other parole provided for by law. Special parole term.

PROHIBITED ACTS B—PENALTIES

SEC. 402. (a) It shall be unlawful for any person—

(1) who is subject to the requirements of part C to distribute or dispense a controlled substance in violation of section 309;

(2) who is a registrant to distribute or dispense a controlled substance not authorized by his registration to another registrant or other authorized person or to manufacture a controlled substance not authorized by his registration;

(3) who is a registrant to distribute a controlled substance in violation of section 305 of this title;

(4) to remove, alter, or obliterate a symbol or label required by section 305 of this title;

(5) to refuse or fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under this title or title III; Post, p. 1285.

(6) to refuse any entry into any premises or inspection authorized by this title or title III;

(7) to remove, break, injure, or deface a seal placed upon controlled substances pursuant to section 304(f) or 511 or to remove or dispose of substances so placed under seal; or Ante, p. 1250, Post, p. 1276.

(8) to use, to his own advantage, or to reveal, other than to duly authorized officers or employees of the United States, or to the courts when relevant in any judicial proceeding under this title or title III, any information acquired in the course of an inspection authorized by this title concerning any method or process which as a trade secret is entitled to protection.

(b) It shall be unlawful for any person who is a registrant to manufacture a controlled substance in schedule I or II which is—

(1) not expressly authorized by his registration and by a quota assigned to him pursuant to section 306; or

(2) in excess of a quota assigned to him pursuant to section 306.

(c)(1) Except as provided in paragraph (2), any person who violates this section shall, with respect to any such violation, be subject to a civil penalty of not more than $25,000. The district courts of the United States (or, where there is no such court in the case of any territory or possession of the United States, then the court in such territory or possession having the jurisdiction of a district court of the United States in cases arising under the Constitution and laws of the United States) shall have jurisdiction in accordance with section 1355 of title 28 of the United States Code to enforce this paragraph. Penalty. Jurisdiction of courts. 62 Stat. 934.

(2)(A) If a violation of this section is prosecuted by an information or indictment which alleges that the violation was committed knowingly and the trier of fact specifically finds that the violation was so committed, such person shall, except as otherwise provided in subparagraph (B) of this paragraph, be sentenced to imprisonment of not more than one year or a fine of not more than $25,000, or both. Penalty.

(B) If a violation referred to in subparagraph (A) was committed after one or more prior convictions of the offender for an offense punishable under this paragraph (2), or for a crime under any other provision of this title or title III or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 2 years, a fine of $50,000, or both. Post, p. 1285. Penalty.

(3) Except under the conditions specified in paragraph (2) of this subsection, a violation of this section does not constitute a crime, and a judgment for the United States and imposition of a civil penalty pursuant to paragraph (1) shall not give rise to any disability or legal disadvantage based on conviction for a criminal offense. Exception.

PROHIBITED ACTS C—PENALTIES

SEC. 403. (a) It shall be unlawful for any person knowingly or intentionally—

(1) who is a registrant to distribute a controlled substance classified in schedule I or II, in the course of his legitimate business, except pursuant to an order or an order form as required by section 308 of this title; Ante, p. 1259.

(2) to use in the course of the manufacture or distribution of a controlled substance a registration number which is fictitious, revoked, suspended, or issued to another person;

(3) to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge;

(4) to furnish false or fraudulent material information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under this title or title III; or

(5) to make, distribute, or possess any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit substance.

(b) It shall be unlawful for any person knowingly or intentionally to use any communication facility in committing or in causing or facilitating the commission of any act or acts constituting a felony under any provision of this title or title III. Each separate use of a communication facility shall be a separate offense under this subsection. For purposes of this subsection, the term "communication facility" means any and all public and private instrumentalities used or useful in the transmission of writing, signs, signals, pictures, or sounds of all kinds and includes mail, telephone, wire, radio, and all other means of communication. "Communication facility."

(c) Any person who violates this section shall be sentenced to a term of imprisonment of not more than 4 years, a fine of not more than $30,000, or both; except that if any person commits such a violation after one or more prior convictions of him for violation of this section, or for a felony under any other provision of this title or title III or other law of the United States relating to narcotic drugs, Penalty.

marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 8 years, a fine of not more than $60,000, or both. Penalty.

PENALTY FOR SIMPLE POSSESSION; CONDITIONAL DISCHARGE AND EXPUNGING OF RECORDS FOR FIRST OFFENSE

SEC. 404. (a) It shall be unlawful for any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice, or except as otherwise authorized by this title or title III. Any person who violates this subsection shall be sentenced to a term of imprisonment of not more than one year, a fine of not more than $5,000, or both, except that if he commits such offense after a prior conviction or convictions under this subsection have become final, he shall be sentenced to a term of imprisonment of not more than 2 years, a fine of not more than $10,000, or both. Post, p. 1285.

(b)(1) If any person who has not previously been convicted of violating subsection (a) of this section, any other provision of this title or title III, or any other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, is found guilty of a violation of subsection (a) of this section after trial or upon a plea of guilty, the court may, without entering a judgment of guilty and with the consent of such person, defer further proceedings and place him on probation upon such reasonable conditions as it may require and for such period, not to exceed one year, as the court may prescribe. Upon violation of a condition of the probation, the court may enter an adjudication of guilt and proceed as otherwise provided. The court may, in its discretion, dismiss the proceedings against such person and discharge him from probation before the expiration of the maximum period prescribed for such person's probation. If during the period of his probation such person does not violate any of the conditions of the probation, then upon expiration of such period the court shall discharge such person and dismiss the proceedings against him. Discharge and dismissal under this subsection shall be without court adjudication of guilt, but a nonpublic record thereof shall be retained by the Department of Justice solely for the purpose of use by the courts in determining whether or not, in subsequent proceedings, such person qualifies under this subsection. Such discharge or dismissal shall not be deemed a conviction for purposes of disqualifications or disabilities imposed by law upon conviction of a crime (including the penalties prescribed under this part for second or subsequent convictions) or for any other purpose. Discharge and dismissal under this section may occur only once with respect to any person. Nonpublic record, retention.

(2) Upon the dismissal of such person and discharge of the proceedings against him under paragraph (1) of this subsection, such person, if he was not over twenty-one years of age at the time of the offense, may apply to the court for an order to expunge from all official records (other than the nonpublic records to be retained by the Department of Justice under paragraph (1)) all recordation relating to his arrest, indictment or information, trial, finding of guilty, and dismissal and discharge pursuant to this section. If the court determines, after hearing, that such person was dismissed and the proceedings against him discharged and that he was not over twenty-one years of age at the time of the offense, it shall enter such order. First offense, expunging of records, order.

The effect of such order shall be to restore such person, in the contemplation of the law, to the status he occupied before such arrest or indictment or information. No person as to whom such order has been entered shall be held thereafter under any provision of any law to be guilty of perjury or otherwise giving a false statement by reason of his failures to recite or acknowledge such arrest, or indictment or information, or trial in response to any inquiry made of him for any purpose.

DISTRIBUTION TO PERSONS UNDER AGE TWENTY-ONE

SEC. 405. (a) Any person at least eighteen years of age who violates section 401(a)(1) by distributing a controlled substance to a person under twenty-one years of age is (except as provided in subsection (b)) punishable by (1) a term of imprisonment, or a fine, or both, up to twice that authorized by section 401(b), and (2) at least twice any special parole term authorized by section 401(b), for a first offense involving the same controlled substance and schedule.

(b) Any person at least eighteen years of age who violates section 401(a)(1) by distributing a controlled substance to a person under twenty-one years of age after a prior conviction or convictions under subsection (a) of this section (or under section 303(b)(2) of the Federal Food, Drug, and Cosmetic Act as in effect prior to the effective date of section 701(b) of this Act) have become final, is punishable by (1) a term of imprisonment, or a fine, or both, up to three times that authorized by section 401(b), and (2) at least three times any special parole term authorized by section 401(b), for a second or subsequent offense involving the same controlled substance and schedule. 82 Stat. 1361. 21 USC 333.

ATTEMPT AND CONSPIRACY

SEC. 406. Any person who attempts or conspires to commit any offense defined in this title is punishable by imprisonment or fine or both which may not exceed the maximum punishment prescribed for the offense, the commission of which was the object of the attempt or conspiracy.

ADDITIONAL PENALTIES

SEC. 407. Any penalty imposed for violation of this title shall be in addition to, and not in lieu of, any civil or administrative penalty or sanction authorized by law.

CONTINUING CRIMINAL ENTERPRISE

SEC. 408. (a)(1) Any person who engages in a continuing criminal enterprise shall be sentenced to a term of imprisonment which may not be less than 10 years and which may be up to life imprisonment, to a fine of not more than $100,000, and to the forfeiture prescribed in paragraph (2); except that if any person engages in such activity after one or more prior convictions of him under this section have become final, he shall be sentenced to a term of imprisonment which may not be less than 20 years and which may be up to life imprisonment, to a fine of not more than $200,000, and to the forfeiture prescribed in paragraph (2). Penalty.

(2) Any person who is convicted under paragraph (1) of engaging in a continuing criminal enterprise shall forfeit to the United States— Forfeiture.

(A) the profits obtained by him in such enterprise, and

(B) any of his interest in, claim against, or property or contractual rights of any kind affording a source of influence over, such enterprise.

(b) For purposes of subsection (a), a person is engaged in a continuing criminal enterprise if—

(1) he violates any provision of this title or title III the punishment for which is a felony, and

Post, p. 1285.

(2) such violation is a part of a continuing series of violations of this title or title III—

(A) which are undertaken by such person in concert with five or more other persons with respect to whom such person occupies a position of organizer, a supervisory position, or any other position of management, and

(B) from which such person obtains substantial income or resources.

(c) In the case of any sentence imposed under this section, imposition or execution of such sentence shall not be suspended, probation shall not be granted, and section 4202 of title 18 of the United States Code and the Act of July 15, 1932 (D.C. Code, secs. 24-203—24-207), shall not apply.

65 Stat. 150.
47 Stat. 697;
61 Stat. 378;
67 Stat. 91;
79 Stat. 113.

(d) The district courts of the United States (including courts in the territories or possessions of the United States having jurisdiction under subsection (a)) shall have jurisdiction to enter such restraining orders or prohibitions, or to take such other actions, including the acceptance of satisfactory performance bonds, in connection with any property or other interest subject to forfeiture under this section, as they shall deem proper.

Jurisdiction of courts.

DANGEROUS SPECIAL DRUG OFFENDER SENTENCING

SEC. 409. (a) Whenever a United States attorney charged with the prosecution of a defendant in a court of the United States for an alleged felonious violation of any provision of this title or title III committed when the defendant was over the age of twenty-one years has reasons to believe that the defendant is a dangerous special drug offender such United States attorney, a reasonable time before trial or acceptance by the court of a plea of guilty or nolo contendere, may sign and file with the court, and may amend, a notice (1) specifying that the defendant is a dangerous special drug offender who upon conviction for such felonious violation is subject to the imposition of a sentence under subsection (b) of this section, and (2) setting out with particularity the reasons why such attorney believes the defendant to be a dangerous special drug offender. In no case shall the fact that the defendant is alleged to be a dangerous special drug offender be an issue upon the trial of such felonious violation, be disclosed to the jury, or be disclosed before any plea of guilty or nolo contendere or verdict or finding of guilty to the presiding judge without the consent of the parties. If the court finds that the filing of the notice as a public record may prejudice fair consideration of a pending criminal matter, it may order the notice sealed and the notice shall not be subject to subpena or public inspection during the pendency of such criminal matter, except on order of the court, but shall be subject to inspection by the defendant alleged to be a dangerous special drug offender and his counsel.

Notice.

Prohibition.

(b) Upon any plea of guilty or nolo contendere or verdict or finding of guilty of the defendant of such felonious violation, a hearing shall be held, before sentence is imposed, by the court sitting without a jury.

Hearing without jury.

Notice.

Presentence report, inspection.

The court shall fix a time for the hearing, and notice thereof shall be given to the defendant and the United States at least ten days prior thereto. The court shall permit the United States and counsel for the defendant, or the defendant if he is not represented by counsel, to inspect the presentence report sufficiently prior to the hearing as to afford a reasonable opportunity for verification. In extraordinary cases, the court may withhold material not relevant to a proper sentence, diagnostic opinion which might seriously disrupt a program of rehabilitation, any source of information obtained on a promise of confidentiality, and material previously disclosed in open court. A court withholding all or part of a presentence report shall inform the parties of its action and place in the record the reasons therefor. The court may require parties inspecting all or part of a presentence report to give notice of any part thereof intended to be controverted. In connection with the hearing, the defendant and the United States shall be entitled to assistance of counsel, compulsory process, and cross-examination of such witnesses as appear at the hearing. A duly authenticated copy of a former judgment or commitment shall be prima facie evidence of such former judgment or commitment. If it appears by a preponderance of the information, including information submitted during the trial of such felonious violation and the sentencing hearing and so much of the presentence report as the court relies upon, that the defendant is a dangerous special drug offender, the court shall sentence the defendant to imprisonment for an appropriate term not to exceed twenty-five years and not disproportionate in severity to the maximum term otherwise authorized by law for such felonious violation. Otherwise it shall sentence the defendant in accordance with the law prescribing penalties for such felonious violation. The court shall place in the record its findings, including an identification of the information relied upon in making such findings, and its reasons for the sentence imposed.

Penalty.

Sentence.

(c) This section shall not prevent the imposition and execution of a sentence of imprisonment for life or for a term exceeding twenty-five years upon any person convicted of an offense so punishable.

(d) Notwithstanding any other provision of this section, the court shall not sentence a dangerous special drug offender to less than any mandatory minimum penalty prescribed by law for such felonious violation. This section shall not be construed as creating any mandatory minimum penalty.

Conditions.

(e) A defendant is a special drug offender for purposes of this section if—

(1) the defendant has previously been convicted in courts of the United States or a State or any political subdivision thereof for two or more offenses involving dealing in controlled substances, committed on occasions different from one another and different from such felonious violation, and punishable in such courts by death or imprisonment in excess of one year, for one or more of such convictions the defendant has been imprisoned prior to the commission of such felonious violation, and less than five years have elapsed between the commission of such felonious violation and either the defendant's release, or parole or otherwise, from imprisonment for one such conviction or his commission of the last such previous offense or another offense involving dealing in controlled substances and punishable by death or imprisonment in excess of one year under applicable laws of the United States or a State or any political subdivision thereof; or

(2) the defendant committed such felonious violation as part of a pattern of dealing in controlled substances which was crimi-

nal under applicable laws of any jurisdiction, which constituted a substantial source of his income, and in which he manifested special skill or expertise; or

(3) such felonious violation was, or the defendant committed such felonious violation in furtherance of, a conspiracy with three or more other persons to engage in a pattern of dealing in controlled substances which was criminal under applicable laws of any jurisdiction, and the defendant did, or agreed that he would, initiate, organize, plan, finance, direct, manage, or supervise all or part of such conspiracy or dealing, or give or receive a bribe or use force in connection with such dealing.

A conviction shown on direct or collateral review or at the hearing to be invalid or for which the defendant has been pardoned on the ground of innocence shall be disregarded for purposes of paragraph (1) of this subsection. In support of findings under paragraph (2) of this subsection, it may be shown that the defendant has had in his own name or under his control income or property not explained as derived from a source other than such dealing. For purposes of paragraph (2) of this subsection, a substantial source of income means a source of income which for any period of one year or more exceeds the minimum wage, determined on the basis of a forty-hour week and fifty-week year, without reference to exceptions, under section 6(a)(1) of the Fair Labor Standards Act of 1938 for an employee engaged in commerce or in the production of goods for commerce, and which for the same period exceeds fifty percent of the defendant's declared adjusted gross income under section 62 of the Internal Revenue Code of 1954. For purposes of paragraph (2) of this subsection, special skill or expertise in such dealing includes unusual knowledge, judgment or ability, including manual dexterity, facilitating the initiation, organizing, planning, financing, direction, management, supervision, execution or concealment of such dealing, the enlistment of accomplices in such dealing, the escape from detection or apprehension for such dealing, or the disposition of the fruits or proceeds of such dealing. For purposes of paragraphs (2) and (3) of this subsection, such dealing forms a pattern if it embraces criminal acts that have the same or similar purposes, results, participants, victims, or methods of commission, or otherwise are interrelated by distinguishing characteristics and are not isolated events.

Substantial source of income.

80 Stat. 836. 29 USC 206.

68A Stat. 17; 83 Stat. 655. 26 USC 62. Dealing.

(f) A defendant is dangerous for purposes of this section if a period of confinement longer than that provided for such felonious violation is required for the protection of the public from further criminal conduct by the defendant.

Defendant, dangerous.

(g) The time for taking an appeal from a conviction for which sentence is imposed after proceedings under this section shall be measured from imposition of the original sentence.

Appeal.

(h) With respect to the imposition, correction, or reduction of a sentence after proceedings under this section, a review of the sentence on the record of the sentencing court may be taken by the defendant or the United States to a court of appeals. Any review of the sentence taken by the United States shall be taken at least five days before expiration of the time for taking a review of the sentence or appeal of the conviction by the defendant and shall be diligently prosecuted. The sentencing court may, with or without motion and notice, extend the time for taking a review of the sentence for a period not to exceed thirty days from the expiration of the time otherwise prescribed by law. The court shall not extend the time for taking a review of the sentence by the United States after the time has expired. A court

Sentence, review.

extending the time for taking a review of the sentence by the United States shall extend the time for taking a review of the sentence or appeal of the conviction by the defendant for the same period. The taking of a review of the sentence by the United States shall be deemed the taking of a review of the sentence and an appeal of the conviction by the defendant. Review of the sentence shall include review of whether the procedure employed was lawful, the findings made were clearly erroneous, or the sentencing court's discretion was abused. The court of appeals on review of the sentence may, after considering the record, including the entire presentence report, information submitted during the trial of such felonious violation and the sentencing hearing, and the findings and reasons of the sentencing court, affirm the sentence, impose or direct the imposition of any sentence which the sentencing court could originally have imposed, or remand for further sentencing proceedings and imposition of sentence, except that a sentence may be made more severe only on review of the sentence taken by the United States and after hearing. Failure of the United States to take a review of the imposition of the sentence shall, upon review taken by the United States of the correction or reduction of the sentence, foreclose imposition of a sentence more severe than that previously imposed. Any withdrawal or dismissal of review of the sentence taken by the United States shall foreclose imposition of a sentence more severe than that reviewed but shall not otherwise foreclose the review of the sentence or the appeal of the conviction. The court of appeals shall state in writing the reasons for its disposition of the review of the sentence. Any review of the sentence taken by the United States may be dismissed on a showing of the abuse of the right of the United States to take such review.

INFORMATION FOR SENTENCING

SEC. 410. Except as otherwise provided in this title or section 303(a) of the Public Health Service Act, no limitation shall be placed on the information concerning the background, character, and conduct of a person convicted of an offense which a court of the United States may receive and consider for the purpose of imposing an appropriate sentence under this title or title III.

70 Stat. 929. 42 USC 242a.

Post, p. [illegible].

PROCEEDINGS TO ESTABLISH PRIOR CONVICTIONS

SEC. 411. (a)(1) No person who stands convicted of an offense under this part shall be sentenced to increased punishment by reason of one or more prior convictions, unless before trial, or before entry of a plea of guilty, the United States attorney files an information with the court (and serves a copy of such information on the person or counsel for the person) stating in writing the previous convictions to be relied upon. Upon a showing by the United States attorney that facts regarding prior convictions could not with due diligence be obtained prior to trial or before entry of a plea of guilty, the court may postpone the trial or the taking of the plea of guilty for a reasonable period for the purpose of obtaining such facts. Clerical mistakes in the information may be amended at any time prior to the pronouncement of sentence.

Prohibition.

(2) An information may not be filed under this section if the increased punishment which may be imposed is imprisonment for a term in excess of three years unless the person either waived or was afforded prosecution by indictment for the offense for which such increased punishment may be imposed.

Previous conviction, affirmation or denial.

(b) If the United States attorney files an information under this section, the court shall after conviction but before pronouncement of sentence inquire of the person with respect to whom the information was filed whether he affirms or denies that he has been previously convicted as alleged in the information, and shall inform him that any challenge to a prior conviction which is not made before sentence is imposed may not thereafter be raised to attack the sentence.

Denial, written response.

Hearing.

(c)(1) If the person denies any allegation of the information of prior conviction, or claims that any conviction alleged is invalid, he shall file a written response to the information. A copy of the response shall be served upon the United States attorney. The court shall hold a hearing to determine any issues raised by the response which would except the person from increased punishment. The failure of the United States attorney to include in the information the complete criminal record of the person or any facts in addition to the convictions to be relied upon shall not constitute grounds for invalidating the notice given in the information required by subsection (a)(1). The hearing shall be before the court without a jury and either party may introduce evidence. Except as otherwise provided in paragraph (2) of this subsection, the United States attorney shall have the burden of proof beyond a reasonable doubt on any issue of fact. At the request of either party, the court shall enter findings of fact and conclusions of law.

Court without jury.

Evidence, introduction.

Constitution of U.S., violation.

(2) A person claiming that a conviction alleged in the information was obtained in violation of the Constitution of the United States shall set forth his claim, and the factual basis therefor, with particularity in his response to the information. The person shall have the burden of proof by a preponderance of the evidence on any issue of fact raised by the response. Any challenge to a prior conviction, not raised by response to the information before an increased sentence is imposed in reliance thereon, shall be waived unless good cause be shown for failure to make a timely challenge.

Sentence, imposition.

(d)(1) If the person files no response to the information, or if the court determines, after hearing, that the person is subject to increased punishment by reason of prior convictions, the court shall proceed to impose sentence upon him as provided by this part.

(2) If the court determines that the person has not been convicted as alleged in the information, that a conviction alleged in the information is invalid, or that the person is otherwise not subject to an increased sentence as a matter of law, the court shall, at the request of the United States attorney, postpone sentence to allow an appeal from that determination. If no such request is made, the court shall impose sentence as provided by this part. The person may appeal from an order postponing sentence as if sentence had been pronounced and a final judgment of conviction entered.

Statute of limitations.

(e) No person who stands convicted of an offense under this part may challenge the validity of any prior conviction alleged under this section which occurred more than five years before the date of the information alleging such prior conviction.

Part E—Administrative and Enforcement Provisions

PROCEDURES

Attorney General, functions, delegation.

Sec. 501. (a) The Attorney General may delegate any of his functions under this title to any officer or employee of the Department of Justice.

Regulations.

(b) The Attorney General may promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this title.

Gifts, etc., acceptance.

(c) The Attorney General may accept in the name of the Department of Justice any form of devise, bequest, gift, or donation where the donor intends to donate property for the purpose of preventing or controlling the abuse of controlled substances. He may take all appropriate steps to secure possession of such property and may sell, assign, transfer, or convey any such property other than moneys.

EDUCATION AND RESEARCH PROGRAMS OF THE ATTORNEY GENERAL

Sec. 502. (a) The Attorney General is authorized to carry out educational and research programs directly related to enforcement of the laws under his jurisdiction concerning drugs or other substances which are or may be subject to control under this title. Such programs may include—

(1) educational and training programs on drug abuse and controlled substances law enforcement for local, State, and Federal personnel;

(2) studies or special projects designed to compare the deterrent effects of various enforcement strategies on drug use and abuse;

(3) studies or special projects designed to assess and detect accurately the presence in the human body of drugs or other substances which are or may be subject to control under this title, including the development of rapid field identification methods which would enable agents to detect microquantities of such drugs or other substances;

(4) studies or special projects designed to evaluate the nature and sources of the supply of illegal drugs throughout the country;

(5) studies or special projects to develop more effective methods to prevent diversion of controlled substances into illegal channels; and

(6) studies or special projects to develop information necessary to carry out his functions under section 201 of this title.

Ante, p. 1245.

(b) The Attorney General may enter into contracts for such educational and research activities without performance bonds and without regard to section 3709 of the Revised Statutes (41 U.S.C. 5).

Research populations, identification, prohibition.

(c) The Attorney General may authorize persons engaged in research to withhold the names and other identifying characteristics of persons who are the subjects of such research. Persons who obtain this authorization may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding to identify the subjects of research for which such authorization was obtained.

Controlled substances, exception.

(d) The Attorney General, on his own motion or at the request of the Secretary, may authorize the possession, distribution, and dispensing of controlled substances by persons engaged in research. Persons who obtain this authorization shall be exempt from State or Federal prosecution for possession, distribution, and dispensing of controlled substances to the extent authorized by the Attorney General.

COOPERATIVE ARRANGEMENTS

Sec. 503. (a) The Attorney General shall cooperate with local, State, and Federal agencies concerning traffic in controlled substances and in suppressing the abuse of controlled substances. To this end, he is authorized to—

(1) arrange for the exchange of information between governmental officials concerning the use and abuse of controlled substances;

(2) cooperate in the institution and prosecution of cases in the courts of the United States and before the licensing boards and courts of the several States;

(3) conduct training programs on controlled substance law enforcement for local, State, and Federal personnel;

(4) maintain in the Department of Justice a unit which will accept, catalog, file, and otherwise utilize all information and statistics, including records of controlled substance abusers and other controlled substance law offenders, which may be received from Federal, State, and local agencies, and make such information available for Federal, State, and local law enforcement purposes; and

(5) conduct programs of eradication aimed at destroying wild or illicit growth of plant species from which controlled substances may be extracted.

Assistance.

(b) When requested by the Attorney General, it shall be the duty of any agency or instrumentality of the Federal Government to furnish assistance, including technical advice, to him for carrying out his functions under this title; except that no such agency or instrumentality shall be required to furnish the name of, or other identifying information about, a patient or research subject whose identity it has undertaken to keep confidential.

Prohibition.

ADVISORY COMMITTEES

Appointment.

Compensation.

Travel expenses, etc.

80 Stat. 498; 83 Stat. 190. 5 USC 5701.

SEC. 504. The Attorney General may from time to time appoint committees to advise him with respect to preventing and controlling the abuse of controlled substances. Members of the committees may be entitled to receive compensation at the rate of $100 for each day (including traveltime) during which they are engaged in the actual performance of duties. While traveling on official business in the performance of duties for the committees, members of the committees shall be allowed expenses of travel, including per diem instead of subsistence, in accordance with subchapter I of chapter 57 of title 5, United States Code.

ADMINISTRATIVE HEARINGS

80 Stat. 381. 5 USC 551.

SEC. 505. (a) In carrying out his functions under this title, the Attorney General may hold hearings, sign and issue subpenas, administer oaths, examine witnesses, and receive evidence at any place in the United States.

(b) Except as otherwise provided in this title, notice shall be given and hearings shall be conducted under appropriate procedures of subchapter II of chapter 5, title 5, United States Code.

SUBPENAS

SEC. 506. (a) In any investigation relating to his functions under this title with respect to controlled substances, the Attorney General may subpena witnesses, compel the attendance and testimony of witnesses, and require the production of any records (including books, papers, documents, and other tangible things which constitute or contain evidence) which the Attorney General finds relevant or material to the investigation. The attendance of witnesses and the production of records may be required from any place in any State or in any territory

or other place subject to the jurisdiction of the United States at any designated place of hearing; except that a witness shall not be required to appear at any hearing more than 500 miles distant from the place where he was served with a subpena. Witnesses summoned under this section shall be paid the same fees and mileage that are paid witnesses in the courts of the United States.

Exception.

Fees.

Service.

(b) A subpena issued under this section may be served by any person designated in the subpena to serve it. Service upon a natural person may be made by personal delivery of the subpena to him. Service may be made upon a domestic or foreign corporation or upon a partnership or other unincorporated association which is subject to suit under a common name, by delivering the subpena to an officer, to a managing or general agent, or to any other agent authorized by appointment or by law to receive service of process. The affidavit of the person serving the subpena entered on a true copy thereof by the person serving it shall be proof of service.

Refusal to obey subpena.

Order.

Failure to obey order, penalty.

Jurisdiction.

(c) In the case of contumacy by or refusal to obey a subpena issued to any person, the Attorney General may invoke the aid of any court of the United States within the jurisdiction of which the investigation is carried on or of which the subpenaed person is an inhabitant, or in which he carries on business or may be found, to compel compliance with the subpena. The court may issue an order requiring the subpenaed person to appear before the Attorney General to produce records, if so ordered, or to give testimony touching the matter under investigation. Any failure to obey the order of the court may be punished by the court as a contempt thereof. All process in any such case may be served in any judicial district in which such person may be found.

JUDICIAL REVIEW

SEC. 507. All final determinations, findings, and conclusions of the Attorney General under this title shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the Attorney General may obtain review of the decision in the United States Court of Appeals for the District of Columbia or for the circuit in which his principal place of business is located upon petition filed with the court and delivered to the Attorney General within thirty days after notice of the decision. Findings of fact by the Attorney General, if supported by substantial evidence, shall be conclusive.

POWERS OF ENFORCEMENT PERSONNEL

SEC. 508. Any officer or employee of the Bureau of Narcotics and Dangerous Drug designated by the Attorney General may—

(1) carry firearms;

(2) execute and serve search warrants, arrest warrants, administrative inspection warrants, subpenas, and summonses issued under the authority of the United States;

(3) make arrests without warrant (A) for any offense against the United States committed in his presence, or (B) for any felony, cognizable under the laws of the United States, if he has probable cause to believe that the person to be arrested has committed or is committing a felony;

(4) make seizures of property pursuant to the provisions of this title; and

(5) perform such other law enforcement duties as the Attorney General may designate.

SEARCH WARRANTS

SEC. 509. (a) A search warrant relating to offenses involving controlled substances may be served at any time of the day or night if the judge or United States magistrate issuing the warrant is satisfied that there is probable cause to believe that grounds exist for the warrant and for its service at such time.

Authority to break and enter under certain conditions.

(b) Any officer authorized to execute a search warrant relating to offenses involving controlled substances the penalty for which is imprisonment for more than one year may, without notice of his authority and purpose, break open an outer or inner door or window of a building, or any part of the building, or anything therein, if the judge or United States magistrate issuing the warrant (1) is satisfied that there is probable cause to believe that (A) the property sought may and, if such notice is given, will be easily and quickly destroyed or disposed of, or (B) the giving of such notice will immediately endanger the life or safety of the executing officer or another person, and (2) has included in the warrant a direction that the officer executing it shall not be required to give such notice. Any officer acting under such warrant, shall, as soon as practicable after entering the premises, identify himself and give the reasons and authority for his entrance upon the premises.

ADMINISTRATIVE INSPECTIONS AND WARRANTS

"Controlled premises."

SEC. 510. (a) As used in this section, the term "controlled premises" means—

(1) places where original or other records or documents required under this title are kept or required to be kept, and

(2) places, including factories, warehouses, or other establishments, and conveyances, where persons registered under section 303 (or exempted from registration under section 302(d)) may lawfully hold, manufacture, or distribute, dispense, administer, or otherwise dispose of controlled substances.

(b)(1) For the purpose of inspecting, copying, and verifying the correctness of records, reports, or other documents required to be kept or made under this title and otherwise facilitating the carrying out of his functions under this title, the Attorney General is authorized, in accordance with this section, to enter controlled premises and to conduct administrative inspections thereof, and of the things specified in this section, relevant to those functions.

(2) Such entries and inspections shall be carried out through officers or employees (hereinafter referred to as "inspectors") designated by the Attorney General. Any such inspector, upon stating his purpose and presenting to the owner, operator, or agent in charge of such premises (A) appropriate credentials and (B) a written notice of his inspection authority (which notice in the case of an inspection requiring, or in fact supported by, an administrative inspection warrant shall consist of such warrant), shall have the right to enter such premises and conduct such inspection at reasonable times.

(3) Except as may otherwise be indicated in an applicable inspection warrant, the inspector shall have the right—

(A) to inspect and copy records, reports, and other documents required to be kept or made under this title;

(B) to inspect, within reasonable limits and in a reasonable manner, controlled premises and all pertinent equipment, finished and unfinished drugs and other substances or materials, containers, and labeling found therein, and, except as provided in paragraph (5) of this subsection, all other things therein (including records, files, papers, processes, controls, and facilities) appropriate for verification of the records, reports, and documents referred to in clause (A) or otherwise bearing on the provisions of this title; and

(C) to inventory any stock of any controlled substance therein and obtain samples of any such substance.

(4) Except when the owner, operator, or agent in charge of the controlled premises so consents in writing, no inspection authorized by this section shall extend to—

(A) financial data;

(B) sales data other than shipment data; or

(C) pricing data.

(c) A warrant under this section shall not be required for the inspection of books and records pursuant to an administrative subpena issued in accordance with section 506, nor for entries and administrative inspections (including seizures of property)—

(1) with the consent of the owner, operator, or agent in charge of the controlled premises;

(2) in situations presenting imminent danger to health or safety;

(3) in situations involving inspection of conveyances where there is reasonable cause to believe that the mobility of the conveyance makes it impracticable to obtain a warrant;

(4) in any other exceptional or emergency circumstance where time or opportunity to apply for a warrant is lacking; or

(5) in any other situations where a warrant is not constitutionally required.

Administrative inspection warrants, issuance and execution.

(d) Issuance and execution of administrative inspection warrants shall be as follows:

"Probable cause."

(1) Any judge of the United States or of a State court of record, or any United States magistrate, may, within his territorial jurisdiction, and upon proper oath or affirmation showing probable cause, issue warrants for the purpose of conducting administrative inspections authorized by this title or regulations thereunder, and seizures of property appropriate to such inspections. For the purposes of this section, the term "probable cause" means a valid public interest in the effective enforcement of this title or regulations thereunder sufficient to justify administrative inspections of the area, premises, building, or conveyance, or contents thereof, in the circumstances specified in the application for the warrant.

(2) A warrant shall issue only upon an affidavit of an officer or employee having knowledge of the facts alleged, sworn to before the judge or magistrate and establishing the grounds for issuing the warrant. If the judge or magistrate is satisfied that grounds for the application exist or that there is probable cause to believe they exist, he shall issue a warrant identifying the area, premises, building, or conveyance to be inspected, the purpose of such inspection, and, where appropriate, the type of property to be inspected, if any. The warrant shall identify the items or types of property to be seized, if any. The warrant shall be directed to a person authorized under subsection (b)(2) to execute it. The warrant shall state the grounds for its issuance and the name of the person or persons whose affidavit has been taken in support thereof. It shall command the person to whom it is directed to inspect the area, premises, building, or conveyance identified for the purpose specified, and, where appropriate, shall direct the seizure of the property specified. The warrant shall direct that it be served during normal business hours. It shall designate the judge or magistrate to whom it shall be returned.

(3) A warrant issued pursuant to this section must be executed and returned within ten days of its date unless, upon a showing by the United States of a need therefor, the judge or magistrate allows additional time in the warrant. If property is seized pursuant to a warrant, the person executing the warrant shall give to the person from whom or from whose premises the property was taken a copy of the warrant and a receipt for the property taken or shall leave the copy and receipt at the place from which the property was taken. The return of the warrant shall be made promptly and shall be accompanied by a written inventory of any property taken. The inventory shall be made in the presence of the person executing the warrant and of the person from whose possession or premises the property was taken, if they are present, or in the presence of at least one credible person other than the person making such inventory, and shall be verified by the person executing the warrant. The judge or magistrate, upon request, shall deliver a copy of the inventory to the person from whom or from whose premises the property was taken and to the applicant for the warrant.

Warrants, filing.

(4) The judge or magistrate who has issued a warrant under this section shall attach to the warrant a copy of the return and all papers filed in connection therewith and shall file them with the clerk of the district court of the United States for the judicial district in which the inspection was made.

FORFEITURES

SEC. 511. (a) The following shall be subject to forfeiture to the United States and no property right shall exist in them:

(1) All controlled substances which have been manufactured, distributed, dispensed, or acquired in violation of this title.

(2) All raw materials, products, and equipment of any kind which are used, or intended for use, in manufacturing, compounding, processing, delivering, importing, or exporting any controlled substance in violation of this title.

(3) All property which is used, or intended for use, as a container for property described in paragraph (1) or (2).

(4) All conveyances, including aircraft, vehicles, or vessels, which are used, or are intended for use, to transport, or in any manner to facilitate the transportation, sale, receipt, possession, or concealment of property described in paragraph (1) or (2), except that—

(A) no conveyance used by any person as a common carrier in the transaction of business as a common carrier shall be forfeited under the provisions of this section unless it shall appear that the owner or other person in charge of such conveyance was a consenting party or privy to a violation of this title or title III; and

Post, p. 1265.

(B) no conveyance shall be forfeited under the provisions of this section by reason of any act or omission established by the owner thereof to have been committed or omitted by any person other than such owner while such conveyance was unlawfully in the possession of a person other than the owner in violation of the criminal laws of the United States, or of any State.

(5) All books, records, and research, including formulas, microfilm, tapes, and data which are used, or intended for use, in violation of this title.

(b) Any property subject to forfeiture to the United States under this title may be seized by the Attorney General upon process issued pursuant to the Supplemental Rules for Certain Admiralty and Maritime Claims by any district court of the United States having jurisdiction over the property, except that seizure without such process may be made when—

(1) the seizure is incident to an arrest or a search under a search warrant or an inspection under an administrative inspection warrant;

(2) the property subject to seizure has been the subject of a prior judgment in favor of the United States in a criminal injunction or forfeiture proceeding under this title;

(3) the Attorney General has probable cause to believe that the property is directly or indirectly dangerous to health or safety; or

(4) the Attorney General has probable cause to believe that the property has been used or is intended to be used in violation of this title.

In the event of seizure pursuant to paragraph (3) or (4) of this subsection, proceedings under subsection (d) of this section shall be instituted promptly.

Property, custody of Attorney General.

(c) Property taken or detained under this section shall not be repleviable, but shall be deemed to be in the custody of the Attorney General, subject only to the orders and decrees of the court or the official having jurisdiction thereof. Whenever property is seized under the provisions of this title, the Attorney General may—

(1) place the property under seal;

(2) remove the property to a place designated by him; or

(3) require that the General Services Administration take custody of the property and remove it to an appropriate location for disposition in accordance with law.

(d) All provisions of law relating to the seizure, summary and judicial forfeiture, and condemnation of property for violation of the customs laws; the disposition of such property or the proceeds from the sale thereof; the remission or mitigation of such forfeitures; and the compromise of claims and the award of compensation to informers in respect of such forfeitures shall apply to seizures and forfeitures incurred, or alleged to have been incurred, under the provisions of this title, insofar as applicable and not inconsistent with the provisions hereof; except that such duties as are imposed upon the customs officer or any other person with respect to the seizure and forfeiture of property under the customs laws shall be performed with respect to seizures and forfeitures of property under this title by such officers, agents, or other persons as may be authorized or designated for that purpose by the Attorney General, except to the extent that such duties arise from seizures and forfeitures effected by any customs officer.

(e) Whenever property is forfeited under this title the Attorney General may—

(1) retain the property for official use;

(2) sell any forfeited property which is not required to be destroyed by law and which is not harmful to the public, but the proceeds from any such sale shall be used to pay all proper expenses of the proceedings for forfeiture and sale including expenses of seizure, maintenance of custody, advertising and court costs;

(3) require that the General Services Administration take custody of the property and remove it for disposition in accordance with law; or

(4) forward it to the Bureau of Narcotics and Dangerous Drugs for disposition (including delivery for medical or scientific use to any Federal or State agency under regulations of the Attorney General).

Controlled substances, forfeiture.

(f) All controlled substances in schedule I that are possessed, transferred, sold, or offered for sale in violation of the provisions of this title shall be deemed contraband and seized and summarily forfeited to the United States. Similarly, all substances in schedule I, which are seized or come into the possession of the United States, the owners of which are unknown, shall be deemed contraband and summarily forfeited to the United States.

(g)(1) All species of plants from which controlled substances in schedules I and II may be derived which have been planted or cultivated in violation of this title, or of which the owners or cultivators are unknown, or which are wild growths, may be seized and summarily forfeited to the United States.

(2) The failure, upon demand by the Attorney General or his duly authorized agent, of the person in occupancy or in control of land or premises upon which such species of plants are growing or being stored, to produce an appropriate registration, or proof that he is the holder thereof, shall constitute authority for the seizure and forfeiture.

(3) The Attorney General, or his duly authorized agent, shall have authority to enter upon any lands, or into any dwelling pursuant to a search warrant, to cut, harvest, carry off, or destroy such plants.

INJUNCTIONS

Jurisdiction of courts.

SEC. 512. (a) The district courts of the United States and all courts exercising general jurisdiction in the territories and possessions of the United States shall have jurisdiction in proceedings in accordance with the Federal Rules of Civil Procedure to enjoin violations of this title.

(b) In case of an alleged violation of an injunction or restraining order issued under this section, trial shall, upon demand of the accused, be by a jury in accordance with the Federal Rules of Civil Procedure.

28 USC app.

ENFORCEMENT PROCEEDINGS

Notice.

SEC. 513. Before any violation of this title is reported by the Director of the Bureau of Narcotics and Dangerous Drugs to any United States attorney for institution of a criminal proceeding, the Director may require that the person against whom such proceeding is contemplated be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.

IMMUNITY AND PRIVILEGE

Refusal to testify, prohibition.

SEC. 514. (a) Whenever a witness refuses, on the basis of his privilege against self-incrimination, to testify or provide other information in a proceeding before a court or grand jury of the United States, involving a violation of this title, and the person presiding over the proceeding communicates to the witness an order issued under this section, the witness may not refuse to comply with the order on the basis of his privilege against self-incrimination. But no testimony or other information compelled under the order issued under subsection (b) of this section or any information obtained by the exploitation of such testimony or other information, may be used against the witness in any criminal case, including any criminal case brought in a court of a State, except a prosecution for perjury, giving a false statement, or otherwise failing to comply with the order.

Order.

(b) In the case of any individual who has been or may be called to testify or provide other information at any proceeding before a court or grand jury of the United States, the United States district court for the judicial district in which the proceeding is or may be held shall issue, upon the request of the United States attorney for such district, an order requiring such individual to give any testimony or provide any other information which he refuses to give or provide on the basis of his privilege against self-incrimination.

(c) A United States attorney may, with the approval of the Attorney General or the Deputy Attorney General, or any Assistant Attorney General designated by the Attorney General, request an order under subsection (b) when in his judgment—

(1) the testimony or other information from such individual may be necessary to the public interest; and

(2) such individual has refused or is likely to refuse to testify or provide other information on the basis of his privilege against self-incrimination.

BURDEN OF PROOF; LIABILITIES

SEC. 515. (a)(1) It shall not be necessary for the United States to negative any exemption or exception set forth in this title in any complaint, information, indictment, or other pleading or in any trial, hearing, or other proceeding under this title, and the burden of going forward with the evidence with respect to any such exemption or exception shall be upon the person claiming its benefit.

Ante, p. 1264.

(2) In the case of a person charged under section 404(a) with the possession of a controlled substance, any label identifying such substance for purposes of section 503(b)(2) of the Federal Food, Drug, and Cosmetic Act shall be admissible in evidence and shall be prima facie evidence that such substance was obtained pursuant to a valid prescription from a practitioner while acting in the course of his professional practice.

65 Stat. 648. 21 USC 353.

(b) In the absence of proof that a person is the duly authorized holder of an appropriate registration or order form issued under this title, he shall be presumed not to be the holder of such registration or form, and the burden of going forward with the evidence with respect to such registration or form shall be upon him.

(c) The burden of going forward with the evidence to establish that a vehicle, vessel, or aircraft used in connection with controlled substances in schedule I was used in accordance with the provisions of this title shall be on the persons engaged in such use.

Criminal liability, prohibition, exception.

(d) Except as provided in sections 2234 and 2235 of title 18, United States Code, no civil or criminal liability shall be imposed by virtue of this title upon any duly authorized Federal officer lawfully engaged in the enforcement of this title, or upon any duly authorized officer of any State, territory, political subdivision thereof, the District of Columbia, or any possession of the United States, who shall be lawfully engaged in the enforcement of any law or municipal ordinance relating to controlled substances.

62 Stat. 803.

PAYMENTS AND ADVANCES

Informers, payment.

SEC. 516. (a) The Attorney General is authorized to pay any person, from funds appropriated for the Bureau of Narcotics and Dangerous Drugs, for information concerning a violation of this title, such sum or sums of money as he may deem appropriate, without reference to any moieties or rewards to which such person may otherwise be entitled by law.

(b) Moneys expended from appropriations of the Bureau of Narcotics and Dangerous Drugs for purchase of controlled substances and subsequently recovered shall be reimbursed to the current appropriation for the Bureau.

(c) The Attorney General is authorized to direct the advance of funds by the Treasury Department in connection with the enforcement of this title. Funds, advancement, authority of Attorney General.

PART F—ADVISORY COMMISSION

ESTABLISHMENT OF COMMISSION ON MARIHUANA AND DRUG ABUSE

SEC. 601. (a) There is established a commission to be known as the Commission on Marihuana and Drug Abuse (hereafter in this section referred to as the "Commission"). The Commission shall be composed of— Membership.

(1) two Members of the Senate appointed by the President of the Senate;

(2) two Members of the House of Representatives appointed by the Speaker of the House of Representatives; and

(3) nine members appointed by the President of the United States.

At no time shall more than one of the members appointed under paragraph (1), or more than one of the members appointed under paragraph (2), or more than five of the members appointed under paragraph (3) be members of the same political party.

(b)(1) The President shall designate one of the members of the Commission as Chairman, and one as Vice Chairman. Seven members of the Commission shall constitute a quorum, but a lesser number may conduct hearings. Quorum.

(2) Members of the Commission who are Members of Congress or full-time officers or employees of the United States shall serve without additional compensation but shall be reimbursed for travel, subsistence, and other necessary expenses incurred in the performance of the duties vested in the Commission. Members of the Commission from private life shall receive $100 per diem while engaged in the actual performance of the duties vested in the Commission, plus reimbursement for travel, subsistence, and other necessary expenses incurred in the performance of such duties. Travel expenses, etc. Compensation.

(3) The Commission shall meet at the call of the Chairman or at the call of a majority of the members thereof. Meetings.

(c)(1) The Commission shall have the power to appoint and fix the compensation of such personnel as it deems advisable, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and the provisions of chapter 51 and subchapter III of chapter 53 of such title, relating to classification and General Schedule pay rates. Personnel. 80 Stat. 443, 467. 5 USC 5101, 5331.

(2) The Commission may procure, in accordance with the provisions of section 3109 of title 5, United States Code, the temporary or intermittent services of experts or consultants. Persons so employed shall receive compensation at a rate to be fixed by the Commission, but not in excess of $75 per diem, including traveltime. While away from his home or regular place of business in the performance of services for the Commission, any such person may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703(b) of title 5, United States Code, for persons in the Government service employed intermittently. 35 F. R. 6247. Experts and consultants. 80 Stat. 416. Travel expenses, etc. 80 Stat. 499; 83 Stat. 190.

(3) The Commission may secure directly from any department or agency of the United States information necessary to enable it to Information, availability.

carry out its duties under this section. Upon request of the Chairman of the Commission, such department or agency shall furnish such information to the Commission.

(d)(1) The Commission shall conduct a study of marihuana including, but not limited to, the following areas: Marihuana, study.

(A) the extent of use of marihuana in the United States to include its various sources, the number of users, number of arrests, number of convictions, amount of marihuana seized, type of user, nature of use;

(B) an evaluation of the efficacy of existing marihuana laws;

(C) a study of the pharmacology of marihuana and its immediate and long-term effects, both physiological and psychological;

(D) the relationship of marihuana use to aggressive behavior and crime;

(E) the relationship between marihuana and the use of other drugs; and

(F) the international control of marihuana.

(2) Within one year after the date on which funds first become available to carry out this section, the Commission shall submit to the President and the Congress a comprehensive report on its study and investigation under this subsection which shall include its recommendations and such proposals for legislation and administrative action as may be necessary to carry out its recommendations. Report to President and Congress.

(e) The Commission shall conduct a comprehensive study and investigation of the causes of drug abuse and their relative significance. The Commission shall submit to the President and the Congress such interim reports as it deems advisable and shall within two years after the date on which funds first become available to carry out this section submit to the President and the Congress a final report which shall contain a detailed statement of its findings and conclusions and also such recommendations for legislation and administrative actions as it deems appropriate. The Commission shall cease to exist sixty days after the final report is submitted under this subsection. Drug abuse, study and investigation. Interim reports. Final report to President and Congress. Termination.

(f) Total expenditures of the Commission shall not exceed $1,000,000. Expenditures, limitation.

PART G—CONFORMING, TRANSITIONAL AND EFFECTIVE DATE, AND GENERAL PROVISIONS

REPEALS AND CONFORMING AMENDMENTS

SEC. 701. (a) Sections 201(v), 301(q), and 511 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(v), 331(q), 360(a) are repealed. Repeals. 79 Stat. 227, 228; 82 Stat. 1361.

(b) Subsections (a) and (b) of section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) are amended to read as follows: Penalties. 82 Stat. 1361.

"SEC. 303. (a) Any person who violates a provision of section 301 shall be imprisoned for not more than one year or fined not more than $1,000, or both.

"(b) Notwithstanding the provisions of subsection (a) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000 or both."

(c) Section 304(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334(a)(2)) is amended (1) by striking out clauses (A) and (D), (2) by striking out "of such depressant or stimulant 79 Stat. 233.

drug or" in clause (C), (3) by adding "and" after the comma at the end of clause (C), and (4) by redesignating clauses (B), (C), and (E) as clauses (A), (B), and (C), respectively.

(d) Section 304(d)(3)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334(d)(3)(iii)) is amended by striking out "depressant or stimulant drugs or". 79 Stat. 233.

(e) Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) is amended (1) in subsection (a) by striking out paragraph (2), by inserting "and" at the end of paragraph (1), and by redesignating paragraph (3) as paragraph (2); (2) by striking out "or in the wholesaling, jobbing, or distributing of any depressant or stimulant drug" in the first sentence of subsection (b); (3) by striking out the last sentence of subsection (b); (4) by striking out "or in the wholesaling, jobbing, or distributing of any depressant or stimulant drug" in the first sentence of subsection (c); (5) by striking out the last sentence of subsection (c); (6) by striking out "(1)" in subsection (d) and by inserting a period after "drug or drugs" in that subsection and deleting the remainder of that subsection; and (7) by striking out "AND CERTAIN WHOLESALERS" in the section heading. 76 Stat. 794; 79 Stat. 231.

(f) Section 702 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 372) is amended by striking out "to depressant or stimulant drugs or" in subsection (e). 79 Stat. 234.

(g) Section 201(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(a)(2)) is amended by inserting a period after "Canal Zone" the first time these words appear and deleting all thereafter in such section 201(a)(2). 76 Stat. 796; 82 Stat. 1362.

(h) The last sentence of section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is amended (1) by striking out "This paragraph" and inserting in lieu thereof "Clause (2) of the third sentence of this paragraph,", and (2) by striking out "section 2 of the Act of May 26, 1922, as amended (U.S.C. 1934, edition, title 21, sec. 173)" and inserting in lieu thereof "the Controlled Substances Import and Export Act". 52 Stat. 1058.

(i)(1) Section 1114 of title 18, United States Code, is amended by striking out "the Bureau of Narcotics" and inserting in lieu thereof "the Bureau of Narcotics and Dangerous Drugs". 65 Stat. 721.

(2) Section 1952 of such title is amended— 75 Stat. 498.

(A) by inserting in subsection (b)(1) "or controlled substances (as defined in section 102(6) of the Controlled Substances Act)" immediately following "narcotics"; and 18 USC 1952.

(B) by striking out "or narcotics" in subsection (c).

(j) Subsection (a) of section 302 of the Public Health Service Act (42 U.S.C. 242(a)) is amended to read as follows: Drugs, study. 58 Stat. 692.

"SEC. 302. (a) In carrying out the purposes of section 301 with respect to drugs the use or misuse of which might result in drug abuse or dependency, the studies and investigations authorized therein shall include the use and misuse of narcotic drugs and other drugs. Such studies and investigations shall further include the quantities of crude opium, coca leaves, and their salts, derivatives, and preparations, and other drugs subject to control under the Controlled Substances Act and Controlled Substances Import and Export Act, together with reserves thereof, necessary to supply the normal and emergency medicinal and scientific requirements of the United States. The results of studies and investigations of the quantities of narcotic drugs or other drugs subject to control under such Acts, together with reserves of such drugs, that are necessary to supply the normal and emergency medicinal and scientific requirements of the United States, shall be Ante, p. 1242. Post, p. 1285. Report to Attorney General.

reported not later than the first day of April of each year to the Attorney General, to be used at his discretion in determining manufacturing quotas or importation requirements under such Acts."

PENDING PROCEEDINGS

SEC. 702. (a) Prosecutions for any violation of law occurring prior to the effective date of section 701 shall not be affected by the repeals or amendments made by such section, or abated by reason thereof.

(b) Civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of section 701 shall not be affected by the repeals or amendments made by such section, or abated by reason thereof.

(c) All administrative proceedings pending before the Bureau of Narcotics and Dangerous Drugs on the date of enactment of this Act shall be continued and brought to final determination in accord with laws and regulations in effect prior to such date of enactment. Where a drug is finally determined under such proceedings to be a depressant or stimulant drug, as defined in section 201(v) of the Federal Food, Drug, and Cosmetic Act, such drug shall automatically be controlled under this title by the Attorney General without further proceedings and listed in the appropriate schedule after he has obtained the recommendation of the Secretary. Any drug with respect to which such a final determination has been made prior to the date of enactment of this Act which is not listed in section 202 within schedules I through V shall automatically be controlled under this title by the Attorney General without further proceedings, and be listed in the appropriate schedule, after he has obtained the recommendations of the Secretary. Ante, p. 1261. Ante, p. 1247.

PROVISIONAL REGISTRATION

SEC. 703. (a) (1) Any person who—

(A) is engaged in manufacturing, distributing, or dispensing any controlled substance on the day before the effective date of section 302, and

(B) is registered on such day under section 510 of the Federal Food, Drug, and Cosmetic Act or under section 4722 of the Internal Revenue Code of 1954, Ante, p. 1262. 68A Stat. 555.

shall, with respect to each establishment for which such registration is in effect under any such section, be deemed to have a provisional registration under section 303 for the manufacture, distribution, or dispensing (as the case may be) of controlled substances.

(2) During the period his provisional registration is in effect under this section, the registration number assigned such person under such section 510 or under such section 4722 (as the case may be) shall be his registration number for purposes of section 303 of this title.

(b) The provisions of section 304, relating to suspension and revocation of registration, shall apply to a provisional registration under this section.

(c) Unless sooner suspended or revoked under subsection (b), a provisional registration of a person under subsection (a)(1) of this section shall be in effect until—

(1) the date on which such person has registered with the Attorney General under section 303 or has had his registration denied under such section, or

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(2) such date as may be prescribed by the Attorney General for registration of manufacturers, distributors, or dispensers, as the case may be,

whichever occurs first.

EFFECTIVE DATES AND OTHER TRANSITIONAL PROVISIONS

SEC. 704. (a) Except as otherwise provided in this section, this title shall become effective on the first day of the seventh calendar month that begins after the day immediately preceding the date of enactment.

(b) Parts A, B, E, and F of this title, section 702, this section, and sections 705 through 709, shall become effective upon enactment.

(c) Sections 305 (relating to labels and labeling), and 306 (relating to manufacturing quotas) shall become effective on the date specified in subsection (a) of this section, except that the Attorney General may by order published in the Federal Register postpone the effective date of either or both of these sections for such period as he may determine to be necessary for the efficient administration of this title.

Ante, p. 1256.

Publication in Federal Register.

CONTINUATION OF REGULATIONS

SEC. 705. Any orders, rules, and regulations which have been promulgated under any law affected by this title and which are in effect on the day preceding enactment of this title shall continue in effect until modified, superseded, or repealed.

SEVERABILITY

SEC. 706. If a provision of this Act is held invalid, all valid provisions that are severable shall remain in effect. If a provision of this Act is held invalid in one or more of its applications, the provision shall remain in effect in all its valid applications that are severable.

SAVING PROVISION

SEC. 707. Nothing in this Act, except this part and, to the extent of any inconsistency, sections 307(c) and 309 of this title, shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the Federal Food, Drug, and Cosmetic Act.

52 Stat. 1040. 21 USC 301.

APPLICATION OF STATE LAW

SEC. 708. No provision of this title shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this title and that State law so that the two cannot consistently stand together.

APPROPRIATIONS AUTHORIZATIONS

SEC. 709. There are authorized to be appropriated for expenses of the Department of Justice in carrying out its functions under this title (except section 103) not to exceed $60,000,000 for the fiscal year ending June 30, 1972, $70,000,000 for the fiscal year ending June 30, 1973, and $90,000,000 for the fiscal year ending June 30, 1974.

Ante, p. 1245.

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TITLE III—IMPORTATION AND EXPORTATION; AMENDMENTS AND REPEALS OF REVENUE LAWS

SHORT TITLE

SEC. 1000. This title may be cited as the "Controlled Substances Import and Export Act".

Citation of title.

PART A—IMPORTATION AND EXPORTATION

DEFINITIONS

SEC. 1001. (a) For purposes of this part—

(1) The term "import" means, with respect to any article, any bringing in or introduction of such article into any area (whether or not such bringing in or introduction constitutes an importation within the meaning of the tariff laws of the United States).

(2) The term "customs territory of the United States" has the meaning assigned to such term by general headnote 2 to the Tariff Schedules of the United States (19 U.S.C. 1202).

77A Stat. 11.

(b) Each term defined in section 102 of title II shall have the same meaning for purposes of this title as such term has for purposes of title II.

Ante, p. 1242.

IMPORTATION OF CONTROLLED SUBSTANCES

SEC. 1002. (a) It shall be unlawful to import into the customs territory of the United States from any place outside thereof (but within the United States), or to import into the United States from any place outside thereof, any controlled substance in schedule I or II of title II, or any narcotic drug in schedule III, IV, or V of title II, except that—

Unlawful acts.

Exceptions.

(1) such amounts of crude opium and coca leaves as the Attorney General finds to be necessary to provide for medical, scientific, or other legitimate purposes, and

(2) such amounts of any controlled substance in schedule I or II or any narcotic drug in schedule III, IV, or V that the Attorney General finds to be necessary to provide for the medical, scientific, or other legitimate needs of the United States—

(A) during an emergency in which domestic supplies of such substance or drug are found by the Attorney General to be inadequate, or

(B) in any case in which the Attorney General finds that competition among domestic manufacturers of the controlled substance is inadequate and will not be rendered adequate by the registration of additional manufacturers under section 303,

Ante, p. 1253.

may be so imported under such regulations as the Attorney General shall prescribe. No crude opium may be so imported for the purpose of manufacturing heroin or smoking opium.

(b) It shall be unlawful to import into the customs territory of the United States from any place outside thereof (but within the United States), or to import into the United States from any place outside thereof, any nonnarcotic controlled substance in schedule III, IV, or V, unless such nonnarcotic controlled substance—

(1) is imported for medical, scientific, or other legitimate uses, and

(2) is imported pursuant to such notification or declaration requirements as the Attorney General may by regulation prescribe.

(c) In addition to the amount of coca leaves authorized to be imported into the United States under subsection (a), the Attorney General may permit the importation of additional amounts of coca leaves. All cocaine and ecgonine (and all salts, derivatives, and preparations from which cocaine or ecgonine may be synthesized or made) contained in such additional amounts of coca leaves imported under this subsection shall be destroyed under the supervision of an authorized representative of the Attorney General.

EXPORTATION OF CONTROLLED SUBSTANCES

SEC. 1003. (a) It shall be unlawful to export from the United States any narcotic drug in schedule I, II, III, or IV unless— Unlawful acts.

(1) it is exported to a country which is a party to—

(A) the International Opium Convention of 1912 for the Suppression of the Abuses of Opium, Morphine, Cocaine, and Derivative Drugs, or to the International Opium Convention signed at Geneva on February 19, 1925; or 38 Stat. 1912. 61 Stat. 2230.

(B) the Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs concluded at Geneva, July 13, 1931, as amended by the protocol signed at Lake Success on December 11, 1946, and the protocol bringing under international control drugs outside the scope of the convention of July 13, 1931, for limiting the manufacture and regulating the distribution of narcotic drugs (as amended by the protocol signed at Lake Success on December 11, 1946), signed at Paris, November 19, 1948; or 48 Stat. 1543. 62 Stat. 1796. 2 UST 1629.

(C) the Single Convention on Narcotic Drugs, 1961, signed at New York, March 30, 1961; 18 UST 1407.

(2) such country has instituted and maintains, in conformity with the conventions to which it is a party, a system for the control of imports of narcotic drugs which the Attorney General deems adequate;

(3) the narcotic drug is consigned to a holder of such permits or licenses as may be required under the laws of the country of import, and a permit or license to import such drug has been issued by the country of import;

(4) substantial evidence is furnished to the Attorney General by the exporter that (A) the narcotic drug is to be applied exclusively to medical or scientific uses within the country of import, and (B) there is an actual need for the narcotic drug for medical or scientific uses within such country; and

(5) a permit to export the narcotic drug in each instance has been issued by the Attorney General.

(b) Notwithstanding subsection (a), the Attorney General may authorize any narcotic drug (including crude opium and coca leaves) in schedule I, II, III, or IV to be exported from the United States to a country which is a party to any of the international instruments mentioned in subsection (a) if the particular drug is to be applied to a special scientific purpose in the country of destination and the authorities of such country will permit the importation of the particular drug for such purpose. Ante, p. 1248.

(c) It shall be unlawful to export from the United States any nonnarcotic controlled substance in schedule I or II unless—

(1) it is exported to a country which has instituted and maintains a system which the Attorney General deems adequate for the control of imports of such substances;

(2) the controlled substance is consigned to a holder of such permits or licenses as may be required under the laws of the country of import;

(3) substantial evidence is furnished to the Attorney General that (A) the controlled substance is to be applied exclusively to medical, scientific, or other legitimate uses within the country to which exported, (B) it will not be exported from such country, and (C) there is an actual need for the controlled substance for medical, scientific, or other legitimate uses within the country; and

(4) a permit to export the controlled substance in each instance has been issued by the Attorney General.

(d) Notwithstanding subsection (c), the Attorney General may authorize any nonnarcotic controlled substance in schedule I or II to be exported from the United States if the particular substance is to be applied to a special scientific purpose in the country of destination and the authorities of such country will permit the importation of the particular drug for such purpose. Ante, p. 1248.

(e) It shall be unlawful to export from the United States to any other country any nonnarcotic controlled substance in schedule III or IV or any controlled substance in schedule V unless—

(1) there is furnished (before export) to the Attorney General documentary proof that importation is not contrary to the laws or regulations of the country of destination;

(2) a special controlled substance invoice, in triplicate, accompanies the shipment setting forth such information as the Attorney General may prescribe to identify the parties to the shipment and the means of shipping, and

(3) two additional copies of the invoice are forwarded to the Attorney General before the controlled substance is exported from the United States.

TRANSSHIPMENT AND IN-TRANSIT SHIPMENT OF CONTROLLED SUBSTANCES

SEC. 1004. Notwithstanding sections 1002, 1003, and 1007—

(1) A controlled substance in schedule I may—

(A) be imported into the United States for transshipment to another country, or

(B) be transferred or transshipped from one vessel, vehicle, or aircraft to another vessel, vehicle, or aircraft within the United States for immediate exportation,

if and only if it is so imported, transferred, or transshipped (i) for scientific, medical, or other legitimate purposes in the country of destination, and (ii) with the prior written approval of the Attorney General (which shall be granted or denied within 21 days of the request).

(2) A controlled substance in schedule II, III, or IV may be so imported, transferred, or transshipped if and only if advance notice is given to the Attorney General in accordance with regulations of the Attorney General.

POSSESSION ON BOARD VESSELS, ETC., ARRIVING IN OR DEPARTING FROM UNITED STATES

SEC. 1005. It shall be unlawful for any person to bring or possess on board any vessel or aircraft, or on board any vehicle of a carrier,

arriving in or departing from the United States or the customs territory of the United States, a controlled substance in schedule I or II or a narcotic drug in schedule III or IV, unless such substance or drug is a part of the cargo entered in the manifest or part of the official supplies of the vessel, aircraft, or vehicle.

Ante, p. 1246.

EXEMPTION AUTHORITY

SEC. 1006. (a) The Attorney General may by regulation exempt from sections 1002 (a) and (b), 1003, 1004, and 1005 any individual who has a controlled substance (except a substance in schedule I) in his possession for his personal medical use, or for administration to an animal accompanying him, if he lawfully obtained such substance and he makes such declaration (or gives such other notification) as the Attorney General may by regulation require.

(b) The Attorney General may by regulation except any compound, mixture, or preparation containing any depressant or stimulant substance listed in paragraph (a) or (b) of schedule III or in schedule IV or V from the applicaton of all or any part of this title if (1) the compound, mixture, or preparation contains one or more active medicinal ingredients not having a depressant or stimulant effect on the central nervous system, and (2) such ingredients are included therein in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse of the substances which do have a depressant or stimulant effect on the central nervous system.

PERSONS REQUIRED TO REGISTER

SEC. 1007. (a) No person may—

(1) import into the customs territory of the United States from any place outside thereof (but within the United States), or import into the United States from any place outside thereof, any controlled substance, or

(2) export from the United States any controlled substance in schedule I, II, III, or IV,

unless there is in effect with respect to such person a registration issued by the Attorney General under section 1008, or unless such person is exempt from registration under subsection (b).

(b) (1) The following persons shall not be required to register under the provisions of this section and may lawfully possess a controlled substance:

(A) An agent or an employee of any importer or exporter registered under section 1008 if such agent or employee is acting in the usual course of his business or employment.

(B) A common or contract carrier or warehouseman, or an employee thereof, whose possession of any controlled substance is in the usual course of his business or employment.

(C) An ultimate user who possesses such substance for a purpose specified in section 102(25) and in conformity with an exemption granted under section 1006(a).

Ante, p. 1245.

(2) The Attorney General may, by regulation, waive the requirement for registration of certain importers and exporters if he finds it consistent with the public health and safety; and may authorize any such importer or exporter to possess controlled substances for purposes of importation and exportation.

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REGISTRATION REQUIREMENTS

SEC. 1008. (a) The Attorney General shall register an applicant to import or export a controlled substance in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on the effective date of this section. In determining the public interest, the factors enumerated in paragraph (1) through (6) of section 303(a) shall be considered.

Ante, p. 1253.

(b) Registration granted under subsection (a) of this section shall not entitle a registrant to import or export controlled substances in schedule I or II other than those specified in the registration.

(c) The Attorney General shall register an applicant to import a controlled substance in schedule III, IV, or V or to export a controlled substance in schedule III or IV, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the factors enumerated in paragraphs (1) through (6) of section 303(d) shall be considered.

(d) No registration shall be issued under this part for a period in excess of one year. Unless the regulations of the Attorney General otherwise provide, section 302(f), 304, 305, and 307 shall apply to persons registered under this section to the same extent such sections apply to persons registered under section 303.

Ante, pp. 1253-1258.

Rules and regulations.

(e) The Attorney General is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration of importers and exporters of controlled substances under this section.

(f) Persons registered by the Attorney General under this section to import or export controlled substances may import or export (and, for the purpose of so importing or exporting, may possess) such substances to the extent authorized by their registration and in conformity with the other provisions of this title and title II.

(g) A separate registration shall be required at each principal place of business where the applicant imports or exports controlled substances.

(h) Except in emergency situations as described in section 1002(a)(2)(A), prior to issuing a registration under this section to a bulk manufacturer of a controlled substance in schedule I or II, and prior to issuing a regulation under section 1002(a) authorizing the importation of such a substance, the Attorney General shall give manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

MANUFACTURE OR DISTRIBUTION FOR PURPOSES OF UNLAWFUL IMPORTATION

SEC. 1009. It shall be unlawful for any person to manufacture or distribute a controlled substance in schedule I or II—

(1) intending that such substance be unlawfully imported into the United States; or

(2) knowing that such substance will be unlawfully imported into the United States.

This section is intended to reach acts of manufacture or distribution committed outside the territorial jurisdiction of the United States. Any person who violates this section shall be tried in the United States district court at the point of entry where such person enters the United States, or in the United States District Court for the District of Columbia.

PROHIBITED ACTS A—PENALTIES

SEC. 1010. (a) Any person who—

(1) contrary to section 1002, 1003, or 1007, knowingly or intionally imports or exports a controlled substance,

(2) contrary to section 1005, knowingly or intentionally brings or possesses on board a vessel, aircraft, or vehicle a controlled substance, or

(3) contrary to section 1009, manufactures or distributes a controlled substance,

shall be punished as provided in subsection (b).

(b)(1) In the case of a violation under subsection (a) with respect to a narcotic drug in schedule I or II, the person committing such violation shall be imprisoned not more than fifteen years, or fined not more than $25,000, or both. If a sentence under this paragraph provides for imprisonment, the sentence shall include a special parole term of not less than three years in addition to such term of imprisonment.

Ante, p. 1248.

(2) In the case of a violation under subsection (a) with respect to a controlled substance other than a narcotic drug in schedule I or II, the person committing such violation shall be imprisoned not more than five years, or be fined not more than $15,000, or both. If a sentence under this paragraph provides for imprisonment, the sentence shall, in in addition to such term of imprisonment, include (A) a special parole term of not less than two years if such controlled substance is in schedule I, II, III, or (B) a special parole term of not less than one year if such controlled substance is in schedule IV.

(c) A special parole term imposed under this section or section 1012 may be revoked if its terms and conditions are violated. In such circumstances the original term of imprisonment shall be increased by the period of the special parole term and the resulting new term of imprisonment shall not be diminished by the time which was spent on special parole. A person whose special parole term has been revoked may be required to serve all or part of the remainder of the new term of imprisonment. The special term provided for in this section and in section 1012 is in addition to, and not in lieu of, any other parole provided for by law.

PROHIBITED ACTS B—PENALTIES

SEC. 1011. Any person who violates section 1004 shall be subject to the following penalties:

(1) Except as provided in paragraph (2), any such person shall, with respect to any such violation, be subject to a civil penalty of not more than $25,000. Sections 402 (c)(1) and (c)(3) shall apply to any civil penalty assessed under this paragraph.

Ante, p. 1262.

(2) If such a violation is prosecuted by an information or indictment which alleges that the violation was committed knowingly or intentionally and the trier of fact specifically finds that the violation was so committed, such person shall be sentenced to imprisonment for not more than one year or a fine of not more than $25,000 or both.

SECOND OR SUBSEQUENT OFFENSES

SEC. 1012. (a) Any person convicted of any offense under this part is, if the offense is a second or subsequent offense, punishable by a term of imprisonment twice that otherwise authorized, by twice the fine otherwise authorized, or by both. If the conviction is for an offense

punishable under section 1010(b), and if it is the offender's second or subsequent offense, the court shall impose, in addition to any term of imprisonment and fine, twice the special parole term otherwise authorized.

(b) For purposes of this section, a person shall be considered convicted of a second or subsequent offense if, prior to the commission of such offense, one or more prior convictions of him for a felony under any provision of this title or title II or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant drugs, have become final.

Ante, p. 1242.

(c) Section 411 shall apply with respect to any proceeding to sentence a person under this section.

Ante, p. 1269.

ATTEMPT AND CONSPIRACY

SEC. 1013. Any person who attempts or conspires to commit any offense defined in this title is punishable by imprisonment or fine or both which may not exceed the maximum punishment prescribed for the offense, the commission of which was the object of the attempt or conspiracy.

ADDITIONAL PENALTIES

SEC. 1014. Any penalty imposed for violation of this title shall be in addition to, and not in lieu of, any civil or administrative penalty or sanction authorized by law.

APPLICABILITY OF PART E OF TITLE II

SEC. 1015. Part E of title II shall apply with respect to functions of the Attorney General (and of officers and employees of the Bureau of Narcotics and Dangerous Drugs) under this title, to administrative and judicial proceedings under this title, and to violations of this title, to the same extent that such part applies to functions of the Attorney General (and such officers and employees) under title II, to such proceedings under title II, and to violations of title II. For purposes of the application of this section to section 510, any reference in such section 510 to "this title" shall be deemed to be a reference to title III, any reference to section 303 shall be deemed to be a reference to section 1008, and any reference to section 302(d) shall be deemed to be a reference to section 1007(b)(2).

Ante, p. 1270.
Ante, p. 1274.
Ante, p. 1285.
Ante, p. 1253.

AUTHORITY OF SECRETARY OF TREASURY

SEC. 1016. Nothing in this Act shall derogate from the authority of the Secretary of the Treasury under the customs and related laws.

PART B—AMENDMENTS AND REPEALS, TRANSITIONAL AND EFFECTIVE DATE PROVISIONS

REPEALS

SEC. 1101. (a) The following provisions of law are repealed:

(1) The Act of February 23, 1887 (21 U.S.C. 191–193).

24 Stat. 409.

(2) The Narcotic Drugs Import and Export Act (21 U.S.C. 171, 173, 174–184, 185).

38 Stat. 275.

(3) The Act of March 28, 1928 (31 U.S.C. 529a).

53 Stat. 1262.

(4) Sections 2(b), 6, 7, and 8 of the Act of June 14, 1930 (21 U.S.C. 162(b), 173a, 197, 198).

46 Stat. 585; 70 Stat. 575.

(5) The Act of July 3, 1930 (21 U.S.C. 199). 46 Stat. 850.
(6) Section 6 of the Act of March 28, 1928 (31 U.S.C. 529g). 53 Stat. 1263.
(7) The Opium Poppy Control Act of 1942 (21 U.S.C. 188–188n). 56 Stat. 1045.
(8) Section 15 of the Act of August 1, 1956 (48 U.S.C. 1421m). 70 Stat. 910.
(9) The Act of July 11, 1941 (21 U.S.C. 184a). 55 Stat. 584.
(10) The Narcotics Manufacturing Act of 1960 (21 U.S.C. 501–517). 74 Stat. 55.

(b) (1) (A) Chapter 68 of title 18 of the United States Code (relating to narcotics) is repealed. 70 Stat. 572. 18 USC 1401–1405.

(B) The item relating to such chapter 68 in the analysis of part I of such title 18 is repealed.

(2) (A) Section 3616 of title 18 of the United States Code (relating to use of confiscated motor vehicles) is repealed. 62 Stat. 840.

(B) The item relating to such section 3616 in the analysis of chapter 229 of such title 18 is repealed. 68A Stat. 549.

(3) (A) Subchapter A of chapter 39 of the Internal Revenue Code of 1954 (relating to narcotic drugs and marihuana) is repealed. 26 USC 4701–4776.

(B) The table of subchapters of such chapter 39 is amended by striking out

"SUBCHAPTER A. Narcotic drugs and marihuana."

(4) (A) Sections 7237 (relating to violation of laws relating to narcotic drugs and to marihuana) and 7238 (relating to violation of laws relating to opium for smoking) of the Internal Revenue Code of 1954 are repealed. 70 Stat. 568; 80 Stat. 1449. 26 USC 7237, 7238.

(B) The table of sections of part II of subchapter A of chapter 75 of the Internal Revenue Code of 1954 is amended by striking out the items relating to such sections 7237 and 7238.

(5) (A) Section 7491 of the Internal Revenue Code of 1954 (relating to burden of proof of exemptions in case of marihuana offenses) is repealed. 26 USC 7491.

(B) The table of sections for subchapter E of chapter 76 of the Internal Revenue Code of 1954 is amended by striking out the item relating to such section 7491.

CONFORMING AMENDMENTS

SEC. 1102. (a) Section 4901(a) of the Internal Revenue Code of 1954 is amended by striking out the comma immediately before "4461" and inserting in lieu thereof "or", and by striking out ", 4721 (narcotic drugs), or 4751 (marihuana)". 79 Stat. 149.

(b) Section 4905(b)(1) of the Internal Revenue Code of 1954 (relating to registration) is amended by striking out ", narcotics, marihuana," and ", 4722, 4753,".

(c) Section 6808 of the Internal Revenue Code of 1954 (relating to special provisions relating to stamps) is amended by striking out paragraph (8).

(d) Section 7012 of the Internal Revenue Code of 1954 (relating to cross references) is amended by striking out subsections (a) and (b).

(e) Section 7103(d)(3) of the Internal Revenue Code of 1954 (relating to bonds required with respect to certain products) is amended by striking out subparagraph (D).

(f) Section 7326 of the Internal Revenue Code of 1954 (relating to disposal of forfeited or abandoned property in special cases) is amended by striking out subsection (b). 72 Stat. 1429.

(g) (1) Section 7607 of the Internal Revenue Code of 1954 (relating to additional authority for Bureau of Narcotics and Bureau of Customs) is amended— 70 Stat. 570.

(A) by striking out "The Commissioner, Deputy Commissioner, Assistant to the Commissioner, and agents of the Bureau of Narcotics of the Department of the Treasury, and officers" and inserting in lieu thereof "Officers";

(B) by striking out in paragraph (2) "narcotic drugs (as defined in section 4731) or marihuana (as defined in section 4761)" and inserting in lieu thereof "narcotic drugs (as defined in section 102(16) of the Controlled Substances Act) or marihuana (as defined in section 102(15) of the Controlled Substances Act)"; and

(C) by striking out "BUREAU OF NARCOTICS AND" in the section heading.

(2) The item relating to section 7607 in the table of contents of subchapter A of chapter 78 of the Internal Revenue Code of 1954 is amended by striking out "Bureau of Narcotics and". 70 Stat. 570.

(h) Section 7609(a) of the Internal Revenue Code of 1954 (relating to cross references) is amended by striking out paragraphs (3) and (4). 72 Stat. 1430.

(i) Section 7641 of the Internal Revenue Code of 1954 (relating to supervision of operations of certain manufacturers) is amended by striking out "opium suitable for smoking purposes,". 68A Stat. 905. 26 USC 7641.

(j) Section 7651 of the Internal Revenue Code of 1954 (relating to administration and collection of taxes in possessions) is amended by striking out "and in sections 4705(b), 4735, and 4762 (relating to taxes on narcotic drugs and marihuana)".

(k) Section 7655(a) of the Internal Revenue Code of 1954 (relating to cross references) is amended by striking out paragraphs (3) and (4).

(l) Section 2901(a) of title 28 of the United States Code is amended by striking out "as defined by section 4731 of the Internal Revenue Code of 1954, as amended," and inserting in lieu thereof "as defined by section 102(16) of the Controlled Substances Act". 80 Stat. 1438.

(m) The last sentence of the second paragraph of section 584 of the Act of June 17, 1930 (19 U.S.C. 1584), is amended to read as follows: "As used in this paragraph, the terms 'opiate' and 'marihuana' shall have the same meaning given those terms by sections 102(17) and 102(15), respectively, of the Controlled Substances Act." 58 Stat. 722; 60 Stat. 39.

(n) (1) The first section of the Act of August 7, 1939 (31 U.S.C. 529a), is repealed. Repeal. 53 Stat. 1262.

(2) Section 3 of such Act (31 U.S.C. 529d) is amended by striking out "or the Commissioner of Narcotics, as the case may be,".

(3) Section 4 of such Act (31 U.S.C. 529e) is amended by striking out "or narcotics" each place it appears.

(4) Section 5 of such Act (31 U.S.C. 529f) is amended by striking out "or narcotics" in the first sentence.

(o) Section 308(c)(2) of the Act of August 27, 1935 (40 U.S.C. 304m) is amended by striking out "Narcotic Drug Import and Export Act" and inserting in lieu thereof "Controlled Substances Act". 49 Stat. 880.

(p) Paragraph (a) of section 301 of the Narcotic Addict Rehabilitation Act of 1966 (42 U.S.C. 3411) is amended by striking out "as defined in section 4731 of the Internal Revenue Code of 1954, as amended," and inserting in lieu thereof "as defined in section 102(16) of the Controlled Substances Act". 80 Stat. 1444.

(q) Paragraph (a) of the first section of the Act of July 15, 1954 (46 U.S.C. 239a) is amended to read as follows: 68 Stat. 484.

"(a) The term 'narcotic drug' shall have the meaning given that term by section 102(16) of the Controlled Substances Act and shall also include marihuana as defined by section 102(15) of such Act."

(r) Paragraph (d) of section 7 of the Act of August 9, 1939 (49 U.S.C. 787) is amended to read as follows: 53 Stat. 1292.

"(d) The term 'narcotic drug' shall have the meaning given that term by section 102(16) of the Controlled Substances Act and shall also include marihuana as defined by section 102(15) of such Act;" "Narcotic drug."

(s) Paragraph (a) of section 4251 of title 18, United States Code, is amended by striking out "as defined in section 4731 of the Internal Revenue Code of 1954, as amended," and inserting in lieu thereof "as defined in section 102(16) of the Controlled Substances Act". 80 Stat. 1442.

(t) The first section of the Act of August 11, 1955 (21 U.S.C. 198a), is amended to read as follows: "That for the purpose of any investigation which, in the opinion of the Secretary of the Treasury, is necessary and proper to the enforcement of section 545 of title 18 of the United States Code (relating to smuggling goods into the United States) with respect to any controlled substance (as defined in section 102 of the Controlled Substances Act), the Secretary of the Treasury may administer oaths and affirmations, subpena witnesses, compel their attendance, take evidence, and require the production of records (including books, papers, documents, and tangible things which constitute or contain evidence) relevant or material to the investigation. The attendance of witnesses and the production of records may be required from any place within the customs territory of the United States, except that a witness shall not be required to appear at any hearing distant more than 100 miles from the place where he was served with subpena. Witnesses summoned by the Secretary shall be paid the same fees and mileage that are paid witnesses in the courts of the United States. Oaths and affirmations may be made at any place subject to the jurisdiction of the United States." Investigations, subpoena power. 69 Stat. 684. 62 Stat. 716. Witnesses, travel expenses.

PENDING PROCEEDINGS

SEC. 1103. (a) Prosecutions for any violation of law occurring prior to the effective date of section 1101 shall not be affected by the repeals or amendments made by such section or section 1102, or abated by reason thereof.

(b) Civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of section 1101 shall not be affected by the repeals or amendments made by such section or section 1102, or abated by reason thereof.

PROVISIONAL REGISTRATION

SEC. 1104. (a) (1) Any person—

(A) who is engaged in importing or exporting any controlled substance on the day before the effective date of section 1007,

(B) who notifies the Attorney General that he is so engaged, and

(C) who is registered on such day under section 510 of the Federal Food, Drug, and Cosmetic Act or under section 4722 of the Internal Revenue Code of 1954, 76 Stat. 794; 79 Stat. 231. 21 USC 360. 68A Stat. 555. 26 USC 4722.

shall, with respect to each establishment for which such registration is in effect under any such section, be deemed to have a provisional registration under section 1008 for the import or export (as the case may be) of controlled substances.

(2) During the period his provisional registration is in effect under this section, the registration number assigned such person under such section 510 or under such section 4722 (as the case may be) shall be his registration number for purposes of part A of this title. Ante, p. 1285.

(b) The provisions of section 304, relating to suspension and revocation of registration, shall apply to a provisional registration under this section. Ante, p. 1255.

(c) Unless sooner suspended or revoked under subsection (b), a provisional registration of a person under subsection (a)(1) of this section shall be in effect until—

(1) the date on which such person has registered with the Attorney General under section 1008 or has had his registration denied under such section, or

(2) such date as may be prescribed by the Attorney General for registration of importers or exporters, as the case may be,

whichever occurs first.

EFFECTIVE DATES AND OTHER TRANSITIONAL PROVISIONS

SEC. 1105. (a) Except as otherwise provided in this section, this title shall become effective on the first day of the seventh calendar month that begins after the day immediately preceding the date of enactment.

(b) Sections 1000, 1001, 1006, 1015, 1016, 1103, 1104, and this section shall become effective upon enactment.

(c)(1) If the Attorney General, pursuant to the authority of section 704(c) of title II, postpones the effective date of section 306 (relating to manufacturing quotas) for any period beyond the date specified in section 704(a) and such postponement applies to narcotic drugs, the repeal of the Narcotics Manufacturing Act of 1960 by paragraph (10) of section 1101(a) of this title is hereby postponed for the same period, except that the postponement made by this paragraph shall not apply to the repeal of sections 4, 5, 13, 15, and 16 of that Act. Ante, pp. 1284, 1257.

(2) Effective for any period of postponement, by paragraph (1) of this subsection, of the repeal of provisions of the Narcotics Manufacturing Act of 1960, that Act shall be applied subject to the following modifications:

(A) The term "narcotic drug" shall mean a narcotic drug as defined in section 102(16) of title II, and all references, in the Narcotics Manufacturing Act of 1960, to a narcotic drug as defined by section 4731 of the Internal Revenue Code of 1954 are amended to refer to a narcotic drug as defined by such section 102(16). "Narcotic drug." Ante, p. 1244.

(B) On and after the date prescribed by the Attorney General pursuant to clause (2) of section 703(c) of title II, the requirements of a manufacturer's license with respect to a basic class of narcotic drug under the Narcotics Manufacturing Act of 1960, and of a registration under section 4722 of the Internal Revenue Code of 1954 as a prerequisite to issuance of such a license, shall be superseded by a requirement of actual registration (as distinguished from provisional registration) as a manufacturer of that class of drug under section 303(a) of title II. Ante, p. 1253.

(C) On and after the effective date of the repeal of such section 4722 by section 1101(b)(3) of this title, but prior to the date specified in subparagraph (B) of this paragraph, the requirement of registration under such section 4722 as a prerequisite of a manufacturer's license under the Narcotics Manufacturing Act of 1960 shall be superseded by a requirement of either (i) actual registration as a manufacturer under section 303 of title II or (ii) provisional registration (by virtue of a preexisting registration under such section 4722) under section 703 of title II.

(d) Any orders, rules, and regulations which have been promulgated under any law affected by this title and which are in effect on the day preceding enactment of this title shall continue in effect until modified, superseded, or repealed.

TITLE IV--REPORT ON ADVISORY COUNCILS

REPORT ON ADVISORY COUNCILS

Reports to Congress.

SEC. 1200. (a) Not later than March 31 of each calendar year after 1970, the Secretary of the Department of Health, Education, and Welfare shall submit a report on the activities of advisory councils (established or organized pursuant to any applicable statute of the Public Health Service Act, Public Law 410, Seventy-eighth Congress, as amended, or the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963, Public Law 88-164, as amended) to the Committee on Labor and Public Welfare of the Senate and the Committee on Interstate and Foreign Commerce of the House of Representatives. Such report shall contain, at least, a list of all such advisory councils, the names and occupations of their members, a description of the function of each advisory council, and a statement of the dates of the meetings of each advisory council.

77 Stat. 282, 42 USC 2661 note.

(b) If the Secretary determines that a statutory advisory council is not needed or that the functions of two or more statutory advisory councils should be combined, he shall include in the report a recommendation that such advisory council be abolished or that such functions be combined.

"Statutory advisory council."

(c) As used in this section, the term "statutory advisory council" means any committee, board, commission, council, or other similar group established or organized pursuant to any applicable statute to advise and make recommendations with respect to the administration or improvement of an applicable program or other related matter.

Approved October 27, 1970.

LEGISLATIVE HISTORY:

HOUSE REPORTS: No. 91-1444 (pts. 1 and 2) (Comm. on Interstate and Foreign Commerce) and No. 91-1603 (Comm. of Conference).
SENATE REPORT No. 91-613 accompanying S. 3246 (Comm. on the Judiciary).
CONGRESSIONAL RECORD, Vol. 116 (1970):
Jan. 23, 24, 26-28, S. 3246 considered and passed Senate.
Sept. 23, 24, considered and passed House.
Oct. 6, 7, considered and passed Senate, amended.
Oct. 8, 14, House agreed to conference report.
Oct. 14, Senate agreed to conference report.

STATEMENT OF HAROLD SHINNICK, PRESIDENT, NATIONAL ASSOCIATION OF RETAIL DRUGGISTS (NARD), ACCOMPANIED BY WILLIAM WOODS, ASSOCIATE GENERAL COUNSEL, NARD, DAVID CLARK, EXECUTIVE DIRECTOR, INDIANA PHAMACEUTICAL ASSOCIATION, IVAN ROSE, PAST PRESIDENT, ARKANSAS PHARMACEUTICAL ASSOCIATION, AND JOHN JOHNSON, FIRST VICE PRESIDENT OF THE NATIONAL ASSOCIATION OF RETAIL DRUGGISTS

Mr. SHINNICK. Thank you very much.

Chairman Bayh and members of the subcommittee, I am Harold J. Shinnick and I am an independent retail pharmacist and owner of a community pharmacy in Chicago, Ill. I appear here today with my associates as president of the National Association of Retail Druggists. On my right is David Woods, also David Clark, executive director, Indiana Pharmaceutical Association. On my left, Ivan Rose, and also on my left, John Johnson of Nebraska.

I also have with us to my left in the back is Willard B. Simmons, executive secretary of the NARD.

NARD is the national association in the United States representing the tens of thousands of pharmacists of the county who own and operate their own pharmacies in the neighborhoods and communities across this land.

We are most appreciative of your invitation to appear here today and applaud the work and efforts of this committee. The Controlled Substances Act of 1970 required significant and substantial changes in the practice of pharmacy, some of which our members have welcomed and others which we have accepted and endured. The independent practitioner of pharmacy has a fine record of serving the people in this country and we, like all America, were concerned about the drug abuse and misuse reaching epidemic proportions. Clearly something had to be done and the Controlled Substances Act was a bold and sweeping plan.

Therefore, NARD is particularly pleased that this committee has taken the initiative to review the implementation and effect of the Controlled Substances Act at this time to determine just how well it is working or administrative implementation of the act. Like you, we do not have the definitive answers to this complex problem though we all wish we did. Drug abuse and misuse is still a serious issue and a serious concern and will continue to be such until we have conquered its problems and causes.

NARD has assembled a group of informed pharmacists who we believe are most knowledgeable to assist this committee in its inquiry.

Mr. Willard Simmons, the executive secretary of the National Association of Retail Druggists, has had a long-standing personal commitment to programs directed to the public and particularly young people to provide information and education on the hazards of drug abuse and misuse. He provided the leadership which sparked an extensive public education program which brought vital and timely information and facts to millions of school-age children, their

parents, and teachers on drug abuse. Mr. Simmons, in addition to his long tenure as an independent pharmacist in his home, Texarkana, Tex., has traveled the length and breadth of this Nation talking with pharmacists and others, which has given him the opportunity to obtain a broad and representative view of the operation and implementation of this act.

Mr. William E. Woods is a pharmacist and attorney who serves as NARD's Washington Representative and Associate General Counsel. He has the experience of working with the act from the original legislative proposals, through the revisions of the implementing regulations, and in identifying an attempting to resolve legal and regulatory issues relating to the act. Mr. Woods has borne the brunt of interpreting the legislation and regulations for our executive committee and members.

We also have with us Mr. David Clark, executive director of the Indiana Pharmaceutical Association. Mr. Clark is also a pharmacist and can provide the valuable insight of the views of an executive of a statewide organization of pharmacists and the problems and issues that concern him and his association relating to the act.

Mr. Ivan Rose is from Arkansas where the pharmacy association and its members are particularly concerned about the rising risk of violent crimes in pharmacies related to controlled substances. In addition to being a pharmacist, Mr. Rose is a member of the Arkansas legislature and has served as a member of the Arkansas Board of Pharmacy and NARD believes that he is particularly well-qualified to assist this committee in its inquiry.

And we also have John Johnson, a pharmacist from Nebraska, who is a leader in Nebraska pharmacy association affairs and who also serves as the first vice president of the National Association of Retail Druggists. Mr. Johnson's experience as a State leader, his fine service as an officer of NARD on the national level, as well as his reputation as an articulate spokesman, suggest that he, too, could serve as a valuable resource for this committee.

To coordinate our presentation in an effort to be most helpful and informative to the committee, we will have Mr. Woods present a statement responding to some of the issues the committee indicated were of interest to it. Thereafter, Messrs. Clark, Rose, and Johnson will present brief supplementary comments reflecting their own special perspectives.

NARD has what we consider a good record of cooperation in the development and implementation of the Controlled Substances Act. And I want to assure the committee that we intend to cooperate fully with this committee and the Drug Enforcement Administration in achieving the objectives of this national effort. However, I would be remiss if I did not also state that our members want and expect that NARD and the Congress will insist that the burdens of compliance will be strictly limited to only that which is necessary to effectuate the purposes of the act, and no more. Our members are finding that the costs in terms of time and money of compliance with an ever-increasing system of State and Federal regulation, of which the CSA is but a part, are becoming more than an individual small businessman can shoulder. Independent pharmacists typically

must rely upon their individual efforts to meet all Government regulatory requirements and frequently only with the guidance of the NARD and their State pharmacy association.

Therefore, NARD does have some suggestions and comments on some points where we believe that the views of our members deserve priority consideration and implementation to assure the pharmacists that they will not have to face the risks and dangers created by this law alone, or in vain.

I thank you.

Senator BAYH. Mr. Woods.

Mr. WOODS. Mr. Chairman, first we would like to express our appreciation for the cooperation that this committee and chairman and staff have shown us in planning for these committee hearings. We have been particularly impressed by the record of this committee and the distinguished chairman, a long record of concern in effective work to deal with the drug abuse problems in this country.

The National Association of Retail Druggists appreciates your invitation to discuss the administration and implementation of the Controlled Substances Act of 1970. When first adopted, this law made sweeping and comprehensive changes in the regulatory scheme for narcotics and drugs subject to abuse. And we have every indication that narcotic addiction may have reached its peak in this country, and that abuses of nonnarcotic drugs are lessening or not increasing at the alarming rate that prompted the enactment of the CSA.

When the proposals which eventually became the Controlled Substances Act of 1970 were being considered, NARD maintained that independent pharmacies were not significant sources of supply for drugs for illicit use. We believe that that was a correct assessment then as well as today. To be sure, there were abuses of drugs prescribed, but by and large this was a significant portion of the problem. To the extent that drugs subject to abuse were prescribed too often, and in abnormally large quantities, or refilled over too long a period, the CSA has brought this problem under control.

NARD believes that the present controls assure, insofar as can be done, that controlled substances that are prescribed will be utilized properly for an appropriate medical purpose. We cannot assure that an enterprising patient, either alone, or in concert with the prescriber, will subvert the intentions of the law. However, we have no evidence that this is a significant or widespread problem.

When the CSA was first adopted, and later as it was implemented, the NARD made every attempt to assure that the law was understood by pharmacists and implemented in a proper manner. We distributed detailed analyses of the regulations promulgated by the Government, prepared a quick reference chart which summarized in readily accessible form the major features of the law, and developed and produced with the cooperation of Smith, Kline, & French Laboratories, a continuing education cassette that explained the requirements of the law in detail. In cooperation with the Government, the reference chart was made available to every pharmacy. And, we have cooperated in making the law workable in every other way through suggestions to the Government, including the

inventory form for the biennial inventory which forms the backbone of the enforcement effort. The inventory form we suggested and insisted the Government make available reduced the biennial inventory from a major undertaking to a relatively minor inconvenience.

NARD early recognized the value of public awareness of and education on the problems and issues of drug abuse and misuse. Mr. Simmons, working with NARD, developed its first and basic sheet on abused drugs, a detailed plan for a 45-minute program on drug abuse to be given for schools and clubs, a list of visual materials available for public presentation, letters for use in soliciting interest of schools and civic groups, and public service announcements for radio and television.

This first kit was mailed to 38,000 independent pharmacists and NARD eventually distributed about 75,000 kits which provided valuable information to local audiences throughout the country.

In early 1969, NARD developed and distributed another kit titled "Drug Abuse Education Goes to School" designed for use by teachers as well as pharmacists. From this kit, thousands of pharmacists worked with teachers and principals planning assemblies, showing films, and bringing drug abuse education to millions of young people.

NARD's public education campaign on drug abuse was one of the most massive, ambitious, and widely acclaimed public service accomplishments undertaken by the profession of pharmacy. We believe it was also one of the most beneficial programs in assisting to acquaint young people and the parents on the hazards of drug abuse.

Currently, NARD has revised its reference chart because it is still useful and in demand by the profession. Our association and its members have offered our continuing support to the Department of Justice in making the law more efficient and effective. We were pleased that the DEA recently authorized the dispersal of controlled substances inventory throughout the general pharmacy inventory consistent with NARD's suggestions.

However, we suggested further that DEA might consider some modification of the CSA schedule identifications on the packages and labels by removing the markings from the labels and requiring that they appear on the side or back of the packages and containers so as not to be so visible to robbers, burglars, and thieves. For some reason unknown to us DEA did not comment on our suggestion or even acknowledge that we commented on the regulations in its commentary published in the Federal Register which did mention all other suggestions and comments. A copy of our submission and the Federal Register notice is attached and explains our views on this point in more detail.

NARD believes that the change in the location of the identification markings would make controlled substances inventories dispersed throughout the pharmacy's general inventory more secure and still provide maximum guidance to pharmacists and others who must rely upon the package labeling to determine the control status. We further believe that our suggestion is practical and reasonable and deserved more than to be ignored by DEA.

Another topic that NARD submits should be reviewed is the advertising and promotion of controlled substances, especially that directed to patients and consumers. The Cost of Living Council had proposed, and hopefully has now abandoned, the concept of pricing lists of prescription drug prices in pharmacies. The Food and Drug Administration is in the process of revising its regulations on reminder advertising and reminder labeling to encourage consumer advertising of prescription drugs. The Department of Justice has traditionally and continually encouraged advertising of prescription drugs and has characterized as trade restraints attempts to restrict or regulate prescription drug advertising.

Other forces are at work in the pharmaceutical industry which show great probability that advertising and promotional practices of drug firms may change radically in the next few years to where consumers, rather than pharmacists and physicians, may be the prime advertising targets for prescription drugs, particularly if the FDA proposal is implemented. We foresee a very real danger that advertising and promotional materials for prescription drugs, including controlled substances, will be published or distributed through lay media, including magazines and periodicals. And with this, there is the very real danger that interest in controlled substances among laymen will be increased. NARD submits that the Congress ought to prohibit advertising and promotion of any controlled substance directed to the public. Retail consumer advertising showing that a patient with a prescription for 24 capsules or tablets of a controlled substance can save money by purchasing a quantity of 100 or 500, has got to increase pressures on prescribers to make these larger quantities available to their patients. Similarly, if consumer advertising, whether price is mentioned or not, touts controlled substances like every other consumer commodity, a false climate of harmlessness will be presented to the public. It would appear FDA has not taken this into consideration.

Congress should now assure, before we reach a problem of urgent and critical proportions, that advertising and promotion of all controlled substances will be limited to pharmacists, physicians, and others with a legitimate medical need or use of the information. Congress should assure that no condition exists or action is permitted which would tend to encourage the consumption or use of controlled substances beyond that quantity that is absolutely justified by medical needs. Anything that lessens the control, or encourages the prescribing or availability of quantities in excess of the amount for immediately justifiable medical needs, inevitably creates the opportunity for misuse and abuse of these drugs.

NARD fails to see, as the Justice Department apparently does, how assuring the best control of prescription drugs, and particularly controlled substances, can be considered a detrimental, anticompetitive restraint. Designating a drug as a controlled substance restricts its distribution and availability as does designating any drug a prescription durg. However, these restrictions are not considered anticompetitive but as necessary in the interest of promotion of public welfare.

NARD is also concerned over the continued relaxed attitude DEA has taken in regard to the mailing of controlled substances. Time and

again, NARD has urged that DEA promulgate a regulation prohibiting the mailing of all controlled substances. Our efforts have appears to be a superficial survey of 16 pharmacies which DEA and been met with hostility and rejection, even to the extent that the Government has had the gall to march forth the results of what other claim justify its position. Meanwhile, there are lay press reports of the ease of diversion of controlled substances from prescription mail order operations and we suspect that many a bottle of controlled substances has been further diverted from the mails enroute to patients.

Assuming that prescription orders received from a distant location by a prescription mail-order operation are legitimate, DEA seems to place great faith in the postal service assuring the safe transit of the drugs themselves. Yet, a prescription drug package is easily identified by shape, markings, and size, and an easy mark for those bent on obtaining quantities for illicit use. On the supposed but unproven economic advantage to the patient, DEA and mail-order outfits attempt to justify the practice. However, if we are to follow a policy based solely upon economic considerations to its absurb end, then we would be required to remove all controlled substances restrictions and limitations. Obviously, the Congress has already determined that the actual and potential abuses and misuses of controlled substances dictates that they be rigidly controlled, despite the economic consequences, in order to serve better overall health objectives.

In fact, perhaps the tendency we see for DEA to increase controls over certain substances by moving them to higher control schedules is a result of its relaxed attitude over advertising and mail-order distribution when these drugs appear to be unsuccessfully controlled on lower schedules.

NARD and its members are greatly concerned over the increased risk of crimes of violence in pharmacies. In the August 2, 1973 issue of the Congressional Record, Senator Frank Church—D–Idaho—cited statistics which confirmed that which practicing pharmacists already knew in less specific terms. Crimes of violence in pharmacies related to controlled substances are increasing at an alarming pace. We have with us some individuals who can give you additional information on their own areas. We have provided the committee with many, many new stories concerning similar crimes throughout the country.

Beginning with the hearings on the proposals which became the Controlled Substances Act, NARD has consistently urged that Congress provide Federal jurisdiction to enforce crimes related to controlled substances in pharmacies. Not uncharacteristically, DEA has opposed our pleas for relief and assistance.

As the CSA is effectively implemented to dry up the illicit sources of controlled substances for pushers and users, there is a correspondingly increased pressure and threat upon legitimate outlets possessing quantities of these substances. Pharmacies are a primary target for those in need of drugs for a number of reasons, not the least of which is that pharmacies are open and accessible to just about every segment of the population, and are found in inner city areas when most other businesses have fled.

We do not suggest that ordinary crimes in pharmacies, like robbery and burglary, be blanketed into Federal jurisdiction. However, we do request that crimes of violence—assault, robbery, burglary, murder, and the like—involving controlled substances be subject to Federal jurisdiction. If a pharmacy were robbed and only money taken, that crime would rightly be a matter of local jurisdiction. However, if the felons clearly were motivated by the presence of, or need to obtain, controlled drugs, evidenced by drugs being part of the booty, then we believe that Federal jurisdiction and prosecution ought to be authorized.

Congress has specifically provided that a person who manufactures, distributes, dispenses, or possesses a controlled substance with intent to distribute, is subject to Federal criminal prosecution and penalties under section 401 of the act—21 USCA 841. Similarly, if a person knowingly or intentionally acquires or obtains possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge, Section 403 of the act—21 USCA 843—provides Federal jurisdiction and penalties. However, if the person obtains the drugs by violence in a pharmacy, the act implies that this is of no Federal concern.

It is appropriate and necessary to simply amend the penalties sections to make it unlawful for any person to obtain, or attempt to obtain, any controlled substance through violent or other unlawful means. The increased threat of violence and crimes in pharmacies is a direct result of the stringent controls imposed by the CSA. It is only fitting that the resources and facilities of the Federal Government be made available to protect pharmacies and apprehend those bent on circumventing the controls of the law.

Federal criminal jurisdiction over crimes of violence and other unlawful conduct relating to controlled substances would provide for more uniform law enforcement action and punishment of violators. As it is now, punishment of drug-related crimes in pharmacies rests upon the varying provisions of State criminal laws. A Federal law would provide a sanction universally applicable in this country that would be more readily understood and heeded and more uniformly applied.

Pharmacists have become the men on the frontiers of the movement to curb and eliminate drug abuse. Our members are health care professionals, not policemen, nor experts in the art of self-defense. However, the focus of criminal activity relating to controlled substances is gravitating to the thousands of pharmacies in this country. Through no fault of their own, pharmacists have been placed in a situation where their lives and property are continually at risk.

NARD believes that pharmacists ought to be supported as they make the sacrifices which necessarily accompany this national push to reduce drug misuse and abuse. We would request that the Congress consider some form of insurance, either without cost or at nominal cost, to cover the costs of the potential tragedy and risks that they face. In this manner, at least those pharmacists who were injured, or disabled, by violence associated with controlled substances, or families of pharmacists killed, would be made financially whole.

Unless some method of assuring pharmacists of greater protection from and involvement of Federal law enforcement machinery and personnel, NARD believes that pharmacists will begin to refuse to stock or handle controlled substances altogether. Such action would have serious detrimental effects on health care which none of us would welcome but there is a limit which society, just in humanistic terms, cannot expect pharmacists to exceed.

The overwhelming percentage of pharmacists in this country practice in independent community pharmacies. Too often our members feel that their needs, suggestions, and requests are ignored or viewed with hostility by those administering the law. The Federal Government has shown little sensitivity or understanding of the very real problems or risks our members face. The Federal effort is apparently paying good dividends in the area of illicit and clandestine operations involving criminal elements but appear ill-equipped to deal with legitimate health care providers, the vast majority of whom are law-abiding citizens. Enforcement personnel, innately suspicious and cynical, accustomed to the challenges of criminal activity, seem to carry these attitudes and perspectives into their regulatory sphere as well.

When NARD suggested that mail-order outfits might be a significant source of controlled drug diversion, BNDD—now DEA—retaliated with a study of 16 pharmacies which superficially proved the converse. The report contained apparent violations, but we and State pharmacy boards were denied access to the specifics of the study, including the names of the outlets surveyed, or even the identity of the violators. We were also denied access to the data before the agency in selecting the sample of pharmacies. Obviously, if the pharmacies surveyed were those for which complaints had been made or for which the Government had reason to believe were less than diligent in complying with the law, the results would naturally be misleading.

NARD has proceeded on the assumption that our goals and those of the Governmental agency administering the law in the area of regulating the legitimate health care system should be complimentary, a cooperative rather than an adversary effort. For our part, we have sought to assure that the legitimate channels of distribution, and pharmacies in particular, are regulated as efficiently as possible in a manner that removes to the extent possible, actual, or potential opportunities for drug diversion and deserve further consideration.

We believe that DEA has sufficient information available to it to identify pharmacists or physicians who may be improperly contributing to traffic and abuse of controlled drugs. Pharmacy suppliers must maintain records for inspection. Where these records show unusual activity, the pharmacy or pharmacies concerned have records showing the names of prescribers which must be maintained. An audit of the pharmacy records should show readily whether the abnormal activity is caused by the pharmacist or by one or more prescribers in that community.

NARD does not believe that we need any additional or further records, triplicate prescriptions, or anything else. The purpose of the elaborate records required by the CSA was to document the distribution of controlled substances. More than likely, all DEA agents would have to do is talk with pharmacists to learn which prescribers, if any, showed abnormal prescribing tendencies for controlled drugs.

This past summer, DEA published a proposal relating to the verification of prescriptions. NARD commented on these regulations in our letter to DEA dated August 3, 1973, copy of which is attached. Our position then as now is that there is no legal provision, whether contained in the regulations or statute, which cannot be circumvented with relative ease unless the provision is so onerous and burdensome as to be impractical. Credit cards are freely available to criminal elements and can be forged with little sophistication. All a drug abuser needs to do is use a name on the prescription blank for which he can furnish suitable identification. Alternatively, if the prescription blank itself is forged, the telephone number need only be that of an accomplice who will, when called, verify the prescription as legitimate. Triplicate prescription blanks can be forged and manufactured as well as conventional forms.

We are not aware of any practical method of devising a fail-safe system to assure the authenticity of the patient named on the prescription or the prescriber signing it.

NARD believes the provisions of the law relating to administrative inspection warrants deserves study, modification, and clarification. At the time the act was considered by the Congress, the law relating to administrative inspections was unsettled. Section 510 appears to deny pharmacists and other registrants fundamental constitutional rights, particularly when it authorizes a warrant to seize certain property on a lesser standard than the Constitution requires.

We believe that pharmacies ought to be protected from harassment and fishing expeditions under the guise of routine inspections. In all cases, inspections should be under an applicable administrative inspection warrant. The law provides ample basis for obtaining such administrative inspection warrants for any legitimate enforcement need while at the same time protecting the rights of the registrants.

Furthermore, where DEA agents know or have reason to believe that certain seizures are anticipated, such warrants would be subject to the usual constitutional "probable cause" standards. Obviously, if DEA anticipates a seizure and has sufficient information to present grounds therefore when it seeks an administrative inspection warrant, that proposed seizure should be guided by the search and seizure requirements of the fourth amendment, not the lesser standards of section 510. Specifically, an administrative inspection warrant should be available to DEA when the objective is something other than routine, random inspections.

This inspection authority is very important. Section 402(a)(6) of the act imposes penalties upon a registrant who refuses any entry into any premises or inspection authorized by the act. It seems that a pharmacist who insists upon an administrative inspection warrant, or a constitutionally required search warrant, commits an offense by that very deed. Certainly this is true if DEA has administrative inspection warrant in circumstances where the registrant believes a search warrant is necessary.

In closing, Mr. Chairman, NARD believes that the CSA is accomplishing the broad purposes for which it was enacted by drying up the illicit sources of controlled substances. However, as the major illicit sources are closed, we must give greater concern to the effects of the increased pressure upon the legitimate channels of distribution. We have attempted to outline here those areas which we believe deserve strengthening.

Thank you.

Senator BAYH. Thank you very much, Mr. Woods.

May I direct some questions, please.

That DEA study that you referred to relating to the pharmacies.

Mr. WOODS. Yes.

Senator BAYH. Abuse potential was disclosed there. Nobody likes it and wants to do more about it than the average hometown pharmacist. I am relatively certain that we can find answers to some of the questions you posed so that indeed perhaps the Association can take some steps to deal with some of these problems as well as find out whether some of those offending pharmacies were classified by the normal standards.

Mr. WOODS. We welcome that information.

Senator BAYH. Has there been any reason given for DEA's refusal to cooperate with you in an effort to find out how the standard was established?

Mr. WOODS. I think that I can put it in perspective by perhaps first quoting the statement by one of the associates at DEA when we indicated our concern about the mail-order prescription, and lack of a physician-patient-pharmacist relationship, and it denied the patient a higher quality of pharmaceutical service because the pharmacist was not in contact with the patient and it did not provide adequate health care standards.

The DEA official's comment was, "you know, this just doesn't happen to be our bag, so we are not that much concerned about health standards." To quote another one over there, the general feeling is that they don't want to offend the little old ladies with tennis shoes that are getting mail-order prescriptions. I think this starts off as a basis of their feeling. Then they went out and did a survey to try to protect the mail-order outfits, whether it was VA or many others they could name. I have seen letters from the VA defending this survey and decrying the inefficiencies of the retail pharmacists and indicating it was the first source of diversion, based on that survey, which I think was a ludicrous statement for the DEA to make and ludicrous position for DEA to take in trying to develop that position with such a scurrilous, inadequate survey.

Senator BAYH. Let me suggest this committee traditionally hasn't been too concerned about stepping on toes. However, I would rather not get into a hassle between mail orders and retail pharmacists. You are concerned about being put in a less favorable position than mail-order operations. But if there is a 25-percent chance of a successful fraud through mail orders, I think something has to be done there, also.

Mr. WOODS. I understand, Mr. Chairman. We certainly agree.

We have instances in VA having automatic remailings every 30 days or so often of drugs to their veterans who are denied the convenience and service in their community. Of course, you get prescriptions back on the VA mail-order program. We have had veterans come into pharmacies and offer to sell these drugs and they say they are not taking them, quit using them and have been prescribed two or three products and they don't want to cut off one drug abuse product because they are afraid they will cut them off of another.

Mr. Johnson, from Nebraska has a case just recently he might give you information about.

Mr. JOHNSON. Senator, just recently our State control revenue group went out to investigate a death in Chadron, Neb., of a white male veteran who died from conditions unknown. Forty-eight hours after his death when he started the autopsy they found he had .41 blood alcohol and he unfortunately died from alcoholism. In investigating the case they found over the past 2 or 3 or 4 years this man had been receiving on a monthly basis 120 Darvon 65, 100 valium, 5 mg and 32 seconal 1½ grains. Interestingly enough, this man had no known income. He lived very high on the hog out there, as we say, and he had cash in his pocket.

Senator BAYH. That is usually an Indiana term. You are perfectly welcome to use it in Nebraska if you want to. Go right ahead. [Laughter.]

Mr. JOHNSON. When they got a little deeper in their investigation it was found out this man was a source of these drugs to the Indian population out there, and this could be documented. Apparently, the only income he had was his monthly automatic refill of three very potent products, one of which is at this time a class 2, in which a new prescription had to be issued each time. This was from the veterans who is in Lincoln, Nebr.

Senator BAYH. Examples like that will help us to more properly assess the extent of the problem. If you have any similar cases, either you gentlemen here or those present or anybody else in your association, we will be glad to have them.

Mr. WOODS. Mr. Chairman, the president of the Arkansas Board of Pharmacy, Mr. Rose, has had experience with another form of mail-order diversion, if you want him to comment now.

Mr. ROSE. Senator, I might just mention in the process of handling in the Arkansas Legislature one of the drug bills in order to find out how readily we could obtain drugs from out-of-State we sent supposedly ficticious prescriptions. Needless to say, when we started to debate this bill on the floor of the House, which I was the author of the bill, when we dumped several thousands of these items, amphetamenes, and barbituates on a table, so that the legislators could see how easily it was to obtain them, we had no trouble in passing the drug control bill in Arkansas.

What I am saying is that anyone can send a prescription, whether bona fide or fictitious, to obtain drugs which you cannot get in a legitimate drugstore. This is the problem we ran into. We were trying to license all distributors in Arkansas so we would have some way we could control. But needless to say, those who want to shift into a State will not register with you, but we were able to get thousands.

Senator BAYH. That is the kind of thing we would like to talk to DEA about and see what can be done.

Mr. ROSE. Yes, I think that would be very good.

Senator BAYH. We are having a vote going on right now over on the floor. Why don't we go ahead with another question or two and the next time the bell rings I will have to leave, and I will get back as quickly as I can get back. I am sorry about that.

Mr. Woods, in your testimony you indicate that the Control Substances Act has dealt with the problems of practitioners who prescribe in abnormally large quantities. This is one of the basic concerns we had. Would you care to amplify that assessment?

Mr. WOODS. Well, I don't know how much can be done in this area. I don't have documentation to the extent of some of these other things. I would be glad to develop it. I really have an idea that situation is increasing in view of the CSA Act. Certainly it was probably happening between the amphetamines, but before some of the drugs went over to schedule 2.

But I think the point we were making or had in mind that community pharmacists will be permitted what was being prescribed in his neighborhood but what was overprescribed by State boards of pharmacists and by DEA.

Senator BAYH. We started several years ago to get BNDD to go along with our recommendations for rescheduling amphetamines and barbituates. We were hit by numerous voices that this was impossible because we were talking about legitimately produced drugs which meet a legitimate medical need of patients; that to control production would result in a number of patients not being able to get the kind of drug they needed to meet their problem. Have you had any complaints like this from any of your pharmacists?

Mr. WOODS. I think I can say to you, Mr. Chairman, this wasn't the community pharmacists of the country that raised this question, but I think they compliment and congratulate the chairman for the courageous effort he took in bringing about the change in amphetamines and moving them over to schedule 2.

Senator BAYH. It was the bureaucrats downtown charged with policing it. I didn't mean to infer that the pharmacists made that charge. I wondered that since we have been able to cut back amphetamines, the speed if you please, the uppers—whether you have had any complaints from your members?

Mr. WOODS. I am inclined to say we have not had any complaints. I may have a resounding difference behind me, but I think everybody is satisfied it should be in schedule 2 and has reduced a problem and we are not having significant complaints.

Senator BAYH. Of course, it may be too early to get an answer to that question as far as the three categories of barbiturates.

We have a problem with barbituates. There are two or three kinds of barbituates that are the drugs of choice of the doctors and as a result they are available in large volume, in wholesale houses, mail-order houses and on your shelves. We have been able to get three of them rescheduled. There are six other barbiturate products that have identical tendencies, shorter acting, that were not rescheduled.

What I am concerned about is that we have had a great demand by abusers for the three, now that they have been rescheduled, the demand will go to the other six and you will have that problem just shift over. So we may be wanting a report on what that history is over the next few months so we can get the people downtown to reschedule these other drugs. They are all in that same class of drugs.

Mr. WOODS. We will be glad to provide any information the committee can use, Mr. Chairman. Some of the gentlemen here at the table would have more specific information on the problem than I would on those particular drugs.

Senator BAYH. Let me compliment NARD for what you have done in the educational area. I think that is so important.

Also, I appreciate your assessment of the advertising problem. I want to look at this carefully to see what can be done.

Right now I am going to vote. I will be back as quickly as I can. I am sorry to prolong your inconvenience.

Mr. WOODS. Mr. Chairman, we have a commitment for a luncheon with Senator Long later today. Will you be returning shortly? Do you wish us to wait?

Senator BAYH. I should be back in 10 minutes and then maybe take another 10. If you have to go now I will understand.

Mr. WOODS. That will be fine. I am hoping you ask me another question about crime so we will be glad to wait.

[A short recess was taken.]

Senator BAYH. We will reconvene with additional apologies to our illustrious panel here.

You have a luncheon, and as I mentioned to Mr. Woods and Mr. Clark a few minutes ago, and Mr. Shinnick, it is entirely possible we will have another vote, I don't know. So rather than get involved in all the questions that I would like to direct to your attention, could I ask your leave to submit these questions in writing?

Mr. WOODS. We will be glad to cooperate in any way, Mr. Chairman.

Senator BAYH. I would like to without objection, place Mr. Clark's statement, which I have in my possession in the record. It was very helpful.

[Mr. Clark's prepared statement may be found at the conclusion of the NARD remarks.]

What has been your experience, if I might ask, Mr. Clark, in Indiana? Mr. Woods mentioned the major emphasis in the urban area and that some had a really significant problem in some of the not traditionally large urban areas. What has been the general problem in Indiana?

Mr. CLARK. The crimes in not-traditionally large areas?

Senator BAYH. We have had some complaints in Lawrenceburg, Middlebury, Rensselaer, Crawfordsville, Fortville and Martinsville, compared to the megopolis complexes where the emphasis on burglary is evident. What has been the pattern?

Mr. CLARK. I think that has been rather widespread and across the board. In metropolitan areas there are obviously a larger concentration. But the increase in urban areas and in smaller towns where there has been traditional or absolutely no break-ins or robberies and so forth, they are now experiencing robberies and break-ins. So for those areas it is a significant increase and they are now being subject to the same type of physical abuse, intimidation and so forth that traditionally only metropolitan pharmacists had been exposed to. So that has spread rather statewide.

Senator BAYH. Let me ask Mr. Woods and you. We have examined S. 2327, which was not referred to the committee until Tuesday. It deals with narcotics, of course, as you mentioned in your statement. One of the things it seems to me perhaps we ought to try to do is look at that from a broader approach. If we are concerned about the impact of criminal activity directed at pharmacists and how that relates to the drug problem, and if we move along this route making that a Federal law violation we shouldn't confine it to the traditional narcotics. What would you think about expanding it to include barbiturates and amphetamines and the other drugs not described as narcotics under the bill?

Mr. WOODS. That would be our position exactly, Senator. We feel wording should be changed to all CSA drugs, as you have suggested.

Senator BAYH. One last question. What would be your judgment on that, Mr. Clark, as far as the impact?

Mr. CLARK. My judgment would be the same. Obviously—but, I would hope that there would be further regulatory changes such as dispersal of controlled substances through the noncontrolled substances area.

Not to drag out the testimony, but I had a rather personal experience in a pharmacy that I managed. There were some 34 or 37 burglaries, and at the time I was a practicing pharmacist and I asked the Board of Pharmacy permission to, in other words, hide at that time Class A narcotic drugs, and the robbers were apprehended. One was shot and killed and the other one was apprehended. So that one action, that dispersal is quite obvious to them. As long as this type of action as we were talking about, including all controlled substances, would be accompanied with other improvement in the regulatory components, yes, absolutely.

Senator BAYH. I hope we can communicate with you further on some of the dispersements and other specifics that we can work into this new approach.

Let me ask you one last question on the triplicate prescription system. Mr. Woods, in your testimony you seem to feel that this really wasn't the answer. What has been the experience in California where the have it for narcotics, and Idaho, New York and Illinois where systems cover the narcotics as well as the nonnarcotics? What have been their experiences?

Mr. WOODS. I think first our concern would be with a Federal triplicate system. We would be more opposed to that than a State system that is consistent with the needs of the State. If the States find hat some kind of triplicate system is workable in their area, why it is okay with us.

I think the Idaho bill has been successful. They have a triplicate system from what I understand. But Mr. Barnett, who is the Secretary of the State Board of Pharmacy there, will be with the group when they testify, National Association of Boards of Pharmacy, and he can provide more on that. California I am not familiar with.

Generally we would be opposed to a Federal triplicate system. One of the problems right now, anybody can call up any printer and have a stack of prescriptions printed. This is a real problem. There may be something that can be done——

Senator BAYH. Providing for serialized prescriptions or something like that, does the BNDD number help in that regard?

Mr. WOODS. I am not sure that I am addressing the question you raise, but just to put a BNDD number on there, doctors' address and everything, BNDD number also. But this area we would like very much to work with you and the committee and do something about forged prescriptions or having adequate records.

Senator BAYH. We certainly don't want to pass any laws that are just going to add to the red tape. We have found some regulations in this area, and firearms area where we have a lot of data that is never collected and never reaches the source, and it is not collected in a way that it is meaningful. Perhaps serialization and your other sugestions might help you do what you need to do to police across the counter more effectively.

Mr. WOODS. In this regard, in trying to make a reasonable commonsense approach coming to a solution of this dimension is the way that this problem should be approached, I think.

Senator BAYH. I have a few other questions here, but you have covered most of the substance in your testimony.

I do want to thank you gentlemen for taking the time and again apologize for the bouncing ball act on the rooms as well as the votes.

Mr. WOODS. I appreciate very much having the opportunity to be with you, and just for a final phrase on the Church bill, we are very much for this type of legislation. It would solve the problem. We don't think DEA's attitude of doing a survey will solve it. If there is some other way we can eliminate crimes in the field we will certainly support it.

Senator BAYH. We want to work in that direction, too. It is consistent to the extent that other manipulations that lead to abuse in narcotics are Federal law violations. To the extent you broaden the area you increase the need for Federal law enforcement agencies or acts to do the job. So we are struggling with that, but that is one suggestion we are considering. It seems to me if we go that route at least a Federal crime ought to be broad enough that it covers all the drugs that are part of the drug culture.

Mr. WOODS. We share the feeling completely in that regard.

Senator BAYH. Thank you very much.

[The prepared statements of Mr. Shinnick, Mr. Wood, Mr. Clark and Mr. Rose together with attachments are as follows:]

STATEMENT OF THE NATIONAL ASSOCIATION OF RETAIL DRUGGISTS

NARD Hearing Witnesses: Harold Shinnick, Chicago, Illinois—President, NARD; William E. Woods, NARD Washington Representative and Associate General Counsel; David Clark, Indianapolis, Indiana—Executive Director, Indiana Pharmaceutical Association, and Arkansas State Board of Pharmacy; Ivan Rose, Rogers, Arkansas—Past President Arkansas Pharmaceutical Association, and Arkansas State Board of Pharmacy; John Johnson, Bellevue, Nebraska—NARD First Vice President and President-Elect of Nebraska Pharmaceutical Association.

STATEMENT BY HAROLD J. SHINNICK, RETAIL PHARMACY OWNER AND PRESIDENT, NATIONAL ASSOCIATION OF RETAIL DRUGGISTS

Chairman Bayh and Members of the Subcommittee: I am Harold J. Shinnick and I am an independent retail pharmacist and owner of a community pharmacy in Chicago, Illinois. I appear here today with my associates as President

of the National Association of Retail Druggists. NARD is the national association in the United States representing the tens of thousands of pharmacists of the country who own and operate their own pharmacies in the neighborhoods and communities across this land.

We are most appreciative of your invitation to appear here today and applaud the work and efforts of this committee. The Controlled Substances Act of 1970 required significant and substantial changes in the practice of pharmacy, some of which our members have welcomed and others which we have accepted and endured. The independent practitioner of pharmacy has a fine record of serving the people of this country and we, like all America, were concerned about the drug abuse and misuse reaching epidemic proportions. Clearly something had to be done and the Controlled Substances Act was a bold and sweeping plan.

Therefore, NARD is particularly pleased that this committee has taken the initiative to review the implementation and effect of the Controlled Substances Act at this time to determine just how well it is working or administrative implementation of the Act. Like you, we do not have the definitive answers to this complex problem though we all wish we did. Drug abuse and misuse is still a serious issue and a serious concern and will continue to be such until we have conquered its problems and causes.

NARD has assembled a group of informed pharmacists who we believe are most knowledgeable to assist this committee in its inquiry.

Mr. Willard Simmons, the Executive Secretary of the National Association of Retail Druggists, has had a long-standing personal commitment to programs directed to the public and particularly young people to provide information and education on the hazards of drug abuse and misuse. He provided the leadership which sparked an extensive public educational program which brought vital and timely information and facts to millions of school age children, their parents, and teachers on drug abuse. Mr. Simmons, in addition to his long tenure as an independent pharmacist in his home, Texarkana, Texas, has traveled the length and bredth of this nation talking with pharmacists and others, which has given him the opportunity to obtain a broad and representative view of the operation and implementation of this Act.

Mr. William E. Woods is a pharmacist and attorney who serves as NARD's Washington Representative and Associate General Counsel. He has the experience of working with the Act from the original legislative proposals, through the revisions of the implementing regulations, and in identifying and attempting to resolve legal and regulatory issues relating to the Act. Mr. Woods has borne the brunt of interpreting the legislation and regulations for our Executive Committee and members.

We also have with us Mr. David Clark, Executive Director of the Indiana Pharmaceutical Association. Mr. Clark is also a pharmacist and can provide the valuable insight of the views of an executive of a statewide organization of pharmacists and the problems and issues that concern him and his association relating to the Act.

Mr. Ivan Rose is from Arkansas where the pharmacy association and its members are particularly concerned about the rising risk of violent crimes in pharmacies related to controlled substances. In addition to being a pharmacist, Mr. Rose is a member of the Arkansas legislature and has served as a member of the Arkansas Board of Pharmacy and NARD believes that he is particularly well-qualified to assist the committee in its inquiry.

And we also have John Johnson, a pharmacist from Nebraska, who is a leader in Nebraska pharmacy association affairs and who also serves as the First Vice President of the National Association of Retail Druggists. Mr. Johnson's experience as a state leader, his fine service as an officer of NARD on the national level, as well as his reputation as an articulate spokesman, suggests that he, too, could serve as a valuable resource for this committee.

To coordinate our presentation in an effort to be most helpful and informative to the committee, we will have Mr. Woods present a statement responding to some of the issues the committee indicated were of interest to it. Thereafter, Messrs. Clark, Rose and Johnson will present brief supplementary comments reflecting their own special perspectives.

NARD has what we consider a good record of cooperation in the development and implementation of the Controlled Substances Act. And I want to assure the committee that we intend to cooperate fully with this committee and the Drug Enforcement Administration in achieving the objectives of this national

effort. However, I would be remiss if I did not also state that our members want and expect the NARD and the Congress will insist that the burdens of compliance will be strictly limited to only that which is necessary to effectuate the purposes of the Act, and no more. Our members are finding that the costs in terms of time and money of compliance with an ever-increasing system of state and federal regulation, of which the CSA is but a part, are becoming more than any individual small businessman can shoulder. Independent pharmacists typically must rely upon their individual efforts to meet *all* government regulatory requirements and frequently only with the guidance of the NARD and their state pharmacy association.

Therefore, NARD does have some suggestions and comments on some points where we believe that the views of our members deserve priority consideration and implementation to assure the pharmacists that they will not have to face the risks and dangers created by this law alone, or in vain.

STATEMENT BY WILLIAM E. WOODS, WASHINGTON REPRESENTATIVE AND ASSOCIATE GENERAL COUNSEL

The National Association of Retail Druggists appreciate your invitation to discuss the administration and implementation of the Controlled Substances Act of 1970. When first adopted, this law made sweeping and comprehensive changes in the regulatory scheme for narcotics and drugs subject to abuse. And we have every indication that narcotic addiction may have reached its peak in this country, and that abuses of non-narcotic drugs are lessening or not increasing at the alarming rate that prompted the enactment of the CSA.

When the proposals which eventually became the Controlled Substances Act of 1970 were being considered, NARD maintained that independent pharmacies were not significant sources of supply for drugs for illicit use. We believe that that was a correct assessment then as well as today. To be sure, there were abuses of drugs prescribed, but by and large this was a significant portion of the problem. To the extent that drugs subject to abuse were prescribed too often, and in abnormally large quantities, or refilled over too long a period, the CSA has brought this problem under control. The law now assures that no prescription can be refilled more than five times, and not later than six months for its date of issue, so it is assured that a prescription is not a ticket to an unlimited supply of any controlled substance for an indefinite period.

NARD believes that the present controls assure, insofar as can be done, that controlled substances that are prescribed will be utilized properly for an appropriate medical purpose. We cannot assure that an enterprising patient, either alone, or in concert with the prescriber, will subvert the intentions of the law. However, we have no evidence that this is a significant or widespread problem.

When the CSA was first adopted, and later as it was implemented, the NARD made every attempt to assure that the law was understood by pharmacists and implemented in a proper manner. We distributed detailed analysis of the regulations promulgated by the Government, prepared a quick reference chart which summarized in readily accessible form the major features of the law, and developed and produced with the cooperation of Smith, Kline and French Laboratories, a continuing education cassette that explained the requirements of the law in detail. In cooperation with the Government, the reference chart was made available to every pharmacy. And, we have cooperated in making the law workable in every other way through suggestions to the Government, including the inventory form for the biennial inventory which forms the backbone of the enforcement effort. The inventory form we suggested and insisted the Government make available reduces the biennial inventory from a major undertaking to a relatively minor inconvenience.

NARD early recognized the value of public awareness of and education on the problems and issues of drug abuse and misuse. NARD developed its first and basic drug abuse educational kit in 1967, and it included a fact sheet on abused drugs, a detailed plan for a 45-minute program on drug abuse to be given for schools and clubs, a list of visual materials available for public presentation, letters for use in soliciting interest of schools and civic groups, and public service announcements for radio and television. Various booklets available from government and other sources were also included.

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DRUG ABUSE: THE PHARMACIST

HEARING

BEFORE THE

SUBCOMMITTEE TO INVESTIGATE
JUVENILE DELINQUENCY

OF THE

COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

NINETY-THIRD CONGRESS

SECOND SESSION

PURSUANT TO

S. Res. 255, Section 12

INVESTIGATION OF JUVENILE DELINQUENCY IN THE UNITED STATES

THE COMPREHENSIVE DRUG ABUSE PREVENTION AND CONTROL ACT OF 1970 (P.L. 91-513) AND ITS RELATIONSHIP TO THE PHARMACIST

MARCH 28, 1974

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DRUG ABUSE: THE PHARMACIST

THURSDAY, MARCH 28, 1974

U.S. SENATE,
SUBCOMMITTEE TO INVESTIGATE JUVENILE DELINQUENCY,
OF THE COMMITTEE ON THE JUDICIARY,
Washington, D.C.

The subcommittee [composed of Senators Bayh, Hart, Burdick, Kennedy, Tunney, Cook, Hruska, Fong and Mathias] met, pursuant to notice, at 10:10 a.m., in room 457, Russell Senate Office Building, Senator Birch Bayh [Chairman of the subcommittee] presiding.

Present: Senator Bayh.

Also present: John M. Rector, staff director and chief counsel; Mary K. Jolly, editorial director and chief clerk; Alice Petrovich, assistant to the chief counsel; Catherine van de Velde, secretary; Peter DiLeo, asistant clerk; Chuck Bruce, Legislative assistant to Senator Hruska; and Pat DeSousa, asistant to Senator Mathias.

Senator BAYH. Our hearing will come to order, with apologies to all of you who are in close proximity to one another here this morning.

We had a different, more ample hearing room guaranteed until yesterday afternoon when one of the other subcommittees decided to meet. Technicalities of the Senate being what they are, that particular room we had belonged to another parent committee rather than our Judiciary Committee, so we got bumped. Because we got bumped yesterday you are rubbing elbows today. I appreciate the tolerance and I am sorry for the inconvenience that some of you are suffering by not having seats.

OPENING STATEMENT OF SENATOR BIRCH BAYH

Today's hearing is the first in a series which we have scheduled to assess the effectiveness of the Nation's drug control laws. In 1969, after conducting hearings on the adequacy of Federal drug control legislation, the subcommittee to investigate juvenile delinquency, with the assistance of many who will testify today, developed a measure which in an amended form became the Comprehensive Drug Abuse Prevention and Control Act of 1970 [Public Law 91-513]. Since 1970 this subcommittee has monitored the implementation of the act and sought to assure that the Federal agencies responsible for its enforcement acted appropriately to curb the illegal importation,

manufacture, distribution, possession and improper use of controlled drugs. This is the oversight function which Senate Committees felt is certainly an important part of our constitutional duties.

We have made considerable progress in the last several years. We have obtained a drastic, but necessary reduction in amphetamine production. We have secured more appropriate control over the production and distribution of other drugs with high abuse potential, including the barbituates and methaqualone.

Although one of the goals we hope to continue this year is to continue the controls of barbituates.

In short, these and similar important steps have effectively reduced illicit traffic and clandestine manufacture of controlled drugs. As a consequence, however, pushers and abusers alike are concentrating their attention on legitimate sources of these drugs, particularly pharmacies.

Pharmacists have always had a special role to fill in the battle against drug traffic and abuse. Through educational efforts they have helped to promote the legitimate use of medicine which when abused presents a danger to the abuser and the community. Through efforts of police carelessness and occasionally unethical colleagues and physicians they have combated the illegitimate use of these drugs. These professionals in the pharmacy business however, urban and rural alike, are today on the frontline of defense.

Department of Justice statistics are alarming. The number of thefts of controlled drugs reported by registrants during the first half of fiscal year 1974 totaled over 3,500 and resulted in the loss of over 14.2 million dosage units of drugs; 85 percent—it is difficult to believe—of all the thefts were from pharmacies and 89 percent of all drugs taken were from pharmacies. Compared to the first half of fiscal year 1973, this constitutes an 18 percent increase—557—in total thefts and a startling 65 percent—up from 57 percent—increase in the percent of all thefts which were from pharmacies. Almost half of the total volume of drugs stolen during these 6 months were amphetamines and barbituates. By far the preferred method of theft, utilized in 2,539—72 percent—of the 3,531 theft incidents, was the night break-in. Armed robbery was the second choice, accounting for an additional 525 thefts. Night break-ins and armed robberies of pharmacies accounted for 89 percent—2,279—and 96 percent—501—respectively of the total incidents of break-ins, burglaries and thefts.

I am particularly concerned about escalating levels of violent crime—burglary, assault, robbery and even murder—committed by criminals attempting to obtain controlled drugs.

Similarly, I am concerned about the far less visible problems of prescription fraud and mail order diversion which both contribute to illicit traffic and abuse of controlled drugs.

We in this committee and I as the chairman of it are interested in an assessment of the 1970 act and its impact on these and related

matters. We are especially interested in learning, from those who are confronted daily with these problems, what we can do to improve the act so that pharmacists can function more fully in their role as a vital link in the health care delivery system while simultaneously fulfilling an equally vital role in the battle to curb drug abuse.

I am appreciative of the cooperation of the organized pharmacy who are scheduled to testify today. Their appearances indicate a willingness to once again work with the subcommittee to meet the challenge of ever-changing and increasingly complex patterns of illegal drug traffic and abuse. These witnesses are uniquely qualified to discuss the impact of the 1970 act and its relationship to the practicing pharmacists. I look forward to a productive and informative session.

I should say, as the committee has studied the entire drug problem, we found that really getting on top of drug abuse and stopping addiction and all that means to our society is very much like trying to deal with the air and pollution. If you stick to one place it moves on to someplace else. So we have had the initial approach to heroin and similarly imported illicit drugs, traffic moving to the legally produced yet illicitly acquired and used drugs which are produced by some of those reputable pharmacies, pharmaceutical firms and dispensed by pharmacists. So our effort has to be, as we try to control production now with some success, to find out from those of you who are in the business of distributing these worthwhile products, when used properly, what we can do to help you, our law enforcement officers, and doctors to stop that one particular part of the problem which, as I mentioned earlier, has shown a large increase.

We have today a very prestigious panel, led by Mr. Harold Shinnick, president, National Association of Retail Druggists, Chicago, accompanied by William E. Woods, associate general counsel, NARD; David Clark, the executive director of the Indiana Pharmaceutical Association who I should welcome personally to the committee. I had a chance to visit Mr. Clark's office.

Mr. Ivan Rose of Arkansas, the past president, I should say publicly on the record that Senator Mcclellan offered to be here and unfortunately for all of us the Appropriations Committee has a hearing which he will Chair. Mr. Johnson, the first vice president and president elect of the Nebraska Pharmaceutical Association.

Gentlemen, you have the floor. We appreciate very much your courtesy in being here and look forward to your testimony.

At this point in the record I would like to insert the texts of the subcommittee's enabling resolution, S.Res. 255, section 12 and the text of Public Law 91-513, the Comprehensive Drug Abuse Prevention and Control Act of 1970.

[The documents were marked Exhibit No. 1 and 2, respectively and are as follows:]

EXHIBIT NO. 1

93D CONGRESS
2D SESSION

S. RES. 255

[Report No. 93–714]

IN THE SENATE OF THE UNITED STATES

JANUARY 30, 1974

Mr. EASTLAND, from the Committee on the Judiciary, reported the following resolution; which was referred to the Committee on Rules and Administration

FEBRUARY 28, 1974

Reported by Mr. CANNON, with amendments

MARCH 1, 1974

Considered, amended, and agreed to

RESOLUTION

Authorizing additional expenditures by the Committee on the Judiciary for inquiries and investigations.

Resolved, That in holding hearings, reporting such hearings, and making investigations as authorized by section 134(a) and 136 of the Legislative Reorganization Act of 1946, as amended, and in accordance with its jurisdiction under rule XXV of the Standing Rules of the Senate so far as applicable, the Committee on the Judiciary, or any subcommittee thereof, is authorized from March 1, 1974, through February 28, 1975, for the purposes stated and within the limitations imposed by the following sections, in its discretion (1) to make expenditures from the contingent

fund of the Senate, (2) to employ personnel, and (3) with the prior consent of the Government department or agency concerned and the Committee on Rules and Administration, to use on a reimbursable basis the services or personnel of any such department or agency.

SEC. 2. The Committee on the Judiciary, or any subcommittee thereof, is authorized from March 1, 1974, through February 28, 1975, to expend not to exceed $4,073,000 to examine, investigate, and make a complete study of any and all matters pertaining to each of the subjects set forth below in succeeding sections of this resolution, said funds to be allocated to the respective specific inquiries and to the procurement of the services of individual consultants or organizations thereof (as authorized by section 202(i) of the Legislative Reorganization Act of 1946, as amended) in accordance with succeeding sections of this resolution.

SEC. 3. Not to exceed $377,800 shall be available for a study or investigation of administrative practice and procedure, of which amount not to exceed $5,000 may be expended for the procurement of individual consultants or organizations thereof.

SEC. 4. Not to exceed $767,000 shall be available for a study or investigation of antitrust and monopoly, of which amount not to exceed $10,000 may be expended for the procurement of individual consultants or organizations thereof.

SEC. 5. Not to exceed $252,000 shall be available for a study or investigation of constitutional amendments, of which amount not to exceed $12,000 may be expended for the procurement of individual consultants or organizations thereof.

SEC. 6. Not to exceed $299,900 shall be available for a study or investigation of constitutional rights, of which amount not to exceed $10,000 may be expended for the procurement of individual consultants or organizations thereof.

SEC. 7. Not to exceed $221,000 shall be available for a study or investigation of criminal laws and procedures, of which amount not to exceed $5,000 may be expended for the procurement of individual consultants or organizations thereof.

SEC. 8. Not to exceed $16,500 shall be available for a study or investigation of Federal charters, holidays, and celebrations.

SEC. 9. Not to exceed $205,000 shall be available for a study or investigation of immigration and naturalization.

SEC. 10. Not to exceed $235,000 shall be available for a study or investigation of improvements in judicial machinery, of which amount not to exceed $10,000 may be expended for the procurement of individual consultants or organizations thereof.

SEC. 11. Not to exceed $400,000 shall be available for a complete and continuing study and investigation of (1) the administration, operation, and enforcement of the Internal Security Act of 1950, as amended, (2) the administration, operation, and enforcement of other laws relating to espionage, sabotage, and the protection of the internal security of the United States, and (3) the extent, nature, and effect of subversive activities in the United States, its territories and possessions, including, but not limited to, espionage, sabotage, and infiltration by persons who are or may be under the domination of the foreign government or organization controlling the world Communist movement or any other movement seeking to overthrow the Government of the United States by force and violence or otherwise threatening the internal security of the United States.

SEC. 12. Not to exceed $353,000 shall be available for a study or investigation of juvenile delinquency, of which amount not to exceed $14,000 may be expended for the procurement of individual consultants or organizations thereof.

SEC. 13. Not to exceed $178,000 shall be available for a study or investigation of patents, trademarks, and copyrights.

SEC. 14. Not to exceed $88,000 shall be available for a study or investigation of national penitentiaries, of which

amount not to exceed $500 may be expended for the procurement of individual consultants or organizations thereof.

SEC. 15. Not to exceed $182,000 shall be available for a study or investigation of refugees and escapees, of which amount not to exceed $2,000 may be expended for the procurement of individual consultants or organizations thereof.

SEC. 16. Not to exceed $64,800 shall be available for a study or investigation of revision and codification.

SEC. 17. Not to exceed $263,000 shall be available for a study or investigation of separation of powers between the executive, judicial, and legislative branches of Government, of which amount not to exceed $12,000 may be expended for the procurement of individual consultants or organizations thereof.

SEC. 18. Not to exceed $150,000 shall be available for a study or investigation of citizens' interests, of which amount not to exceed $5,000 may be expended for the procurement of individual consultants or organizations thereof.

SEC. 19. Not to exceed $20,000 shall be available for a study or investigation of Federal Bureau of Investigation oversight.

SEC. 20. The committee shall report its findings, together with such recommendations for legislation as it deems advisable with respect to each study or investigation for

which expenditure is authorized by this resolution, to the Senate at the earliest practicable date, but not later than February 28, 1975.

SEC. 21. Expenses of the committee under this resolution shall be paid from the contingent fund of the Senate upon vouchers approved by the chairman of the committee.

EXHIBIT No. 2

Public Law 91-513
91st Congress, H. R. 18583
October 27, 1970

An Act

84 STAT. 1236

To amend the Public Health Service Act and other laws to provide increased research into, and prevention of, drug abuse and drug dependence; to provide for treatment and rehabilitation of drug abusers and drug dependent persons, and to strengthen existing law enforcement authority in the field of drug abuse.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Comprehensive Drug Abuse Prevention and Control Act of 1970".

Comprehensive Drug Abuse Prevention and Control Act of 1970.

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84 STAT. 1237

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TITLE I REHABILITATION PROGRAMS RELATING TO DRUG ABUSE

PROGRAMS UNDER COMMUNITY MENTAL HEALTH CENTERS ACT RELATING TO DRUG ABUSE

SECTION 1. (a) Part D of the Community Mental Health Centers Act is amended as follows:

(1) Sections 251, 252, and 253 of such part (42 U.S.C. 2688k, 2688l, and 2688m) are each amended by inserting "and other persons with drug abuse and drug dependence problems" immediately after "narcotic addicts" each place those words appear in those sections.

(2) Clauses (A) and (C) of section 252 of such part are each amended by inserting ", drug abuse, and drug dependence" immediately after "narcotic addiction".

(3) The heading for such part is amended to read as follows:

"PART D—NARCOTIC ADDICTION, DRUG ABUSE, AND DRUG DEPENDENCE PREVENTION AND REHABILITATION".

(b) Part F of such Act is amended as follows:

(1) Section 261(a) of such part (42 U.S.C. 2688o) is amended by striking out "$30,000,000 for the fiscal year ending June 30, 1971, $35,000,000 for the fiscal year ending June 30, 1972, and $40,000,000 for the fiscal year ending June 30, 1973" and inserting in lieu thereof "$40,000,000 for the fiscal year ending June 30, 1971, $60,000,000 for the fiscal year ending June 30, 1972, and $80,000,000 for the fiscal year ending June 30, 1973".

(2) Section 261(a) of such part is further amended by inserting ", drug abuse, and drug dependence" immediately after "narcotic addiction".

(3) Sections 261(c) and 264 are each amended by inserting "and other persons with drug abuse and drug dependence problems" immediately after "narcotic addicts".

(4) The section headings for sections 261 and 263 are each amended by striking out "AND NARCOTIC ADDICTS" and inserting in lieu thereof ", NARCOTIC ADDICTS, AND OTHER PERSONS WITH DRUG ABUSE AND DRUG DEPENDENCE PROBLEMS".

(c) Part D of such Act is further amended by redesignating sections 253 and 254 as sections 254 and 255, respectively, and by adding after section 252 the following new section:

"DRUG ABUSE EDUCATION

"SEC. 253. (a) The Secretary is authorized to make grants to States and political subdivisions thereof and to public or nonprofit private agencies and organizations, and to enter into contracts with other private agencies and organizations, for—

"(1) the collection, preparation, and dissemination of educational materials dealing with the use and abuse of drugs and the prevention of drug abuse, and

"(2) the development and evaluation of programs of drug abuse education directed at the general public, school-age children, and special high-risk groups.

"(b) The Secretary, acting through the National Institute of Mental Health, shall (1) serve as a focal point for the collection and dissemination of information related to drug abuse; (2) collect, prepare, and disseminate materials (including films and other educational devices) dealing with the abuse of drugs and the prevention of drug abuse; (3) provide for the preparation, production, and conduct of programs of public education (including those using films and other educational devices); (4) train professional and other persons to organize and participate in programs of public education in relation to drug abuse; (5) coordinate activities carried on by such departments, agencies, and instrumentalities of the Federal Government as he shall designate with respect to health education aspects of drug abuse; (6) provide technical assistance to State and local health and educational agencies with respect to the establishment and implementation of programs and procedures for public education on drug abuse; and (7) undertake other activities essential to a national program for drug abuse education.

"(c) The Secretary, acting through the National Institute of Mental Health, is authorized to develop and conduct workshops, institutes, and other activities for the training of professional and other personnel to work in the area of drug abuse education.

"(d) To carry out the purposes of this section, there are authorized to be appropriated $3,000,000 for the fiscal year ending June 30, 1971, $12,000,000 for the fiscal year ending June 30, 1972, and $14,000,000 for the fiscal year ending June 30, 1973."

(d) Such part D is further amended by adding at the end thereof the following new section:

"SPECIAL PROJECTS FOR NARCOTIC ADDICTS AND DRUG DEPENDENT PERSONS

"SEC. 256. (a) The Secretary is authorized to make grants to public or nonprofit private agencies and organizations to cover a portion of the costs of programs for treatment and rehabilitation of narcotic addicts or drug dependent persons which include one or more of the following: (1) Detoxification services or (2) institutional services (including medical, psychological, educational, or counseling services) or (3) community-based aftercare services.

"(b) Grants under this section for the costs of any treatment and rehabilitation program—

"(1) may be made only for the period beginning with the first day of the first month for which such a grant is made and ending with the close of eight years after such first day; and

"(2)(A) except as provided in subparagraph (B), may not exceed 80 per centum of such costs for each of the first two years after such first day, 75 per centum of such costs for the third year after such first day, 60 per centum of such costs for the fourth year after such first day, 45 per centum of such costs for the fifth year after such first day, and 30 per centum of such costs for each of the next three years after such first day; and

"(B) in the case of any such program providing services for persons in an area designated by the Secretary as an urban or rural poverty area, such grants may not exceed 90 per centum of such costs for each of the first two years after such first day, 80 per centum of such costs for the third year after such first day, 75 per centum of such costs for the fourth and fifth years after such first day, and 70 per centum of such costs for each of the next three years after such first day.

"(c) No application for a grant authorized by this section shall be approved by the Secretary unless such application is forwarded through the State agency responsible for administering the plan submitted pursuant to section 204 of this Act or, if there be a separate State agency, designated by the Governor as responsible for planning, coordinating, and executing the State's efforts in the treatment and

rehabilitation of narcotic addicts and drug dependent persons, through such latter agency, which shall submit to the Secretary such comments as it deems appropriate. No application for a grant under this section for a program to provide services for persons in an area in which is located a facility constructed as a new facility after the date of enactment of this section with funds provided under a grant under part A or this part shall be approved unless such application contains satisfactory assurance that, to the extent feasible, such program will be included as part of the programs conducted in or through such facility.

"(d) The Secretary shall make grants under this section for projects within the States in accordance with criteria determined by him designed to provide priority for grant applications in States, and in areas within the States, having the higher percentages of population who are narcotic addicts or drug dependent persons.

"(e) There are authorized to be appropriated to carry out this section not to exceed $20,000,000 for the fiscal year ending June 30, 1971; $30,000,000 for the fiscal year ending June 30, 1972; and $35,000,000 for the fiscal year ending June 30, 1973."

BROADER TREATMENT AUTHORITY IN PUBLIC HEALTH SERVICE HOSPITALS FOR PERSONS WITH DRUG ABUSE AND OTHER DRUG DEPENDENCE PROBLEMS

SEC. 2. (a) Part E of title III of the Public Health Service Act is amended as follows:

(1) Section 341(a) of such part is amended by adding immediately after "addicts" the second time it appears the following: "and other persons with drug abuse and drug dependence problems".

(2)(A) Sections 342, 343, 344, and 346 of such part are each amended by inserting "or other persons with drug abuse and drug dependence problems" immediately after "addicts" each place it appears in those sections.

(B) The section heading of section 342 of such part is amended by inserting "OR OTHER PERSONS WITH DRUG ABUSE AND DRUG DEPENDENCE PROBLEMS" after "ADDICTS".

(3) Sections 343 and 344 of such part are each amended by inserting "or other person with a drug abuse or other drug dependence problem" immediately after "addict" each place it appears in those sections.

(4) Sections 343, 344, and 347 of such part are each amended by inserting ", drug abuse, or drug dependence" immediately after "addiction" each place it appears in those sections.

(5) Section 346 of such part is amended by inserting "or substance controlled under the Controlled Substances Act" immediately after "habit-forming narcotic drug".

(6) The heading for such part is amended to read as follows:

"PART E—NARCOTIC ADDICTS AND OTHER DRUG ABUSERS".

(b) Section 2 of the Public Health Service Act (42 U.S.C. 201) is amended by adding after paragraph (p) the following new paragraph:

"(q) The term 'drug dependent person' means a person who is using a controlled substance (as defined in section 102 of the Controlled Substances Act) and who is in a state of psychic or physical dependence, or both, arising from the use of that substance on a continuous basis. Drug dependence is characterized by behavioral and other responses which include a strong compulsion to take the substance on a continuous basis in order to experience its psychic effects or to avoid the discomfort caused by its absence."

RESEARCH UNDER THE PUBLIC HEALTH SERVICE ACT IN DRUG USE, ABUSE, AND ADDICTION

SEC. 3. (a) Section 303(a) of the Public Health Service Act (42 U.S.C. 242a(a)) is amended by adding after and below paragraph (2) the following:

"The Secretary may authorize persons engaged in research on the use and effect of drugs to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."

(b) Section 314(d)(2) of the Public Health Service Act is amended—

(1) by striking out "and" at the end of subparagraph (I);

(2) by striking out the period at the end of subparagraph (J) and inserting in lieu thereof "; and"; and

(3) by adding after subparagraph (J) the following new subparagraph:

"(K) provide for services for the prevention and treatment of drug abuse and drug dependence, commensurate with the extent of the problem."

(c) Section 507 of the Public Health Service Act (42 U.S.C. 225a) is amended—

(1) by striking out "available for research, training, or demonstration project grants pursuant to this Act" and inserting in lieu thereof "available under this Act for research, training, or demonstration project grants or for grants to expand existing treatment and research programs and facilities for alcoholism, narcotic addiction, drug abuse, and drug dependence, and appropriations available under the Community Mental Health Centers Act for construction and staffing of community mental health centers and alcoholism and narcotic addiction, drug abuse, and drug dependence facilities", and

(2) by inserting immediately before the period at the end thereof the following: ", except that grants to such Federal institutions may be funded at 100 per centum of the costs".

MEDICAL TREATMENT OF NARCOTIC ADDICTION

SEC. 4. The Secretary of Health, Education, and Welfare, after consultation with the Attorney General and with national organizations representative of persons with knowledge and experience in the treatment of narcotic addicts, shall determine the appropriate methods of professional practice in the medical treatment of the narcotic addiction of various classes of narcotic addicts, and shall report thereon from time to time to the Congress.

TITLE II—CONTROL AND ENFORCEMENT

PART A—SHORT TITLE; FINDINGS AND DECLARATION; DEFINITIONS

SHORT TITLE

SEC. 100. This title may be cited as the "Controlled Substances Act". [illegible] of 1941.

FINDINGS AND DECLARATIONS

SEC. 101. The Congress makes the following findings and declarations:

(1) Many of the drugs included within this title have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people.

(2) The illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people.

(3) A major portion of the traffic in controlled substances flows through interstate and foreign commerce. Incidents of the traffic which are not an integral part of the interstate or foreign flow, such as manufacture, local distribution, and possession, nonetheless have a substantial and direct effect upon interstate commerce because—

(A) after manufacture, many controlled substances are transported in interstate commerce,

(B) controlled substances distributed locally usually have been transported in interstate commerce immediately before their distribution, and

(C) controlled substances possessed commonly flow through interstate commerce immediately prior to such possession.

(4) Local distribution and possession of controlled substances contribute to swelling the interstate traffic in such substances.

(5) Controlled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate. Thus, it is not feasible to distinguish, in terms of controls, between controlled substances manufactured and distributed interstate and controlled substances manufactured and distributed intrastate.

(6) Federal control of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic.

(7) The United States is a party to the Single Convention on Narcotic Drugs, 1961, and other international conventions designed to establish effective control over international and domestic traffic in controlled substances.

DEFINITIONS

SEC. 102. As used in this title:

(1) The term "addict" means any individual who habitually uses any narcotic drug so as to endanger the public morals, health, safety, or welfare, or who is so far addicted to the use of narcotic drugs as to have lost the power of self-control with reference to his addiction.

(2) The term "administer" refers to the direct application of a controlled substance to the body of a patient or research subject by—

(A) a practitioner (or, in his presence, by his authorized agent), or

(B) the patient or research subject at the direction and in the presence of the practitioner,

whether such application be by injection, inhalation, ingestion, or any other means.

(3) The term "agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser; except that such term does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman, when acting in the usual and lawful course of the carrier's or warehouseman's business.

(4) The term "Bureau of Narcotics and Dangerous Drugs" means the Bureau of Narcotics and Dangerous Drugs in the Department of Justice.

(5) The term "control" means to add a drug or other substance, or immediate precursor, to a schedule under part B of this title, whether by transfer from another schedule or otherwise.

(6) The term "controlled substance" means a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of this title. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1954.

(7) The term "counterfeit substance" means a controlled substance which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number, or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person or persons who in fact manufactured, distributed, or dispensed such substance and which thereby falsely purports or is represented to be the product of, or to have been distributed by, such other manufacturer, distributor, or dispenser.

(8) The terms "deliver" or "delivery" mean the actual, constructive, or attempted transfer of a controlled substance, whether or not there exists an agency relationship.

(9) The term "depressant or stimulant substance" means—

(A) a drug which contains any quantity of (i) barbituric acid or any of the salts of barbituric acid; or (ii) any derivative of barbituric acid which has been designated by the Secretary as habit forming under section 502(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(d)); or

(B) a drug which contains any quantity of (i) amphetamine or any of its optical isomers; (ii) any salt of amphetamine or any salt of an optical isomer of amphetamine; or (iii) any substance which the Attorney General, after investigation, has found to be, and by regulation designated as, habit forming because of its stimulant effect on the central nervous system; or

(C) lysergic acid diethylamide; or

(D) any drug which contains any quantity of a substance which the Attorney General, after investigation, has found to have, and by regulation designated as having, a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect.

(10) The term "dispense" means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

(11) The term "distribute" means to deliver (other than by administering or dispensing) a controlled substance. The term "distributor" means a person who so delivers a controlled substance.

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(12) The term "drug" has the meaning given that term by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act.

(13) The term "felony" means any Federal or State offense classified by applicable Federal or State law as a felony.

(14) The term "manufacture" means the production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of such substance or labeling or relabeling of its container; except that such term does not include the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice. The term "manufacturer" means a person who manufactures a drug or other substance.

(15) The term "marihuana" means all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.

(16) The term "narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(A) Opium, coca leaves, and opiates.

(B) A compound, manufacture, salt, derivative, or preparation of opium, coca leaves, or opiates.

(C) A substance (and any compound, manufacture, salt, derivative, or preparation thereof) which is chemically identical with any of the substances referred to in clause (A) or (B).

Such term does not include decocainized coca leaves or extracts of coca leaves, which extracts do not contain cocaine or ecgonine.

(17) The term "opiate" means any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability.

(18) The term "opium poppy" means the plant of the species Papaver somniferum L., except the seed thereof.

(19) The term "poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

(20) The term "practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

(21) The term "production" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.

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(22) The term "immediate precursor" means a substance—

(A) which the Attorney General has found to be and by regulation designated as being the principal compound used, or produced primarily for use, in the manufacture of a controlled substance;

(B) which is an immediate chemical intermediary used or likely to be used in the manufacture of such controlled substance; and

(C) the control of which is necessary to prevent, curtail, or limit the manufacture of such controlled substance.

(23) The term "Secretary", unless the context otherwise indicates, means the Secretary of Health, Education, and Welfare.

(24) The term "State" means any State, territory, or possession of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Trust Territory of the Pacific Islands, and the Canal Zone.

(25) The term "ultimate user" means a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.

(26) The term "United States", when used in a geographic sense, means all places and waters, continental or insular, subject to the jurisdiction of the United States.

INCREASED NUMBERS OF ENFORCEMENT PERSONNEL

SEC. 103. (a) During the fiscal year 1971, the Bureau of Narcotics and Dangerous Drugs is authorized to add at least 300 agents, together with necessary supporting personnel, to the number of enforcement personnel currently available to it.

Appropriation.

(b) There are authorized to be appropriated not to exceed $6,000,000 for the fiscal year 1971 and for each fiscal year thereafter to carry out the provisions of subsection (a).

PART B—AUTHORITY TO CONTROL; STANDARDS AND SCHEDULES

AUTHORITY AND CRITERIA FOR CLASSIFICATION OF SUBSTANCES

SEC. 201. (a) The Attorney General shall apply the provisions of this title to the controlled substances listed in the schedules established by section 202 of this title and to any other drug or other substance added to such schedules under this title. Except as provided in subsections (d) and (e), the Attorney General may by rule—

(1) add to such a schedule or transfer between such schedules any drug or other substance if he—

(A) finds that such drug or other substance has a potential for abuse, and

(B) makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 202 for the schedule in which such drug is to be placed; or

(2) remove any drug or other substance from the schedules if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule.

Hearing opportunity. Rules. 80 Stat. 381. 5 USC 551.

Rules of the Attorney General under this subsection shall be made on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by subchapter II of chapter 5 of title 5 of the United States Code. Proceedings for the issuance, amendment, or

repeal of such rules may be initiated by the Attorney General (1) on his own motion, (2) at the request of the Secretary, or (3) on the petition of any interested party.

(b) The Attorney General shall, before initiating proceedings under subsection (a) to control a drug or other substance or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance. In making such evaluation and recommendations, the Secretary shall consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of subsection (c) and any scientific or medical considerations involved in paragraphs (1), (4), and (5) of such subsection. The recommendations of the Secretary shall include recommendations with respect to the appropriate schedule, if any, under which such drug or other substance should be listed. The evaluation and the recommendations of the Secretary shall be made in writing and submitted to the Attorney General within a reasonable time. The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance. If the Attorney General determines that these facts and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or substantial evidence that the drug or other substance should be removed entirely from the schedules, he shall initiate proceedings for control or removal, as the case may be, under subsection (a).

(c) In making any finding under subsection (a) of this section or under subsection (b) of section 202, the Attorney General shall consider the following factors with respect to each drug or other substance proposed to be controlled or removed from the schedules:

(1) Its actual or relative potential for abuse.

(2) Scientific evidence of its pharmacological effect, if known.

(3) The state of current scientific knowledge regarding the drug or other substance.

(4) Its history and current pattern of abuse.

(5) The scope, duration, and significance of abuse.

(6) What, if any, risk there is to the public health.

(7) Its psychic or physiological dependence liability.

(8) Whether the substance is an immediate precursor of a substance already controlled under this title.

(d) If control is required by United States obligations under international treaties, conventions, or protocols in effect on the effective date of this part, the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by subsection (a) of this section or section 202(b) and without regard to the procedures prescribed by subsections (a) and (b) of this section.

(e) The Attorney General may, without regard to the findings required by subsection (a) of this section or section 202(b) and without regard to the procedures prescribed by subsections (a) and (b) of this section, place an immediate precursor in the same schedule in which the controlled substance of which it is an immediate precursor is placed or in any other schedule with a higher numerical designation. If the Attorney General designates a substance as an immediate precursor and places it in a schedule, other substances shall not be placed in a schedule solely because they are its precursors.

(f) If, at the time a new-drug application is submitted to the Secretary for any drug having a stimulant, depressant, or hallucinogenic effect on the central nervous system, it appears that such drug has an abuse potential, such information shall be forwarded by the Secretary to the Attorney General.

(g)(1) The Attorney General shall by regulation exclude any nonnarcotic substance from a schedule if such substance may, under the Federal Food, Drug, and Cosmetic Act, be lawfully sold over the counter without a prescription.

(2) Dextromethorphan shall not be deemed to be included in any schedule by reason of enactment of this title unless controlled after the date of such enactment pursuant to the foregoing provisions of this section.

SCHEDULES OF CONTROLLED SUBSTANCES

SEC. 202. (a) There are established five schedules of controlled substances, to be known as schedules I, II, III, IV, and V. Such schedules shall initially consist of the substances listed in this section. The schedules established by this section shall be updated and republished on a semiannual basis during the two-year period beginning one year after the date of enactment of this title and shall be updated and republished on an annual basis thereafter.

(b) Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on the effective date of this part, and except in the case of an immediate precursor, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance. The findings required for each of the schedules are as follows:

(1) SCHEDULE I.—

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has no currently accepted medical use in treatment in the United States.

(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

(2) SCHEDULE II.—

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.

(C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.

(3) SCHEDULE III.—

(A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

(4) SCHEDULE IV.—

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

(5) SCHEDULE V.—

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

(c) Schedules I, II, III, IV, and V shall, unless and until amended pursuant to section 201, consist of the following drugs or other substances, by whatever official name, common or usual name, chemical name, or brand name designated:

SCHEDULE I

Opiates.

(a) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Acetylmethadol.
(2) Allylprodine.
(3) Alphacetylmathadol.
(4) Alphameprodine.
(5) Alphamethadol.
(6) Benzethidine.
(7) Betacetylmethadol.
(8) Betameprodine.
(9) Betamethadol.
(10) Betaprodine.
(11) Clonitazene.
(12) Dextromoramide.
(13) Dextrorphan.
(14) Diampromide.
(15) Diethylthiambutene.
(16) Dimenoxadol.
(17) Dimepheptanol.
(18) Dimethylthiambutene.
(19) Dioxaphetyl butyrate.
(20) Dipipanone.
(21) Ethylmethylthiambutene.
(22) Etonitazene.
(23) Etoxeridine.
(24) Furethidine.
(25) Hydroxypethidine.
(26) Ketobemidone.
(27) Levomoramide.
(28) Levophenacylmorphan.
(29) Morpheridine.
(30) Noracymethadol.
(31) Norlevorphanol.
(32) Normethadone.
(33) Norpipanone.
(34) Phenadoxone.
(35) Phenampromide.

(36) Phenomorphan.
(37) Phenoperidine.
(38) Piritramide.
(39) Proheptazine.
(40) Properidine.
(41) Racemoramide.
(42) Trimeperidine.

Opium derivatives.

(b) Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Acetorphine.
(2) Acetyldihydrocodeine.
(3) Benzylmorphine.
(4) Codeine methylbromide.
(5) Codeine-N-Oxide.
(6) Cyprenorphine.
(7) Desomorphine.
(8) Dihydromorphine.
(9) Etorphine.
(10) Heroin.
(11) Hydromorphinol.
(12) Methyldesorphine.
(13) Methylhydromorphine.
(14) Morphine methylbromide.
(15) Morphine methylsulfonate.
(16) Morphine-N-Oxide.
(17) Myrophine.
(18) Nicocodeine.
(19) Nicomorphine.
(20) Normorphine.
(21) Pholcodine.
(22) Thebacon.

Hallucinogenic substances.

(c) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) 3,4-methylenedioxy amphetamine.
(2) 5-methoxy-3,4-methylenedioxy amphetamine.
(3) 3,4,5-trimethoxy amphetamine.
(4) Bufotenine.
(5) Diethyltryptamine.
(6) Dimethyltryptamine.
(7) 4-methyl-2,5-dimethoxyamphetamine.
(8) Ibogaine.
(9) Lysergic acid diethylamide.
(10) Marihuana.
(11) Mescaline.
(12) Peyote.
(13) N-ethyl-3-piperidyl benzilate.
(14) N-methyl-3-piperidyl benzilate.
(15) Psilocybin.
(16) Psilocyn.
(17) Tetrahydrocannabinols.

SCHEDULE II

Substances, vegetable origin or chemical synthesis.

(a) Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.

(2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (1), except that these substances shall not include the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) Coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine.

Opiates.

(b) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Alphaprodine.
(2) Anileridine.
(3) Bezitramide.
(4) Dihydrocodeine.
(5) Diphenoxylate.
(6) Fentanyl.
(7) Isomethadone.
(8) Levomethorphan.
(9) Levorphanol.
(10) Metazocine.
(11) Methadone.
(12) Methadone-Intermediate, 4-cyano - 2 - dimethylamino-4,4-diphenyl butane.
(13) Moramide-Intermediate, 2 - methyl - 3 - morpholino-1, 1-diphenylpropane-carboxylic acid.
(14) Pethidine.
(15) Pethidine-Intermediate-A, 4 - cyano-1-methyl-4-phenylpiperidine.
(16) Pethidine-Intermediate-B, ethyl - 4-phenylpiperidine-4-carboxylate.
(17) Pethidine-Intermediate-C, 1-methyl - 4 - phenylpiperidine-4-carboxylic acid.
(18) Phenazocine.
(19) Piminodine.
(20) Racemethorphan.
(21) Racemorphan.

Methamphetamine.

(c) Unless specifically excepted or unless listed in another schedule, any injectable liquid which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.

SCHEDULE III

Stimulants.

(a) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers.

(2) Phenmetrazine and its salts.

(3) Any substance (except an injectable liquid) which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.

(4) Methylphenidate.

Depressants.

(b) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid.

(2) Chorhexadol.
(3) Glutethimide.
(4) Lysergic acid.
(5) Lysergic acid amide.
(6) Methyprylon.
(7) Phencyclidine.
(8) Sulfondiethylmethane.
(9) Sulfonethylmethane.
(10) Sulfonmethane.

Narcotic drugs.

(c) Nalorphine.

(d) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof:

(1) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.

(2) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(3) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.

(4) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(5) Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(6) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, noncontrolled ingredients in recognized therapeutic amounts.

(7) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, noncontrolled ingredients in recognized therapeutic amounts.

(8) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams, with one or more active, noncontrolled ingredients in recognized therapeutic amounts.

SCHEDULE IV

(1) Barbital.
(2) Chloral betaine.
(3) Chloral hydrate.
(4) Ethchlorvynol.
(5) Ethinamate.
(6) Methohexital.
(7) Meprobamate.
(8) Methylphenobarbital.
(9) Paraldehyde.
(10) Petrichloral.
(11) Phenobarbital.

SCHEDULE V

Any compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

(1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.

(2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.

(3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.

(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.

(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.

(b) The Attorney General may by regulation except any compound, mixture, or preparation containing any depressant or stimulant substance in paragraph (a) or (b) of schedule III or in schedule IV or V from the application, of all or any part of this title if (1) the compound, mixture, or preparation contains one or more active medicinal ingredients not having a depressant or stimulant effect on the central nervous system, and (2) such ingredients are included therein in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse of the substances which do have a depressant or stimulant effect on the central nervous system.

PART C REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

RULES AND REGULATIONS

SEC. 301. The Attorney General is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances.

PERSONS REQUIRED TO REGISTER

SEC. 302. (a) Every person who manufactures, distributes, or dispenses any controlled substance or who proposes to engage in the manufacture, distribution, or dispensing of any controlled substance, shall obtain annually a registration issued by the Attorney General in accordance with the rules and regulations promulgated by him.

(b) Persons registered by the Attorney General under this title to manufacture, distribute, or dispense controlled substances are authorized to possess, manufacture, distribute, or dispense such substances (including any such activity in the conduct of research) to the extent authorized by their registration and in conformity with the other provisions of this title.

(c) The following persons shall not be required to register and may lawfully possess any controlled substance under this title:

(1) An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance if such agent or employee is acting in the usual course of his business or employment.

(2) A common or contract carrier or warehouseman, or an employee thereof, whose possession of the controlled substance is in the usual course of his business or employment.

(3) An ultimate user who possesses such substance for a purpose specified in section 102(25).

(d) The Attorney General may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and safety.

(e) A separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances.

(f) The Attorney General is authorized to inspect the establishment of a registrant or applicant for registration in accordance with the rules and regulations promulgated by him.

REGISTRATION REQUIREMENTS

SEC. 303. (a) The Attorney General shall register an applicant to manufacture controlled substances in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on the effective date of this part. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately com-

(4) compliance with applicable State and local law;

(5) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(6) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(7) past experience in the manufacture of controlled substances, and the existence in the establishment of effective controls against diversion; and

(8) such other factors as may be relevant to and consistent with the public health and safety.

For Attorney General to register applicants to distribute controlled substances in schedule I or II unless he determines that the issuance of such registrations is consistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

Registration granted under this section shall not entitle a registrant to manufacture or distribute controlled substances in schedule I or II other than those specified in the registration. Registration for any quantity of those controlled substances in excess of the quota assigned pursuant to section 306.

(d) The Attorney General shall register an applicant to manufacture controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule III, IV, or V compounded therefrom into other than legitimate medical, scientific, or industrial channels;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture, distribution, and dispensing of controlled substances, and the existence in the establishment of effective controls against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(e) The Attorney General shall register an applicant to distribute controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(f) Practitioners shall be registered to dispense or conduct research with controlled substances in schedule II, III, IV, or V if they are authorized to dispense or conduct research under the law of the State in which they practice. Separate registration under this part for practitioners engaging in research with nonnarcotic controlled substances in schedule II, III, IV, or V, who are already registered under this part in another capacity, shall not be required. Pharmacies (as distinguished from pharmacists) when engaged in commercial activities, shall be registered to dispense controlled substances in schedule II, III, IV, or V if they are authorized to dispense under the law of the State in which they regularly conduct business. Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Secretary, who shall determine qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol. The Secretary, in determining the merits of each research protocol, shall consult with the Attorney General as to effective procedures to adequately safeguard against diversion of such controlled substances from legitimate medical or scientific use. Registration for the purpose of bona fide research with controlled substances in schedule I by a practitioner deemed qualified by the Secretary may be denied by the Attorney General only on a ground specified in section 304(a).

DENIAL, REVOCATION, OR SUSPENSION OF REGISTRATION

SEC. 304. (a) A registration pursuant to section 303 to manufacture, distribute, or dispense a controlled substance may be suspended or revoked by the Attorney General upon a finding that the registrant

(1) has materially falsified any application filed pursuant to or required by this title or title III;

(2) has been convicted of a felony under this title or title III or any other law of the United States, or of any State, relating to any substance defined in this title as a controlled substance; or

(3) has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances.

(b) The Attorney General may limit revocation or suspension of a registration to the particular controlled substance with respect to which grounds for revocation or suspension exist.

Service of order to show cause.

(c) Before taking action pursuant to this section, or pursuant to a denial of registration under section 303, the Attorney General shall serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended. The order to show cause shall contain a statement of the basis thereof and shall call upon the applicant or registrant to appear before the Attorney

General at a time and place stated in the order, but in no event less than thirty days after the date of receipt of the order. Proceedings to deny, revoke, or suspend shall be conducted pursuant to this section in accordance with subchapter II of chapter 5 of title 5 of the United States Code. Such proceedings shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under this title or any other law of the United States.

Ante, p. 1251.
5 USC 551.

Registration, suspension.

(d) The Attorney General may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this section, in cases where he finds that there is an imminent danger to the public health or safety. Such suspension shall continue in effect until the conclusion of such proceedings, including judicial review thereof, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction.

(e) The suspension or revocation of a registration under this section shall operate to suspend or revoke any quota applicable under section 306.

(f) In the event the Attorney General suspends or revokes a registration granted under section 303, all controlled substances owned or possessed by the registrant pursuant to such registration at the time of suspension or the effective date of the revocation order, as the case may be, may, in the discretion of the Attorney General, be placed under seal. No disposition may be made of any controlled substances under seal until the time for taking an appeal has elapsed or until all appeals have been concluded except that a court, upon application therefor, may at any time order the sale of perishable controlled substances. Any such order shall require the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final, all such controlled substances (or proceeds of sale deposited in court) shall be forfeited to the United States; and the Attorney General shall dispose of such controlled substances in accordance with section 511(e).

Post, p. [illegible].

LABELING AND PACKAGING REQUIREMENTS

Symbol.

SEC. 305. (a) It shall be unlawful to distribute a controlled substance in a commercial container unless such container, when and as required by regulations of the Attorney General, bears a label (as defined in section 201(k) of the Federal Food, Drug, and Cosmetic Act) containing an identifying symbol for such substance in accordance with such regulations. A different symbol shall be required for each schedule of controlled substances.

[illegible] Stat. 1041.
21 USC 321.

(b) It shall be unlawful for the manufacturer of any controlled substance to distribute such substance unless the labeling (as defined in section 201(m) of the Federal Food, Drug, and Cosmetic Act) of such substance contains, when and as required by regulations of the Attorney General, the identifying symbol required under subsection (a).

Same.

(c) The Secretary shall prescribe regulations under section 503(b) of the Federal Food, Drug, and Cosmetic Act which shall provide that the label of a drug listed in schedule II, III, or IV shall, when dispensed to or for a patient, contain a clear, concise warning that it is a crime to transfer the drug to any person other than the patient.

[illegible] Stat. 1060.
21 USC 353.

Unlawful distribution.

(d) It shall be unlawful to distribute controlled substances in schedule I or II, and narcotic drugs in schedule III or IV, unless the bottle or other container, stopper, covering, or wrapper thereof is securely sealed as required by regulations of the Attorney General.

QUOTAS APPLICABLE TO CERTAIN SUBSTANCES

Production quotas.

SEC. 306. (a) The Attorney General shall determine the total quantity and establish production quotas for each basic class of controlled substance in schedules I and II to be manufactured each calendar year to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. Production quotas shall be established in terms of quantities of each basic class of controlled substance and not in terms of individual pharmaceutical dosage forms prepared from or containing such a controlled substance.

(b) The Attorney General shall limit or reduce individual production quotas to the extent necessary to prevent the aggregate of individual quotas from exceeding the amount determined necessary each year by the Attorney General under subsection (a). The quota of each registered manufacturer for each basic class of controlled substance in schedule I or II shall be revised in the same proportion as the limitation or reduction of the aggregate of the quotas. However, if any registrant, before the issuance of a limitation or reduction in quota, has manufactured in excess of his revised quota, the amount of the excess shall be subtracted from his quota for the following year.

Manufacturing quotas.

(c) On or before July 1 of each year, upon application therefor by a registered manufacturer, the Attorney General shall fix a manufacturing quota for the basic classes of controlled substances in schedules I and II that the manufacturer seeks to produce. The quota shall be subject to the provisions of subsections (a) and (b) of this section. In fixing such quotas, the Attorney General shall determine the manufacturer's estimated disposal, inventory, and other requirements for the calendar year; and, in making his determination, the Attorney General shall consider the manufacturer's current rate of disposal, the trend of the national disposal rate during the preceding calendar year, the manufacturer's production cycle and inventory position, the economic availability of raw materials, yield and stability problems, emergencies such as strikes and fires, and other factors.

(d) The Attorney General shall, upon application and subject to the provisions of subsections (a) and (b) of this section, fix a quota for a basic class of controlled substance in schedule I or II for any registrant who has not manufactured that basic class of controlled substance during one or more preceding calendar years. In fixing such quota, the Attorney General shall take into account the registrant's reasonably anticipated requirements for the current year; and, in making his determination of such requirements, he shall consider such factors specified in subsection (c) of this section as may be relevant.

New registrant.

(e) At any time during the year any registrant who has applied for or received a manufacturing quota for a basic class of controlled substance in schedule I or II may apply for an increase in that quota to meet his estimated disposal, inventory, and other requirements during the remainder of that year. In passing upon the application the Attorney General shall take into consideration any occurrences since the filing of the registrant's initial quota application that may require an increased manufacturing rate by the registrant during the balance of the year. In passing upon the application the Attorney General may also take into account the amount, if any, by which the determination of the Attorney General under subsection (a) of this section exceeds the aggregate of the quotas of all registrants under this section.

Controlled substances, incidental production, exception.

(f) Notwithstanding any other provisions of this title, no registration or quota may be required for the manufacture of such quantities of controlled substances in schedules I and II as incidentally and

necessarily result from the manufacturing process used for the manufacture of a controlled substance with respect to which its manufacturer is duly registered under this title. The Attorney General may, by regulation, prescribe restrictions on the retention and disposal of such incidentally produced substances.

Restrictions.

RECORDS AND REPORTS OF REGISTRANTS

Inventory.

SEC. 307. (a) Except as provided in subsection (c)—

(1) every registrant under this title shall, on the effective date of this section, or as soon thereafter as such registrant first engages in the manufacture, distribution, or dispensing of controlled substances, and every second year thereafter, make a complete and accurate record of all stocks thereof on hand, except that the regulations prescribed under this section shall permit each such biennial inventory (following the initial inventory required by this paragraph) to be prepared on such registrant's regular general physical inventory date (if any) which is nearest to and does not vary by more than six months from the biennial date that would otherwise apply;

(2) on the effective date of each regulation of the Attorney General controlling a substance that immediately prior to such date was not a controlled substance, each registrant under this title manufacturing, distributing, or dispensing such substance shall make a complete and accurate record of all stocks thereof on hand; and

(3) on and after the effective date of this section, every registrant under this title manufacturing, distributing, or dispensing a controlled substance or substances shall maintain, on a current basis, a complete and accurate record of each such substance manufactured, received, sold, delivered, or otherwise disposed of by him, except that this paragraph shall not require the maintenance of a perpetual inventory.

Availability.

(b) Every inventory or other record required under this section (1) shall be in accordance with, and contain such relevant information as may be required by, regulations of the Attorney General, (2) shall (A) be maintained separately from all other records of the registrant, or (B) alternatively, in the case of nonnarcotic controlled substances, be in such form that information required by the Attorney General is readily retrievable from the ordinary business records of the registrant, and (3) shall be kept and be available, for at least two years, for inspection and copying by officers or employees of the United States authorized by the Attorney General.

Non-applicability.

(c) The foregoing provisions of this section shall not apply

(1)(A) with respect to narcotic controlled substances in schedule II, III, IV, or V, to the prescribing or administering of such substances by a practitioner in the lawful course of his professional practice; or

(B) with respect to nonnarcotic controlled substances in schedule II, III, IV, or V, to any practitioner who dispenses such substances to his patients, unless the practitioner is regularly engaged in charging his patients, either separately or together with charges for other professional services, for substances so dispensed;

(2)(A) to the use of controlled substances, at establishments registered under this title which keep records with respect to such substances, in research conducted in conformity with an exemption granted under section 505(i) or 512(j) of the Federal Food, Drug, and Cosmetic Act;

52 Stat. 1052; 76 Stat. 783. 82 Stat. 343. 21 USC 355, 360b.

(B) to the use of controlled substances, at establishments registered under this title which keep records with respect to such substances, in preclinical research or in teaching; or

(3) to the extent of any exemption granted to any person, with respect to all or part of such provisions, by the Attorney General by or pursuant to regulation on the basis of a finding that the application of such provisions (or part thereof) to such person is not necessary for carrying out the purposes of this title.

(d) Every manufacturer registered under section 303 shall, at such time or times and in such form as the Attorney General may require, make periodic reports to the Attorney General of every sale, delivery, or other disposal by him of any controlled substance, and each distributor shall make such reports with respect to narcotic controlled substances, identifying by the registration number assigned under this title the person or establishment (unless exempt from registration under section 302(d)) to whom such sale, delivery, or other disposal was made.

[illegible]. 1052; [illegible]. 783. [illegible]. 343. [illegible]. 355, 360b.

(e) Regulations under sections 505(i) and 512(j) of the Federal Food, Drug, and Cosmetic Act, relating to investigational use of drugs, shall include such procedures as the Secretary, after consultation with the Attorney General, determines are necessary to insure the security and accountability of controlled substances used in research to which such regulations apply.

ORDER FORMS

Unlawful distribution.

SEC. 308. (a) It shall be unlawful for any person to distribute a controlled substance in schedule I or II to another except in pursuance of a written order of the person to whom such substance is distributed, made on a form to be issued by the Attorney General in blank in accordance with subsection (d) and regulations prescribed by him pursuant to this section.

Non-applicability.

(b) Nothing in subsection (a) shall apply to

(1) the exportation of such substances from the United States in conformity with title III;

[illegible], 1[illegible].

(2) the delivery of such a substance to or by a common or contract carrier for carriage in the lawful and usual course of its business, or to or by a warehouseman for storage in the lawful and usual course of its business; but where such carriage or storage is in connection with the distribution by the owner of the substance to a third person, this paragraph shall not relieve the distributor from compliance with subsection (a).

Preservation and availability.

(c)(1) Every person who in pursuance of an order required under subsection (a) distributes a controlled substance shall preserve such order for a period of two years, and shall make such order available for inspection and copying by officers and employees of the United States duly authorized for that purpose by the Attorney General, and by officers or employees of States or their political subdivisions who are charged with the enforcement of State or local laws regulating the production, or regulating the distribution or dispensing, of controlled substances and who are authorized under such laws to inspect such orders.

Duplicate, preservation and availability.

(2) Every person who gives an order required under subsection (a) shall, at or before the time of giving such order, make or cause to be made a duplicate thereof on a form to be issued by the Attorney General in blank in accordance with subsection (d) and regulations prescribed by him pursuant to this section, and shall, if such order is accepted, preserve such duplicate for a period of two years and make it available for inspection and copying by the officers and employees mentioned in paragraph (1) of this subsection.

(d) (1) The Attorney General shall issue forms pursuant to subsections (a) and (c)(2) only to persons validly registered under section 303 (or exempted from registration under section 302(d)). Whenever any such form is issued to a person, the Attorney General shall, before delivery thereof, insert therein the name of such person, and it shall be unlawful for any other person (A) to use such form for the purpose of obtaining controlled substances or (B) to furnish such form to any person with intent thereby to procure the distribution of such substances.

(2) The Attorney General may charge reasonable fees for the issuance of such forms in such amounts as he may prescribe for the purpose of covering the cost to the United States of issuing such forms, and other necessary activities in connection therewith.

(e) It shall be unlawful for any person to obtain by means of order forms issued under this section controlled substances for any purpose other than their use, distribution, dispensing, or administration in the conduct of a lawful business in such substances or in the course of his professional practice or research.

PRESCRIPTIONS

SEC. 309. (a) Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed without the written prescription of a practitioner, except that in emergency situations, as prescribed by the Secretary by regulation after consultation with the Attorney General, such drug may be dispensed upon oral prescription in accordance with section 503(b) of that Act. Prescriptions shall be retained in conformity with the requirements of section 307 of this title. No prescription for a controlled substance in schedule II may be refilled.

(b) Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed without a written or oral prescription in conformity with section 503(b) of that Act. Such prescriptions may not be filled or refilled more than six months after the date thereof or be refilled more than five times after the date of the prescription unless renewed by the practitioner.

(c) No controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medical purpose.

(d) Whenever it appears to the Attorney General that a drug not considered to be a prescription drug under the Federal Food, Drug, and Cosmetic Act should be so considered because of its abuse potential, he shall so advise the Secretary and furnish to him all available data relevant thereto.

PART D—OFFENSES AND PENALTIES

PROHIBITED ACTS A—PENALTIES

SEC. 401. (a) Except as authorized by this title, it shall be unlawful for any person knowingly or intentionally—

(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance; or

(2) to create, distribute, or dispense, or possess with intent to distribute or dispense, a counterfeit substance.

(b) Except as otherwise provided in section 405, any person who violates subsection (a) of this section shall be sentenced as follows:

(1) (A) In the case of a controlled substance in schedule I or II which is a narcotic drug, such person shall be sentenced to a term of imprisonment of not more than 15 years, a fine of not more than $25,000, or both. If any person commits such a violation after one or more prior convictions of him for an offense punishable under this paragraph, or for a felony under any other provision of this title or title III or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 30 years, a fine of not more than $50,000, or both. Any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a special parole term of at least 3 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a special parole term of at least 6 years in addition to such term of imprisonment.

(B) In the case of a controlled substance in schedule I or II which is not a narcotic drug or in the case of any controlled substance in schedule III, such person shall be sentenced to a term of imprisonment of not more than 5 years, a fine of not more than $15,000, or both. If any person commits such a violation after one or more prior convictions of him for an offense punishable under this paragraph, or for a felony under any other provision of this title or title III or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 10 years, a fine of not more than $30,000, or both. Any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a special parole term of at least 2 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a special parole term of at least 4 years in addition to such term of imprisonment.

(2) In the case of a controlled substance in schedule IV, such person shall be sentenced to a term of imprisonment of not more than 3 years, a fine of not more than $10,000, or both. If any person commits such a violation after one or more prior convictions of him for an offense punishable under this paragraph, or for a felony under any other provision of this title or title III or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 6 years, a fine of not more than $20,000, or both. Any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a special parole term of at least one year in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a special parole term of at least 2 years in addition to such term of imprisonment.

(3) In the case of a controlled substance in schedule V, such person shall be sentenced to a term of imprisonment of not more than one year, a fine of not more than $5,000, or both. If any person commits such a violation after one or more convictions of him for an offense punishable under this paragraph, or for a crime under any other provision of this title or title III or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 2 years, a fine of not more than $10,000, or both.

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(4) Notwithstanding paragraph (1)(B) of this subsection, any person who violates subsection (c) of this section by distributing a small amount of marihuana for no remuneration shall be treated as provided in subsections (a) and (b) of section 404.

Marihuana, simple possession.

(c) A special parole term imposed under this section or section 405 may be revoked if its terms and conditions are violated. In such circumstances the original term of imprisonment shall be increased by the period of the special parole term and the resulting new term of imprisonment shall not be dimmished by the time which was spent on special parole. A person whose special parole term has been revoked may be required to serve all or part of the remainder of the new term of imprisonment. A special parole term provided for in this section or section 405 shall be in addition to, and not in lieu of, any other parole provided for by law.

Special parole terms.

PROHIBITED ACTS B—PENALTIES

SEC. 402. (a) It shall be unlawful for any person

(1) who is subject to the requirements of part C to distribute or dispense a controlled substance in violation of section 309;

(2) who is a registrant to distribute or dispense a controlled substance not authorized by his registration to another registrant or other authorized person or to manufacture a controlled substance not authorized by his registration;

(3) who is a registrant to distribute a controlled substance in violation of section 305 of this title;

(4) to remove, alter, or obliterate a symbol or label required by section 305 of this title;

(5) to refuse or fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under this title or title III;

Post, p. [illegible].

(6) to refuse any entry into any premises or inspection authorized by this title or title III;

(7) to remove, break, injure, or deface a seal placed upon controlled substances pursuant to section 304(f) or 511 or to remove or dispose of substances so placed under seal; or

Ante, p. [illegible], [illegible].

(8) to use, to his own advantage, or to reveal, other than to duly authorized officers or employees of the United States, or to the courts when relevant in any judicial proceeding under this title or title III, any information acquired in the course of an inspection authorized by this title concerning any method or process which as a trade secret is entitled to protection.

(b) It shall be unlawful for any person who is a registrant to manufacture a controlled substance in schedule I or II which is—

(1) not expressly authorized by his registration and by a quota assigned to him pursuant to section 306; or

(2) in excess of a quota assigned to him pursuant to section 306.

(c)(1) Except as provided in paragraph (2), any person who violates this section shall, with respect to any such violation, be subject to a civil penalty of not more than $25,000. The district courts of the United States (or, where there is no such court in the case of any territory or possession of the United States, then the court in such territory or possession having the jurisdiction of a district court of the United States in cases arising under the Constitution and laws of the United States) shall have jurisdiction in accordance with section 1355 of title 28 of the United States Code to enforce this paragraph.

Penalty.

Jurisdiction of courts.

28 USC 1355.

84 STAT. 1263

(2)(A) If a violation of this section is prosecuted by an information or indictment which alleges that the violation was committed knowingly and the trier of fact specifically finds that the violation was so committed, such person shall, except as otherwise provided in subparagraph (B) of this paragraph, be sentenced to imprisonment of not more than one year or a fine of not more than $25,000, or both.

Penalty.

(B) If a violation referred to in subparagraph (A) was committed after one or more prior convictions of the offender for an offense punishable under this paragraph (2), or for a crime under any other provision of this title or title III or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 2 years, a fine of $50,000, or both.

Post, p. [illegible].

Penalty.

(3) Except under the conditions specified in paragraph (2) of this subsection, a violation of this section does not constitute a crime, and a judgment for the United States and imposition of a civil penalty pursuant to paragraph (1) shall not give rise to any disability or legal disadvantage based on conviction for a criminal offense.

Exception.

PROHIBITED ACTS C—PENALTIES

SEC. 403. (a) It shall be unlawful for any person knowingly or intentionally—

(1) who is a registrant to distribute a controlled substance classified in schedule I or II, in the course of his legitimate business, except pursuant to an order or an order form as required by section 308 of this title;

(2) to use in the course of the manufacture or distribution of a controlled substance a registration number which is fictitious, revoked, suspended, or issued to another person;

(3) to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge;

(4) to furnish false or fraudulent material information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under this title or title III; or

(5) to make, distribute, or possess any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit substance.

(b) It shall be unlawful for any person knowingly or intentionally to use any communication facility in committing or in causing or facilitating the commission of any act or acts constituting a felony under any provision of this title or title III. Each separate use of a communication facility shall be a separate offense under this subsection. For purposes of this subsection, the term "communication facility" means any and all public and private instrumentalities used or useful in the transmission of writing, signs, signals, pictures, or sounds of all kinds and includes mail, telephone, wire, radio, and all other means of communication.

"Communication facility."

(c) Any person who violates this section shall be sentenced to a term of imprisonment of not more than 4 years, a fine of not more than $30,000, or both; except that if any person commits such a violation after one or more prior convictions of him for violation of this section, or for a felony under any other provision of this title or title III or other law of the United States relating to narcotic drugs,

Penalty.

The effect of such order shall be to restore such person to the status occupied before the arrest or indictment or information. No person as to whom such order has been entered shall be held thereafter under any provision of any law to be guilty of perjury or otherwise giving a false statement by reason of his failure to recite or acknowledge such arrest, or indictment or information, or trial in response to any inquiry made of him for any purpose.

DISPOSITION OF PERSONS UNDER AGE TWENTY-ONE

SEC. [illegible]. Any person at least eighteen years of age who violates section [illegible] by distributing a controlled substance to a person under twenty-one years of age (except as provided in subsection [illegible]) is punishable by a term of imprisonment, or a fine, or both, up to twice that authorized by section [illegible], but at least twice any special parole term authorized by section [illegible], for a first offense involving a controlled substance listed in schedule [illegible].

Any person at least eighteen years of age who violates section [illegible] by distributing a controlled substance to a person under twenty-one years of age after a prior conviction under section [illegible] of the Federal Drug Abuse Control Amendments of 1965 or after a prior conviction for a felony under any other provision of the Federal Food, Drug, and Cosmetic Act or a felony prior to the effective date of section [illegible] of this Act has become final, is punishable by a term of imprisonment or a fine, or both, up to three times that authorized by section [illegible], but at least three times any special parole term authorized by section [illegible], for a second or subsequent distribution to the same person of a controlled substance listed in schedule [illegible].

ATTEMPT AND CONSPIRACY

SEC. [illegible]. Any person who attempts or conspires to commit any offense defined in this title is punishable by imprisonment or fine or both which may not exceed the maximum punishment prescribed for the offense, the commission of which was the object of the attempt or conspiracy.

ADDITIONAL PENALTIES

SEC. [illegible]. Any penalty imposed for violation of this title shall be in addition to, and not in lieu of, any civil or administrative penalty or sanction authorized by law.

CONTINUING CRIMINAL ENTERPRISE

SEC. [illegible]. (a) Any person who engages in a continuing criminal enterprise shall be sentenced to a term of imprisonment which may not be less than [illegible] years and which may be up to life imprisonment, to a fine of not more than $[illegible], and to the forfeiture prescribed in paragraph (2); except that if any person engages in such activity after one or more prior convictions of him under this section have become final, he shall be sentenced to a term of imprisonment which may not be less than [illegible] years and which may be up to life imprisonment, to a fine of not more than $[illegible], and to the forfeiture prescribed in paragraph (2).

(2) Any person who is convicted under paragraph (1) of engaging in a continuing criminal enterprise shall forfeit to the United States—

(A) the profits obtained by him in such enterprise, and

(B) any of his interest in, claim against, or property or contractual rights of any kind affording a source of influence over, such enterprise.

(b) For purposes of subsection (a), a person is engaged in a continuing criminal enterprise if:

(1) he violates any provision of this title or title III the punishment for which is a felony, and

(2) such violation is a part of a continuing series of violations of this title or title III

(A) which are undertaken by such person in concert with five or more other persons with respect to whom such person occupies a position of organizer, a supervisory position, or any other position of management, and

(B) from which such person obtains substantial income or resources.

(c) In the case of any sentence imposed under this section, imposition or execution of such sentence shall not be suspended, probation shall not be granted, and section 4202 of title 18 of the United States Code and the Act of July 15, 1932 (D.C. Code, secs. 24-203—24-207), shall not apply.

(d) The district courts of the United States (including courts in the territories or possessions of the United States having jurisdiction under subsection (a)) shall have jurisdiction to enter such restraining orders or probations or to take such other actions (including the acceptance of satisfactory performance bonds, in connection with any property or other interest subject to forfeiture under this section, as they shall deem proper.

DANGEROUS SPECIAL DRUG OFFENDER SENTENCING

SEC. 409. (a) Whenever a United States attorney charged with the prosecution of a defendant in a court of the United States for an alleged felonious violation of any provision of this title or title III committed when the defendant was over the age of twenty one years has reason to believe that the defendant is a dangerous special drug offender such United States attorney, a reasonable time before trial or acceptance by the court of a plea of guilty or nolo contendere, may sign and file with the court, and may amend, a notice (1) specifying that the defendant is a dangerous special drug offender who upon conviction for such felonious violation is subject to the imposition of a sentence under subsection (b) of this section, and (2) setting out with particularity the reasons why such attorney believes the defendant to be a dangerous special drug offender. In no case shall the fact that the defendant is alleged to be a dangerous special drug offender be an issue upon the trial of such felonious violation, be disclosed to the jury, or be disclosed before any plea of guilty or nolo contendere or verdict or finding of guilty to the presiding judge without the consent of the parties. If the court finds that the filing of the notice as a public record may prejudice fair consideration of a pending criminal matter, it may order the notice sealed and the notice shall not be subject to subpena or public inspection during the pendency of such criminal matter, except on order of the court, but shall be subject to inspection by the defendant alleged to be a dangerous special drug offender and his counsel.

(b) Upon any plea of guilty or nolo contendere or verdict or finding of guilty of the defendant of such felonious violation, a hearing shall be held, before sentence is imposed, by the court sitting without a jury.

The court shall fix a time for the hearing, and notice of the time shall be given to the defendant and the United States at least ten days prior thereto. The court shall permit the United States and counsel for the defendant, or the defendant if he is not represented by counsel, to inspect the presentence report sufficiently prior to the hearing to afford a reasonable opportunity for verification. In extraordinary cases, the court may withhold from the defendant any report or portion thereof, disclosure of which might result in harm to any person or reveal information obtained upon the promise of confidentiality, and may withhold previously disclosed information. A court withholding all or part of a presentence report shall inform the parties of its action and place in the record the reasons for such order. The court may require the investigative agency that prepared the report to make available for the hearing such agent as the court desires to testify with respect to any part thereof subject to controversy. In connection with the hearing, the defendant and the United States shall be entitled to the assistance of counsel, compulsory process, and cross-examination of such witnesses as appear at the hearing. A duly authenticated copy of a former judgment or commitment shall be prima facie evidence of such former judgment or commitment. If it appears by a preponderance of the information, including information adduced during the trial of such felonious violation and the sentencing hearing and stated in the presentence report, that the defendant is a dangerous special drug offender, the court shall sentence the defendant to imprisonment for an appropriate term not to exceed twenty five years and not disproportionate in severity to the maximum term otherwise authorized by law for such felonious violation. Otherwise it shall sentence the defendant in accordance with the law prescribing penalties for such felonious violation. The court shall place in the record its findings, including an identification of the information relied upon in making such findings, and its reasons for the sentence imposed.

(c) This section shall not prevent the imposition and execution of a sentence of imprisonment for life or for a term exceeding twenty five years upon any person convicted of an offense so punishable.

(d) Notwithstanding any other provision of this section, the court shall not sentence a dangerous special drug offender to less than any mandatory minimum penalty prescribed by law for such felonious violation. This section shall not be construed as creating any mandatory minimum penalty.

(e) A defendant is a special drug offender for purposes of this section if:

(1) the defendant has previously been convicted in courts of the United States or a State or any political subdivision thereof for two or more offenses involving dealing in controlled substances, committed on occasions different from one another and different from such felonious violation, and punishable in such courts by death or imprisonment in excess of one year, for one or more of such convictions the defendant has been imprisoned prior to the commission of such felonious violation, and less than five years have elapsed between the commission of such felonious violation and either the defendant's release, or parole or otherwise, from imprisonment for one such conviction or his commission of the last such previous offense or another offense involving dealing in controlled substances and punishable by death or imprisonment in excess of one year under applicable laws of the United States or a State or any political subdivision thereof; or

(2) the defendant committed such felonious violation as part of a pattern of dealing in controlled substances which was criminal

[illegible] under applicable rules of [illegible] which constituted a substantial source of his income, and in which he manifested special skills and expertise;

[illegible] such felonious violation the defendant committed such felonious violation in furtherance of a conspiracy with three or more other persons engaging in a pattern of dealing in controlled substances [illegible] applicable laws of the United States, and that he derived substantial income or resources from such activity;

[illegible] agreed that he would, [illegible] supervise, plan, finance, direct, manage, or supervise all or part of [illegible] or give or receive a bribe [illegible]

[illegible] review or at the hearing to [illegible] was clearly erroneous for the purposes of paragraph [illegible] The burden of [illegible] under paragraph [illegible] of this [illegible] to the defendant that the [illegible] or his own [illegible] or property not explained as derived [illegible] source of the [illegible] For purposes of paragraph [illegible] of [illegible] income means [illegible] source of [illegible] for the purpose [illegible] 25 [illegible] 25 [illegible] [illegible] wage determination [illegible] forty hour week and fifty [illegible] with reference to [illegible] under section [illegible] the Fair Labor Standards Act of 1938, for an employee engaged [illegible] production of goods for commerce, and who is for the [illegible] period exceeds fifty percent of the defendant's [illegible] adjusted gross income under section 62 of the Internal Revenue Code of 1954. For purposes of paragraph [illegible] of this subsection, special skill [illegible] including [illegible] knowledge, judgment or [illegible] including manual dexterity, in dictating the initiation, organization, planning, financing, direction, management, supervision, execution or concealment of such dealing, the employment of accomplices in such dealing, the escape by the defendant from apprehension for such dealing or the disposition of the funds or proceeds of such dealing. For purpose of paragraphs (2) and (3) of this subsection, such dealing forms a pattern if it embraces criminal acts that have the same or similar purposes, results, participants, victims, or methods of commission, or otherwise are interrelated by distinguishing characteristics and are not isolated events.

(c) A defendant is dangerous for purposes of this section if a period of confinement longer than that provided for such felonious violation is required for the protection of the public from further criminal conduct by the defendant.

(g) The time for taking an appeal from a conviction for which sentence is imposed after proceedings under this section shall be measured from imposition of the original sentence.

(h) With respect to the imposition, correction, or reduction of a sentence after proceedings under this section, a review of the sentence on the record of the sentencing court may be taken by the defendant or the United States to a court of appeals. Any review of the sentence taken by the United States shall be taken at least five days before expiration of the time for taking a review of the sentence or appeal of the conviction by the defendant and shall be diligently prosecuted. The sentencing court may, with or without motion and notice, extend the time for taking a review of the sentence for a period not to exceed thirty days from the expiration of the time otherwise prescribed by law. The court shall not extend the time for taking a review of the sentence by the United States after the time has expired. A court extending the time for taking a review of the sentence by the United States shall extend the time for taking a review of the sentence on appeal of the conviction by the defendant for the same period. The taking of a review of the sentence by the United States shall be deemed the taking of a review of the sentence and an appeal of the conviction by the defendant. Review of the sentence shall include review of whether the procedure employed was lawful, the findings were not clearly erroneous, or the sentencing court's discretion was not exceeded. The court of appeals on review of the sentence may, after considering the record, including the entire presentence report, information submitted during the trial of such felonious violation and the sentencing hearing, and the findings and reasons of the sentencing court, affirm the sentence, impose or direct the imposition of any sentence which the sentencing court could originally have imposed, or remand for further sentencing proceedings and imposition of sentence, except that a sentence may be made more severe only on review of the sentence taken by the United States and after hearing. Failure of the United States to take a review of the imposition of the sentence shall, upon review taken by the United States of the correction or reduction of the sentence, foreclose imposition of a sentence more severe than that previously imposed. Any withdrawal or dismissal of review of the sentence taken by the United States shall foreclose imposition of a sentence more severe than that reviewed but shall not otherwise foreclose the review of the sentence or the appeal of the conviction. The court of appeals shall state in writing the reasons for its disposition of the review of the sentence. Any review of the sentence taken by the United States may be dismissed on a showing of the abuse of the right of the United States to take such review.

INFORMATION FOR SENTENCING

SEC. [illegible] Except as otherwise provided in this title or section 3577 of the Public Health Service Act, no limitation shall be placed on the information concerning the background, character, and conduct of a person convicted of an offense which a court of the United States may receive and consider for the purpose of imposing an appropriate sentence under this title or title III.

PROCEEDINGS TO ESTABLISH PRIOR CONVICTIONS

SEC. 111. (a)(1) No person who stands convicted of an offense under this part shall be sentenced to increased punishment by reason of one or more prior convictions, unless before trial, or before entry of a plea of guilty, the United States attorney files an information with the court (and serves a copy of such information on the person or counsel for the person) stating in writing the previous convictions to be relied upon. Upon a showing by the United States attorney that facts regarding prior convictions could not with due diligence be obtained prior to trial or before entry of a plea of guilty, the court may postpone the trial or the taking of the plea of guilty for a reasonable period for the purpose of obtaining such facts. Clerical mistakes in the information may be amended at any time prior to the pronouncement of sentence.

(2) An information may not be filed under this section if the increased punishment which may be imposed is imprisonment for a term in excess of three years unless the person either waived or was afforded prosecution by indictment for the offense for which such increased punishment may be imposed.

(c) If the United States attorney files an information under this section, the court shall after conviction but before pronouncement of sentence inquire of the person with respect to whom the information was filed whether he affirms or denies that he has been previously convicted as alleged in the information, and shall inform him that any challenge to a prior conviction which is not made before sentence is imposed may not thereafter be raised to attack the sentence. Previous conviction, affirmation or denial.

(d) If the person denies any allegation of the information of prior conviction, or claims that any conviction alleged is invalid, he shall file a written response to the information. A copy of the response shall be served upon the United States attorney. The court shall hold a hearing to determine any issues raised by the response which would except the person from increased punishment. The failure of the United States attorney to include in the information the complete criminal record of the person or any facts in addition to the convictions to be relied upon shall not constitute grounds for invalidating the notice given in the information required by subsection (a)(1). The hearing shall be before the court without a jury and either party may introduce evidence. Except as otherwise provided in paragraph (2) of this subsection, the United States attorney shall have the burden of proof beyond a reasonable doubt on any issue of fact. At the request of either party, the court shall enter findings of fact and conclusions of law. Denial, written response. Hearing. Court without jury. Evidence, introduction.

(2) A person claiming that a conviction alleged in the information was obtained in violation of the Constitution of the United States shall set forth his claim, and the factual basis therefor, with particularity in his response to the information. The person shall have the burden of proof by a preponderance of the evidence on any issue of fact raised by the response. Any challenge to a prior conviction, not raised by response to the information before an increased sentence is imposed in reliance thereon, shall be waived unless good cause be shown for failure to make a timely challenge. Constitution of U.S., violation.

(e)(1) If the person files no response to the information, or if the court determines, after hearing, that the person is subject to increased punishment by reason of prior convictions, the court shall proceed to impose sentence upon him as provided by this part. Sentence, imposition.

(2) If the court determines that the person has not been convicted as alleged in the information, that a conviction alleged in the information is invalid, or that the person is otherwise not subject to an increased sentence as a matter of law, the court shall, at the request of the United States attorney, postpone sentence to allow an appeal from that determination. If no such request is made, the court shall impose sentence as provided by this part. The person may appeal from an order postponing sentence as if sentence had been pronounced and a final judgment of conviction entered.

(f) No person who stands convicted of an offense under this part may challenge the validity of any prior conviction alleged under this section which occurred more than five years before the date of the information alleging such prior conviction. Statute of limitations.

Part E—Administrative and Enforcement Provisions

PROCEDURES

Sec. 501. (a) The Attorney General may delegate any of his functions under this title to any officer or employee of the Department of Justice. Attorney General, functions, delegation.

Regulations.

(b) The Attorney General may promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this title.

Gifts, etc., acceptance.

(c) The Attorney General may accept in the name of the Department of Justice any form of devise, bequest, gift, or donation where the donor intends to donate property for the purpose of preventing or controlling the abuse of controlled substances. He may take all appropriate steps to secure possession of such property and may sell, assign, transfer, or convey any such property other than moneys.

EDUCATION AND RESEARCH PROGRAMS OF THE ATTORNEY GENERAL

Sec. 502. (a) The Attorney General is authorized to carry out educational and research programs directly related to enforcement of the laws under his jurisdiction concerning drugs or other substances which are or may be subject to control under this title. Such programs may include—

(1) educational and training programs on drug abuse and controlled substances law enforcement for local, State, and Federal personnel;

(2) studies or special projects designed to compare the deterrent effects of various enforcement strategies on drug use and abuse;

(3) studies or special projects designed to assess and detect accurately the presence in the human body of drugs or other substances which are or may be subject to control under this title, including the development of rapid field identification methods which would enable agents to detect microquantities of such drugs or other substances;

(4) studies or special projects designed to evaluate the nature and sources of the supply of illegal drugs throughout the country;

(5) studies or special projects to develop more effective methods to prevent diversion of controlled substances into illegal channels; and

(6) studies or special projects to develop information necessary to carry out his functions under section 201 of this title.

Ante, p. 1245.

(b) The Attorney General may enter into contracts for such educational and research activities without performance bonds and without regard to section 3709 of the Revised Statutes (41 U.S.C. 5).

Research populations, identification, prohibition.

(c) The Attorney General may authorize persons engaged in research to withhold the names and other identifying characteristics of persons who are the subjects of such research. Persons who obtain this authorization may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding to identify the subjects of research for which such authorization was obtained.

Controlled substances, exception.

(d) The Attorney General, on his own motion or at the request of the Secretary, may authorize the possession, distribution, and dispensing of controlled substances by persons engaged in research. Persons who obtain this authorization shall be exempt from State or Federal prosecution for possession, distribution, and dispensing of controlled substances to the extent authorized by the Attorney General.

COOPERATIVE ARRANGEMENTS

Sec. 503. (a) The Attorney General shall cooperate with local, State, and Federal agencies concerning traffic in controlled substances and in suppressing the abuse of controlled substances. To this end, he is authorized to—

(1) arrange for the exchange of information between governmental officials concerning the use and abuse of controlled substances;

(2) cooperate in the institution and prosecution of cases in the courts of the United States and before the licensing boards and courts of the several States;

(3) conduct training programs on controlled substance law enforcement for local, State, and Federal personnel;

(4) maintain in the Department of Justice a unit which will accept, catalog, file, and otherwise utilize all information and statistics, including records of controlled substance abusers and other controlled substance law offenders, which may be received from Federal, State, and local agencies, and make such information available for Federal, State, and local law enforcement purposes; and

(5) conduct programs of eradication aimed at destroying wild or illicit growth of plant species from which controlled substances may be extracted.

Assistance.

(b) When requested by the Attorney General, it shall be the duty of any agency or instrumentality of the Federal Government to furnish assistance, including technical advice, to him for carrying out his functions under this title; except that no such agency or instrumentality shall be required to furnish the name of, or other identifying information about, a patient or research subject whose identity it has undertaken to keep confidential.

Prohibition.

ADVISORY COMMITTEES

Appointment.

Compensation.

Travel expenses, etc.

SEC. 504. The Attorney General may from time to time appoint committees to advise him with respect to preventing and controlling the abuse of controlled substances. Members of the committees may be entitled to receive compensation at the rate of $100 for each day (including traveltime) during which they are engaged in the actual performance of duties. While traveling on official business in the performance of duties for the committees, members of the committees shall be allowed expenses of travel, including per diem instead of subsistence, in accordance with subchapter I of chapter 57 of title 5, United States Code.

80 Stat. 416; 83 Stat. 190. 5 USC 5701.

ADMINISTRATIVE HEARINGS

SEC. 505. (a) In carrying out his functions under this title, the Attorney General may hold hearings, sign and issue subpenas, administer oaths, examine witnesses, and receive evidence at any place in the United States.

(b) Except as otherwise provided in this title, notice shall be given and hearings shall be conducted under appropriate procedures of subchapter II of chapter 5, title 5, United States Code.

80 Stat. 381. 5 USC 551.

SUBPENAS

SEC. 506. (a) In any investigation relating to his functions under this title with respect to controlled substances, the Attorney General may subpena witnesses, compel the attendance and testimony of witnesses, and require the production of any records (including books, papers, documents, and other tangible things which constitute or contain evidence) which the Attorney General finds relevant or material to the investigation. The attendance of witnesses and the production of records may be required from any place in any State or in any territory

or other place subject to the jurisdiction of the United States at any designated place of hearing; except that a witness shall not be required to appear at any hearing more than 500 miles distant from the place where he was served with a subpena. Witnesses summoned under this section shall be paid the same fees and mileage that are paid witnesses in the courts of the United States.

Exception.

Fees.

Service.

(b) A subpena issued under this section may be served by any person designated in the subpena to serve it. Service upon a natural person may be made by personal delivery of the subpena to him. Service may be made upon a domestic or foreign corporation or upon a partnership or other unincorporated association which is subject to suit under a common name, by delivering the subpena to an officer, to a managing or general agent, or to any other agent authorized by appointment or by law to receive service of process. The affidavit of the person serving the subpena entered on a true copy thereof by the person serving it shall be proof of service.

Refusal to obey subpena.

Order.

Failure to obey order, penalty.

Jurisdiction.

(c) In the case of contumacy by or refusal to obey a subpena issued to any person, the Attorney General may invoke the aid of any court of the United States within the jurisdiction of which the investigation is carried on or of which the subpenaed person is an inhabitant, or in which he carries on business or may be found, to compel compliance with the subpena. The court may issue an order requiring the subpenaed person to appear before the Attorney General to produce records, if so ordered, or to give testimony touching the matter under investigation. Any failure to obey the order of the court may be punished by the court as a contempt thereof. All process in any such case may be served in any judicial district in which such person may be found.

JUDICIAL REVIEW

SEC. 507. All final determinations, findings, and conclusions of the Attorney General under this title shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the Attorney General may obtain review of the decision in the United States Court of Appeals for the District of Columbia or for the circuit in which his principal place of business is located upon petition filed with the court and delivered to the Attorney General within thirty days after notice of the decision. Findings of fact by the Attorney General, if supported by substantial evidence, shall be conclusive.

POWERS OF ENFORCEMENT PERSONNEL

SEC. 508. Any officer or employee of the Bureau of Narcotics and Dangerous Drug designated by the Attorney General may—

(1) carry firearms;

(2) execute and serve search warrants, arrest warrants, administrative inspection warrants, subpenas, and summonses issued under the authority of the United States;

(3) make arrests without warrant (A) for any offense against the United States committed in his presence, or (B) for any felony, cognizable under the laws of the United States, if he has probable cause to believe that the person to be arrested has committed or is committing a felony;

(4) make seizures of property pursuant to the provisions of this title; and

(5) perform such other law enforcement duties as the Attorney General may designate.

SEARCH WARRANTS

SEC. 509. (a) A search warrant relating to offenses involving controlled substances may be served at any time of the day or night if the judge or United States magistrate issuing the warrant is satisfied that there is probable cause to believe that grounds exist for the warrant and for its service at such time.

Authority to break and enter under certain conditions.

(b) Any officer authorized to execute a search warrant relating to offenses involving controlled substances the penalty for which is imprisonment for more than one year may, without notice of his authority and purpose, break open an outer or inner door or window of a building, or any part of the building, or anything therein, if the judge or United States magistrate issuing the warrant (1) is satisfied that there is probable cause to believe that (A) the property sought may and, if such notice is given, will be easily and quickly destroyed or disposed of, or (B) the giving of such notice will immediately endanger the life or safety of the executing officer or another person, and (2) has included in the warrant a direction that the officer executing it shall not be required to give such notice. Any officer acting under such warrant, shall, as soon as practicable after entering the premises, identify himself and give the reasons and authority for his entrance upon the premises.

ADMINISTRATIVE INSPECTIONS AND WARRANTS

SEC. 510. (a) As used in this section, the term "controlled premises" means—

"Controlled premises."

(1) places where original or other records or documents required under this title are kept or required to be kept, and

(2) places, including factories, warehouses, or other establishments, and conveyances, where persons registered under section 305 (or exempted from registration under section 502(d)) may lawfully hold, manufacture, or distribute, dispense, administer, or otherwise dispose of controlled substances.

(b)(1) For the purpose of inspecting, copying, and verifying the correctness of records, reports, or other documents required to be kept or made under this title and otherwise facilitating the carrying out of his functions under this title, the Attorney General is authorized, in accordance with this section, to enter controlled premises and to conduct administrative inspections thereof, and of the things specified in this section, relevant to those functions.

(2) Such entries and inspections shall be carried out through officers or employees (hereinafter referred to as "inspectors") designated by the Attorney General. Any such inspector, upon stating his purpose and presenting to the owner, operator, or agent in charge of such premises (A) appropriate credentials and (B) a written notice of his inspection authority (which notice in the case of an inspection requiring, or in fact supported by, an administrative inspection warrant shall consist of such warrant), shall have the right to enter such premises and conduct such inspection at reasonable times.

(3) Except as may otherwise be indicated in an applicable inspection warrant, the inspector shall have the right—

(A) to inspect and copy records, reports, and other documents required to be kept or made under this title;

(B) to inspect, within reasonable limits and in a reasonable manner, controlled premises and all pertinent equipment, finished and unfinished drugs and other substances or materials, containers, and labeling found therein, and, except as provided in paragraph (5) of this subsection, all other things therein (including records, files, papers, processes, controls, and facilities) appropriate for verification of the records, reports, and documents referred to in clause (A) or otherwise bearing on the provisions of this title; and

(C) to inventory any stock of any controlled substance therein and obtain samples of any such substance.

(4) Except when the owner, operator, or agent in charge of the controlled premises so consents in writing, no inspection authorized by this section shall extend to—

(A) financial data;

(B) sales data other than shipment data; or

(C) pricing data.

(c) A warrant under this section shall not be required for the inspection of books and records pursuant to an administrative subpena issued in accordance with section 506, nor for routine and administrative inspections (including seizures of property)—

(1) with the consent of the owner, operator, or agent in charge of the controlled premises;

(2) in situations presenting imminent danger to health or safety;

(3) in situations involving inspection of conveyances where there is reasonable cause to believe that the mobility of the conveyance makes it impracticable to obtain a warrant;

(4) in any other exceptional or emergency circumstance where time or opportunity to apply for a warrant is lacking; or

(5) in all other situations where a warrant is not constitutionally required.

(d) Issuance and execution of administrative inspection warrants shall be as follows:

(1) Any judge of the United States or of a State court of record, or any United States magistrate, may, within his territorial jurisdiction, and upon proper oath or affirmation showing probable cause, issue warrants for the purpose of conducting administrative inspections authorized by this title or regulations thereunder, and seizures of property appropriate to such inspections. For the purposes of this section, the term "probable cause" means a valid public interest in the effective enforcement of this title or regulations thereunder sufficient to justify administrative inspections of the area, premises, building, or conveyance, or contents thereof, in the circumstances specified in the application for the warrant.

"Probable cause."

(2) A warrant shall issue only upon an affidavit of an officer or employee having knowledge of the facts alleged, sworn to before the judge or magistrate and establishing the grounds for issuing the warrant. If the judge or magistrate is satisfied that grounds for the application exist or that there is probable cause to believe they exist, he shall issue a warrant identifying the area, premises, building, or conveyance to be inspected, the purpose of such inspection, and, where appropriate, the type of property to be inspected, if any. The warrant shall identify the items or types of property to be seized, if any. The warrant shall be directed to a person authorized under subsection (b)(2) to execute it. The warrant shall state the grounds for its issuance and the name of the person or persons whose affidavit has been taken in support thereof. It shall command the person to whom it is directed to inspect the area, premises, building, or conveyance identified for the purpose specified, and, where appropriate, shall direct the seizure of the property specified. The warrant shall direct that it be served during normal business hours. It shall designate the judge or magistrate to whom it shall be returned.

(3) A warrant issued pursuant to this section must be executed and returned within ten days of its date unless, upon a showing by the United States of a need therefor, the judge or magistrate allows additional time in the warrant. If property is seized pursuant to a warrant, the person executing the warrant shall give to the person from whom or from whose premises the property was taken a copy of the warrant and a receipt for the property taken or shall leave the copy and receipt at the place from which the property was taken. The return of the warrant shall be made promptly and shall be accompanied by a written inventory of any property taken. The inventory shall be made in the presence of the person executing the warrant and of the person from whose possession or premises the property was taken, if they are present, or in the presence of at least one credible person, other than the person making such inventory, and shall be verified by the person executing the warrant. The judge or magistrate, upon request, shall deliver a copy of the inventory to the person from whom or from whose premises the property was taken and to the applicant for the warrant.

Warrants, return.

(4) The judge or magistrate who has issued a warrant under this section shall attach to the warrant a copy of the return and all papers filed in connection therewith and shall file them with the clerk of the district court of the United States for the judicial district in which the inspection was made.

FORFEITURES

SEC. 511. (a) The following shall be subject to forfeiture to the United States and no property right shall exist in them:

(1) All controlled substances which have been manufactured, distributed, dispensed, or acquired in violation of this title.

(2) All raw materials, products, and equipment of any kind which are used, or intended for use, in manufacturing, compounding, processing, delivering, importing, or exporting any controlled substance in violation of this title.

(3) All property which is used, or intended for use, as a container for property described in paragraph (1) or (2).

(4) All conveyances, including aircraft, vehicles, or vessels, which are used, or are intended for use, to transport, or in any manner to facilitate the transportation, sale, receipt, possession, or concealment of property described in paragraph (1) or (2), except that—

(A) no conveyance used by any person as a common carrier in the transaction of business as a common carrier shall be forfeited under the provisions of this section unless it shall appear that the owner or other person in charge of such conveyance was a consenting party or privy to a violation of this title or title III; and

(B) no conveyance shall be forfeited under the provisions of this section by reason of any act or omission established by the owner thereof to have been committed or omitted by any person other than such owner while such conveyance was unlawfully in the possession of a person other than the owner in violation of the criminal laws of the United States, or of any State.

(5) All books, records, and research, including formulas, microfilm, tapes, and data which are used, or intended for use, in violation of this title.

(b) Any property subject to forfeiture to the United States under this title may be seized by the Attorney General upon process issued pursuant to the Supplemental Rules for Certain Admiralty and Maritime Claims by any district court of the United States having jurisdiction over the property, except that seizure without such process may be made when—

(1) the seizure is incident to an arrest or a search under a search warrant or an inspection under an administrative inspection warrant;

(2) the property subject to seizure has been the subject of a prior judgment in favor of the United States in a criminal injunction or forfeiture proceeding under this title;

(3) the Attorney General has probable cause to believe that the property is directly or indirectly dangerous to health or safety; or

(4) the Attorney General has probable cause to believe that the property has been used or is intended to be used in violation of this title.

In the event of seizure pursuant to paragraph (3) or (4) of this subsection, proceedings under subsection (d) of this section shall be instituted promptly.

Property, custody of Attorney General.

(c) Property taken or detained under this section shall not be repleviable, but shall be deemed to be in the custody of the Attorney General, subject only to the orders and decrees of the court or the official having jurisdiction thereof. Whenever property is seized under the provisions of this title, the Attorney General may—

(1) place the property under seal;

(2) remove the property to a place designated by him; or

(3) require that the General Services Administration take custody of the property and remove it to an appropriate location for disposition in accordance with law.

(d) All provisions of law relating to the seizure, summary and judicial forfeiture, and condemnation of property for violation of the customs laws; the disposition of such property or the proceeds from the sale thereof; the remission or mitigation of such forfeitures; and the compromise of claims and the award of compensation to informers in respect of such forfeitures shall apply to seizures and forfeitures incurred, or alleged to have been incurred, under the provisions of this title, insofar as applicable and not inconsistent with the provisions hereof; except that such duties as are imposed upon the customs officer or any other person with respect to the seizure and forfeiture of property under the customs laws shall be performed with respect to seizures and forfeitures of property under this title by such officers, agents, or other persons as may be authorized or designated for that purpose by the Attorney General, except to the extent that such duties arise from seizures and forfeitures effected by any customs officer.

(e) Whenever property is forfeited under this title the Attorney General may—

(1) retain the property for official use;

(2) sell any forfeited property which is not required to be destroyed by law and which is not harmful to the public, but the proceeds from any such sale shall be used to pay all proper expenses of the proceedings for forfeiture and sale including expenses of seizure, maintenance of custody, advertising and court costs;

(3) require that the General Services Administration take custody of the property and remove it for disposition in accordance with law; or

(4) forward it to the Bureau of Narcotics and Dangerous Drugs for disposition (including delivery for medical or scientific use to any Federal or State agency under regulations of the Attorney General).

Controlled substances, forfeiture.

(f) All controlled substances in schedule I that are possessed, transferred, sold, or offered for sale in violation of the provisions of this title shall be deemed contraband and seized and summarily forfeited to the United States. Similarly, all substances in schedule I, which are seized or come into the possession of the United States, the owners of which are unknown, shall be deemed contraband and summarily forfeited to the United States.

(g)(1) All species of plants from which controlled substances in schedules I and II may be derived which have been planted or cultivated in violation of this title, or of which the owners or cultivators are unknown, or which are wild growths, may be seized and summarily forfeited to the United States.

(2) The failure, upon demand by the Attorney General or his duly authorized agent, of the person in occupancy or in control of land or premises upon which such species of plants are growing or being stored, to produce an appropriate registration, or proof that he is the holder thereof, shall constitute authority for the seizure and forfeiture.

(3) The Attorney General, or his duly authorized agent, shall have authority to enter upon any lands, or into any dwelling pursuant to a search warrant, to cut, harvest, carry off, or destroy such plants.

INJUNCTIONS

Jurisdiction of courts.

SEC. 512. (a) The district courts of the United States and all courts exercising general jurisdiction in the territories and possessions of the United States shall have jurisdiction in proceedings in accordance with the Federal Rules of Civil Procedure to enjoin violations of this title.

(b) In case of an alleged violation of an injunction or restraining order issued under this section, trial shall, upon demand of the accused, be by a jury in accordance with the Federal Rules of Civil Procedure.

ENFORCEMENT PROCEEDINGS

Notice.

SEC. 513. Before any violation of this title is reported by the Director of the Bureau of Narcotics and Dangerous Drugs to any United States attorney for institution of a criminal proceeding, the Director may require that the person against whom such proceeding is contemplated be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.

IMMUNITY AND PRIVILEGE

Refusal to testify, prohibition.

SEC. 514. (a) Whenever a witness refuses, on the basis of his privilege against self-incrimination, to testify or provide other information in a proceeding before a court or grand jury of the United States, involving a violation of this title, and the person presiding over the proceeding communicates to the witness an order issued under this section, the witness may not refuse to comply with the order on the basis of his privilege against self-incrimination. But no testimony or other information compelled under the order issued under subsection (b) of this section or any information obtained by the exploitation of such testimony or other information, may be used against the witness in any criminal case, including any criminal case brought in a court of a State, except a prosecution for perjury, giving a false statement, or otherwise failing to comply with the order.

Order.

(b) In the case of any individual who has been or may be called to testify or provide other information at any proceeding before a court or grand jury of the United States, the United States district court for the judicial district in which the proceeding is or may be held shall issue, upon the request of the United States attorney for such district, an order requiring such individual to give any testimony or provide any other information which he refuses to give or provide on the basis of his privilege against self-incrimination.

(c) A United States attorney may, with the approval of the Attorney General or the Deputy Attorney General, or any Assistant Attorney General designated by the Attorney General, request an order under subsection (b) when in his judgment—

(1) the testimony or other information from such individual may be necessary to the public interest; and

(2) such individual has refused or is likely to refuse to testify or provide other information on the basis of his privilege against self-incrimination.

BURDEN OF PROOF; LIABILITIES

Ante, p. 1234.

SEC. 515. (a)(1) It shall not be necessary for the United States to negative any exemption or exception set forth in this title in any complaint, information, indictment, or other pleading or in any trial, hearing, or other proceeding under this title, and the burden of going forward with the evidence with respect to any such exemption or exception shall be upon the person claiming its benefit.

75 Stat. 648. 21 USC 353.

(2) In the case of a person charged under section 404(a) with the possession of a controlled substance, any label identifying such substance for purposes of section 503(b)(2) of the Federal Food, Drug, and Cosmetic Act shall be admissible in evidence and shall be prima facie evidence that such substance was obtained pursuant to a valid prescription from a practitioner while acting in the course of his professional practice.

(b) In the absence of proof that a person is the duly authorized holder of an appropriate registration or order form issued under this title, he shall be presumed not to be the holder of such registration or form, and the burden of going forward with the evidence with respect to such registration or form shall be upon him.

(c) The burden of going forward with the evidence to establish that a vehicle, vessel, or aircraft used in connection with controlled substances in schedule I was used in accordance with the provisions of this title shall be on the persons engaged in such use.

Criminal liability, prohibition, exception. 62 Stat. 803.

(d) Except as provided in sections 2234 and 2235 of title 18, United States Code, no civil or criminal liability shall be imposed by virtue of this title upon any duly authorized Federal officer lawfully engaged in the enforcement of this title, or upon any duly authorized officer of any State, territory, political subdivision thereof, the District of Columbia, or any possession of the United States, who shall be lawfully engaged in the enforcement of any law or municipal ordinance relating to controlled substances.

PAYMENTS AND ADVANCES

Informers, payment.

SEC. 516. (a) The Attorney General is authorized to pay any person, from funds appropriated for the Bureau of Narcotics and Dangerous Drugs, for information concerning a violation of this title, such sum or sums of money as he may deem appropriate, without reference to any moieties or rewards to which such person may otherwise be entitled by law.

(b) Moneys expended from appropriations of the Bureau of Narcotics and Dangerous Drugs for purchase of controlled substances and subsequently recovered shall be reimbursed to the current appropriation for the Bureau.

(c) The Attorney General is authorized to direct the advance of funds by the Treasury Department in connection with the enforcement of this title.

PART F—ADVISORY COMMISSION

ESTABLISHMENT OF COMMISSION ON MARIHUANA AND DRUG ABUSE

SEC. 601. (a) There is established a commission to be known as the Commission on Marihuana and Drug Abuse (hereafter in this section referred to as the "Commission"). The Commission shall be composed of:

(1) two Members of the Senate appointed by the President of the Senate;

(2) two Members of the House of Representatives appointed by the Speaker of the House of Representatives; and

(3) nine members appointed by the President of the United States.

At no time shall more than one of the members appointed under paragraph (1), or more than one of the members appointed under paragraph (2), or more than five of the members appointed under paragraph (3) be members of the same political party.

(b)(1) The President shall designate one of the members of the Commission as Chairman, and one as Vice Chairman. Seven members of the Commission shall constitute a quorum, but a lesser number may conduct hearings.

(2) Members of the Commission who are Members of Congress or full time officers or employees of the United States shall serve without additional compensation but shall be reimbursed for travel, subsistence, and other necessary expenses incurred in the performance of the duties vested in the Commission. Members of the Commission from private life shall receive $100 per diem while engaged in the actual performance of the duties vested in the Commission, plus reimbursement for travel, subsistence, and other necessary expenses incurred in the performance of such duties.

(3) The Commission shall meet at the call of the Chairman or at the call of a majority of the members thereof.

(c)(1) The Commission shall have the power to appoint and fix the compensation of such personnel as it deems advisable, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and the provisions of chapter 51 and subchapter III of chapter 53 of such title, relating to classification and General Schedule pay rates.

(2) The Commission may procure, in accordance with the provisions of section 3109 of title 5, United States Code, the temporary or intermittent services of experts or consultants. Persons so employed shall receive compensation at a rate to be fixed by the Commission, but not in excess of $75 per diem, including traveltime. While away from his home or regular place of business in the performance of services for the Commission, any such person may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703(b) of title 5, United States Code, for persons in the Government service employed intermittently.

(3) The Commission may secure directly from any department or agency of the United States information necessary to enable it to

carry out its duties under this section. Upon request of the Chairman of the Commission, such department or agency shall furnish such information to the Commission.

Marihuana, study.

(d)(1) The Commission shall conduct a study of marihuana including, but not limited to, the following areas:

(A) the extent of use of marihuana in the United States to include its various sources, the number of users, number of arrests, number of convictions, amount of marihuana seized, type of user, nature of use;

(B) an evaluation of the efficacy of existing marihuana laws;

(C) a study of the pharmacology of marihuana and its immediate and long term effects, both physiological and psychological;

(D) the relationship of marihuana use to aggressive behavior and crime;

(E) the relationship between marihuana and the use of other drugs; and

(F) the international control of marihuana.

Report to President and Congress.

(2) Within one year after the date on which funds first become available to carry out this section, the Commission shall submit to the President and the Congress a comprehensive report on its study and investigation under this subsection which shall include its recommendations and such proposals for legislation and administrative action as may be necessary to carry out its recommendations.

Drug abuse, study and investigation. Interim reports. Final report to President and Congress. Termination. Expenditures, limitation.

(e) The Commission shall conduct a comprehensive study and investigation of the causes of drug abuse and their relative significance. The Commission shall submit to the President and the Congress such interim reports as it deems advisable and shall within two years after the date on which funds first become available to carry out this section submit to the President and the Congress a final report which shall contain a detailed statement of its findings and conclusions and also such recommendations for legislation and administrative actions as it deems appropriate. The Commission shall cease to exist sixty days after the final report is submitted under this subsection.

(f) Total expenditures of the Commission shall not exceed $1,000,000.

PART G—CONFORMING, TRANSITIONAL AND EFFECTIVE DATE, AND GENERAL PROVISIONS

REPEALS AND CONFORMING AMENDMENTS

Repeals. 70 Stat. 227, 234, 228; 82 Stat. 1361. Penalties. 82 Stat. 1361.

SEC. 701. (a) Sections 201(v), 301(q), and 511 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(v), 331(q), 360(a) are repealed.

(b) Subsections (a) and (b) of section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) are amended to read as follows:

"SEC. 303. (a) Any person who violates a provision of section 301 shall be imprisoned for not more than one year or fined not more than $1,000, or both.

"(b) Notwithstanding the provisions of subsection (a) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000 or both."

70 Stat. 233.

(c) Section 304(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334(a)(2)) is amended (1) by striking out clauses (A) and (D), (2) by striking out "of such depressant or stimulant

drug or" in clause (C), (3) by adding "and" after the comma at the end of clause (C), and (4) by redesignating clauses (B), (C), and (E) as clauses (A), (B), and (C), respectively.

(d) Section 304(d)(3)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334(d)(3)(iii)) is amended by striking out "depressant or stimulant drugs or". 79 Stat. 233.

(e) Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) is amended (1) in subsection (a) by striking out paragraph (2), by inserting "and" at the end of paragraph (1), and by redesignating paragraph (3) as paragraph (2); (2) by striking out "or in the wholesaling, jobbing, or distributing of any depressant or stimulant drug" in the first sentence of subsection (b); (3) by striking out the last sentence of subsection (b); (4) by striking out "or in the wholesaling, jobbing, or distributing of any depressant or stimulant drug" in the first sentence of subsection (c); (5) by striking out the last sentence of subsection (c); (6) by striking out "(1)" in subsection (d) and by inserting a period after "drug or drugs" in that subsection and deleting the remainder of that subsection; and (7) by striking out "AND CERTAIN WHOLESALERS" in the section heading. 76 Stat. 794; 79 Stat. 231.

(f) Section 702 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 372) is amended by striking out "to depressant or stimulant drugs or" in subsection (e). 79 Stat. 234.

(g) Section 201(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(a)(2)) is amended by inserting a period after "Canal Zone" the first time these words appear and deleting all thereafter in such section 201(a)(2). 76 Stat. 706; 82 Stat. 1362.

(h) The last sentence of section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is amended (1) by striking out "This paragraph" and inserting in lieu thereof "Clause (2) of the third sentence of this paragraph.", and (2) by striking out "section 2 of the Act of May 26, 1922, as amended (U.S.C. 1934, edition, title 21, sec. 173)" and inserting in lieu thereof "the Controlled Substances Import and Export Act". 52 Stat. 1055.

(i)(1) Section 1114 of title 18, United States Code, is amended by striking out "the Bureau of Narcotics" and inserting in lieu thereof "the Bureau of Narcotics and Dangerous Drugs". 65 Stat. 721.

(2) Section 1952 of such title is amended—

(A) by inserting in subsection (b)(1) "or controlled substances (as defined in section 102(6) of the Controlled Substances Act)" immediately following "narcotics"; and 75 Stat. 498. 18 USC 1952.

(B) by striking out "or narcotics" in subsection (c).

(j) Subsection (a) of section 302 of the Public Health Service Act (42 U.S.C. 242(a)) is amended to read as follows: Drugs, study. 58 Stat. 692.

"SEC. 302. (a) In carrying out the purposes of section 301 with respect to drugs the use or misuse of which might result in drug abuse or dependency, the studies and investigations authorized therein shall include the use and misuse of narcotic drugs and other drugs. Such studies and investigations shall further include the quantities of crude opium, coca leaves, and their salts, derivatives, and preparations, and other drugs subject to control under the Controlled Substances Act and Controlled Substances Import and Export Act, together with reserves thereof, necessary to supply the normal and emergency medicinal and scientific requirements of the United States. The results of studies and investigations of the quantities of narcotic drugs or other drugs subject to control under such Acts, together with reserves of such drugs, that are necessary to supply the normal and emergency medicinal and scientific requirements of the United States, shall be Ante, p. 1247. Post, p. 1299. Report to Attorney General.

reported not later than the first day of April of each year to the Attorney General, to be used at his discretion in determining manufacturing quotas or importation requirements under such Acts."

PENDING PROCEEDINGS

SEC. 702. (a) Prosecutions for any violation of law occurring prior to the effective date of section 701 shall not be affected by the repeals or amendments made by such section, or abated by reason thereof.

(b) Civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of section 701 shall not be affected by the repeals or amendments made by such section or abated by reason thereof.

(c) All administrative proceedings pending before the Bureau of Narcotics and Dangerous Drugs on the date of enactment of this Act shall be continued and brought to final determination in accord with laws and regulations in effect prior to such date of enactment. Where a drug is finally determined under such proceedings to be a depressant or stimulant drug, as defined in section 201(v) of the Federal Food, Drug, and Cosmetic Act, such drug shall automatically be controlled under this title by the Attorney General without further proceedings and listed in the appropriate schedule after he has obtained the recommendation of the Secretary. Any drug with respect to which such a final determination has been made prior to the date of enactment of this Act which is not listed in section 202 within schedules I through V shall automatically be controlled under this title by the Attorney General without further proceedings, and be listed in the appropriate schedule, after he has obtained the recommendations of the Secretary. Ante, p. 1231.

PROVISIONAL REGISTRATION

SEC. 703. (a) (1) Any person who

(A) is engaged in manufacturing, distributing, or dispensing any controlled substance on the day before the effective date of section 302, and

(B) is registered on such day under section 510 of the Federal Food, Drug, and Cosmetic Act or under section 4722 of the Internal Revenue Code of 1954,

shall, with respect to each establishment for which such registration is in effect under any such section, be deemed to have a provisional registration under section 302 for the manufacture, distribution, or dispensing (as the case may be) of controlled substances. Ante, p. 1231. 68A Stat. 550.

(2) During the period his provisional registration is in effect under this section, the registration number assigned such person under such section 510 or under such section 4722 (as the case may be) shall be his registration number for purposes of section 303 of this title.

(b) The provisions of section 304, relating to suspension and revocation of registration, shall apply to a provisional registration under this section.

(c) Unless sooner suspended or revoked under subsection (b), a provisional registration of a person under subsection (a)(1) of this section shall be in effect until—

(1) the date on which such person has registered with the Attorney General under section 303 or has had his registration denied under such section, or

(2) such date as may be prescribed by the Attorney General for registration of manufacturers, distributors, or dispensers, as the case may be,

whichever occurs first.

EFFECTIVE DATES AND OTHER TRANSITIONAL PROVISIONS

SEC. 704. (a) Except as otherwise provided in this section, this title shall become effective on the first day of the seventh calendar month that begins after the day immediately preceding the date of enactment.

(b) Parts A, B, E, and F of this title, section 702, this section, and sections 705 through 709, shall become effective upon enactment.

(c) Sections 305 (relating to labels and labeling), and 306 (relating to manufacturing quotas) shall become effective on the date specified in subsection (a) of this section, except that the Attorney General may by order published in the Federal Register postpone the effective date of either or both of these sections for such period as he may determine to be necessary for the efficient administration of this title.

Ante, p. 1256.

Publication in Federal Register.

CONTINUATION OF REGULATIONS

SEC. 705. Any orders, rules, and regulations which have been promulgated under any law affected by this title and which are in effect on the day preceding enactment of this title shall continue in effect until modified, superseded, or repealed.

SEVERABILITY

SEC. 706. If a provision of this Act is held invalid, all valid provisions that are severable shall remain in effect. If a provision of this Act is held invalid in one or more of its applications, the provision shall remain in effect in all its valid applications that are severable.

SAVING PROVISION

SEC. 707. Nothing in this Act, except this part and, to the extent of any inconsistency, sections 307(e) and 309 of this title, shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the Federal Food, Drug, and Cosmetic Act.

52 Stat. 1040; 21 USC 301.

APPLICATION OF STATE LAW

SEC. 708. No provision of this title shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this title and that State law so that the two cannot consistently stand together.

APPROPRIATIONS AUTHORIZATIONS

SEC. 709. There are authorized to be appropriated for expenses of the Department of Justice in carrying out its functions under this title (except section 103) not to exceed $60,000,000 for the fiscal year ending June 30, 1972, $70,000,000 for the fiscal year ending June 30, 1973, and $90,000,000 for the fiscal year ending June 30, 1974.

Ante, p. 1245.

TITLE III—IMPORTATION AND EXPORTATION; AMENDMENTS AND REPEALS OF REVENUE LAWS

SHORT TITLE

SEC. 1000. This title may be cited as the "Controlled Substances Import and Export Act".

Citation of title.

PART A—IMPORTATION AND EXPORTATION

DEFINITIONS

SEC. 1001. (a) For purposes of this part—

(1) The term "import" means, with respect to any article, any bringing in or introduction of such article into any area (whether or not such bringing in or introduction constitutes an importation within the meaning of the tariff laws of the United States).

(2) The term "customs territory of the United States" has the meaning assigned to such term by general headnote 2 to the Tariff Schedules of the United States (19 U.S.C. 1202).

77A Stat. 11.

(b) Each term defined in section 102 of title II shall have the same meaning for purposes of this title as such term has for purposes of title II.

Ante, p. 1242.

IMPORTATION OF CONTROLLED SUBSTANCES

Unlawful acts.

SEC. 1002. (a) It shall be unlawful to import into the customs territory of the United States from any place outside thereof (but within the United States), or to import into the United States from any place outside thereof, any controlled substance in schedule I or II of title II, or any narcotic drug in schedule III, IV, or V of title II, except that—

Exceptions.

(1) such amounts of crude opium and coca leaves as the Attorney General finds to be necessary to provide for medical, scientific, or other legitimate purposes, and

(2) such amounts of any controlled substance in schedule I or II or any narcotic drug in schedule III, IV, or V that the Attorney General finds to be necessary to provide for the medical, scientific, or other legitimate needs of the United States—

(A) during an emergency in which domestic supplies of such substance or drug are found by the Attorney General to be inadequate, or

(B) in any case in which the Attorney General finds that competition among domestic manufacturers of the controlled substance is inadequate and will not be rendered adequate by the registration of additional manufacturers under section 303,

Ante, p. 1253.

may be so imported under such regulations as the Attorney General shall prescribe. No crude opium may be so imported for the purpose of manufacturing heroin or smoking opium.

(b) It shall be unlawful to import into the customs territory of the United States from any place outside thereof (but within the United States), or to import into the United States from any place outside thereof, any nonnarcotic controlled substance in schedule III, IV, or V, unless such nonnarcotic controlled substance—

(1) is imported for medical, scientific, or other legitimate uses, and

(2) is imported pursuant to such notification or declaration requirements as the Attorney General may by regulation prescribe.

(c) In addition to the amount of coca leaves authorized to be imported into the United States under subsection (a), the Attorney General may permit the importation of additional amounts of coca leaves. All cocaine and ecgonine (and all salts, derivatives, and preparations from which cocaine or ecgonine may be synthesized or made) contained in such additional amounts of coca leaves imported under this subsection shall be destroyed under the supervision of an authorized representative of the Attorney General.

EXPORTATION OF CONTROLLED SUBSTANCES

SEC. 1003. (a) It shall be unlawful to export from the United States any narcotic drug in schedule I, II, III, or IV unless— Unlawful acts.

(1) it is exported to a country which is a party to—

(A) the International Opium Convention of 1912 for the Suppression of the Abuses of Opium, Morphine, Cocaine, and Derivative Drugs, or to the International Opium Convention signed at Geneva on February 19, 1925; or 38 Stat. 1912, 61 Stat. 2230.

(B) the Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs concluded at Geneva, July 13, 1931, as amended by the protocol signed at Lake Success on December 11, 1946, and the protocol bringing under international control drugs outside the scope of the convention of July 13, 1931, for limiting the manufacture and regulating the distribution of narcotic drugs (as amended by the protocol signed at Lake Success on December 11, 1946), signed at Paris, November 19, 1948; or 48 Stat. 1543, 62 Stat. 1796, 2 UST 1629.

(C) the Single Convention on Narcotic Drugs, 1961, signed at New York, March 30, 1961; 18 UST 1407.

(2) such country has instituted and maintains, in conformity with the conventions to which it is a party, a system for the control of imports of narcotic drugs which the Attorney General deems adequate;

(3) the narcotic drug is consigned to a holder of such permits or licenses as may be required under the laws of the country of import, and a permit or license to import such drug has been issued by the country of import;

(4) substantial evidence is furnished to the Attorney General by the exporter that (A) the narcotic drug is to be applied exclusively to medical or scientific uses within the country of import, and (B) there is an actual need for the narcotic drug for medical or scientific uses within such country; and

(5) a permit to export the narcotic drug in each instance has been issued by the Attorney General.

(b) Notwithstanding subsection (a), the Attorney General may authorize any narcotic drug (including crude opium and coca leaves) in schedule I, II, III, or IV to be exported from the United States to a country which is a party to any of the international instruments mentioned in subsection (a) if the particular drug is to be applied to a special scientific purpose in the country of destination and the authorities of such country will permit the importation of the particular drug for such purpose. Ante, p. 1248.

(c) It shall be unlawful to export from the United States any nonnarcotic controlled substance in schedule I or II unless—

(1) it is exported to a country which has instituted and maintains a system which the Attorney General deems adequate for the control of imports of such substances;

(2) the controlled substance is consigned to a holder of such permits or licenses as may be required under the laws of the country of import;

(3) substantial evidence is furnished to the Attorney General that (A) the controlled substance is to be applied exclusively to medical, scientific, or other legitimate uses within the country to which exported, (B) it will not be exported from such country, and (C) there is an actual need for the controlled substance for medical, scientific, or other legitimate uses within the country; and

(4) a permit to export the controlled substance in each instance has been issued by the Attorney General.

(d) Notwithstanding subsection (c), the Attorney General may authorize any nonnarcotic controlled substance in schedule I or II to be exported from the United States if the particular substance is to be applied to a special scientific purpose in the country of destination and the authorities of such country will permit the importation of the particular drug for such purpose. Ante, p. 1248.

(e) It shall be unlawful to export from the United States to any other country any nonnarcotic controlled substance in schedule III or IV or any controlled substance in schedule V unless—

(1) there is furnished (before export) to the Attorney General documentary proof that importation is not contrary to the laws or regulations of the country of destination;

(2) a special controlled substance invoice, in triplicate, accompanies the shipment setting forth such information as the Attorney General may prescribe to identify the parties to the shipment and the means of shipping, and

(3) two additional copies of the invoice are forwarded to the Attorney General before the controlled substance is exported from the United States.

TRANSSHIPMENT AND IN-TRANSIT SHIPMENT OF CONTROLLED SUBSTANCES

SEC. 1004. Notwithstanding sections 1002, 1003, and 1007—

(1) A controlled substance in schedule I may—

(A) be imported into the United States for transshipment to another country, or

(B) be transferred or transshipped from one vessel, vehicle, or aircraft to another vessel, vehicle, or aircraft within the United States for immediate exportation,

if and only if it is so imported, transferred, or transshipped (i) for scientific, medical, or other legitimate purposes in the country of destination, and (ii) with the prior written approval of the Attorney General (which shall be granted or denied within 21 days of the request).

(2) A controlled substance in schedule II, III, or IV may be so imported, transferred, or transshipped if and only if advance notice is given to the Attorney General in accordance with regulations of the Attorney General.

POSSESSION ON BOARD VESSELS, ETC., ARRIVING IN OR DEPARTING FROM UNITED STATES

SEC. 1005. It shall be unlawful for any person to bring or possess on board any vessel or aircraft, or on board any vehicle of a carrier,

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arriving in or departing from the United States or the customs territory of the United States, a controlled substance in schedule I or II or a narcotic drug in schedule III or IV, unless such substance or drug is a part of the cargo entered in the manifest or part of the official supplies of the vessel, aircraft, or vehicle.

Ante, p. 1288.

EXEMPTION AUTHORITY

SEC. 1006. (a) The Attorney General may by regulation exempt from sections 1002 (a) and (b), 1003, 1004, and 1005 any individual who has a controlled substance (except a substance in schedule I) in his possession for his personal medical use, or for administration to an animal accompanying him, if he lawfully obtained such substance and he makes such declaration (or gives such other notification) as the Attorney General may by regulation require.

(b) The Attorney General may by regulation except any compound, mixture, or preparation containing any depressant or stimulant substance listed in paragraph (a) or (b) of schedule III or in schedule IV or V from the application of all or any part of this title if (1) the compound, mixture, or preparation contains one or more active medicinal ingredients not having a depressant or stimulant effect on the central nervous system, and (2) such ingredients are included therein in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse of the substances which do have a depressant or stimulant effect on the central nervous system.

PERSONS REQUIRED TO REGISTER

SEC. 1007. (a) No person may—

(1) import into the customs territory of the United States from any place outside thereof (but within the United States), or import into the United States from any place outside thereof, any controlled substance, or

(2) export from the United States any controlled substance in schedule I, II, III, or IV,

unless there is in effect with respect to such person a registration issued by the Attorney General under section 1008, or unless such person is exempt from registration under subsection (b).

(b)(1) The following persons shall not be required to register under the provisions of this section and may lawfully possess a controlled substance:

(A) An agent or an employee of any importer or exporter registered under section 1008 if such agent or employee is acting in the usual course of his business or employment.

(B) A common or contract carrier or warehouseman, or an employee thereof, whose possession of any controlled substance is in the usual course of his business or employment.

(C) An ultimate user who possesses such substance for a purpose specified in section 102(25) and in conformity with an exemption granted under section 1006(a).

Ante, p. 1288.

(2) The Attorney General may, by regulation, waive the requirement for registration of certain importers and exporters if he finds it consistent with the public health and safety; and may authorize any such importer or exporter to possess controlled substances for purposes of importation and exportation.

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REGISTRATION REQUIREMENTS

SEC. 1008. (a) The Attorney General shall register an applicant to import or export a controlled substance in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on the effective date of this section. In determining the public interest, the factors enumerated in paragraph (1) through (6) of section 303(a) shall be considered.

Ante, p. 1283.

(b) Registration granted under subsection (a) of this section shall not entitle a registrant to import or export controlled substances in schedule I or II other than those specified in the registration.

(c) The Attorney General shall register an applicant to import a controlled substance in schedule III, IV, or V or to export a controlled substance in schedule III or IV, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the factors enumerated in paragraphs (1) through (6) of section 303(d) shall be considered.

(d) No registration shall be issued under this part for a period in excess of one year. Unless the regulations of the Attorney General otherwise provide, section 302(f), 304, 305, and 307 shall apply to persons registered under this section to the same extent such sections apply to persons registered under section 303.

Ante, pp. 1282-1284.

Rules and regulations.

(e) The Attorney General is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration of importers and exporters of controlled substances under this section.

(f) Persons registered by the Attorney General under this section to import or export controlled substances may import or export (and, for the purpose of so importing or exporting, may possess) such substances to the extent authorized by their registration and in conformity with the other provisions of this title and title II.

(g) A separate registration shall be required at each principal place of business where the applicant imports or exports controlled substances.

(h) Except in emergency situations as described in section 1002(a)(2)(A), prior to issuing a registration under this section to a bulk manufacturer of a controlled substance in schedule I or II, and prior to issuing a regulation under section 1002(a) authorizing the importation of such a substance, the Attorney General shall give manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

MANUFACTURE OR DISTRIBUTION FOR PURPOSES OF UNLAWFUL IMPORTATION

SEC. 1009. It shall be unlawful for any person to manufacture or distribute a controlled substance in schedule I or II—

(1) intending that such substance be unlawfully imported into the United States; or

(2) knowing that such substance will be unlawfully imported into the United States.

This section is intended to reach acts of manufacture or distribution committed outside the territorial jurisdiction of the United States. Any person who violates this section shall be tried in the United States district court at the point of entry where such person enters the United States, or in the United States District Court for the District of Columbia.

PROHIBITED ACTS A—PENALTIES

SEC. 1010. (a) Any person who—

(1) contrary to section 1002, 1003, or 1007, knowingly or intentionally imports or exports a controlled substance,

(2) contrary to section 1005, knowingly or intentionally brings or possesses on board a vessel, aircraft, or vehicle a controlled substance, or

(3) contrary to section 1009, manufactures or distributes a controlled substance,

shall be punished as provided in subsection (b).

(b)(1) In the case of a violation under subsection (a) with respect to a narcotic drug in schedule I or II, the person committing such violation shall be imprisoned not more than fifteen years, or fined not more than $25,000, or both. If a sentence under this paragraph provides for imprisonment, the sentence shall include a special parole term of not less than three years in addition to such term of imprisonment. Ante, p. 1249.

(2) In the case of a violation under subsection (a) with respect to a controlled substance other than a narcotic drug in schedule I or II, the person committing such violation shall be imprisoned not more than five years, or be fined not more than $15,000, or both. If a sentence under this paragraph provides for imprisonment, the sentence shall, in in addition to such term of imprisonment, include (A) a special parole term of not less than two years if such controlled substance is in schedule I, II, III, or (B) a special parole term of not less than one year if such controlled substance is in schedule IV.

(c) A special parole term imposed under this section or section 1012 may be revoked if its terms and conditions are violated. In such circumstances the original term of imprisonment shall be increased by the period of the special parole term and the resulting new term of imprisonment shall not be diminished by the time which was spent on special parole. A person whose special parole term has been revoked may be required to serve all or part of the remainder of the new term of imprisonment. The special term provided for in this section and in section 1012 is in addition to, and not in lieu of, any other parole provided for by law.

PROHIBITED ACTS B—PENALTIES

SEC. 1011. Any person who violates section 1004 shall be subject to the following penalties:

(1) Except as provided in paragraph (2), any such person shall, with respect to any such violation, be subject to a civil penalty of not more than $25,000. Sections 402 (c)(1) and (c)(3) shall apply to any civil penalty assessed under this paragraph. Ante, p. 1262.

(2) If such a violation is prosecuted by an information or indictment which alleges that the violation was committed knowingly or intentionally and the trier of fact specifically finds that the violation was so committed, such person shall be sentenced to imprisonment for not more than one year or a fine of not more than $25,000 or both.

SECOND OR SUBSEQUENT OFFENSES

SEC. 1012. (a) Any person convicted of any offense under this part is, if the offense is a second or subsequent offense, punishable by a term of imprisonment twice that otherwise authorized, by twice the fine otherwise authorized, or by both. If the conviction is for an offense

punishable under section 1010(b), and if it is the offender's second or subsequent offense, the court shall impose, in addition to any term of imprisonment and fine, twice the special parole term otherwise authorized.

(b) For purposes of this section, a person shall be considered convicted of a second or subsequent offense if, prior to the commission of such offense, one or more prior convictions of him for a felony under any provision of this title or title II or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant drugs, have become final. Ante, p. 1247.

(c) Section 411 shall apply with respect to any proceeding to sentence a person under this section. Ante, p. 1269.

ATTEMPT AND CONSPIRACY

SEC. 1013. Any person who attempts or conspires to commit any offense defined in this title is punishable by imprisonment or fine or both which may not exceed the maximum punishment prescribed for the offense, the commission of which was the object of the attempt or conspiracy.

ADDITIONAL PENALTIES

SEC. 1014. Any penalty imposed for violation of this title shall be in addition to, and not in lieu of, any civil or administrative penalty or sanction authorized by law.

APPLICABILITY OF PART E OF TITLE II

SEC. 1015. Part E of title II shall apply with respect to functions of the Attorney General (and of officers and employees of the Bureau of Narcotics and Dangerous Drugs) under this title, to administrative and judicial proceedings under this title, and to violations of this title, to the same extent that such part applies to functions of the Attorney General (and such officers and employees) under title II, to such proceedings under title II, and to violations of title II. For purposes of the application of this section to section 510, any reference in such section 510 to "this title" shall be deemed to be a reference to title III, any reference to section 303 shall be deemed to be a reference to section 1008, and any reference to section 302(d) shall be deemed to be a reference to section 1007(b)(2). Ante, p. 1270. Ante, p. 1274. Ante, p. 1285. Ante, p. 1253.

AUTHORITY OF SECRETARY OF TREASURY

SEC. 1016. Nothing in this Act shall derogate from the authority of the Secretary of the Treasury under the customs and related laws.

PART B—AMENDMENTS AND REPEALS, TRANSITIONAL AND EFFECTIVE DATE PROVISIONS

REPEALS

SEC. 1101. (a) The following provisions of law are repealed:

(1) The Act of February 23, 1887 (21 U.S.C. 191–193). 24 Stat. 409.

(2) The Narcotic Drugs Import and Export Act (21 U.S.C. 171, 173, 174–184, 185). 38 Stat. 275. 53 Stat. 1262.

(3) The Act of March 28, 1928 (31 U.S.C. 529a).

(4) Sections 2(b), 6, 7, and 8 of the Act of June 14, 1930 (21 U.S.C. 162(b), 173a, 197, 198). 46 Stat. 585; 70 Stat. 575.

(5) The Act of July 3, 1930 (21 U.S.C. 199). 46 Stat. 850.
(6) Section 6 of the Act of March 28, 1928 (31 U.S.C. 529g). 53 Stat. 1263.
(7) The Opium Poppy Control Act of 1942 (21 U.S.C. 188–188n). 56 Stat. 1045.
(8) Section 15 of the Act of August 1, 1956 (48 U.S.C. 1421m). 70 Stat. 918.
(9) The Act of July 11, 1941 (21 U.S.C. 184a). 55 Stat. 584.
(10) The Narcotics Manufacturing Act of 1960 (21 U.S.C. 501–517). 74 Stat. 55.

(b)(1)(A) Chapter 68 of title 18 of the United States Code (relating to narcotics) is repealed. 70 Stat. 572. 18 USC 1401–1405.

(B) The item relating to such chapter 68 in the analysis of part I of such title 18 is repealed.

(2)(A) Section 3616 of title 18 of the United States Code (relating to use of confiscated motor vehicles) is repealed. 62 Stat. 845.

(B) The item relating to such section 3616 in the analysis of chapter 229 of such title 18 is repealed. 68A Stat. 544. 26 USC 4701–4776.

(3)(A) Subchapter A of chapter 39 of the Internal Revenue Code of 1954 (relating to narcotic drugs and marihuana) is repealed.

(B) The table of subchapters of such chapter 39 is amended by striking out

"SUBCHAPTER A. Narcotic drugs and marihuana."

(4)(A) Sections 7237 (relating to violation of laws relating to narcotic drugs and to marihuana) and 7238 (relating to violation of laws relating to opium for smoking) of the Internal Revenue Code of 1954 are repealed. 70 Stat. 568; 80 Stat. 1444. 26 USC 7237, 7238.

(B) The table of sections of part II of subchapter A of chapter 75 of the Internal Revenue Code of 1954 is amended by striking out the items relating to such sections 7237 and 7238.

(5)(A) Section 7491 of the Internal Revenue Code of 1954 (relating to burden of proof of exemptions in case of marihuana offenses) is repealed. 26 USC 7491.

(B) The table of sections for subchapter E of chapter 76 of the Internal Revenue Code of 1954 is amended by striking out the item relating to such section 7491.

CONFORMING AMENDMENTS

SEC. 1102. (a) Section 4901(a) of the Internal Revenue Code of 1954 is amended by striking out the comma immediately before "4461" and inserting in lieu thereof "or", and by striking out ", 4721 (narcotic drugs), or 4751 (marihuana)". 79 Stat. 140.

(b) Section 4905(b)(1) of the Internal Revenue Code of 1954 (relating to registration) is amended by striking out ", narcotics, marihuana," and ", 4722, 4753,".

(c) Section 6808 of the Internal Revenue Code of 1954 (relating to special provisions relating to stamps) is amended by striking out paragraph (8).

(d) Section 7012 of the Internal Revenue Code of 1954 (relating to cross references) is amended by striking out subsections (a) and (b).

(e) Section 7103(d)(3) of the Internal Revenue Code of 1954 (relating to bonds required with respect to certain products) is amended by striking out subparagraph (D).

(f) Section 7326 of the Internal Revenue Code of 1954 (relating to disposal of forfeited or abandoned property in special cases) is amended by striking out subsection (b). 72 Stat. 1429.

(g)(1) Section 7607 of the Internal Revenue Code of 1954 (relating to additional authority for Bureau of Narcotics and Bureau of Customs) is amended— 70 Stat. 570.

(A) by striking out "The Commissioner, Deputy Commissioner, Assistant to the Commissioner, and agents of the Bureau of Narcotics of the Department of the Treasury, and officers" and inserting in lieu thereof "Officers";

(B) by striking out in paragraph (2) "narcotic drugs (as defined in section 4731) or marihuana (as defined in section 4761)" and inserting in lieu thereof "narcotic drugs (as defined in section 102(16) of the Controlled Substances Act) or marihuana (as defined in section 102(15) of the Controlled Substances Act)"; and

(C) by striking out "BUREAU OF NARCOTICS AND" in the section heading.

(2) The item relating to section 7607 in the table of contents of subchapter A of chapter 78 of the Internal Revenue Code of 1954 is amended by striking out "Bureau of Narcotics and".

(h) Section 7609(a) of the Internal Revenue Code of 1954 (relating to cross references) is amended by striking out paragraphs (3) and (4). 72 Stat. 1430.

(i) Section 7641 of the Internal Revenue Code of 1954 (relating to supervision of operations of certain manufacturers) is amended by striking out "opium suitable for smoking purposes,". 68A Stat. 905. 26 USC 7641.

(j) Section 7651 of the Internal Revenue Code of 1954 (relating to administration and collection of taxes in possessions) is amended by striking out "and in sections 4705(b), 4735, and 4762 (relating to taxes on narcotic drugs and marihuana)".

(k) Section 7655(a) of the Internal Revenue Code of 1954 (relating to cross references) is amended by striking out paragraphs (3) and (4).

(l) Section 2901(a) of title 28 of the United States Code is amended by striking out "as defined by section 4731 of the Internal Revenue Code of 1954, as amended," and inserting in lieu thereof "as defined by section 102(16) of the Controlled Substances Act". 80 Stat. 1438.

(m) The last sentence of the second paragraph of section 584 of the Act of June 17, 1930 (19 U.S.C. 1584), is amended to read as follows: "As used in this paragraph, the terms 'opiate' and 'marihuana' shall have the same meaning given those terms by sections 102(17) and 102(15), respectively, of the Controlled Substances Act." 58 Stat. 722; 60 Stat. 39.

(n) (1) The first section of the Act of August 7, 1939 (31 U.S.C. 529a), is repealed. Repeal. 53 Stat. 1262.

(2) Section 3 of such Act (31 U.S.C. 529d) is amended by striking out "or the Commissioner of Narcotics, as the case may be,".

(3) Section 4 of such Act (31 U.S.C. 529e) is amended by striking out "or narcotics" each place it appears.

(4) Section 5 of such Act (31 U.S.C. 529f) is amended by striking out "or narcotics" in the first sentence.

(o) Section 308(c)(2) of the Act of August 27, 1935 (40 U.S.C. 304m) is amended by striking out "Narcotic Drug Import and Export Act" and inserting in lieu thereof "Controlled Substances Act". 49 Stat. 880.

(p) Paragraph (a) of section 301 of the Narcotic Addict Rehabilitation Act of 1966 (42 U.S.C. 3411) is amended by striking out "as defined in section 4731 of the Internal Revenue Code of 1954, as amended," and inserting in lieu thereof "as defined in section 102(16) of the Controlled Substances Act". 80 Stat. 1444.

(q) Paragraph (a) of the first section of the Act of July 15, 1954 (46 U.S.C. 239a) is amended to read as follows: 68 Stat. 484.

"(a) The term 'narcotic drug' shall have the meaning given that term by section 102(16) of the Controlled Substances Act and shall also include marihuana as defined by section 102(15) of such Act."

(r) Paragraph (d) of section 7 of the Act of August 9, 1939 (49 U.S.C. 787) is amended to read as follows:

53 Stat. 1292.

"(d) The term 'narcotic drug' shall have the meaning given that term by section 102(16) of the Controlled Substances Act and shall also include marihuana as defined by section 102(15) of such Act;"

"Narcotic drug."

(s) Paragraph (a) of section 4251 of title 18, United States Code, is amended by striking out "as defined in section 4731 of the Internal Revenue Code of 1954, as amended," and inserting in lieu thereof "as defined in section 102(16) of the Controlled Substances Act".

80 Stat. 1442.

(t) The first section of the Act of August 11, 1955 (21 U.S.C. 198a), is amended to read as follows: "That for the purpose of any investigation which, in the opinion of the Secretary of the Treasury, is necessary and proper to the enforcement of section 545 of title 18 of the United States Code (relating to smuggling goods into the United States) with respect to any controlled substance (as defined in section 102 of the Controlled Substances Act), the Secretary of the Treasury may administer oaths and affirmations, subpena witnesses, compel their attendance, take evidence, and require the production of records (including books, papers, documents, and tangible things which constitute or contain evidence) relevant or material to the investigation. The attendance of witnesses and the production of records may be required from any place within the customs territory of the United States, except that a witness shall not be required to appear at any hearing distant more than 100 miles from the place where he was served with subpena. Witnesses summoned by the Secretary shall be paid the same fees and mileage that are paid witnesses in the courts of the United States. Oaths and affirmations may be made at any place subject to the jurisdiction of the United States."

Investigations, subpoena power.
69 Stat. 684.

Witnesses, travel expenses.
62 Stat. 716.

PENDING PROCEEDINGS

SEC. 1103. (a) Prosecutions for any violation of law occurring prior to the effective date of section 1101 shall not be affected by the repeals or amendments made by such section or section 1102, or abated by reason thereof.

(b) Civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of section 1101 shall not be affected by the repeals or amendments made by such section or section 1102, or abated by reason thereof.

PROVISIONAL REGISTRATION

SEC. 1104. (a) (1) Any person —

(A) who is engaged in importing or exporting any controlled substance on the day before the effective date of section 1007,

(B) who notifies the Attorney General that he is so engaged, and

(C) who is registered on such day under section 510 of the Federal Food, Drug, and Cosmetic Act or under section 4722 of the Internal Revenue Code of 1954,

shall, with respect to each establishment for which such registration is in effect under any such section, be deemed to have a provisional registration under section 1008 for the import or export (as the case may be) of controlled substances.

76 Stat. 794; 79 Stat. 231. 21 USC 360. 68A Stat. 559. 26 USC 4722.

(2) During the period his provisional registration is in effect under this section, the registration number assigned such person under such section 510 or under such section 4722 (as the case may be) shall be his registration number for purposes of part A of this title.

Ante, p. 1285.

Ante, p. 1255.

(b) The provisions of section 304, relating to suspension and revocation of registration, shall apply to a provisional registration under this section.

(c) Unless sooner suspended or revoked under subsection (b), a provisional registration of a person under subsection (a)(1) of this section shall be in effect until—

(1) the date on which such person has registered with the Attorney General under section 1008 or has had his registration denied under such section, or

(2) such date as may be prescribed by the Attorney General for registration of importers or exporters, as the case may be,

whichever occurs first.

EFFECTIVE DATES AND OTHER TRANSITIONAL PROVISIONS

SEC. 1105. (a) Except as otherwise provided in this section, this title shall become effective on the first day of the seventh calendar month that begins after the day immediately preceding the date of enactment.

(b) Sections 1000, 1001, 1006, 1015, 1016, 1103, 1104, and this section shall become effective upon enactment.

Ante, p. 1284, [illegible].

(c)(1) If the Attorney General, pursuant to the authority of section 704(c) of title II, postpones the effective date of section 306 (relating to manufacturing quotas) for any period beyond the date specified in section 704(a) and such postponement applies to narcotic drugs, the repeal of the Narcotics Manufacturing Act of 1960 by paragraph (10) of section 1101(a) of this title is hereby postponed for the same period, except that the postponement made by this paragraph shall not apply to the repeal of sections 4, 5, 13, 15, and 16 of that Act.

(2) Effective for any period of postponement, by paragraph (1) of this subsection, of the repeal of provisions of the Narcotics Manufacturing Act of 1960, that Act shall be applied subject to the following modifications:

(A) The term "narcotic drug" shall mean a narcotic drug as defined in section 102(16) of title II, and all references, in the Narcotics Manufacturing Act of 1960, to a narcotic drug as defined by section 4731 of the Internal Revenue Code of 1954 are amended to refer to a narcotic drug as defined by such section 102(16).

"Narcotic drug." Ante, p. 1244.

(B) On and after the date prescribed by the Attorney General pursuant to clause (2) of section 703(c) of title II, the requirements of a manufacturer's license with respect to a basic class of narcotic drug under the Narcotics Manufacturing Act of 1960, and of a registration under section 4722 of the Internal Revenue Code of 1954 as a prerequisite to issuance of such a license, shall be superseded by a requirement of actual registration (as distinguished from provisional registration) as a manufacturer of that class of drug under section 303(a) of title II.

Ante, p. 1253.

(C) On and after the effective date of the repeal of such section 4722 by section 1101(b)(3) of this title, but prior to the date specified in subparagraph (B) of this paragraph, the requirement of registration under such section 4722 as a prerequisite of a manufacturer's license under the Narcotics Manufacturing Act of 1960 shall be superseded by a requirement of either (i) actual registration as a manufacturer under section 303 of title II or (ii) provisional registration (by virtue of a preexisting registration under such section 4722) under section 703 of title II.

(d) Any orders, rules, and regulations which have been promulgated under any law affected by this title and which are in effect on the day preceding enactment of this title shall continue in effect until modified, superseded, or repealed.

TITLE IV—REPORT ON ADVISORY COUNCILS

REPORT ON ADVISORY COUNCILS

Reports to Congress.

SEC. 1200. (a) Not later than March 31 of each calendar year after 1970, the Secretary of the Department of Health, Education, and Welfare shall submit a report on the activities of advisory councils (established or organized pursuant to any applicable statute of the Public Health Service Act, Public Law 410, Seventy-eighth Congress, as amended, or the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963, Public Law 88-164, as amended) to the Committee on Labor and Public Welfare of the Senate and the Committee on Interstate and Foreign Commerce of the House of Representatives. Such report shall contain, at least, a list of all such advisory councils, the names and occupations of their members, a description of the function of each advisory council, and a statement of the dates of the meetings of each advisory council.

79 Stat. 642. 42 USC 201 note. 77 Stat. 282. 42 USC 2661 note.

(b) If the Secretary determines that a statutory advisory council is not needed or that the functions of two or more statutory advisory councils should be combined, he shall include in the report a recommendation that such advisory council be abolished or that such functions be combined.

"Statutory advisory council."

(c) As used in this section, the term "statutory advisory council" means any committee, board, commission, council, or other similar group established or organized pursuant to any applicable statute to advise and make recommendations with respect to the administration or improvement of an applicable program or other related matter.

Approved October 27, 1970.

LEGISLATIVE HISTORY:

HOUSE REPORTS: No. 91-1444 (pts. 1 and 2) (Comm. on Interstate and Foreign Commerce) and No. 91-1603 (Comm. of Conference).
SENATE REPORT No. 91-613 accompanying S. 3246 (Comm. on the Judiciary).
CONGRESSIONAL RECORD, Vol. 116 (1970):
Jan. 23, 24, 26-28, S. 3246 considered and passed Senate.
Sept. 23, 24, considered and passed House.
Oct. 6, 7, considered and passed Senate, amended.
Oct. 8, 14, House agreed to conference report.
Oct. 14, Senate agreed to conference report.

STATEMENT OF HAROLD SHINNICK, PRESIDENT, NATIONAL ASSOCIATION OF RETAIL DRUGGISTS (NARD), ACCOMPANIED BY WILLIAM WOODS, ASSOCIATE GENERAL COUNSEL, NARD, DAVID CLARK, EXECUTIVE DIRECTOR, INDIANA PHAMACEUTICAL ASSOCIATION, IVAN ROSE, PAST PRESIDENT, ARKANSAS PHARMACEUTICAL ASSOCIATION, AND JOHN JOHNSON, FIRST VICE PRESIDENT OF THE NATIONAL ASSOCIATION OF RETAIL DRUGGISTS

Mr. SHINNICK. Thank you very much.

Chairman Bayh and members of the subcommittee, I am Harold J. Shinnick and I am an independent retail pharmacist and owner of a community pharmacy in Chicago, Ill. I appear here today with my associates as president of the National Association of Retail Druggists. On my right is David Woods, also David Clark, executive director, Indiana Pharmaceutical Association. On my left, Ivan Rose, and also on my left, John Johnson of Nebraska.

I also have with us to my left in the back is Willard B. Simmons, executive secretary of the NARD.

NARD is the national association in the United States representing the tens of thousands of pharmacists of the county who own and operate their own pharmacies in the neighborhoods and communities across this land.

We are most appreciative of your invitation to appear here today and applaud the work and efforts of this committee. The Controlled Substances Act of 1970 required significant and substantial changes in the practice of pharmacy, some of which our members have welcomed and others which we have accepted and endured. The independent practitioner of pharmacy has a fine record of serving the people in this country and we, like all America, were concerned about the drug abuse and misuse reaching epidemic proportions. Clearly something had to be done and the Controlled Substances Act was a bold and sweeping plan.

Therefore, NARD is particularly pleased that this committee has taken the initiative to review the implementation and effect of the Controlled Substances Act at this time to determine just how well it is working or administrative implementation of the act. Like you, we do not have the definitive answers to this complex problem though we all wish we did. Drug abuse and misuse is still a serious issue and a serious concern and will continue to be such until we have conquered its problems and causes.

NARD has assembled a group of informed pharmacists who we believe are most knowledgeable to assist this committee in its inquiry.

Mr. Willard Simmons, the executive secretary of the National Association of Retail Druggists, has had a long-standing personal commitment to programs directed to the public and particularly young people to provide information and education on the hazards of drug abuse and misuse. He provided the leadership which sparked an extensive public education program which brought vital and timely information and facts to millions of school-age children, their

parents, and teachers on drug abuse. Mr. Simmons, in addition to his long tenure as an independent pharmacist in his home, Texarkana, Tex., has traveled the length and breadth of this Nation talking with pharmacists and others, which has given him the opportunity to obtain a broad and representative view of the operation and implementation of this act.

Mr. William E. Woods is a pharmacist and attorney who serves as NARD's Washington Representative and Associate General Counsel. He has the experience of working with the act from the original legislative proposals, through the revisions of the implementing regulations, and in identifying an attempting to resolve legal and regulatory issues relating to the act. Mr. Woods has borne the brunt of interpreting the legislation and regulations for our executive committee and members.

We also have with us Mr. David Clark, executive director of the Indiana Pharmaceutical Association. Mr. Clark is also a pharmacist and can provide the valuable insight of the views of an executive of a statewide organization of pharmacists and the problems and issues that concern him and his association relating to the act.

Mr. Ivan Rose is from Arkansas where the pharmacy association and its members are particularly concerned about the rising risk of violent crimes in pharmacies related to controlled substances. In addition to being a pharmacist, Mr. Rose is a member of the Arkansas legislature and has served as a member of the Arkansas Board of Pharmacy and NARD believes that he is particularly well-qualified to assist this committee in its inquiry.

And we also have John Johnson, a pharmacist from Nebraska, who is a leader in Nebraska pharmacy association affairs and who also serves as the first vice president of the National Association of Retail Druggists. Mr. Johnson's experience as a State leader, his fine service as an officer of NARD on the national level, as well as his reputation as an articulate spokesman, suggest that he, too, could serve as a valuable resource for this committee.

To coordinate our presentation in an effort to be most helpful and informative to the committee, we will have Mr. Woods present a statement responding to some of the issues the committee indicated were of interest to it. Thereafter, Messrs. Clark, Rose, and Johnson will present brief supplementary comments reflecting their own special perspectives.

NARD has what we consider a good record of cooperation in the development and implementation of the Controlled Substances Act. And I want to assure the committee that we intend to cooperate fully with this committee and the Drug Enforcement Administration in achieving the objectives of this national effort. However, I would be remiss if I did not also state that our members want and expect that NARD and the Congress will insist that the burdens of compliance will be strictly limited to only that which is necessary to effectuate the purposes of the act, and no more. Our members are finding that the costs in terms of time and money of compliance with an ever-increasing system of State and Federal regulation, of which the CSA is but a part, are becoming more than an individual small businessman can shoulder. Independent pharmacists typically

must rely upon their individual efforts to meet all Government regulatory requirements and frequently only with the guidance of the NARD and their State pharmacy association.

Therefore, NARD does have some suggestions and comments on some points where we believe that the views of our members deserve priority consideration and implementation to assure the pharmacists that they will not have to face the risks and dangers created by this law alone, or in vain.

I thank you.

Senator BAYH. Mr. Woods.

Mr. WOODS. Mr. Chairman, first we would like to express our appreciation for the cooperation that this committee and chairman and staff have shown us in planning for these committee hearings. We have been particularly impressed by the record of this committee and the distinguished chairman, a long record of concern in effective work to deal with the drug abuse problems in this country.

The National Association of Retail Druggists appreciates your invitation to discuss the administration and implementation of the Controlled Substances Act of 1970. When first adopted, this law made sweeping and comprehensive changes in the regulatory scheme for narcotics and drugs subject to abuse. And we have every indication that narcotic addiction may have reached its peak in this country, and that abuses of nonnarcotic drugs are lessening or not increasing at the alarming rate that prompted the enactment of the CSA.

When the proposals which eventually became the Controlled Substances Act of 1970 were being considered, NARD maintained that independent pharmacies were not significant sources of supply for drugs for illicit use. We believe that that was a correct assessment then as well as today. To be sure, there were abuses of drugs prescribed, but by and large this was a significant portion of the problem. To the extent that drugs subject to abuse were prescribed too often, and in abnormally large quantities, or refilled over too long a period, the CSA has brought this problem under control.

NARD believes that the present controls assure, insofar as can be done, that controlled substances that are prescribed will be utilized properly for an appropriate medical purpose. We cannot assure that an enterprising patient, either alone, or in concert with the prescriber, will subvert the intentions of the law. However, we have no evidence that this is a significant or widespread problem.

When the CSA was first adopted, and later as it was implemented, the NARD made every attempt to assure that the law was understood by pharmacists and implemented in a proper manner. We distributed detailed analyses of the regulations promulgated by the Government, prepared a quick reference chart which summarized in readily accessible form the major features of the law, and developed and produced with the cooperation of Smith, Kline, & French Laboratories, a continuing education cassette that explained the requirements of the law in detail. In cooperation with the Government, the reference chart was made available to every pharmacy. And, we have cooperated in making the law workable in every other way through suggestions to the Government, including the

inventory form for the biennial inventory which forms the backbone of the enforcement effort. The inventory form we suggested and insisted the Government make available reduced the biennial inventory from a major undertaking to a relatively minor inconvenience.

NARD early recognized the value of public awareness of and education on the problems and issues of drug abuse and misuse. Mr. Simmons, working with NARD, developed its first and basic sheet on abused drugs, a detailed plan for a 45-minute program on drug abuse to be given for schools and clubs, a list of visual materials available for public presentation letters for use in soliciting interest of schools and civic groups, and public service announcements for radio and television.

This first kit was mailed to 38,000 independent pharmacists and NARD eventually distributed about 75,000 kits which provided valuable information to local audiences throughout the country.

In early 1969, NARD developed and distributed another kit titled "Drug Abuse Education Goes to School" designed for use by teachers as well as pharmacists. From this kit, thousands of pharmacists worked with teachers and principals planning assemblies, showing films, and bringing drug abuse education to millions of young people.

NARD's public education campaign on drug abuse was one of the most massive, ambitious, and widely acclaimed public service accomplishments undertaken by the profession of pharmacy. We believe it was also one of the most beneficial programs in assisting to acquaint young people and the parents on the hazards of drug abuse.

Currently, NARD has revised its reference chart because it is still useful and in demand by the profession. Our association and its members have offered our continuing support to the Department of Justice in making the law more efficient and effective. We were pleased that the DEA recently authorized the dispersal of controlled substances inventory throughout the general pharmacy inventory consistent with NARD's suggestions.

However, we suggested further that DEA might consider some modification of the CSA schedule identifications on the packages and labels by removing the markings from the labels and requiring that they appear on the side or back of the packages and containers so as not to be so visible to robbers, burglars, and thieves. For some reason unknown to us DEA did not comment on our suggestion or even acknowledge that we commented on the regulations in its commentary published in the Federal Register which did mention all other suggestions and comments. A copy of our submission and the Federal Register notice is attached and explains our views on this point in more detail.

NARD believes that the change in the location of the identification markings would make controlled substances inventories dispersed throughout the pharmacy's general inventory more secure and still provide maximum guidance to pharmacists and others who must rely upon the package labeling to determine the control status. We further believe that our suggestion is practical and reasonable and deserved more than to be ignored by DEA.

Another topic that NARD submits should be reviewed is the advertising and promotion of controlled substances, especially that directed to patients and consumers. The Cost of Living Council had proposed, and hopefully has now abandoned, the concept of pricing lists of prescription drug prices in pharmacies. The Food and Drug Administration is in the process of revising its regulations on reminder advertising and reminder labeling to encourage consumer advertising of prescription drugs. The Department of Justice has traditionally and continually encouraged advertising of prescription drugs and has characterized as trade restraints attempts to restrict or regulate prescription drug advertising.

Other forces are at work in the pharmaceutical industry which show great probability that advertising and promotional practices of drug firms may change radically in the next few years to where consumers, rather than pharmacists and physicians, may be the prime advertising targets for prescription drugs, particularly if the FDA proposal is implemented. We foresee a very real danger that advertising and promotional materials for prescription drugs, including controlled substances, will be published or distributed through lay media, including magazines and periodicals. And with this, there is the very real danger that interest in controlled substances among laymen will be increased. NARD submits that the Congress ought to prohibit advertising and promotion of any controlled substance directed to the public. Retail consumer advertising showing that a patient with a prescription for 24 capsules or tablets of a controlled substance can save money by purchasing a quantity of 100 or 500, has got to increase pressures on prescribers to make these larger quantities available to their patients. Similarly, if consumer advertising, whether price is mentioned or not, touts controlled substances like every other consumer commodity, a false climate of harmlessness will be presented to the public. It would appear FDA has not taken this into consideration.

Congress should now assure, before we reach a problem of urgent and critical proportions, that advertising and promotion of all controlled substances will be limited to pharmacists, physicians, and others with a legitimate medical need or use of the information. Congress should assure that no condition exists or action is permitted which would tend to encourage the consumption or use of controlled substances beyond that quantity that is absolutely justified by medical needs. Anything that lessens the control, or encourages the prescribing or availability of quantities in excess of the amount for immediately justifiable medical needs, inevitably creates the opportunity for misuse and abuse of these drugs.

NARD fails to see, as the Justice Department apparently does, how assuring the best control of prescription drugs, and particularly controlled substances, can be considered a detrimental, anticompetitive restraint. Designating a drug as a controlled substance restricts its distribution and availability as does designating any drug a prescription drug. However, these restrictions are not considered anticompetitive but as necessary in the interest of promotion of public welfare.

NARD is also concerned over the continued relaxed attitude DEA has taken in regard to the mailing of controlled substances. Time and

again. NARD has urged that DEA promulgate a regulation prohibiting the mailing of all controlled substances. Our efforts have appears to be a superficial survey of 16 pharmacies which DEA and been met with hostility and rejection, even to the extent that the Government has had the gall to march forth the results of what other claim justify its position. Meanwhile, there are lay press reports of the ease of diversion of controlled substances from prescription mail order operations and we suspect that many a bottle of controlled substances has been further diverted from the mails enroute to patients.

Assuming that prescription orders received from a distant location by a prescription mail-order operation are legitimate, DEA seems to place great faith in the postal service assuring the safe transit of the drugs themselves. Yet, a prescription drug package is easily identified by shape, markings, and size, and an easy mark for those bent on obtaining quantities for illicit use. On the supposed but unproven economic advantage to the patient, DEA and mail-order outfits attempt to justify the practice. However, if we are to follow a policy based solely upon economic considerations to its absurb end, then we would be required to remove all controlled substances restrictions and limitations. Obviously, the Congress has already determined that the actual and potential abuses and misuses of controlled substances dictates that they be rigidly controlled, despite the economic consequences, in order to serve better overall health objectives.

In fact, perhaps the tendency we see for DEA to increase controls over certain substances by moving them to higher control schedules is a result of its relaxed attitude over advertising and mail-order distribution when these drugs appear to be unsuccessfully controlled on lower schedules.

NARD and its members are greatly concerned over the increased risk of crimes of violence in pharmacies. In the August 2, 1973 issue of the Congressional Record, Senator Frank Church—D-Idaho—cited statistics which confirmed that which practicing pharmacists already knew in less specific terms. Crimes of violence in pharmacies related to controlled substances are increasing at an alarming pace. We have with us some individuals who can give you additional information on their own areas. We have provided the committee with many, many new stories concerning similar crimes throughout the country.

Beginning with the hearings on the proposals which became the Controlled Substances Act, NARD has consistently urged that Congress provide Federal jurisdiction to enforce crimes related to controlled substances in pharmacies. Not uncharacteristically, DEA has opposed our pleas for relief and assistance.

As the CSA is effectively implemented to dry up the illicit sources of controlled substances for pushers and users, there is a correspondingly increased pressure and threat upon legitimate outlets possessing quantities of these substances. Pharmacies are a primary target for those in need of drugs for a number of reasons, not the least of which is that pharmacies are open and accessible to just about every segment of the population, and are found in inner city areas when most other businesses have fled.

We do not suggest that ordinary crimes in pharmacies, like robbery and burglary, be blanketed into Federal jurisdiction. However, we do request that crimes of violence—assault, robbery, burglary, murder, and the like—involving controlled substances be subject to Federal jurisdiction. If a pharmacy were robbed and only money taken, that crime would rightly be a matter of local jurisdiction. However, if the felons clearly were motivated by the presence of, or need to obtain, controlled drugs, evidenced by drugs being part of the booty, then we believe that Federal jurisdiction and prosecution ought to be authorized.

Congress has specifically provided that a person who manufactures, distributes, dispenses, or possesses a controlled substance with intent to distribute, is subject to Federal criminal prosecution and penalties under section 401 of the act—21 USCA 841. Similarly, if a person knowingly or intentionally acquires or obtains possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge, Section 403 of the act—21 USCA 843—provides Federal jurisdiction and penalties. However, if the person obtains the drugs by violence in a pharmacy, the act implies that this is of no Federal concern.

It is appropriate and necessary to simply amend the penalties sections to make it unlawful for any person to obtain, or attempt to obtain, any controlled substance through violent or other unlawful means. The increased threat of violence and crimes in pharmacies is a direct result of the stringent controls imposed by the CSA. It is only fitting that the resources and facilities of the Federal Government be made available to protect pharmacies and apprehend those bent on circumventing the controls of the law.

Federal criminal jurisdiction over crimes of violence and other unlawful conduct relating to controlled substances would provide for more uniform law enforcement action and punishment of violators. As it is now, punishment of drug-related crimes in pharmacies rests upon the varying provisions of State criminal laws. A Federal law would provide a sanction universally applicable in this country that would be more readily understood and heeded and more uniformly applied.

Pharmacists have become the men on the frontiers of the movement to curb and eliminate drug abuse. Our members are health care professionals, not policemen, nor experts in the art of self-defense. However, the focus of criminal activity relating to controlled substances is gravitating to the thousands of pharmacies in this country. Through no fault of their own, pharmacists have been placed in a situation where their lives and property are continually at risk.

NARD believes that pharmacists ought to be supported as they make the sacrifices which necessarily accompany this national push to reduce drug misuse and abuse. We would request that the Congress consider some form of insurance, either without cost or at nominal cost, to cover the costs of the potential tragedy and risks that they face. In this manner, at least those pharmacists who were injured, or disabled, by violence associated with controlled substances, or families of pharmacists killed, would be made financially whole.

Unless some method of assuring pharmacists of greater protection from and involvement of Federal law enforcement machinery and personnel, NARD believes that pharmacists will begin to refuse to stock or handle controlled substances altogether. Such action would have serious detrimental effects on health care which none of us would welcome but there is a limit which society, just in humanistic terms, cannot expect pharmacists to exceed.

The overwhelming percentage of pharmacists in this country practice in independent community pharmacies. Too often our members feel that their needs, suggestions, and requests are ignored or viewed with hostility by those administering the law. The Federal Government has shown little sensitivity or understanding of the very real problems or risks our members face. The Federal effort is apparently paying good dividends in the area of illicit and clandestine operations involving criminal elements but appear ill-equipped to deal with legitimate health care providers, the vast majority of whom are law-abiding citizens. Enforcement personnel, innately suspicious and cynical, accustomed to the challenges of criminal activity, seem to carry these attitudes and perspectives into their regulatory sphere as well.

When NARD suggested that mail-order outfits might be a significant source of controlled drug diversion, BNDD—now DEA—retaliated with a study of 16 pharmacies which superficially proved the converse. The report contained apparent violations, but we and State pharmacy boards were denied access to the specifics of the study, including the names of the outlets surveyed, or even the identity of the violators. We were also denied access to the data before the agency in selecting the sample of pharmacies. Obviously, if the pharmacies surveyed were those for which complaints had been made or for which the Government had reason to believe were less than diligent in complying with the law, the results would naturally be misleading.

NARD has proceeded on the assumption that our goals and those of the Governmental agency administering the law in the area of regulating the legitimate health care system should be complimentary, a cooperative rather than an adversary effort. For our part, we have sought to assure that the legitimate channels of distribution, and pharmacies in particular, are regulated as efficiently as possible in a manner that removes to the extent possible, actual, or potential opportunities for drug diversion and deserve further consideration.

We believe that DEA has sufficient information available to it to identify pharmacists or physicians who may be improperly contributing to traffic and abuse of controlled drugs. Pharmacy suppliers must maintain records for inspection. Where these records show unusual activity, the pharmacy or pharmacies concerned have records showing the names of prescribers which must be maintained. An audit of the pharmacy records should show readily whether the abnormal activity is caused by the pharmacist or by one or more prescribers in that community.

NARD does not believe that we need any additional or further records, triplicate prescriptions, or anything else. The purpose of the elaborate records required by the CSA was to document the distribution of controlled substances. More than likely, all DEA agents would have to do is talk with pharmacists to learn which prescribers, if any, showed abnormal prescribing tendencies for controlled drugs.

This past summer, DEA published a proposal relating to the verification of prescriptions. NARD commented on these regulations in our letter to DEA dated August 3, 1973, copy of which is attached. Our position then as now is that there is no legal provision, whether contained in the regulations or statute, which cannot be circumvented with relative ease unless the provision is so onerous and burdensome as to be impractical. Credit cards are freely available to criminal elements and can be forged with little sophistication. All a drug abuser needs to do is use a name on the prescription blank for which he can furnish suitable identification. Alternatively, if the prescription blank itself is forged, the telephone number need only be that of an accomplice who will, when called, verify the prescription as legitimate. Triplicate prescription blanks can be forged and manufactured as well as conventional forms.

We are not aware of any practical method of devising a fail-safe system to assure the authenticity of the patient named on the prescription or the prescriber signing it.

NARD believes the provisions of the law relating to administrative inspection warrants deserves study, modification, and clarification. At the time the act was considered by the Congress, the law relating to administrative inspections was unsettled. Section 510 appears to deny pharmacists and other registrants fundamental constitutional rights, particularly when it authorizes a warrant to seize certain property on a lesser standard than the Constitution requires.

We believe that pharmacies ought to be protected from harassment and fishing expeditions under the guise of routine inspections. In all cases, inspections should be under an applicable administrative inspection warrant. The law provides ample basis for obtaining such administrative inspection warrants for any legitimate enforcement need while at the same time protecting the rights of the registrants.

Furthermore, where DEA agents know or have reason to believe that certain seizures are anticipated, such warrants would be subject to the usual constitutional "probable cause" standards. Obviously, if DEA anticipates a seizure and has sufficient information to present grounds therefore when it seeks an administrative inspection warrant, that proposed seizure should be guided by the search and seizure requirements of the fourth amendment, not the lesser standards of section 510. Specifically, an administrative inspection warrant should be available to DEA when the objective is something other than routine, random inspections.

This inspection authority is very important. Section 402(a)(6) of the act imposes penalties upon a registrant who refuses any entry into any premises or inspection authorized by the act. It seems that a pharmacist who insists upon an administrative inspection warrant, or a constitutionally required search warrant, commits an offense by that very deed. Certainly this is true if DEA has administrative inspection warrant in circumstances where the registrant believes a search warrant is necessary.

In closing, Mr. Chairman, NARD believes that the CSA is accomplishing the broad purposes for which it was enacted by drying up the illicit sources of controlled substances. However, as the major illicit sources are closed, we must give greater concern to the effects of the increased pressure upon the legitimate channels of distribution. We have attempted to outline here those areas which we believe deserve strengthening.

Thank you.

Senator BAYH. Thank you very much, Mr. Woods.

May I direct some questions, please.

That DEA study that you referred to relating to the pharmacies.

Mr. WOODS. Yes.

Senator BAYH. Abuse potential was disclosed there. Nobody likes it and wants to do more about it than the average hometown pharmacist. I am relatively certain that we can find answers to some of the questions you posed so that indeed perhaps the Association can take some steps to deal with some of these problems as well as find out whether some of those offending pharmacies were classified by the normal standards.

Mr. WOODS. We welcome that information.

Senator BAYH. Has there been any reason given for DEA's refusal to cooperate with you in an effort to find out how the standard was established?

Mr. WOODS. I think that I can put it in perspective by perhaps first quoting the statement by one of the associates at DEA when we indicated our concern about the mail-order prescription, and lack of a physician-patient-pharmacist relationship, and it denied the patient a higher quality of pharmaceutical service because the pharmacist was not in contact with the patient and it did not provide adequate health care standards.

The DEA official's comment was, "you know, this just doesn't happen to be our bag, so we are not that much concerned about health standards." To quote another one over there, the general feeling is that they don't want to offend the little old ladies with tennis shoes that are getting mail-order prescriptions. I think this starts off as a basis of their feeling. Then they went out and did a survey to try to protect the mail-order outfits, whether it was VA or many others they could name. I have seen letters from the VA defending this survey and decrying the inefficiencies of the retail pharmacists and indicating it was the first source of diversion, based on that survey, which I think was a ludicrous statement for the DEA to make and ludicrous position for DEA to take in trying to develop that position with such a scurrilous, inadequate survey.

Senator BAYH. Let me suggest this committee traditionally hasn't been too concerned about stepping on toes. However, I would rather not get into a hassle between mail orders and retail pharmacists. You are concerned about being put in a less favorable position than mail-order operations. But if there is a 25-percent chance of a successful fraud through mail orders, I think something has to be done there, also.

Mr. WOODS. I understand, Mr. Chairman. We certainly agree.

We have instances in VA having automatic remailings every 30 days or so often of drugs to their veterans who are denied the convenience and service in their community. Of course, you get prescriptions back on the VA mail-order program. We have had veterans come into pharmacies and offer to sell these drugs and they say they are not taking them, quit using them and have been prescribed two or three products and they don't want to cut off one drug abuse product because they are afraid they will cut them off of another.

Mr. Johnson, from Nebraska has a case just recently he might give you information about.

Mr. JOHNSON. Senator, just recently our State control revenue group went out to investigate a death in Chadron, Neb., of a white male veteran who died from conditions unknown. Forty-eight hours after his death when he started the autopsy they found he had .41 blood alcohol and he unfortunately died from alcoholism. In investigating the case they found over the past 2 or 3 or 4 years this man had been receiving on a monthly basis 120 Darvon 65, 100 valium, 5 mg and 32 seconal 1½ grains. Interestingly enough, this man had no known income. He lived very high on the hog out there, as we say, and he had cash in his pocket.

Senator BAYH. That is usually an Indiana term. You are perfectly welcome to use it in Nebraska if you want to. Go right ahead. [Laughter.]

Mr. JOHNSON. When they got a little deeper in their investigation it was found out this man was a source of these drugs to the Indian population out there, and this could be documented. Apparently, the only income he had was his monthly automatic refill of three very potent products, one of which is at this time a class 2, in which a new prescription had to be issued each time. This was from the veterans who is in Lincoln, Nebr.

Senator BAYH. Examples like that will help us to more properly assess the extent of the problem. If you have any similar cases, either you gentlemen here or those present or anybody else in your association, we will be glad to have them.

Mr. WOODS. Mr. Chairman, the president of the Arkansas Board of Pharmacy, Mr. Rose, has had experience with another form of mail-order diversion, if you want him to comment now.

Mr. ROSE. Senator, I might just mention in the process of handling in the Arkansas Legislature one of the drug bills in order to find out how readily we could obtain drugs from out-of-State we sent supposedly ficticious prescriptions. Needless to say, when we started to debate this bill on the floor of the House, which I was the author of the bill, when we dumped several thousands of these items, amphetamenes, and barbituates on a table, so that the legislators could see how easily it was to obtain them, we had no trouble in passing the drug control bill in Arkansas.

What I am saying is that anyone can send a prescription, whether bona fide or fictitious, to obtain drugs which you cannot get in a legitimate drugstore. This is the problem we ran into. We were trying to license all distributors in Arkansas so we would have some way we could control. But needless to say, those who want to shift into a State will not register with you, but we were able to get thousands.

Senator BAYH. That is the kind of thing we would like to talk to DEA about and see what can be done.

Mr. ROSE. Yes. I think that would be very good.

Senator BAYH. We are having a vote going on right now over on the floor. Why don't we go ahead with another question or two and the next time the bell rings I will have to leave, and I will get back as quickly as I can get back. I am sorry about that.

Mr. Woods, in your testimony you indicate that the Control Substances Act has dealt with the problems of practitioners who prescribe in abnormally large quantities. This is one of the basic concerns we had. Would you care to amplify that assessment?

Mr. WOODS. Well, I don't know how much can be done in this area. I don't have documentation to the extent of some of these other things. I would be glad to develop it. I really have an idea that situation is increasing in view of the CSA Act. Certainly it was probably happening between the amphetamines, but before some of the drugs went over to schedule 2.

But I think the point we were making or had in mind that community pharmacists will be permitted what was being prescribed in his neighborhood but what was overprescribed by State boards of pharmacists and by DEA.

Senator BAYH. We started several years ago to get BNDD to go along with our recommendations for rescheduling amphetamines and barbituates. We were hit by numerous voices that this was impossible because we were talking about legitimately produced drugs which meet a legitimate medical need of patients: that to control production would result in a number of patients not being able to get the kind of drug they needed to meet their problem. Have you had any complaints like this from any of your pharmacists?

Mr. WOODS. I think I can say to you, Mr. Chairman, this wasn't the community pharmacists of the country that raised this question, but I think they compliment and congratulate the chairman for the courageous effort he took in bringing about the change in amphetamines and moving them over to schedule 2.

Senator BAYH. It was the bureaucrats downtown charged with policing it. I didn't mean to infer that the pharmacists made that charge. I wondered that since we have been able to cut back amphetamines, the speed if you please, the uppers—whether you have had any complaints from your members?

Mr. WOODS. I am inclined to say we have not had any complaints. I may have a resounding difference behind me, but I think everybody is satisfied it should be in schedule 2 and has reduced a problem and we are not having significant complaints.

Senator BAYH. Of course, it may be too early to get an answer to that question as far as the three categories of barbiturates.

We have a problem with barbituates. There are two or three kinds of barbituates that are the drugs of choice of the doctors and as a result they are available in large volume, in wholesale houses, mail-order houses and on your shelves. We have been able to get three of them rescheduled. There are six other barbiturate products that have identical tendencies, shorter acting, that were not rescheduled.

What I am concerned about is that we have had a great demand by abusers for the three, now that they have been rescheduled, the demand will go to the other six and you will have that problem just shift over. So we may be wanting a report on what that history is over the next few months so we can get the people downtown to reschedule these other drugs. They are all in that same class of drugs.

Mr. WOODS. We will be glad to provide any information the committee can use, Mr. Chairman. Some of the gentlemen here at the table would have more specific information on the problem than I would on those particular drugs.

Senator BAYH. Let me compliment NARD for what you have done in the educational area. I think that is so important.

Also, I appreciate your assessment of the advertising problem. I want to look at this carefully to see what can be done.

Right now I am going to vote. I will be back as quickly as I can. I am sorry to prolong your inconvenience.

Mr. WOODS. Mr. Chairman, we have a commitment for a luncheon with Senator Long later today. Will you be returning shortly? Do you wish us to wait?

Senator BAYH. I should be back in 10 minutes and then maybe take another 10. If you have to go now I will understand.

Mr. WOODS. That will be fine. I am hoping you ask me another question about crime so we will be glad to wait.

[A short recess was taken.]

Senator BAYH. We will reconvene with additional apologies to our illustrious panel here.

You have a luncheon, and as I mentioned to Mr. Woods and Mr. Clark a few minutes ago, and Mr. Shinnick, it is entirely possible we will have another vote. I don't know. So rather than get involved in all the questions that I would like to direct to your attention, could I ask your leave to submit these questions in writing?

Mr. WOODS. We will be glad to cooperate in any way, Mr. Chairman.

Senator BAYH. I would like to without objection, place Mr. Clark's statement, which I have in my possession in the record. It was very helpful.

[Mr. Clark's prepared statement may be found at the conclusion of the NARD remarks.]

What has been your experience, if I might ask, Mr. Clark, in Indiana? Mr. Woods mentioned the major emphasis in the urban area and that some had a really significant problem in some of the not traditionally large urban areas. What has been the general problem in Indiana?

Mr. CLARK. The crimes in not-traditionally large areas?

Senator BAYH. We have had some complaints in Lawrenceburg, Middlebury, Rensselaer, Crawfordsville, Fortville and Martinsville, compared to the megopolis complexes where the emphasis on burglary is evident. What has been the pattern?

Mr. CLARK. I think that has been rather widespread and across the board. In metropolitan areas there are obviously a larger concentration. But the increase in urban areas and in smaller towns where there has been traditional or absolutely no break-ins or robberies and so forth, they are now experiencing robberies and break-ins. So for those areas it is a significant increase and they are now being subject to the same type of physical abuse, intimidation and so forth that traditionally only metropolitan pharmacists had been exposed to. So that has spread rather statewide.

Senator BAYH. Let me ask Mr. Woods and you. We have examined S. 2327, which was not referred to the committee until Tuesday. It deals with narcotics, of course, as you mentioned in your statement. One of the things it seems to me perhaps we ought to try to do is look at that from a broader approach. If we are concerned about the impact of criminal activity directed at pharmacists and how that relates to the drug problem, and if we move along this route making that a Federal law violation we shouldn't confine it to the traditional narcotics. What would you think about expanding it to include barbiturates and amphetamines and the other drugs not described as narcotics under the bill?

Mr. WOODS. That would be our position exactly, Senator. We feel wording should be changed to all CSA drugs, as you have suggested.

Senator BAYH. One last question. What would be your judgment on that, Mr. Clark, as far as the impact?

Mr. CLARK. My judgment would be the same. Obviously—but, I would hope that there would be further regulatory changes such as dispersal of controlled substances through the noncontrolled substances area.

Not to drag out the testimony, but I had a rather personal experience in a pharmacy that I managed. There were some 34 or 37 burglaries, and at the time I was a practicing pharmacist and I asked the Board of Pharmacy permission to, in other words, hide at that time Class A narcotic drugs, and the robbers were apprehended. One was shot and killed and the other one was apprehended. So that one action, that dispersal is quite obvious to them. As long as this type of action as we were talking about, including all controlled substances, would be accompanied with other improvement in the regulatory components, yes, absolutely.

Senator BAYH. I hope we can communicate with you further on some of the dispersements and other specifics that we can work into this new approach.

Let me ask you one last question on the triplicate prescription system. Mr. Woods, in your testimony you seem to feel that this really wasn't the answer. What has been the experience in California where the have it for narcotics, and Idaho, New York and Illinois where systems cover the narcotics as well as the nonnarcotics? What have been their experiences?

Mr. WOODS. I think first our concern would be with a Federal triplicate system. We would be more opposed to that than a State system that is consistent with the needs of the State. If the States find hat some kind of triplicate system is workable in their area, why it is okay with us.

I think the Idaho bill has been successful. They have a triplicate system from what I understand. But Mr. Barnett, who is the Secretary of the State Board of Pharmacy there, will be with the group when they testify, National Association of Boards of Pharmacy, and he can provide more on that. California I am not familiar with.

Generally we would be opposed to a Federal triplicate system. One of the problems right now, anybody can call up any printer and have a stack of prescriptions printed. This is a real problem. There may be something that can be done-----

Senator BAYH. Providing for serialized prescriptions or something like that, does the BNDD number help in that regard?

Mr. WOODS. I am not sure that I am addressing the question you raise, but just to put a BNDD number on there, doctors' address and everything, BNDD number also. But this area we would like very much to work with you and the committee and do something about forged prescriptions or having adequate records.

Senator BAYH. We certainly don't want to pass any laws that are just going to add to the red tape. We have found some regulations in this area, and firearms area where we have a lot of data that is never collected and never reaches the source, and it is not collected in a way that it is meaningful. Perhaps serialization and your other sugestions might help you do what you need to do to police across the counter more effectively.

Mr. WOODS. In this regard, in trying to make a reasonable commonsense approach coming to a solution of this dimension is the way that this problem should be approached, I think.

Senator BAYH. I have a few other questions here, but you have covered most of the substance in your testimony.

I do want to thank you gentlemen for taking the time and again apologize for the bouncing ball act on the rooms as well as the votes.

Mr. WOODS. I appreciate very much having the opportunity to be with you, and just for a final phrase on the Church bill, we are very much for this type of legislation. It would solve the problem. We don't think DEA's attitude of doing a survey will solve it. If there is some other way we can eliminate crimes in the field we will certainly support it.

Senator BAYH. We want to work in that direction, too. It is consistent to the extent that other manipulations that lead to abuse in narcotics are Federal law violations. To the extent you broaden the area you increase the need for Federal law enforcement agencies or acts to do the job. So we are struggling with that, but that is one suggestion we are considering. It seems to me if we go that route at least a Federal crime ought to be broad enough that it covers all the drugs that are part of the drug culture.

Mr. WOODS. We share the feeling completely in that regard.

Senator BAYH. Thank you very much.

[The prepared statements of Mr. Shinnick, Mr. Wood, Mr. Clark and Mr. Rose together with attachments are as follows:]

STATEMENT OF THE NATIONAL ASSOCIATION OF RETAIL DRUGGISTS

NARD Hearing Witnesses: Harold Shinnick, Chicago, Illinois—President, NARD; William E. Woods, NARD Washington Representative and Associate General Counsel; David Clark, Indianapolis, Indiana—Executive Director, Indiana Pharmaceutical Association, and Arkansas State Board of Pharmacy; Ivan Rose, Rogers, Arkansas—Past President Arkansas Pharmaceutical Association, and Arkansas State Board of Pharmacy; John Johnson, Bellevue, Nebraska—NARD First Vice President and President-Elect of Nebraska Pharmaceutical Association.

STATEMENT BY HAROLD J. SHINNICK, RETAIL PHARMACY OWNER AND PRESIDENT, NATIONAL ASSOCIATION OF RETAIL DRUGGISTS

Chairman Bayh and Members of the Subcommittee: I am Harold J. Shinnick and I am an independent retail pharmacist and owner of a community pharmacy in Chicago, Illinois. I appear here today with my associates as President

of the National Association of Retail Druggists. NARD is the national association in the United States representing the tens of thousands of pharmacists of the country who own and operate their own pharmacies in the neighborhoods and communities across this land.

We are most appreciative of your invitation to appear here today and applaud the work and efforts of this committee. The Controlled Substances Act of 1970 required significant and substantial changes in the practice of pharmacy, some of which our members have welcomed and others which we have accepted and endured. The independent practitioner of pharmacy has a fine record of serving the people of this country and we, like all America, were concerned about the drug abuse and misuse reaching epidemic proportions. Clearly something had to be done and the Controlled Substances Act was a bold and sweeping plan.

Therefore, NARD is particularly pleased that this committee has taken the initiative to review the implementation and effect of the Controlled Substances Act at this time to determine just how well it is working or administrative implementation of the Act. Like you, we do not have the definitive answers to this complex problem though we all wish we did. Drug abuse and misuse is still a serious issue and a serious concern and will continue to be such until we have conquered its problems and causes.

NARD has assembled a group of informed pharmacists who we believe are most knowledgeable to assist this committee in its inquiry.

Mr. Willard Simmons, the Executive Secretary of the National Association of Retail Druggists, has had a long-standing personal commitment to programs directed to the public and particularly young people to provide information and education on the hazards of drug abuse and misuse. He provided the leadership which sparked an extensive public educational program which brought vital and timely information and facts to millions of school age children, their parents, and teachers on drug abuse. Mr. Simmons, in addition to his long tenure as an independent pharmacist in his home, Texarkana, Texas, has traveled the length and breith of this nation talking with pharmacists and others, which has given him the opportunity to obtain a broad and representative view of the operation and implementation of this Act.

Mr. William E. Woods is a pharmacist and attorney who serves as NARD's Washington Representative and Associate General Counsel. He has the experience of working with the Act from the original legislative proposals, through the revisions of the implementing regulations, and in identifying and attempting to resolve legal and regulatory issues relating to the Act. Mr. Woods has borne the brunt of interpreting the legislation and regulations for our Executive Committee and members.

We also have with us Mr. David Clark, Executive Director of the Indiana Pharmaceutical Association. Mr. Clark is also a pharmacist and can provide the valuable insight of the views of an executive of a statewide organization of pharmacists and the problems and issues that concern him and his association relating to the Act.

Mr. Ivan Rose is from Arkansas where the pharmacy association and its members are particularly concerned about the rising risk of violent crimes in pharmacies related to controlled substances. In addition to being a pharmacist, Mr. Rose is a member of the Arkansas legislature and has served as a member of the Arkansas Board of Pharmacy and NARD believes that he is particularly well-qualified to assist the committee in its inquiry.

And we also have John Johnson, a pharmacist from Nebraska, who is a leader in Nebraska pharmacy association affairs and who also serves as the First Vice President of the National Association of Retail Druggists. Mr. Johnson's experience as a state leader, his fine service as an officer of NARD on the national level, as well as his reputation as an articulate spokesman, suggests that he, too, could serve as a valuable resource for this committee.

To coordinate our presentation in an effort to be most helpful and informative to the committee, we will have Mr. Woods present a statement responding to some of the issues the committee indicated were of interest to it. Thereafter, Messrs. Clark, Rose and Johnson will present brief supplementary comments reflecting their own special perspectives.

NARD has what we consider a good record of cooperation in the development and implementation of the Controlled Substances Act. And I want to assure the committee that we intend to cooperate fully with this committee and the Drug Enforcement Administration in achieving the objectives of this national

effort. However, I would be remiss if I did not also state that our members want and expect the NARD and the Congress will insist that the burdens of compliance will be strictly limited to only that which is necessary to effectuate the purposes of the Act, and no more. Our members are finding that the costs in terms of time and money of compliance with an ever-increasing system of state and federal regulation, of which the CSA is but a part, are becoming more than any individual small businessman can shoulder. Independent pharmacists typically must rely upon their individual efforts to meet *all* government regulatory requirements and frequently only with the guidance of the NARD and their state pharmacy association.

Therefore, NARD does have some suggestions and comments on some points where we believe that the views of our members deserve priority consideration and implementation to assure the pharmacists that they will not have to face the risks and dangers created by this law alone, or in vain.

STATEMENT BY WILLIAM E. WOODS, WASHINGTON REPRESENTATIVE AND ASSOCIATE GENERAL COUNSEL

The National Association of Retail Druggists appreciate your invitation to discuss the administration and implementation of the Controlled Substances Act of 1970. When first adopted, this law made sweeping and comprehensive changes in the regulatory scheme for narcotics and drugs subject to abuse. And we have every indication that narcotic addiction may have reached its peak in this country, and that abuses of non-narcotic drugs are lessening or not increasing at the alarming rate that prompted the enactment of the CSA.

When the proposals which eventually became the Controlled Substances Act of 1970 were being considered, NARD maintained that independent pharmacies were not significant sources of supply for drugs for illicit use. We believe that that was a correct assessment then as well as today. To be sure, there were abuses of drugs prescribed, but by and large this was a significant portion of the problem. To the extent that drugs subject to abuse were prescribed too often, and in abnormally large quantities, or refilled over too long a period, the CSA has brought this problem under control. The law now assures that no prescription can be refilled more than five times, and not later than six months for its date of issue, so it is assured that a prescription is not a ticket to an unlimited supply of any controlled substance for an indefinite period.

NARD believes that the present controls assure, insofar as can be done, that controlled substances that are prescribed will be utilized properly for an appropriate medical purpose. We cannot assure that an enterprising patient, either alone, or in concert with the prescriber, will subvert the intentions of the law. However, we have no evidence that this is a significant or widespread problem.

When the CSA was first adopted, and later as it was implemented, the NARD made every attempt to assure that the law was understood by pharmacists and implemented in a proper manner. We distributed detailed analysis of the regulations promulgated by the Government, prepared a quick reference chart which summarized in readily accessible form the major features of the law, and developed and produced with the cooperation of Smith, Kline and French Laboratories, a continuing education cassette that explained the requirements of the law in detail. In cooperation with the Government, the reference chart was made available to every pharmacy. And, we have cooperated in making the law workable in every other way through suggestions to the Government, including the inventory form for the biennial inventory which forms the backbone of the enforcement effort. The inventory form we suggested and insisted the Government make available reduces the biennial inventory from a major undertaking to a relatively minor inconvenience.

NARD early recognized the value of public awareness of and education on the problems and issues of drug abuse and misuse. NARD developed its first and basic drug abuse educational kit in 1967, and it included a fact sheet on abused drugs, a detailed plan for a 45-minute program on drug abuse to be given for schools and clubs, a list of visual materials available for public presentation, letters for use in soliciting interest of schools and civic groups, and public service announcements for radio and television. Various booklets available from government and other sources were also included.

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This first kit was mailed to 38,000 independent pharmacists and NARD eventually distributed about 75,000 kits which provided valuable information to local audience throughout the country.

In early 1969, NARD developed and distributed another kit titled "Drug Abuse Education Goes to School" designed for use by teachers as well as pharmacists. From this kit, thousands of pharmacists worked with teachers and principals planning assemblies, showing films, and bringing drug abuse education to millions of young people. The kit included plans for poster and essay contents on the broad subject of drug abuse, as well as specific materials to assist guidance counsellors, driver education teachers and science teachers.

NARD's public education campaign on drug abuse was one of the most massive, ambitious, and widely acclaimed public service accomplishments undertaken by the profession of pharmacy. We believe it was also one of the most beneficial programs in assisting to acquaint young people and the parents on the hazards of drug abuse.

Currently, NARD has revised its reference chart because it is still useful and in demand by the profession. Our association and its members have offered our continuing support to the Department of Justice in making the law more efficient and effective. We are pleased that the DEA recently authorized the disbursal of controlled substances inventory throughout the general pharmacy inventory consistent with NARD's suggestions.

However, we suggested further that DEA might consider some modification of the CSA Schedule identifications on the packages and labels by removing the markings from the labels and requiring that they appear on the side or back of the packages and containers so as not to be visible to robbers, burglars, and thieves. For some reason unknown to us, DEA did not comment on our suggestion or even acknowledge that we commented on the regulations in its commentary published in the Federal Register which did mention all other suggestions and comments. A copy of our submission and the Federal Register notice is attached and explains our views on its point in more detail.

NARD believes that the change in the location of the identification markings would make controlled substances inventories dispersed throughout the pharmacy's general inventory more secure and still provide maximum guidance to pharmacists and others who must rely upon the package labeling to determine the control status. We further believe that our suggestion is practical and reasonable and deserved more than to be ignored by DEA.

Another topic that NARD submits should be reviewed is the advertising and promotion of controlled substances, especially that directed to patients and consumers. The Cost of Living Council had proposed, and hopefully has now abandoned, the concept of pricing lists of prescription drug prices in pharmacies. The Food and Drug Administration is in the process of revising its regulations on reminder advertising and reminder labeling to encourage consumer advertising of prescription drugs. The Department of Justice has traditionally and continually encouraged advertising of prescription drugs and has characterized as trade restraints attempts to restrict or regulate prescription drug advertising.

Other forces are at work in the pharmaceutical industry which show great probability that advertising and promotional practices of drug firms may change radically in the next few years to where consumers, rather than pharmacists and physicians, may be the prime advertising targets for prescription drugs, particularly if the FDA proposal is implemented. We foresee a very real danger that advertising and promotional materials for prescription drugs, including controlled substances, will be published or distributed through lay media, including magazines and periodicals. And with this, there is the very real danger that interest in controlled substances among laymen will be increased. NARD submits that the Congress ought to prohibit advertising and promotion of any controlled substance directed to the general public. Retail consumer advertising showing that a patient with a prescription for 24 capsules or tablets of the controlled substance can save money by purchasing a quantity of 100 or 500, has got to increase pressures on prescribers to make these larger quantities available to their patients. Similarly, if consumer advertising, whether price is mentioned or not, touts controlled substances like every other consumer commodity, a false climate of harmlessness will be presented to the public.

Congress should now assure, before we reach a problem of urgent and critical proportions, that advertising and promotion of all controlled substances will

be limited to pharmacists, physicians, and others with a legitimate medical need or use for the information. Congress should assure that no condition exists or action is permitted which would tend to encourage the consumption or use of controlled substances beyond that quantity that is absolutely justified by medical needs. Anything that lessens the control, or encourages the prescribing or availability of quantities in excess of the amount for immediately justifiable medical needs, inevitably creates the opportunity for misuse and abuse of these drugs.

NARD fails to see, as the Justice Department apparently does, how assuring the best control of prescription drugs, and particularly controlled substances, can be considered a detrimental, anticompetitive restraint. Designating a drug as a controlled substance restricts its distribution and availability as does designating any drug a prescription drug. However, these restrictions are not considered anticompetitive but as necessary in the interest of promotion of public welfare.

NARD is also concerned over the continued relaxed attitude DEA has taken in regard to the mailing of controlled substances. Time and again, NARD has urged the DEA promulgate a regulation prohibiting the mailing of all controlled substances. Our efforts have been met with hostility and rejection, even to the extent that the government has had the gall to march forth the results of what appears to be a superficial survey of 16 pharmacies which DEA and others claim justify its position. Meanwhile, there are lay press reports of the ease of diversion of controlled substances from prescription mail-order operations and we suspect that many a bottle of controlled substances has been further diverted from the mails enroute to patients.

Assuming that prescription orders received from a distant location by a prescription mail-order operation are legitimate, DEA seems to place great faith in the postal service assuring the safe transit of the drugs themselves. Yet, a prescription drug package is easily identified by shape, markings, and size, and an easy mark for those bent on obtaining quantities for illicit uses. On the supposed but unproven economic advantage to the patient, DEA and mail-order outfits attempt to justify the practice. However, if we are to follow a policy based solely upon economic considerations to its absurd end, then we would be required to remove all controlled substances restrictions and limitations. Obviously, the Congress has already determined that the actual and potential abuses and misuses of controlled substances dictates that they be rigidly controlled, despite the economic consequences, in order to serve better over all health objectives.

In fact, perhaps the tendency we see for DEA to increase controls over certain substances by moving them to higher control schedules is a result of its relaxed attitude over advertising and mail-order distribution when these drugs appear to be unsuccessfully controlled in lower schedules.

NARD and its members are greatly concerned over the increased risk of crimes of violence in pharmacies. In the August 2, 1973 issue of the Congressional Record, Senator Frank Church (D–Idaho) cited statistics which confirmed that which practicing pharmacists already knew in less specific terms. Crimes of violence in pharmacies related to controlled substances are increasing at an alarming pace. We have with us some individuals who can give you additional information on their own areas.

Beginning with the hearings on the proposals which became the Controlled Substances Act, NARD has consistently urged that Congress provide Federal jurisdiction to enforce crimes related to controlled substances in pharmacies. Not uncharacteristically, DEA has opposed our pleas for relief and assistance.

As the CSA is effectively implemented to dry up the illicit sources of controlled substances for pushers and users, there is a corresponding increased pressure and threat upon legitimate outlets possesing quantities of these substances. Pharmacies are a primary target for those in need of drugs for a number of reasons, not the least of which is that pharmacies are open and accessible to just about every segment of the population, and are found in inner city areas when most other businesses have fled.

We do not suggest that ordinary crimes in pharmacies, like robbery and burglary, be blanketed into Federal jurisdiction. However, we do request that crimes of violence—assault, robbery, burglary, murder, and the like—involving controlled substances be subject to Federal jurisdiction. If a pharmacy were robbed and only money taken, that crime would rightly be a matter of local jurisdiction. However, if the felons clearly were motivated by the presence

of, or need to obtain, controlled drugs, evidenced by drugs being part of the booty, then we believe that Federal jurisdiction and prosecution ought to be authorized.

Congress has specifically provided that a person who manufactures, distributes, dispenses, or possesses a controlled substance with intent to distribute it, is subject to Federal criminal prosecution and penalties under Section 401 of the Act (21 U.S.C.A. 841). Similarly, if a person knowingly or intentionally acquires or obtains possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge, Section 403 (21 U.S.C.A. 843) provides Federal jurisdiction and penalties. However, if the person obtains the drugs by violence in a pharmacy, the act implies that this is of no Federal concern.

It is appropriate and necessary to simply amend the penalties sections to make it unlawful for any person to obtain, or attempt to obtain, any controlled substance through violent or other unlawful means. The increased threat of violence and crime in pharmacies is a direct result of the stringent controls imposed by the CSA. It is only fitting that the resources and facilities of the Federal government be made available to protect pharmacies and apprehend those bent on circumventing the controls of the law.

Federal criminal jurisdiction over crimes of violence and other unlawful conduct relating to controlled substances would provide for more uniform law enforcement action and punishment of violators. As it is now, punishment of drug-related crimes in pharmacies rests upon the varying provisions of state criminal laws. A Federal law would provide a sanction universally applicable in this country that would be more readily understood and heeded and more uniformly applied.

Pharmacists have become the men on the frontiers of the movement to curb and eliminate drug abuse. Our members are health care professionals, not policemen, nor experts in the art of self-defense. However, the focus of criminal activity relating to controlled substances is gravitating to the thousands of pharmacies of this country. Through no fault of their own, pharmacists have been placed in a situation where their lives and property are continually at risk.

NARD believes that pharmacists ought to be supported as they make the sacrifices which necessarily accompany this national push to reduce drug misuse and abuse. We request that the Congress consider some form of insurance, either without cost or at nominal cost, to cover the costs of the potential tragedy and risks that they face. In this manner, at least those pharmacists who were injured, or disabled, by violence associated with controlled substances, or families of pharmacists killed, would be made financially whole.

Unless some method of assuring pharmacists of greater protection from and involvement of Federal law enforcement machinery and personnel, NARD believes that pharmacists will begin to refuse to stock or handle controlled substances altogether. Such action would have serious detrimental effects on health care which none of us would welcome but there is a limit which society, just in humanistic terms, cannot expect pharmacists to exceed.

The overwhelming percentage of pharmacists in this country practice in independent community pharmacies. Too often our members feel that their needs, suggestions, and requests are ignored or viewed with hostility by those administering the law. The Federal government has shown little sensitivity or understanding of the very real problems or risks our members face. The Federal effort is apparently paying good dividends in the area of illicit and clandestine operations involving criminal elements but appears ill-equipped to deal with legitimate health care providers, the vast majority of whom are law-abiding citizens. Enforcement personnel, innately suspicious and cynical, accustomed to the challenges of criminal activity seem to carry these attitudes and perspectives into their regulatory sphere as well.

When NARD suggested that mail-order outfits might be a significant source of controlled drug diversion, BNDD (now DEA) retaliated with a study of 16 pharmacies which superficially proved the converse. The report contained apparent violations, but we and state pharmacy boards were denied access to the specifics of the study, including the names of the outlets surveyed, or even the identity of the violators. We were also denied access to the data before the agency in selecting the sample of pharmacis. Obviously, if the pharmacies surveyed were those for which complaints had been made or

for which the government had reason to believe were less than diligent in complying with the law, the results would be misleading.

NARD has proceeded on the assumption that our goals and those of the governmental agency administering the law in the area of regulating the legitimate health care system should be complimentary, a cooperative rather than an adversary effort. For our part, we have sought to assure that the legitimate channels of distribution, and pharmacies in particular, are regulated as efficiently as possible in a manner that removes to the extent possible, actual, or potential opportunities for drug diversion and deserve further consideration.

We believe that DEA has sufficient information available to it to identify pharmacists or physicians who may be improperly contributing to traffic and abuse of controlled drugs. Pharmacy suppliers must maintain records for inspection. Where these records show unusual activity, the pharmacy or pharmacies concerned have records showing the names of prescribers which must be maintained. An audit of the pharmacy records should show readily whether the abnormal activity is caused by the pharmacist or by one or more prescribers in that community.

NARD does not believe that we need any additional or further records, triplicate prescriptions, or anything else. The purpose of the elaborate records required by the CSA was to document the distribution of controlled substances. More than likely, all DEA agents would have to do is talk with pharmacists to learn which prescribes, if any, showed abnormal prescribing tendencies for controlled drugs.

Last summer, DEA published a proposal relating to the verification of prescriptions. NARD commented on those regulations in our letter to DEA dated August 3, 1973, is attached. Our position then as now is that there is no legal provision, whether contained in the regulations or statute, which cannot be circumvented with relative ease unless the provision is so onerous and burdensome as to be impractical. Credit cards are freely available to criminal elements and can be forced with little sophistication. All a drug abuser needs to do is use a name on the prescription blank for which he can furnish suitable identification. Alternatively, if the prescription blank itself is forged, the telephone number ned only be that of an accomplice who will, when called, verify the prescription as legitimate. Triplicate prescription blanks can be forged and manufactured as well as conventional forms.

We are not aware of any practical method of devising a fail-safe system to assure the authenticity of the patient named on the prescription or the prescriber signing it.

NARD believes that the provisions of the law relating to administrative inspetcion warrants deserves study, modification, and clarification. At the time the Act was considered by the Congress, the law relating to administrative inspections was unsettled. Section 510 appears to deny pharmacies and other registrants fundamental constitutional rights, particularly when it authorizes a warrant to seize certain property on a lesser standard than the Constitution requires.

We believe that pharmacies ought to be protected from harrassment and fishing expeditions under the guise of routine inspections. In all cases, inspections should be under an applicable administrative inspection warrant. The law provides ample basis for obtaining such administrative inspection warrants for any legitimate enforcement need while at the same time protecting the rights of the registrants.

Furthermore, where DEA agents know or have reason to believe that certain seizures are anticipated, such warrants should be subject to the usual constitutional "probable cause" standards. Obviously, if DEA anticipates a seizure and has sufficient information to present grounds therefor when it seeks an administrative inspection warrant, that proposed seizure should be guided by the search and seizure requirements of the Fourth Amendment, not the lesser standards of Sction 510. Specifically, an administrative inspection warrant should not be available to DEA when the objective is something other than routine, random inspections.

This inspection authority is very important. Section 402(a)(6) of the Act imposes penalties upon a registrant who refuses any entry into any premises or inspection authorized by the Act. It seems that a pharmacist who insists upon an administrative inspection warrant, or a constitutionally required search warrant, commits an offense by that very deed. Certainly this is true if DEA has an administrative inspection warrant in circumstances where the registrant believes a search warrant is necessary.

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In closing, NARD believes that the CSA is accomplishing the broad purposes for which it was enacted by drying up the illicit sources of controlled substances. However, as the major illicit sources are closed, we must give greater concern to the effects of the increased pressure upon the legitimate channels of distribution. We have attempted to outline here those areas which we believe deserve strengthening.

THE NATIONAL ASSOCIATION OF RETAIL DRUGGISTS,
Washington, D.C., August 3, 1973.

Re: DEA Draft of Proposed CSA Prescription Verification Regulations 21 CFR 306

OFFICE OF COMPLIANCE,
Drug Enforcement Administration
Washington, D.C.

GENTLEMEN: The National Association of Retail Druggists has consistently taken the position, which we firmly believe is correct, that adequate pharmaceutical services cannot be provided through the various mail-order operations. Time and again we have urged that these anomalous attempts at providing pharmaceutical services be prohibited and we continue in that effort because we believe it is correct and proper.

With regard to Controlled Substances, there is the added aspect of diversion of the drugs en route to the patient. Contrary to some misguided statements that have been publicly made, NARD has never accused veterans or the aged of being drug pushers. Our concern is directed at what happens to the drugs en route, and there is ample evidence that criminal elements do divert many articles of value from the mails and other forms of public delivery, from bank statements to drugs. There is also evidence of over-supply of CSA drugs through the mail-order pharmacies. NARD's public comments have clearly defined our area of concern on diversion, notwithstanding the deliberate and self-serving misconstruing of these statements that have been made for public consumption by others.

We continue to urge, as we have in the past, that DEA promulgate regulations prohibiting prescription mail-order operations from sending controlled substances through the mails and other forms of public delivery. The problems and issues created and the solutions are quite different whether we consider an environment in which mail-order operations are freely permitted or whether we are considering customary community pharmacy service.

In our view, the draft regulations and the whole concept of drug abuse is treated and considered primarily as one of greater policing of pharmacies and legitimate channels of drug distribution from manufacturer to patient. Beginning with the Drug Abuse Control Amendments of 1965, pharmacy has repeatedly taken the view that adequate authority exists to deal with infractions of the law and regulations without additional record-keeping and paperwork. We view the additional burdens imposed upon community pharmacists by these draft regulations as indefensible, intolerable, and ineffective.

Every time an issue of drug abuse arises, pharmacies incur additional regulation and paperwork burdens. Experience since DACA indicates that perhaps efforts to curb drug abuse have been misdirected in whole or in part. Even if the draft regulations were to become effective—and we urge that they not be adopted—drug abuse would not be eliminated and probably not significantly lessened.

Triplicate prescription orders can be forged and manufactured as well as the more customary prescription blank. It will not be very long before the regulations, if implemented, will have to be amended to place further restraints upon triplicate prescriptions and even more intricate control mechanisms.

Proposed Section 306.08 completely misses the issue of the forged prescription. If the drug abuser uses his own name, or a name for which he can furnish suitable identification, the pharmacist has discharged his legal responsibility under subsection (a). In this day when credit cards are freely available to criminal elements, and can themselves be forged with little sophistication, the fraud mode would merely change to using stolen blanks or making up bogus blanks on which the name and address of the latest stolen credit card or driver's license was available.

NARD's position is that no set of regulations can be devised which cannot be circumvented with relative ease unless the regulations are so onerous and

burdensome as to be impractical. Certainly, this result would not be in the best interest of the public with legitimate pharmaceutical needs. Costs and manpower requirement for both pharmacists and prescribers would be exorbitant.

The proposed draft regulation makes no exception for the vast majority of cases where the pharmacist knows the patient either by sight or personally. Over the years patients of community pharmacies in particular become known to the pharmacist and hence the display of any identification is not only unnecessary and superfluous, but might be taken as an insult by the patient and even interfere with patient-physician relationships. Further, pharmacists in a given community become familiar with the handwriting of various prescribers and know it without reference to or maintenance of any exemplar reference file. No provision is made for these situations. In those cases where a prescription by a prescriber not customarily known to the pharmacist is presented, it is unlikely that the pharmacist will have the required exemplar of his signature and other data required by the draft available. The only alternative in this context would be to verify the prescription by phone, and this may not be feasible if the prescription is presented after office hours, late at night, or over a weekend, or holiday—precisely the times when need for medication might be most acute.

We believe that greater control of written prescriptions could be more effectively accomplished by approaching the issue from the prescriber's side. If each prescriber had to place some distinctive stamp or symbol bearing his name or DEA number or both on the prescription order at the time it was issued, then stolen prescription blanks would be less of a problem. Obviously such stamps could not be quickly forged or counterfeited. In addition, if the symbol was in the form of a stamp or other device and it is stolen, the prescriber would immediately know it. We note that some hosptials have used a rubber stamp with the physician's DEA number and printed name to reduce fraudulent orders and with apparent success.

Further, NARD believes that greater use of present legal authority should be attempted before hamstringing either pharmacists or prescribers with additional policing regulations. A more active and aggressive enforcement of current regulations would certainly make all health care practitioners more cautious when dealing with controlled substances.

We further suggest greater educational efforts to sensitize pharmacists and physicians on the various fraud modes and means of detecting suspicious circumstances requiring close surveillance. Frequent mail contacts from DEA and use of the professional association, pharmacy board, and trade media on problems and abuse activity in various areas could be most helpful to pharmacists and provide timely alerts on possible abuse potential.

Very truly yours,

WILLIAM E. WOODS,
Washington Representative and
Associate General Counsel.

THE NATIONAL ASSOCIATION OF RETAIL DRUGGISTS,
Washington, D.C. December 5, 1973.

MR. JOHN R. BARTELS, JR.,
Administrator,
Drug Enforcement Administration,
Washington, D.C.

DEAR MR. BARTELS: The National Association of Retail Druggists is in general accord with the principles announced in the proposed revision of the physical security controls for practitioners published in the October 25, 1972 issue of the Federal Register. With the increase in the numbers of products being added to Schedule II controls, we can only assume that this trend will continue. Retail pharmacists face a quandry in deciding how to best obstruct theft, control diversion, and assure thesecurity of controlled substances in their possession.

While NARD encourages and supports the implementation of the proposed amended security regulations which would permit the dispersal of the inventory of Schedule II substances through the general inventory, we are more concerned about seeking a consensus on cooperative efforts to find a long-range solution to this vexing security problem. We are particularly con-

cerned that the preamble to the Federal Register notice describes the amended regulation as a temporary or interim measure while we look at stock dispersal as one of the most fruitful methods of efficiently and effectively seeking our common objective of controlled substance security in a pragmatic manner.

Several measures can be taken with relative ease to increase the effectiveness of the dispersal concept and we request your comments and support for each of them. NARD has been urging that the Controlled Substances Act be amended to provide that it be a federal crime to steal, or attempt to steal, in any manner (burglary, robbery, larceny, etc.), controlled substances from a pharmacy. Senator Church has proposed such a measure (S. 2327) which we support. This is no panacea, we recognize, but there is a parallel to bank robberies where the federal "rap" is a considerably greater deterrent than is the garden variety of larceny, robbery, or burglary under local state laws. Furthermore, the knowledge that federal agents are better equipped and more experienced investigators of such crimes adds a further deterrent to those who would obtain drugs unlawfully from retail pharmacies. Even without extensive use of federal agents, federal jurisdiction is well known for its curtailment of criminal activity. We would emphasize that our members throughout the United States are being murdered, assaulted, robbed, and burglarized because they are dispensing drugs controlled by a federal enactment and these pharmacists are licensed under this federal act.

It is important to recognize that we are not dealing with neophytes when we are considering large scale burglaries of pharmacies for controlled substances. These crimes could be multi-state in character and effectively organized to obtain supplies for illicit uses as traditional illicit sources become closed. Similarly, these elements who could and would pursue pharmacies as a source of controlled substances for illicit uses can be expected to have knowledge, or the ability to develop the knowledge, to circumvent virtually any physical or electronic security surveillance device within the economic means of the vast percentage of community pharmacies.

Frankly, NARD does not see any practical means of assuring the security of controlled substances in a pharmacy 24 hours a day, 7 days a week, 52 weeks a year, even given the sophisticated internal surveillance and internal and external alarm systems available today. The unheeded clanging of burglar alarms until a police officer happens upon the scene in routine patrol in urban centers is all too common these days. Certainly such alarms might not even be heard and be much less effective in sparsely-populated areas where community pharmacies predominate. The hidden criminal in a store steals CSA drugs, "breaks out," and is gone regardless of an alarm.

We have no evidence that the considerable economic cost of these systems effectively increases the security of controlled substances in pharmacies when pitted against determined and often desperate men. We suspect that the increase in effectiveness is marginal at best.

Requiring safes and strong boxes in every pharmacy is equally uncompelling as a long-range solution. The high initial cost of such a security device large enough to store the inventories of today's Schedule II drugs with a margin for expansion is a significant factor to be considered. Equally important from our view is that consolidating in one place the supplies of the most potent and most sought-after controlled substances with highest potential for abuse in the pharmacy would encourage, not discourage, burglaries. If potential burglars need only to identify the strong box or safe in a pharmacy and concentrate on removing it as a unit, or penetrating its interior, the whole cache of controlled substances can be more effectively and efficiently purloined. While stealing away in the midnight hours with a safe in tow in an urban setting is not improbable, it is highly probable in a rural or suburban area, and once removed the safe can be opened leisurely and in relative safety at a location less susceptible to detection.

As pressures mount because of increased surveillance and difficulty of obtaining controlled substances in urban areas, those seeking controlled substances will seek out the rural and less populated areas as targets. Ironically, these more remote locations will more likely be sources of greater supplies because their remoteness necessarily requires larger inventories.

When CSA regulations were first proposed, we urged that labels show the schedule of the products. We would now recommend the removal of the schedule markings required by Sections 1302.03 and 1302.04 on the outer containers, at least on those controlled substances that have been in their

respective schedules for a reasonable period of time. The schedule control symbol could still appear on the container itself, but not on the front panels. They might be placed on the back panel of the label. Present regulations require the schedule markings to appear on the front of the dispensing package and this was necessary and beneficial in the transitory period.

Dispersal of the inventory of the controlled substances throughout the pharmacy inventory we believe to be the most effective means of obstructing large scale theft of controlled substances. Because of the variety of inventory stocking systems, alphabetically, by firm, by dosage form, etc., employed in pharmacies, there is no consistent pattern for a thief to follow after gaining entry. However, with the clear markings showing CSA schedules in bold type on the front label panel of all containers, the thief need only seek out all packages which show the large II, III or IV on the face. With such markings camouflaged, either by exposure to the pharmacist only after removed from the outer carton on the shelf, or by looking at the back panel or the top of the container closure or screw cap, this ease of identification for the thief is removed. He would then have to know exactly what drugs, by name, were in the various schedules and once knowing that, locate those drugs in the pharmacy's inventory.

Any pharmacist who has ever worked parttime in several pharmacies, or who associates himself with a new employer, will attest to the fact that the individual idiosyncracies of pharmacy inventory stocking systems defy resolution without a full explanation. If stock dispersal can present such a substantial obstacle to a knowledgeable pharmacist, it must present an overwhelming obstacle and immense frustration for those seeking to identify and remove surreptitiously or clandestinely controlled substances from a pharmacy.

In conclusion, the NARD has recommended dispersal of CSA substances since the CSA act was first proposed and we commend the Drug Enforcement concern with improving security measures and assure you of our desire to cooperate in effectuating reasonable controls that will prevent diversion of CSA drugs, we feel DEA should demonstrate greater interest in the rapidly escalating number of crimes committed against retail pharmacies. The NARD officers and members of Congress are receiving more newspaper clippings and reports from local and state pharmaceutical association officers and executives on crimes against pharmacies than on any other subject today. Since most of the atrocious and heinous crimes are related to CSA drugs, we are most disappointed that DEA is opposing the bills in Congress aimed at the criminal activity that is endangering the lives of our members and their customers—the public—throughout the United States.

Sincerely,

WILLIAM E. WOODS,
Washington Representative and
Associate General Counsel.

ARKANSAS STATE BOARD OF PHARMACY,
Little Rock, Ark., December 11, 1973.

Mr. WILLIAM E. WOODS,
Washington Representative,
National Assoc. of Retail Druggists,
Washington, D.C.

DEAR BILL: In answer to your December 3 correspondence I have no objection to your use of the materials in any way you please. In answer to your latter question, I am sure that there are many avenues that need to be considered regarding prescription drugs being sold through the mail. Many of these things have already been tried and, as you stated, do not seem to be working. What I will mention may not be new to you because you have been much abreast of the mail order situation; however, in our case the Pharmacy Board in our state, and I suppose in most others, was set up for one purpose—to assist in the protection of public health and welfare. It was and still is my intention to look at the drug situation from that standpoint.

In regard to the mail order prescriptions, our attorney, Eugene R. Warren, and myself, before mailing fake prescriptions to out-of-state mail order houses, did the same type of mail order program on retail pharmacy outlets all over the State of Arkansas. Out of the 600+ retail stores we purchased by fake prescription some 22 purchases. The pharmacists who filled these prescriptions

without determining that there had actually been a physician-patient-pharmacist relation were called before the Board and received some type of disciplinary action. Only when we had cleaned our own house, so to speak, did we mail these fake prescriptions to mail order houses scattered about the country. We did, as you know, obtain many drugs, including some Schedule II drugs, and could have obtained no telling how many more had we not felt that we had obtained the necessary evidence to prove how easy it was to obtain prescription drugs with fake prescriptions from mail order houses.

It seems that most of the articles I have read, as far as advertising by these mail order houses, indicate a terrific monetary saving. It appears to me that this is taking advantage of the poor, indigent people in many cases rather than assisting them as is claimed. In one incident we noticed a publication in a church bulletin claiming to be Pastors' Prescription Service. The prescriptions filled as a result of this type of advertising, which claim to save these people as much as 40 percent, seem to come from the same mail order prescription house that probably would start a William E. Woods Prescription Service if he so desired for whatever group he claimed to represent.

We contacted several persons by phone. Many of them admitted to us that they had not compared local prescription prices but, as a result of reading what might be false and misleading advertising in such journals as "Retired Persons," veterans journals, church journals, and others, had simply mailed their prescriptions to these people. A telephone survey to retail outlets throughout the State of Arkansas found that a prescription for 50 pills from one of the mail order concerns was actually $1.50 more than these same pills could have been purchased at some local pharmacy.

If I can be of any service to any organization who desires to prevent this type of prescription legend drug sales, I will be glad to correspond with them. I feel that this type of advertising, in addition to being a type of professional rape, in so many cases is taking advantage of poor, indigent rural people, who have had no chance to compare the socalled price savings with other pharmaceutical services offered.

Sincerely yours,

WOODROW T. LITTLE.

ARKANSAS STATE BOARD OF PHARMACY,
Little Rock, Ark., November 28, 1973

Mr. WILLIAM E. WOODS,
National Assoc. of Retail Druggists,
Washington, D.C.

DEAR BILL: I certainly can appreciate your concern over the mail order prescription business. Enclosed you will find statements where I have purchased controlled substances from one particular mail order house that continues to send me statements. At the same time purchases were made from this mail order outfit several were made from other mail order houses out of state. The Pulaski County Grand Jury has indicated three pharmacists from out of state mail order houses, but it appears doubtful at this time that we can force them to stand trial.

Also enclosed you will find an identical type of prescription from which these drugs were purchased, it being, of course, a complete hoax. There is no Dr. H. H. Chandler. H. H. Chandler is a friend of mine with the Handwriting and Document Division of the Arkansas State Police. Mrs. Nancy Henry is simply a cooked up name that, so far as we knew at the time of writing, there was no such person in the State of Arkansas. Ferndale, Arkansas, was a set-up situation, it being a small community some 15 miles from Little Rock, and arrangements were made with the postmistress to forward to my office deliveries made to that small postoffice for either myself of Mrs. Nancy Henry. I do not know at this time just how many purchases were made over a period of some three years. However, at the time we were sending out these fake prescriptions it appeared we could have purchased any amount that we asked for. Most of the purchases made were turned over to the State Attorney General's office and, as far as I know, they are still in his possession.

I thought perhaps the enclosed statements could add to proof you already have that this practice was certainly not in the best interests of the health and welfare of the citizens of our country.

Sincerely yours,

WOODROW T. LITTLE.

TESTIMONY OF DAVID A. CLARK, EXECUTIVE DIRECTOR, INDIANA PHARMACEUTICAL ASSOCIATION

Senator Bayh, members of the committee, I am David Clark, Executive Director of the Indiana Pharmaceutical Association. I would like to thank you for giving me this opportunity to share some of our Association's thoughts with you.

The pharmacists of Indiana are entrusted with the responsibility to safeguard and judiciously dispense controlled substances in accordance with the rules and regulations as set forth in the Controlled Substances Act of 1970.

As you well know, there is no other commodity on earth subject to more controls than narcotic and Controlled Substances. Because of the potentially dangerous nature of these drugs, if misused, pharmacists have for many years been faced with the almost heroic task of keeping up with the many changes in laws, rules, and regulations promulgated concerning these drugs.

One effect of the Controlled Substances Act was to seemingly diminish the ready access to the so-called street drugs. This decreased availability led to an increased number of robberies and burglaries of pharmacies that continues to worsen each day.

In gathering information to document this last statement, our office obtained the following figures from the Indiana Office of the Drug Enforcement Administration in Indianapolis. During 1971 there were fifty robberies or burglaries of pharmacies in Indiana involving controlled substances reported to D.E.A. In the following year there were 91 robberies or burglaries of pharmacies in Indiana involving controlled substances, or an increase of 82% in just one year after the enactment of the Controlled Substances Act. The very next year the number rose to 109 for a total increase in Indiana in two years of 118%. An increase of these of these proportions surely could not be a coincidence.

The pharmacists of Indiana are not panic striken, because they have always ben subject to a certain amount of risk, intimidation, and abuse by drug addicts. We are, however, very concerned with the rate of increase in the number and brutality of armed robberies committed in the past years. I have previously provided your committee with press clips recounting some of the cases I referred to previously in this statement. I would like to cite one particular instance and quote from the newspaper articles related to this case.

The following is excerpted from the evening edition of the Indianapolis News, September 17, 1973.

Front Page Headlines:

"Pharmacist Slain When 2 Hold Up Northside Store."

"A 73 year-old pharmacist was shot and killed today in a holdup at a Northside drugstore.

"Police said William D. Knox, 6046 Broadway, who had been employed at the Norwaldo Pharmacy the last 13 years, was pronounced dead at the scene.

"Investigators said two men, one armed with a handgun, entered the pharmacy on the northwest corner of Norwaldo and 46th Streets, about 10:15 a.m.

"An unidentified cashier said the robbers made her and Knox and two women customers lie on the floor while they went behind the prescription counter and rifled drawers and cabinets, apparently searching for cash and drugs.

"She said Knox was lying on the floor behind the prescription counter and one of the men suddenly shot him in the chest for no apparent reason.

"After he was shot, Knox kept repeating, "Oh my God, oh my God," until he lost consciousness and died."

We know that this kind of tragedy will always be a possibility, however, we are seeking your help in finding methods to minimize the occurrence of these crimes.

We were quite pleased with the recent regulation which allowed pharmacists to disperse Schedule II drugs throughout the non-controlled inevntory. This will go a long way to minimize the quantity of these drugs stolen as a result of burglaries. We would further recommend that serious thought be given to prohibiting the mail order distribution of all schedules of controlled substances. We feel this would further lessen the possibility of diversion of these dangerous drugs.

In conclusion, Gentlemen, I wish to offer the services of the staff of the Indiana Pharmaceutical Association and its members in any fact finding venture this committee might like to conduct to determine how best to ensure that only those with legitimate need have access to controlled substances.

Thank you.

PREPARED STATEMENT BY IVAN ROSE, OWNER OF RETAIL PHARMACY, ROGERS, ARK.

It is a pleasure for me to come from Arkansas and appear before this committee to express my feelings on the drug-related crimes we are experiencing.

Just last month the pharmacists of Arkansas were dramatically reminded that we are the ever-growing targets of "drug freaks" and "drug addicts" who are finding that traditional sources of illicit supplies are drying up. Each of our pharmacists in community practice must live and practice with the realization that today he may be "hit" for his inventory of controlled drugs and money and may even lose his life as did my neighbor pharmacist. He was called to his store in the early morning hours and after opening the safes where the drugs and money were he was shot from behind. This did not happen in some big city and too often it is the small town pharmacy that gets hit.

In the past year, two of our pharmacists have lost their lives, and seven were injured in 144 drug-related armed robberies in Arkansas. These are not just ordinary robberies but robberies because pharmacies possess something that other establishments do not have—controlled drugs which can be used to satisfy and sustain a habit for a short time.

Congress has made clear its determination to eliminate the illicit trafficking in narcotics, stimulants, and depressants. Congress has recognized the problem but inadvertently may have failed to recognize that as its federal program became increasingly effective, tremendous pressure would be placed upon the legitimate sources of controlled substances. Maybe you have failed to recognize that the drug abuser is often erratic, unpredictable and even desperate in seeking out a means to satisfy his needs.

The result is that pharmacists in Arkansas and throughout the country find themselves ill-equipped to defend themselves in this new environment. Our pharmacies are widely dispersed, open holidays, weekends and late at night to serve the legitimate health needs of the community. I find it necessary for the protection of my customers as well as myself to ask the police to go with me on any after-hours calls.

We desperately need some protection and help if we are to continue to serve the pharmaceutical needs of our communities fully and adequately. A weapon in the hands of a nervous and drug-starved abuser invites certain death at the slightest provocation or just because the drug take is not as great as it might be. Too many pharmacists have already sacrificed their lives in this cause and we in Arkansas plead for your help.

We need a law that will make stealing or attempting to steal controlled substances from a pharmacy a federal offense. We know that a federal "rap" is a considerably greater deterrent than is the garden variety of larceny and robbery under local state laws. Furthermore, the knowledge that federal agents are better equipped and more experienced investigators of such crimes adds a further deterrent to those who would obtain drugs unlawfully from retail pharmacies.

I would emphasize that our pharmacists in Arkansas and throughout the United States are being assaulted, robbed and burglarized because we are dispensing drugs controlled by a federal enactment and we are licensed under this Federal act.

Our alternative is simply to refuse to stock or dispense controlled substances and post public notices to that effect. This would be a hardship to the public and pharmacists but it should remove the threat that each day a pharmacist opens his door to serve the pharmaceutical needs of his community he may be the victim of a drug-crazed individual and another statistic.

Gentlement we need your help in sponsoring appropriate legislation such as SB2327 by Senator Frank Church. Won't you help the pharmacists of your community?

[Additional correspondence from NARD was marked "Exhibit No. 3", and is as follows:]

EXHIBIT NO. 3

THE NATIONAL ASSOCIATION OF RETAIL DRUGGISTS,
Chicago, Ill., April 5, 1974.

HON. BIRCH BAYH,
Chairman,
Subcommittee to Investigate Juvenile Delinquency,
Committee on the Judiciary,
U.S. Senate,
Washington, D.C.

DEAR SENATOR BAYH: On behalf of the officers and members of the National Association of Retail Druggists, I wish to express our appreciation for the courtesies shown our organization by you and members of your staff during our recent appearance before your Subcommittee on Juvenile Delinquency at the oversight hearings on the Comprehensive Drug Abuse Prevention and Control Act of 1970.

We certainly wish to compliment you on your sincere concern over the drug abuse problems in the United States and to encourage you to continue to examine the legislation, regulations and programs related thereto. I can assure you the NARD wishes to be responsive to the needs of your committee concerning this nationally important subject and will cooperate with you in every way possible to eliminate the drug diversion and drug abuse schemes that have plagued this nation for so many years.

In reviewing in my own mind the penetrating questions raised by you during the hearing and considering problems brought to our attention, it would seem to me that the committee might consider three restrictions which would eliminate many of the drug abuse problems. These are briefly stated as follows and, of course, we would be glad to provide any additional information needed by you or the committee:

1. Statutory prohibitions against advertising CSA drugs in newspapers or through the mails.
2. Statutory provisions against physicians prescribing CSA drugs in quantities exceeding the patient's needs for 30 days.
3. Statutory prohibitions against mailing CSA drugs.

These three suggestions are in response to concern expressed during the hearings about diversion or illicit traffic of CSA drugs.

In addition to the foregoing, we would again emphasize the unbelievable amount of crime against retail pharmacists because they are handling these federally-controlled drug products. Since the enactment of the 1970 Comprehensive Drug Abue Prevention and Control Act, it is doubtful that any subject has had more attention in mail received in the NARD Chicago and Washington Offices than this subject of crime against pharmacists—such as robberies, burglaries, assaults and murders, all related to CSA drugs.

Anything that can be done to bring about enactment of the Churchill bill S. 2327, or the Nix bill H.R. 5976 with its approximately 50 cosponsors, will mean much to our membership and the 15 million customers passing through these stores daily who are subject to the possibility of being injured during the commission of these crimes in drugstores. Should your committee decide that some variations of this proposed legislation is necessary, we will gladly support any proposal that will accomplish the same results.

Senator, we are of the opinion and we are greatly concerned that DEA's expressed willingness to only survey the matter is an inadequate response to our request and would not provide the relief sought by 120,000 pharmacists and their customers.

Again, we wish to thank you for the many courtesies shown to us during the appearance before your committee, and we assure you of our cooperation at all times.

You have our best wishes.

Sincerely,

WILLARD B. SIMMONS,
Executive Secretary.

Senator BAYH. Our next witness is Mr. Robert Bolger, the president of the National Association of Chain Drugstores, accompanied by Ed Spearbeck and Michael Zagorac. Gentlemen, we appreciate your being here.

STATEMENT OF ROBERT J. BOLGER, PRESIDENT, NATIONAL ASSOCIATION OF CHAIN DRUG STORES, ACCOMPANIED BY EDWARD SPEARBECK, VICE PRESIDENT, PROFESSIONAL RELATIONS, DRUG FAIR, AND MICHAEL ZAGORAC, JR., VICE PRESIDENT, NACDS

Mr. BOLGER. Thank you.

I am Robert J. Bolger. As you indicated, I have with me on my right Michael Zagorac, Jr., vice president, NACDS, and on my left is Mr. Edward Spearbeck, vice president of Drug Fair, who is operating 156 stores.

We appreciate this opportunity to present our views on the adequacy of Federal drug control laws and their impact on pharmacy.

The National Association of Chain Drug Stores (NACDS) represents the management of 228 chain drug corporations throughout the United States. Our members operate approximatley 9,000 drugstores in addition to 1,500 pharmacy leased departments. Within our membership we have the largest and the smallest chain drug corporations in the nation for our basic membership criteria is that each member operate at least four pharmacies or prescription departments. More than half of our membership would be considered small businessmen.

As providers of the major portion of the Nation's drug products and pharmaceutical services, we are indeed interested in the work of this subcommittee. Since the enactment of comprehensive Drug Abuse Prevention and Control Act of 1970, we believe the Federal agency charged with the implementation and the administration of this act has done a commendable job. Over the past few years this agency's professional and dedicated staff has accomplished the impossible task of organizing and administering our Nation's dangerous drug control laws. Our association and our members have worked closely with the agency to ensure our full compliance with the law and regulations. Many times we have not agreed with the agency's actions and have vigorously opposed policies and regulations which we believe would be detrimental to the pharmacy services, drug control and the American public.

For within our Nation's drug distribution system the pharmacy and the pharmacist have a key responsibility. As the last link in the drug distribution channel the drugstore, through the services of a pharmacy, provides prescription medication—controlled and noncontrolled—to the American consumer. In order to provide these drugs and services to the American public the pharmacist has found an increasing regulation of his business and practice by Government. With the 1970 law an even greater paperwork burden was placed upon him. Concurrently, with heightened public awareness of drug abuse, he became a target for those persons who saw him as a potential source of drugs, cash, or merchandise.

The problem of burglary, theft and armed robbery in pharmacy is serious. As one DEA official stated: "The drugstore of today is all too frequently a combat zone within which robberies, burglaries, assaults and even killings are becomig commonplace." Some of the hair-raising episodes and tragedies many pharmacists have experienced are only now coming to light; and unfortunately, the future doesn't appear to be changing for the better. For "while oher types of businesses also find themselves caught up in this undeclared war, the pharmacy is particularly vulnerable because of its controlled drug stocks. As enforcement efforts continue to be more successful in reducing both the quantity and quality of street drugs, the vulnerability of the pharmacy as an alternate source of supply increases."

Drug Enforcement Administration statistics, very similar to what you had said earlier in the beginning of this hearing, give us one perspective of the problem. In 1972, there were 5,065 drug thefts involving 64 million dosage units reported to DEA. In 1973, thefts increased some 25 percent to a total of 6,974. These statistics are along impressive but further examination reveals a bleak situation within pharmacy. That is, in July–September 1972, pharmacy thefts accounted for 49 percent of the total. From October–December 1972, pharmcy thefts has increased to 65 percent of the total. In 1973, the figures has jumped dramatically to 81 percent of all thefts. The one bright spot in this statistical picture is that the total number of dosage units involved has been dramatically reduced by 50 percent of the 1972 figures. Nonetheless, it clearly points out the explosive theft, burglary and armed robbery situation in pharmacy.

Up to this point, the crime problem within pharmacies has been primarily one of theft, but we do believe that armed robbery of pharmacies is also increasing. And we do not wish to put our pharmacists, employees or customers in any life-threatening situations. I am sure that this committee as well as the responsible Government agencies have an extensive file on the horror stories and tragedies concerning pharmacy theft and robbery. I can only say that our own members' experiences would further substantiate these experiences.

In response to this growing problem remedial legislation has been introduced in the Congress. Basically, these measures would impose a Federal penalty for robbery or attempted robbery of controlled substances from a pharmacy by force, violence or intimidation. The bills provide for penalties of a $5,000 fine and/or 10 years in prison. We are indeed fortunate to have some members of Congress recognize the problems facing our Nation's pharmacies. But while they are a step in the right direction, we are not convinced that they go far enough to effectively deal with the problem.

We believe that the Federal Government should impose stricter penalties upon those who perpetuate burglary, theft or robbery of a pharmacy to gain controlled substances. This legislation will serve as a basic deterrent and assist the pharmacist in his struggle to combat drug related crimes in his community. But more importantly, since the Government anticipates that the new Federal

restrictions and tighter security placed upon other sources of controlled substances will generate an even greater pressure upon the retail pharmacy, the Federal Government should recognize its impact and aid pharmacies in meeting this challenge.

We believe that drug related crimes in pharmacies should not be limited to those of force and violence but must include theft, and burglary, which is unlike the NARd position. Only in this manner can the pharmacist and pharmacy be assured of some measure of protection through Federal enforcement efforts. It is simply unfair to expect drugstores to bear a greater burden and risk for drug control without additional Federal protection.

Moreover, most crimes dealing with controlled substances at pharmacy level are left to local authorities under the present law. Aside from the fact that there is no uniformity in the manner in which drugstore crimes are treated at the local level, it does not appear to be a priority item for the Federal agencies involved. The Drug Enforcement Administration has indicated that it does not have the manpower necessary to investigate and act on the local level. Although some effort is being generated through the support of drug investigative units with the use of LEAA funds, there are a few States in which these units are really actually operating.

As we view it, the laws place pharmacies in a delicate and dangerous position. And although most pharmacists as well as their management have accepted the requirements of the law and cooperated to do their part, what we now need is some positive action upon the part of the Federal Government to insure that its efforts to close off channels of drug diversion do not send hoards of addicts, pushers and other criminals into the Nation's pharmacies. This would severely disrupt the primary role of the community pharmacy of providing necessary medications to the public.

With Federal assistance the pharmacies and pharmacists can better assist law enforcement officials in identifying drug law offenders as well as providing the necessary evidence for prosecution of offenders. But there appears to be little incentive to provide such information as most offenders are not brought to justice. Furthermore, a pharmacist cannot be placed in a position of jeopardizing his relationship with a medical practitioner or a customer. He can produce the records he is required to maintain by law, but he cannot enforce the law: this is the responsibility of the authorities.

Too many times in the past pharmacists have been left "holding the bag" in their efforts to assist law enforcement officials. Hopefully, stricter Federal laws will overcome these problems by providing for greater involvement by Federal enforcement officials.

Pharmacies are doing their part attempting to meet the increased number of robberies and thefts. Many stores have upgraded their security systems by installing alarm systems, further restricting access to controlled substances storage areas, reducing inventory of controlled substances as well as setting up monitoring programs for controlled substance purchases at store level. These are actions that our members have taken across the Nation. In addition, we strongly support the strengthening of the law to eliminate practitioners, pharmacies and other registrants who violate that law.

Although many of our members have taken these measures there is a limit to the physical security safeguards a pharmacy can institute. We would hope that the day would never come when a pharmacy would be turned into a fortress containing vaults, iron bars or other security safeguards. We would hope that drug abuse or drug control aspects of pharmacy practice would not have an overbearing influence. For a pharmacy's primary purpose within the community is to serve all customers in need of prscription medication and pharmaceutical services. This primary purpose must be preserved just as control drugs must be protected.

Another area of concern is that of prescription fraud or forged prescriptions. Last year the Drug Enforcement Administration released a report entitled "Project Script." This survey was the first phase of a three-part study which would determine vulnerability, frequency, and alternative solutions to the problem. To our knowledge the agency has only conducted the first portion of this study.

The problem of the forged prescription is not new to pharmacy. If anything, the impact of the Controlled Substances Act has increased the pharmacist's awareness of this valuable role in the drug control effort. We believe that pharmacists do screen prescriptions, especially controlled substances, in a very conscientious and professional manner. Although many people believe that forgeries of this nature are in the increase, we are not aware of any information to substantiate this. We would agree with the conclusion drawn from the DEA study:

> While we would prefer to see a complete preclusion of the facility in prescription fraud, that goal is probably unobtainable. Hence, we do not yet know what is practicable, acceptable level of prescription fraud perpetrations.

If the pharmacist does not know the patient, there are several methods by which he can assure himself that the prescription is bona fide. He may question the patient, he may call the physician, or he may even request further identification from the patient. The method utilized depends upon the individual circumstances. Therefore, the adoption of any arbitrary, cumbersome method of verifying prescription for a controlled substance should not be instituted by the Federal Government. In critiquing "Project Script" last year, we recommended that representatives of pharmacy, medicine, and consumer groups be convened by DEA to discuss the problem and its solution.

Although we do not support a requirement that pharmacists verify the identity of all patients with prescriptions for controlled substances, we do agree with the practice of requiring pharmacists initial all prescriptions dispensed by them. In several States this is a legal requirement while in others pharmacists perform this as a means of professional practice.

One possible solution to the fraudulent prescription problem is to implement a triplicate prescription system for drugs listed in schedule II. Several States have already implemented such systems with varying degrees of success—Illinois, California, New York. In working with DEA we have requested that a study of the various systems be implemented to that we can better determine whether or

not utilization of a triplicate prescription form would be a viable solution to the forgery problem. Since a system of this nature may require an amendment to the existing law, we would hope that this subcommittee would also encourage the agency to provide this data.

In our preceding comments we have dealt primarily with some of the pertinent drug control issues.

Senator BAYH. Will you excuse me, please.

Mr. BOLGER. Yes.

Senator BAYH. I will ask my chief counsel, Mr. Rector, to sit and preside. I have three or four questions for him to ask. I will get back as quickly as I can. You are busy. The other witnesses are patiently waiting. I am accustomed to going without lunch or eating at various stages, hot and cold. This is not the kind of liability I want to impose on anybody else. Why don't you go on and I will be back as soon as I can. Perhaps you will be through by the time I get back.

Mr. BOLGER. Thank you.

In our preceding comments we have dealt primarily with some of the pertinent drug control issues. One area which we are greatly concerned with does not fall directly into any of these categories. At present the law only provides that pharmacies will be granted DEA registration upon licensure by the appropriate State agency. Thus, once a pharmacy is licensed and given a permit number by the State agency, DEA will then issue its registration. We would hope that this present DEA procedure for registration of new pharmacies could be improved to permit concurrent DEA registration with State pharmacy licensure. Since the enactment of the Controlled Substances Act many pharmacies have not received the required DEA registration materials until several days after the pharmacy has been opened. In these cases the pharmacies were forced to open without the necessary stock of controlled substances and unable to adequately serve the public.

Although Drug Enforcement Administration has been most helpful in modifying its present registration methods and procedures to help alleviate this problem, there are still many instances in which drugstores must open without appropriate controlled drug stocks. We have suggested a method by which this registration could be received concurrently with the State permit with little chance of fraud or diversion. We hope that this subcommittee will further inquire as to how the registration of new pharmacies may be improved.

In conclusion we hope the committee will give further consideration to legislation which will provide for stricter penalties for both robbery, theft, and burglary of controlled substances from drugstores. The impact of the Federal drug control effort has been to increase the pharmacies' risk within the distribution channel: Therefore, we believe the pharmacy problems should be given a higher priority within the major enforcement agency.

Second, while pharmacies should be encouraged to improve their security, we hope that the physical security required at a community pharmacy will not make it an impregnable fortress to the millions of consumers who visit our stores for prescription medications and many other essential items.

Third, we believe that the question of forged prescriptions is one of great concern to pharmacy as well as to Government. Initial surveys have indicated that pharmacies are vulnerable to such fraudulent practices. We would hope that simple incumbered systems of meeting this problem could be developed once we have a full understanding of how widespread the practice is.

Fourth, we hope that the registration of new pharmacies will be improved and hope that provision will be made in the law which will permit concurrent registration of drugstores with their State permit.

And lastly, we hope that the DEA will be encouraged to set up a committee of representatives from pharmacy, medicine, and consumers to discuss all problems relating to availability of controlled drugs to the American public.

Mr. Chairman, we thank you.

Mr. RECTOR. I think because of time limitations we will ask three or four questions and submit supplemental questions, if that is all right with you.

With regard to the Church bill, we were intending on expanding it to include other than narcotic controlled substances. We gather that you are in accord with moving in that direction?

Mr. BOLGER. We would be in accord with that.

Mr. RECTOR. There is some ambiquity in the bill. It refers in part to narcotic substances, and there are a number of other ambiquities in the bill. We are interested in strengthening the bill and clarifying its impact and anything you can do to assist us in that manner we would appreciate.

Mr. BOLGER. We would be in support of that, Mr. Rector.

Mr. RECTOR. We are particularly interested in your concern that that pharmacist not be put in a circumstance where he or she would jeopardize relationships with a practitioner. Naturally there is a personal relationship between the pharmacist and physician who make use of the particular pharmacy. But what, additionally, can pharmacies do with regard to doctors, practitioners who are either distributing improperly or perhaps even illegally? Is there any obligation on the part of the pharmacist to bring this to the attention of law enforcement officers or medical society or what have you?

Mr. BOLGER. There is no question about that. We meant in that particular part of our testimony that the areas of theft, armed robbery, and burglary that the pharmacist is the only one to protect himself. What I am saying in answer to this question—Mr. Spearbeck, could you call physicians up and bring this to their attention?

Mr. SPEARBECK. Yes, this happens routinely. We do contact them, but I think, basically, the one thing we keep running into in this is where we are put in the position of being the enforcer. We are, indeed, fulfilling the professional obligations of pharmacy, but we are also the enforcers of DEA, determining this, and then going to the physician and determining it, too. Somewhere we should break that chain. We shouldn't have all that responsibility.

Mr. RECTOR. Isn't it true in many respects State boards of pharmacy and other similar organizations have similar responsibilities

with regard to enforcing the 1970 act? I think that in a good number of States there are memoranda of understanding with regard to enforcing the act. We weren't talking so much about armed robberies and assaults and that sort of thing. We are talking about the more subtle problems that occur from time to time where you have physicians who are either improperly prescribing or physicians who are prescribing illegally. They are relatively rare in most communities, but a couple of bad apples in a barrel can cause real problems. We have seen communities where one or more doctors have cranked out amphetamines like they are going out of style while filling their pocketbooks at the same time. We are concerned about dealing effectively with those types of problems.

Mr. ZAGORAC. One problem, Mr. Rector, you are correct. We have attempted to deal with this problem. We have provided this information to the local authorities and in many cases to the State authorities, but they do have problems in actually trying to bring convictions.

One experience that I think is rather commonplace is that the authorities will come in and ask a pharmacist to help them by continuing to dispense prescriptions so that they can build their evidence against a physician, et cetera. In many cases the pharmacist has been left, after they have attempted to do something with the physician, sort of holding the bag and that physician knows that the data has been gathered from a specific store and so then he refuses to use that store.

Mr. RECTOR. There is no followup in the law enforcement end of it? When you refer to "holding the bag" or when you have not made particularly happy the physician that you have reported what do you mean?

Mr. ZAGORAC. The other part is in many cases a law enforcement official would say we would like you to, in the case of a physician who may be over-prescribing or something, not to dispense or cut down on the prescriptions that you will dispense for patients of this physician. While they may want us to do that under the Controlled Substances Act, there are such laws as libel, et cetera. Physicians just contact their attorneys and they call our pharmacists and our members and say you have no right to tell my patients that their prescriptions cannot be filled.

Mr. RECTOR. I believe a number of States have limited the dosage units per prescription, and that can cause, of course, an increase in cost and a lot of other complications. Perhaps that is not necessarily the best way to go, either.

In any case, we had a couple of other quesions. You have commented that most offenders commiting crimes against the pharmacist are not typically brought to justice. We would like you to elaborate on your thoughts as to why that is the case. Is it a problem with law enforcement? If so what can we do to facilitate enforcement?

Mr. BOLGER. When the local authorities have the responsibility in this particular area, our members have experienced inconsistency across the board in determining who is a priority person to go after. That is why one of our strong points today was to get increased appropriations or what, so that the Federal DEA people

have the responsibility for this particular thing in the pharmacy. We found there is a real wide variance of who the local authorities will go after to prosecute. Our experience has not been very good over the last couple of years in talking to some of our members of people being prosecuted in areas that may not be for nonviolent crimes.

Mr. RECTOR. I would think that many Senators would initially want to see what can be done to facilitate the local and State effort. I think the predominant view of Federalism would lean toward State and local law enforcement efforts in these cases.

I have seen the comments from the Justice Department on the Church bill, and that is one of the issues they raise. Another issue is the cost. They estimate, based on the number of felonies committed against pharmacists, that 175 additional officers and personnel to support them would be required. It would also take an annual appropriation of $5 million. So in this time of special concern about economy, when you talk about $5 million you will definitely be asked what is happening on the State and local level.

Mr. BOLGER. I think it is too early to have any experience on how effective the task force groups have been. Is that what you are probably alluding to?

Mr. RECTOR. They didn't make specific references to the task force special units, but I am sure that was implicit in what they were saying: "let's give this a chance to see what yield comes from those effort."

Mr. ZAGORAC. One other point that may be of note is that in picking up an offender who has, let's say, robbed a pharmacy, either armed robbery or burglary or something of that nature, this may not be as high priority as breaking a local drug ring or catching someone who has just hijacked a big truck or something of that nature. In this case of a small, in comparison, a small quantity of items. This is what our problem is. While we have a great number of stores, they are usually small quantities in relation to the other types of diversion that are taken, and it doesn't seem a high priority problem.

Mr. RECTOR. We are appreciative of that problem. There is apparently a preference for the "French Connection" type of case.

We had one last question. What has the experience of your members been regarding shipments lost or stolen from suppliers?

Mr. BOLGER. From our membership standpoint that has been practically negligible. I have heard in the last couple of years maybe one or two cases from some major pharmaceutical manufacturers to chain drug warehouses and the people had been apprehended.

Mr. SPEARBECK. Very minimal in his company.

Mr. BOLGER. But we would generally get this information if it was growing to any significant amount. I am referring to a couple yeares ago where several of our large pharmaceutical companies had truck diversions to warehouse or didn't show up, and that was about three years ago in the Northeast area.

Senator BAYH. Thank you very much, gentlemen. Again, I apologize for the dilemma in which we find ourselves. I dislike showing signs of discourtesy. I don't mean to be that way.

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Mr. BOLGER. Thank you, Senator.

[Mr. Bolger's prepared statements is as follows:]

PREPARED STATEMENT OF ROBERT J. BOLGER, PRESIDENT, NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Mr. Chairman, we appreciate this opportunity to present our views on the adequacy of Federal drug control laws and their impact on pharmacy.

The National Association of Chain Drug Stores (NACDS) represents the management of 228 chain drug corporations throughout the United States. Our members operate approximately 9,000 drugstores in addition to 1,500 pharmacy leased departments. Within our membership we have the largest and the smallest chain drug corporations in the Nation for our basic membership criteria is that each member operate at least four pharmacies or prescription departments. More than half of our membership would be considered small businessmen.

As providers of the major portion of the Nation's drug products and pharmaceutical services, we are indeed interested in the work of this subcommittee. Since the enactment of Comprehensive Drug Abuse Prevention and Control Act of 1970, we believe the Federal Agency charged with the implementation and the administration of thsi act has done a commendable job. Over the past few years this agency's professional and dedicated staff has accomplished the impossible task of organizing and administering our Nation's dangerous drug control laws. Our association and our members have worked closely with the agency to ensure our full compliance with the law and regulations. Many times we have not agreed with the Agency's actions and have vigorously opposed policies and regulations which we believe would be detrimental to the pharmacy services, drug control and the American public.

For within our Nation's drug distribution system the pharmacy and the pharmacist have a key responsibility. As the last link in the drug distribution channel the drugstore, through the services of a pharmacy, provides prescription medication—controlled and non-controlled—to the American consumer. In order to provide these drugs and services to the American public the pharmacist has found an increasing regulation of his business and practice by Government. With the 1970 law an even greater paperwork burden was placed upon him. Concurrently, with heightened public awareness of drug abuse, he became a primary drug abuse information source. Unfortunately, he also became a target for those persons who saw him as a potential source for drugs, cash, or merchandise.

The problem of burglary, theft and armed robbery in pharmacy is serious. As one DEA official recently state: "the drugstore of today is all too frequently a combat zone within which robberies, burglaries, assaults and even killings are becoming common place." Some of the hair-raising episodes and tragedies many pharmacists have experienced are only now coming to light; and unfortunately, the future doesn't appear to be changing for the better. For "while other types of businesses also find themselves caught up in this undeclared war, the pharmacy is particularly vulnerable because of its controlled drug stocks. As enforcement efforts continue to be more successful in reducing both the quantity and quality of street drugs, the vulnerability of the pharmacy as an alternate source of supply increases."

Drug enforcement administration statistics give us one perspective of the problem. In 1972, there were 5,065 drug thefts involving 64 million dosage units reported to DEA. In 1973, thefts increased some 25% to a total of 6,974. These statistics are alone impressive but further examination reveals a bleak situation within pharmacy. That is, in July–September 1972, pharmacy thefts accounted for 49% of the total. From October–December 1972, pharmacy thefts has increased to 65% of the total. In 1973, the figure has jumped dramatically to 81% of all thefts. The one bright spot in this statistical picture is that the total number of dosage units involved has been dramatically reduced by 50% of the 1972 figure. Nonetheless, it clearly points out the explosive theft, burglary and armed robbery situation in pharmacy.

Up to this point, the crime problem within pharmacies has been primarily one of theft, but we do believe that armed robbery of pharmacies is also increasing. And we do not wish to put our pharmacists, employees or customers into any life-threatening situations. I am sure that this committee as well as the responsible Government agencies have an extensive file on the horror stories and tragedies concerning pharmacy theft and robbery. I can only say that our own members' experiences would further substantiate these experiences.

In response to this growing problem remedial legislation has been introduced in the Congress. Basically, these measures would impose a Federal penalty for rubbery or attempted robbery of controlled substances from a pharmacy by force, violation or intimidation. The bills provide for penalties of a $5,000.00 fine and/or ten years in prison. We are indeed fortunate to have some members of Congress recognize the problems facing our Nation's pharmacies. But while they are a step in the right direction, we are not convinced that they go far enough to effectively deal with the problem.

We believe that the Federal Government should impose stricter penalties upon those who perpetrate burglary, theft or robbery of a pharmacy to gain controlled substances. This legislation will serve as a basic deterrent and assist the pharmacist in his struggle to combat drug related crimes in his community. But more importantly, since the Government anticipates that the new Federal restrictions and tighter security placed upon other sources of controlled substances will generate an even greater pressure upon the retail pharmacy, the Federal Government should recognize its impact and aid pharmacies in meeting this challenge.

We believe that drug related crimes in pharmacy should not be limited to those of force and violence but must include theft, and burglary. Only in this manner can the pharmacist and pharmacy be assured of some measure of protection through Federal enforcement efforts. It is simply unfair to expect drugstores to bear a greater burden and risk for drug control without additional Federal protection.

Moreover, most crimes dealing with controlled substances at pharmacy level are left to local authorities under the present law. Aside from the fact that there is no uniformity in the manner in which drugstore crimes are treated at the local level, it does not appear to be a priority item for the Federal agencies involved. The Drug Enforcement Administration has indicated that it does not have the manpower necessary to investigate and act on the local level. Although some effort is being generated through the support of drug investigative units with the use of LEAA funds, there are a few states in which these units are actually operating.

As we view it, the laws place pharmacies in a delicate and dangerous position. And although most pharmacists as well as their management have accepted the requirements of law and cooperated to do their part, what we now need is some positive action upon part of the Federal Government to ensure that its efforts to close off channels of drug diversion do not send hoardes of addicts, pushers and other criminals into the Nation's pharmacies. This would severely disrupt the primary role of the community pharmacy of providing necessary medications to the public.

With Federal assistance the pharmacies and pharmacists can better assist law enforcement officials in identifying drug law offenders as well as providing the necessary evidence for prosecution of offenders. But there appears to be little incentive to provide such information as most offenders are not brought to justice. Furthermore, a pharmacist cannot be placed in a position of jeopardizing his relationship mith a medical practitioner or a customer. He can produce the records he is required to maintain by law, but he cannot enforce the law: This is the responsibility of the authorities. Too many times in the past pharmacists have been left "holding the bag" in their efforts to assist law enforcement officials. Hopefully, stricter Federal laws will overcome these problems by providing for greater involvement by Federal enforcement officials.

Pharmacies are doing their part attempting to met the increased number of robberies and thefts. Many stores have upgraded their security systems by installing alarm systems, further restricting access to controlled substances storage areas, reducing inventory of controlled substances as well as setting up monitoring programs for controlled substance purchases at store level. These are actions that our members have taken across the Nation. In addition, we strongly support the strengthening of the law to eliminate practitioners, pharmacies and other registrants who violate the law.

Although many of our members have taken these measures there is a limit to the physical security safeguards a pharmacy can institute. We would hope that the day would never come when a pharmacy would be turned into a fortress containing vaults, iron bars or other such security safeguards. We would hope that drug abuse control aspects of pharmacy practice would not have an over bearing influence. For a pharmacy's primary purpose within the community is to serve all customers in need of prescription medication and pharmaceutical

services. This primary purpose must be preserved just as control drugs must be protected.

Another area of concern is that of prescription fraud or forged prescriptions. Last year the Drug Enforcement Administration released a report entitled "Project Script". This survey was the first phase of a three part study which would determine vulnerability, frequency and alternative solutions to the problem. To our knowledge the Agency has only conducted the first portion of this study.

The problem of the forged prescription is not new to pharmacy. If anything, the impact of the Controlled Substances Act has increased the pharmacists awareness of his valuable role in the drug control effort. We believe that pharmacists do screen prescriptions, especially controlled substances, in a very conscientious and professional manner. Although many people believe that forgeries of this nature are on the increase, we are not aware of any information to substantiate this. We would agree with the conclusion drawn from the DEA study "while we would prefer to see a complete preclusion of the facility prescription fraud that goal is probably unobtainable. Hence, we do not yet know what is practicable, acceptable level of prescription fraud perpetrations."

If the pharmacist does not know the patient, there are several methods by which he can assure himself that the prescription is bona fide. He may question the patient, he may call the physician or he may even request further identification from the patient. The method utilized depends upon the individual circumstances. Therefore, the adoption of any arbitrary, cumbersome method of verifying prescription for a controlled substance should not be instituted by the Federal Government. In critiquing project scrip last year, we recommended that representatives of pharmacy, medicine and consumer groups be convened at DEA to discuss the problem and its solution.

Although we do not support a requirement that pharmacists verify the identity of all patients with prescriptions for controlled substances, we do agree with the practice of requiring pharmacists initial all prescription dispensed by them. In several States this is a legal requirement while in others pharmacists perform this as a means of professional practice.

One possible solution to the fraudulent prescription problem is to implement a triplicate prescription system for drugs listed in Schedule II. Several States hav already implemented such systems with varying degrees of success—Illinois, California, Nsw York. In working with DEA we have requested that a study of the various systems be implemented so that we can better determine whether or not utilization of a triplicate prescription form would be a viable solution to the forgery problem. Since a system of this nature may require an amendment to the existing law, we would hope that this subcommittee would also encourage the agency to provide this data.

In our preceeding comments we have dealt primarily with some of the pertinent drug control issues. One area which we are greatly concerned with does not fall directly into any of these categories. At present the law only provides that pharmacies will be granted DEA registration upon licensure by the appropriate State agency. Thus, once a pharmacy is licensed and given a permit number by the State agency, DEA will then issue its registration. We would hope that the present DEA procedure for registration of new pharmacies could be improved to permit concurrent DEA registration with State pharmacy licensure. Since the enactment of the Controlled Substances Act many pharmacies have not received the required DEA registration materials until several days after the pharmacy has been opened. In these cases the pharmacies were forced to open without the necessary stocks of controlled substances and unable to adequately serve the public.

Although Drug Enforcement Administration has been most helpful in modifying its present registration methods and procedures to alleviate this problem, there are still many instances in which drugstores must open without appropriate controlled drug stocks. We have suggested a method by which this registration could be received concurrently with the State permit with little chance of fraud or diversion. We hope that this subcommittee will further inquire as to how the registration of new pharmacies may be improved.

In conclusion, we hope the committee will give further consideration to legislation which will provide for stricter penalties for both robbery, theft and burglary of controlled substances from drugstores. The impact of the Federal drug control effort has been to increase the pharmacies risk within the distribution channel: therefore, we believe the pharmacy problems should be given a higher priority within our major enforcement agency.

Secondly, while pharmacies should be encouraged to improve their security, we hope that the physical security required at a community pharmacy will not make it an impregnable fortress to the millions of consumers who visit our stores for prescription medications and many other essential items.

Thirdly, we believe that the question of forged prescriptions is one of great concern to pharmacy as well as to Government. Initial surveys have indicated that pharmacies are vulnerable to such fraudulent practices. We would hope that simple unincumbered systems of meeting this problem could be developed once we have a full understanding of how wide spread the practice is.

Fourthly, we hope that the registration of new pharmacies will be improved and hope that provision will be made in the law which will permit concurrent registration of drugstores with their State permit.

And lastly, we hope that the DEA will be encouraged to set up a committee of representatives from pharmacy, medicine, and consumers to discuss all problems relating to availability of controlled drugs to the American public.

Mr. Chairman, we thank you.

Senator BAYH. The next witnesses are Mr. John McHugh, National Manager Pharmacy Service, American Association of Retired Persons National Retired Teachers Association, accompanied by Mr. Fred Wegner.

Gentlemen, we appreciate you being here, and I am sorry for the hectic day. So please proceed.

STATEMENT OF JOHN R. McHUGH, NATIONAL MANAGER PHARMACY SERVICE, AMERICAN ASSOCIATION OF RETIRED PERSONS NATIONAL RETIRED TEACHERS ASSOCIATION, ACCOMPANIED BY FRED WEGNER, LEGISLATIVE REPRESENTATIVE, AARP-NRTA

Mr. McHUGH. Thank you, Mr. Chairman.

My name is John R. McHugh, and I am president of Retired Persons Services and National Manager of Retired Persons Pharmacies, serving the more than 6.6 million members of the National Retired Teachers Association and the American Association of Retired Persons. I am also a registered pharmacist in the States of Florida and the District of Columbia and a member of several State and national pharmaceutical associations.

Retired Person Service, a nonprofit corporation in the District of Columbia, is broadly committed to enhancing and improving the social and economic welfare of older Americans. A major program of RPS is concerned with the costly burden of medications among a significant segment of the elderly population. Our efforts in helping to ameliorate this critical problem include national and State legislative and regulatory efforts, publicity in trade and general media, educational articles and program directed at members of the two associations and the establishment of pharmacies, conveniently located in five States, to make reasonably priced, quality medications available to members and others by mail or walk-in.

The Comprehensive Drug Abuse Prevention and Control Act of 1970 is a necessary and important instrument in the weaponry of a society committed to action aaginst the malignancy of drug abuse with its attendent crime and human waste. Every American is indebted to the distinguished chairman and members of this sub-

committee for this responsible and corrective legislation. The reduction of drug-related deaths, crime and trafficking since 1970 is proof of the efficacy of your commendable efforts.

Nearly a year ago, NRTA, AARP, and the Associations' Pharmacy Service became apprehensive about amendments to the act by the Secretary of Health, Education, and Welfare and the Administrator of the Bureau of Narcotics and Dangerous Drugs, now known as the Drug Enforcement Administration. We voiced our concern on behalf of older Americans that the upward transfer of more controlled substances into schedule II was creating an additional economic burden to many patients and was probably interfering with legitimate therapeutic uses of these drugs.

Our only objection to these transfers was and is the prohibition against refills for schedule II controlled substances due to the intermingling of narcotics and nonnarcotic drugs. All of us need to be primarily concerned with the lowering the high costs of medication and making it easier for the suffering patient to follow his drug regimen. Refill authorizations help to accomplish both these aims, by cutting down on costs in money and time to patients and physicians alike, requiring less frequent office visits, and lowering transportation expenses. We do not object to any of the other provisions that apply to schedule II drugs, such as manufacturing quotas, order form requirements, and security controls. We were variously informed by FDA officials that the agency was "reconsidering the proper schedule of some of the barbiturates in light of comments received from you and others" and that it regretted "we cannot take measures to rectify the situation because our functions and alternatives are restricted by legislation."

The immediate problem for geriatric patients as well as others with anxiety and tension symptoms, is that barbiturates, sedatives, hypnotics and tranquilizers are not infrequently prescribed for long term, even lifelong, maintenance therapy. It is not unusual for a post-cardiac patient to take a drug, such as butisol sodium, three times a day for several years. To require this patient to obtain a new Rx every month would be an unreasonable economic burden. Particularly for persons of advanced age, the possibility of physical and psychological dependence on these substances does not take on the significance comparable with drug dependency among younger people.

Our appeal is for a legislative amendment to the act which will permit the refilling of prescriptions for nonnarcotic and nonamphetimine schedule II controlled substances when so indicated by the prescribing practitioner. Separating narcotic from nonnarcotic drugs into two categories within schedule II suggests itself as one possible remedy.

We also find objectionable the actions of a number of States which have reserved to themselves discretion over which substances they will designate as narcotic and in which schedule they will be placed. The obvious effect of 50 different controlled substances acts on this Nation's drug delivery system boggles the imagination and demands unified control by Federal Government. At least one State, Massachusetts, has created a further complication and hardship by unduly limiting the quantity of schedule II and III controlled substances that can be dispensed at one time. An AARP member living in Massachuetts reports to us that this requirement has nearly tripled his cost for nembutal and, in his words, made his druggist richer. If Federal preemption is needed to correct the inequities in State drug legislation and regulations, then we urge this necessary course of action.

Retired Persons Pharmacies, during their 15 years of existence, have experienced no robberies or thefts nor any known instances of fraudulent prescriptions, other than ones perpetrated in the course of investigations by regulatory and licensing agencies. BNDD (now DEA) surveys before and after the 1970 Controlled Substances Act concluded that mail-order prescriptions are not a significant source of diversion. This is hardly surprising, since they cannot dispense narcotics by mail, which is their primary delivery method, and are utilized chiefly as sources of maintenance medication by the chronically ill.

As good as their record is in the regard, they have taken various voluntary steps to avoid possible diversions of controlled substances. Virtually every mail-service pharmacy, including our own, heavily utilizes WATS (wide area telephone service) lines to verify prescriptions for controlled substances. In our Washington, D.C. pharmacy alone we have ten fulltime people including a chief pharmacist who do nothing but contact physicians around the country to verify prescriptions. The phone bill for the Washington pharmacy alone is approximately $4,000 a month.

Separate inspections of prescriptions by different pharmacists, practitioner signature comparisons, membership numbers, and spot checks of prscribers of controlled substances are among the other procedures employed by these pharmacies to authenticate prescriptions

Retired Persons Pharmacies have urged DEA officials to require triplicate prescription forms for schedule II controlled substances. With growing computerization of the drug delivery system, we view this control method as an imminent and logical step forward. Computer checks of schedule II substances could help DEA in establishing manufacturing quotas and in their drug enforcement responsibilities by identifying practitioners who are suspected of selling prescriptions and patients who shop for prescriptions among a number of physicians. Beyond their value to DEA, triplicate forms can provide important data to FDA in such areas as drug utilization review, prescribing practices of practitioners, dispensing by pharmacies, and the drug usage of patients. We strongly urge and support the use of triplicate prescription blanks. Triplicate blanks have been tried before in other systems. The test is not to have the blank but what you do with it. Modern data processing certainly would allow the use—one witness this morning mentioned you could forge triplicate blanks as well as regular prescription blanks. That is true. Computerization of these blanks would allow the authorities to move in quickly and find out who is forging these blanks, who is passing them, and which doctors are selling their prescriptions.

It seems to us that Congress is uniquely suited not only to insisting that each Federal agency fulfills its specific legislative mandate but to assuring that the cooperation and coordination between executive departments and agencies provide the fullest efficiency in administration. The American consumers as well as the professions and industries regulated by these agencies will benefit from the outcome.

Strict drug abuse laws and enforcement seem to us more properly directed toward the criminal whose activities involve smuggling, illicit manufacturing, or diversion from legitimate sources. In this respect, we see value in making robbery and theft of controlled substances a Federal crime. I personally was the victim of a holdup in which controlled drugs were demanded and supplied. A man came into a pharmacy where I was working just a few years ago and asked to buy some barbiturates. I refused to sell them without a prescription. He produced a $5 bill. I still refused. He went away and 5 minutes later he came back with his hand in a paper bag and I assumed he had a prescription in that bag so I gave him some controlled drugs.

Senator BAYH. You gave him what?

Mr. MCHUGH. Some controlled drugs. He may have had a gun.

Further, we support making it a Federal crime to knowingly carry, mail, telephone, or otherwise transport a fraudulent prescription order for a controlled substance in interstate commerce.

On the other hand, lawmakers and regulators would do well to avoid unduly strict controls whose chief attribute is to interfere with the physician-patient-pharmacist relationship and the legitimate delivery and use of medication. We place patient identity verification by pharmacists in this category, and would oppose similar proposals which would cause delays in dispensing medication by mail. Such measures are unnecessary, unworkable and would be more observed in omission than in commission.

Equity obliges me to remark about some in organized pharmacy who urge this subcommittee to make mail-service pharmacies an issue. Every age of history has had its Tories who cling to the past, fear competition and abhor change. Thomas Jefferson reproved those of his day in these words:

> As the progress of the human mind becomes more developed, more enlightened, as new discoveries are made, new truths discovered, and manners and opinions changed, with the change of circumstances, institutions must advance also to keep pace with the times.

Retired Persons Pharmacies serve members of the Nation's largest elderly associations, NRTA and AARP. Other mail-service pharmacies serve military veterans, union members, retired Federal employees, teachers and other consumers. Those of us in mail-service pharmacies are both professional pharmacists and proud participants in a modern and growing segment of the drug delivery system, providing a vitally important service to people who need or want it. We are actively helping patients who are chronically ill, immobile, isolated, and often heavily burdened by high, personal drug expenditures. To impugn the reputations and discredit the needs of these people by citing "old ladies in tennis shoes" or "drug abusing veterans," as was done by a previous witness, is grossly unfair and does not, we believe, represent the views of the thousands of pharmacists throughout the Nation who are dedicated to serving all Americans.

Yet there are retail druggists who would seek to deny patients their right to choose a mail-service pharmacy. There are retail druggists who would and have urged this subcommittee to prohibit the mailing of medication. There are retail druggists who would impute diversion problems to mail-service pharmacies while turning blind eyes and deaf ears to Government surveys that indicate a far greater incidence of fraudulent prescriptions among their own kind. I think we would all be better served in trying to see what we can do to minimize the vulnerability which was pointed out in DEA's survey, "Project Script." I am not at all proud that mail-service pharmacies were found to have a 25 percent vulnerability as compared to community pharmacies' 56 percent vulnerability. All of us can do better. We have made many changes in our own operations since then and rather than try to discredit the survey, I would support Mr. Bolger's statement a little bit ago where he urged the DEA to do the second part of the survey, to find out the prevalence of fraudulent prescriptions. They have pointed out the vulnerability and I think we should accept that and do what we can to minimize it, but the study should be carried on and we would recommend that.

There are retail druggists who would ostensibly view with horror any disruption of the so-called "patient-pharmacist" relationship, yet are not all hesitant in their own businesses to inject between themselves and their customers a part-time clerk or teenage delivery boy.

We urge them to put aside these fantasies of a world that never was and face up to the realities of life. Consumers are on the march. What they—not the pharmacists—want is surely what we will get.

Consumers are fed up with wide and unwarranted disparities in retail drug prices. Consumers are fed up with both physicians and pharmacists who often seem to function as selling agents for brand-name drug manufacturers. Consumers are fed up with a manufacturer-physician-pharmacist fraternity that excludes them from every aspect of the drug delivery system, except to pay their bills.

All of us in the pharmacy profession, in Congress, and in the regulatory agencies must consider first the unfortunate patient. Surely, protection of legitimate drug users is at least as important as detection of illicit drug abusers. With this as the guiding principle of these hearings, we have no doubt American consumers will be well served.

Thank you very much, Mr. Chairman.

Senator BAYH. Thank you very much, Mr. McHugh. If I might, I have a few questions to ask, but rather than take your time now, it is late and we have two other groups of witnesses, would it be all right to ask you and Mr. Wegner, to respond to these questions in writing?

Mr. MCHUGH. Sure.

Senator BAYH. I apologize again for the hectic pace today and that you have been exposed to it, and inconvenienced by it. We

look forward to working with you because you do serve a large and important constituency in the area of need. I appreciate your concern that this need be supplied and at the same time we minimize the abuse of controlled substances.

I appreciate your contribution and look forward to the answers to these questions to help sort out our record.

Thank you, gentlemen.

[Mr. McHugh's prepared statement and articles entitled: "The Mail-Order Prescription Drug Industry" and "The Rise of Mail-Service Pharmacies"—marked "Exhibit Nos. 4 and 5"—are as follow:]

PREPARED STATEMENT OF JOHN R. MCHUGH, R. PH., NATIONAL MANAGER, RETIRED PERSONS PHARMACIES, THE PHARMACY SERVICE OF THE AMERICAN ASSOCIATION OF RETIRED PERSONS NATIONAL RETIRED TEACHERS ASSOCIATION

My name is John R. McHugh, and I am president of Retired Persons Services and National Manager of Retired Persons Pharmacies, serving the more than 6.6 million members of the National Retired Teachers Association and the American Association of Retired Persons. I am also a registered pharmacist in the states of Florida and the District of Columbia and a member of several state and national pharamceutical associations.

Retired Persons Services, a non-profit corporation in the District of Columbia, is broadly committed to enhancing and improving the social and economic welfare of older Americans. A major program of RPS is concerned with the costly burden of medications among a significant segment of the elderly population. Our efforts in helping to ameliorate this critical problem include national and state legislative and regulatory efforts, publicity in trade and general media, educational articles and programs directed at members of the two Associations, and the establishment of pharmacies, conveniently located in five sates, to make reasonably priced, quality medications available to members and others by mail or walk-in.

The Comprehensive Drug Abuse Prevention and Control Act of 1970 is a necessary and important instrument in the weaponry of a society committed to action against the malignancy of drug abuse with its attendant crime and human waste. Every American is indebted to the distinguished chairman and members of this Subcommittee for this responsible and corrective legislation. The reduction of drug-related deaths, crime and trafficking since 1970 is proof of the efficacy of your commendable efforts.

Nearly a year ago, NRTA, AARP, and the Associations' Pharmacy Service became apprehensive about amendments to the Act by the Secretary of Health, Education and Welfare and the Administrator of the Bureau of Narcotics and Dangerous Drugs, now the Drug Enforcement Administration. We voiced our concern on behalf of older Americans that the upward transfer of more controlled substances into Schedule II was creating an additional economic burden to many patients and was probably interfering with legitimate therapeutic uses of these drugs.

Our only objection to these transfers was and is the prohibition against refills for Schedule II controlled substances due to the intermingling of narcotics and nonnarcotic drugs. All of us need to be primarily concerned with lowering the high costs of medication and making it easier for the suffering patient to follow his drug regimen. Refill authorizations help to accomplish both these aims, by cutting down on the costs in money and time to patients and physicians alike, requiring less frequent office visits, and lowering transportation expenses. We do not object to any of the other provisions that apply to Schedule II drugs, such as manufacturing quotas, order form requirements, and security controls. We were variously informed by FDA officials that the agency was "reconsidering the proper schedule of some of the barbiturates in light of comments received from you and others" and that it regretted "we cannot take measures to rectify the situation because our functions and alternatives are restricted by legislation."

The immediate problem for geriatric patients, as well as others with anxiety and tension symptoms, is that barbiturates, sedatives, hypnotics and tranquilizers are not infrequently prescribed for long-term, even lifelong, maintenance therapy. It is not unusual for a post-cardiac patient to take a drug, such as Butisol Sodium, three times a day for several years. To require this patient to obtain a new Rx every month would be an unreasonable economic burden. Particularly for persons of advanced age, the possibility of physical and psychological dependence on these substances does not take on the significance comparable with drug dependency among younger people.

Our appeal is for a legislative amendment to the Act which will permit the refilling of prescriptions for nonnarcotic Schedule II controlled substances when so indicated by the prescribing practitioner. Separating narcotic from nonnarcotic drugs into two categories within Schedule II suggests itself as one possible remedy.

We also find objectionable the actions of a number of states which have reserved to themselves discretion over which substances they will designate as narcotic and in which schedule they will be placed. The obvious effect of 50 different controlled substances acts on this nation's drug delivery system boggles the imagination and demands unified control by the federal government. At least one state, Massachusetts, has created a further complication and hardship by unduly limiting the quantity of Schedule II and III controlled substances that can be dispensed at one time. An AARP member living in Massachusetts reports to us that this requirement has nearly tripled his cost for Nembutal and, in his words, made his druggist richer. If federal preemption is needed to correct the inequities in state drug legislation and regulations, then we urge this necessary course of action.

Retired Persons Pharmacies, during their 15 years of existence, have experienced no robberies or thefts nor any known instances of fraudulent prescriptions, other than ones perpetrated in the course of investigations by regulatory and licensing agencies. BNDD (now DEA) surveys before and after the 1970 Controlled Substances Act concluded that mail-order prescriptions are not a significant source of diversion. This is hardly surprising since they cannot dispense narcotics by mail, which is their primary delivery method, and are utilized chiefly as sources of maintenance medication by the chronically ill.

As good as their record is in this regard, they have taken various voluntary steps to avoid possible diversions of controlled substances. Virtually every mail-service pharmacy, including our own, heavily utilizes WATS (wide-area telephone service) lines to verify prescriptions for controlled substances. Separate inspections of prescriptions by different pharmacists, practitioner signature comparisons, membership numbers, and spot checks of prescribers of controlled substances are among the other procedures employed by these pharmacies to authenticate prescriptions.

Retired Persons Pharmacies have urged DEA officials to require triplicate prescription forms for Schedule II controlled substances. With growing computerization of the drug delivery system, we view this control method as an imminent and logical step forward. Computer checks of Schedule II prescriptions could help DEA in establishing manufacturing quotas and in their drug enforcement responsibilities by identifying practitioners who are suspected of selling prescriptions and patients who shop for prescriptions among a number of physicians. Beyond their value to DEA, triplicate forms can provide important data to FDA in such areas as drug utilization review, prescribing practices of practitioners, dispensing by pharmacies, and the drug usage of patients. It seems to us that Congress is uniquely suited not only to insisting that each federal agency fulfills its specific legislative mandate but to assuring that cooperation and coordination between executive departments and agencies provide the fullest efficiency in administration. The American consumers as well as the professions and industries regulated by these agencies will benefit from the outcome.

Stringent drug abuse laws and enforcement seem to us more properly directed toward the criminal whose activities involve smuggling, illicit manufacturing or diversion from legitimate sources. In this respect, we see value in making robbery and theft of controlled substances a federal crime. Further, we support making it a federal crime to knowingly carry, mail, telephone or otherwise transport a fraudulent prescription order for a controlled substance in interstate commerce.

On the other hand, lawmakers and regulators would do well to avoid unduly strict controls whose chief attribute is to interfere with the physician-patient-

pharmacist relationship and the legitimate delivery and use of medication. We place the patient identity verification by pharmacists in this category and would oppose similar proposals which would cause delays in dispensing medication by mail. Such measures are unnecessary, unworkable and would be more observed in omission than in commission.

Equity obliges me to remark about some in organized pharmacy who urge this Subcommittee to make mail-service pharmacies an issue. Every age of history has had its Tories who cling to the past, fear competition and abhor change. Thomas Jefferson reproved those of his day in these words: "As the progress of the human mind becomes more developed, more enlightened, as new discoveries are made, new truths discovered and manners and opinions changed, with the change of circumstances, institutions must advance also to keep pace with the times."

Retired Persons Pharmacies serve members of the nation's largest elderly associations, NRTA and AARP. Other mail-service pharmacies serve military veterans, union members, retired federal employees, teachers and other consumers. Those of us in mail-service pharmacies are both professional pharmacists and proud participants in a modern and growing segment of the drug delivery system, providing a vitally important service to people who need or want it. We are actively helping patients who are chronically ill, immobile, isolated, and often heavily burdened by high, personal drug expenditures.

Yet there are retail druggists who would seek to deny patients their right to choose a mail-service pharmacy. There are retail druggists who would and have urged this Subcommittee to prohibit the mailing of medication. There are retail druggists who would impute diversion problems to mail-service pharmacies while turning blind eyes and deaf ears to government surveys that indicate a far greater incidence of fraudulent prescriptions among their own kind. There are retail druggists who would ostensibly view with horror any disruption to the so-called "patient-pharmacist" relationship, yet are not at all hesitant in their own businesses to inject between themselves and their customers a part-time clerk or teenage delivery boy.

We urge them to put aside these fantasies of a world that never was and face up to the realities of life. Consumers are on the march. What they—not the pharmacists—want is surely what they will get.

Consumers are fed up with wide and unwarranted disparities in retail drug prices. Consumers are fed up with both physicians and pharmacists who often seem to function as selling agents for brand-name drug manufacturers. Consumers are fed up with a manufacturer-physician-pharmacist fraternity that excludes them from any accountability, except to pay their bills.

All of us in the pharmacy profession, in Congress, and in the regulatory agencies must consider first the unfortunate patient. Surely, protection of legitimate drug users is at least as important as detection of illicit drug abusers. With this as the guiding principle of these hearings, we have no doubt American consumers will be well served.

Thank you.

[From Health Services Reports, November 1973]

EXHIBIT No. 4

THE MAIL-ORDER PRESCRIPTION DRUG INDUSTRY

(By Albert I. Wertheimer, Ph. D., and James E. Knoben,[1] PharmD)

The practice of mailing prescription and other medications to consumers in the United States probably had its origin in rural America. Before the general availability of the automobile, rural inhabitants often were dependent upon the U.S. mail for delivery of medicines and health supplies from their local pharmacy. This practice was not only a convenience to the consumer, but an essential

[1] Dr. Wertheimer and Dr. Knoben were formerly on the staff of the Pharmacy-Related Programs Branch, National Center for Health Services Research and Development, Health Resources Administration. Dr. Wertheimer is now associate professor, University of Minnesota College of Pharmacy; Dr. Knoben is now at Yale University. Tearsheet requests to Dr. Albert I. Wertheimer, University of Minnesota College of Pharmacy, Minneapolis, Minn. 55455.

health service as well—one in which physician, pharmacist, and patient were active participants.

The Veterans Administration has used the mails for distributing medicines to its ambulant patients for many years. This practice was expanded greatly with the return of veterans after World War II and has continued to grow, proving convenient and economical for both parties. In more recent times, the National Retired Teachers Association and American Association of Retired Persons (NRTA-AARP) has been distributing prescription medications to its members through a program that is now a featured service.

As the volume of prescriptions delivered by mail has increased, the practice has come under continuing, and at times critical, surveillance, particularly by organized pharmacy. Because available information to characterize the nature and extent of the mail-order prescription industry has not been collected and scrutinized, we undertook to assemble as much factual information as could be obtained.

Professional organizations and State boards of pharmacy were contacted for the names of firms engaged in high-volume, mail-order distribution of prescription drugs. A list of approximately 60 organizations was compiled. Data were then collected through a combination of personal and telephone interviews from 10 of the larger organizations, using a standard set of questions relating to the data reported in the remainder of this paper. These organizations are responsible for approximately 90 percent of the volume of mail-order prescription drugs in the United States. This report constitutes a profile of the mail-order prescription drug industry as constructed from our study. For purposes of convenience, mail-order prescription suppliers can be classified as follows:

1. Nonprofit government, such as the Veterans Administration drug program, which began in 1946.
2. Nonprofit private, such as the NRTA-AARP drug program, which began in 1959
3. For-profit specialized (limited) programs, such as the Western Medical Company, which caters to the drug needs of epileptic patients
4. For-profit, open, public drug programs, such of Pharmaceutical Services, Inc.

GENERAL FEATURES OF MAIL-ORDER SERVICES

Patients' characteristics. The marketing data of these firms and the kinds of drugs supplied suggest that most mail-order suppliers serve elderly patients with chronic conditions who live in rural areas and use a high volume of prescription drugs.

Services offered. Most of the 60 organizations offer walk-in as well as mail-order service and dispense prescription drugs, nonprescription drugs and limited sundry items. Many of the organizations dispense and mail Bureau of Narcotics and Dangerous Drugs (BNDD) schedule II (abusable) prescription drugs; however, only the Veterans Administration is allowed by postal regulation to mail narcotic drugs. The National Retired Teachers Association dispenses only two schedule II drugs: Preludin and Ritalin and, in each case, the prescriber is telephoned. Pharmaceutical Services, Inc., dispenses no schedule II-controlled druge.

Prescription pricing. Mail-order prices are generally competitive with prices prevailing in urban areas; the price advantage in some organizations is approximately 25 percent below the retail price. No uniformity in pricing policy was found; examples of both markup and professional fee pricing mechanisms were encountered. The high volume of prescription orders is an industrywide trait, necessary to offer the low price. Most organizations distribute a brochure or catalog describing the services offered and listing the prices for nonprescription products. Usually, only those firms in the for-profit category list prescription drug prices in their literature, which is distributed to the public.

Prescription processing and services. To assure themselves of the authenticity of a mailed-in prescription and to protect themselves from legal prosecution, firms usually take special precautions to screen out fraudulent orders. Among the steps they follow are a manual inspection of the prescription order by a pharmacist or specially trained technician, telephone verification in the case of suspected prescription orders, and comparison with known samples of handwriting, if these are available. In membership organizations, the patron's name is checked against the membership roster as an additional security check. The

majority of these organizations maintain WATS (wide-area telephone service) lines due to the volume of long distance telephone calls made for verification purposes.

Most firms do not maintain drug-use profiles of patients. Few suppliers perform any drug interaction surveillance or monitoring of patients' drug regimens. Records are kept by all of the firms for purposes of medication refills and financial accounting.

Inquiries from patients are handled in most instances by one experienced person. Correspondence encompasses answers to price requests, answers to clinical questions, notification that a product contains a narcotic agent and must be dispensed locally, answers to inquiries regarding lost of late shipments, as well as need for receipts, special delivery, or the completion of insurance claim forms.

Prescription dispensing. Pharmacists dispense or supervise the drug dispensing operations. They are licensed by the State in which they practice and must, therefore, follow that State's regulations. A limited sampling discloses a ratio of approximately 100 to 150 prescriptions dispensed per pharmacist per working day; most organizations use a large number of technicians in the dispensing process. Ratios varying from one to eight technicians per pharmacist were found. These ratios compare with about 60 prescriptions dispensed per pharmacist per working day in the group medical clinic *(1)* and with about 80 prescriptions per day dispensed in community pharmacies which may employ one to two pharmacists during a given period *(2)*.

Prescription shipping. All organizations attempt to ship medications on the same day that the prescription order is received. Generally 3 to 5 days are required for delivery by mail. The drugs are usually packed in boxes, which may be marked "medicine," and sent via first- or third-class mail or by the United Parcel Service. United Parcel Service mail delivery is preferred by some organizations because the patient must sign a receipt, and three attempts to deliver are made prior to the return of the medication to the sender.

The mail-order firms report a few losses, thefts, and late deliveries. In a letter dated October 18, 1972, the Better Business Bureau of Metropolitan Washington, D.C., reported that during March through August 1972, 13 inquiries and 11 complaints were made in the category of drugs and medicines, a category that includes all medications purchased from all sources; this total represents only 0.1 percent of the complaint volume.

Prescription volume and drugs dispensed. The market volume of mail-order prescription drugs can only be estimated at best, due to the diverse nature of the industry. Based on our discussions with knowledgeable industry representatives, we estimate that roughly 17 million prescriptions are dispensed annually through mail-order channels, 11 million of these by nonprofit firms and organizations. This volume compares with 155 million prescriptions dispensed by chain pharmacies and 959 million prescriptions by independent community pharmacies in 1971 *(3)*.

The most frequently dispensed mail-order prescription drugs in 1972 for one organization, the National Retired Teachers Association and American Association of Retired Persons, are listed. While the population served by this group is clearly older than the population at large, this list is probably a good approxibation of the drugs most frequently dispensed by all the mail-order firms.

Aldactazide
Aldomet, 250 mg
Atromid-S
Butazolidin Alka
Cyclopasmol, 200 mg
D. B. I.-T.D., 50 mg
Diabinese, 250 mg
Dilantin, 100 mg
Diuril, 500 mg
Equanil, 400 mg
Esidrix, 50 mg
Hydrodiuril, 50 mg
Hygroton, 100 mg
Inderal, 10 mg
Indocin, 25 mg
Indovin, 50 mg
Lasix, 40 mg
Librium, 5 mg
Librium, 10 mg
Lomotil, 2.5 mg
Meprobamate, 400 mg
Orinase, 0.5 gm
Pavabid capsules
Peritrate, 20 mg
Premarin, 1.25 mg
Quindine, 3 gr
Regroton
Tandearil, 100 mg
Thyroid, 2 gr
Tofranil, 25 mg
Tolinase, 250 mg
Valium, 5 mg
Vasodilan, 10 mg

Summary data. The characteristics of selected mail-order prescription drug programs are given in the table. A number of characteristics unique to certain programs are detailed more fully in the subsequent section.

SPECIAL FEATURES OF PROGRAMS

Certain mail-order prescription drug suppliers merit further consideration by virtue of specific characteristics or features in their operation. Programs that have such a special feature are recounted in this section.

The Veterans Administration program is unique in several aspects. It is the only organization currently allowed by postal regulation to distribute narcotics through the mails (that is, by registered mail). In addition, its 28 million veteran beneficiaries (excluding dependents) comprise the largest single group of recipients. In 1972, these veterans acquired 7 million mail-order prescription medications.

COMPARISON OF FEATURES OF MAIL-ORDER PRESCRIPTION ORGANIZATIONS

Organization and population served	Also sells			Other services			
	Over-the-counter drugs	Sundries	Payment	Walk-in service	Patient profiles	WATS lines [1]	Use outside vendors
Federal Prescriptions Service, Inc. (public).	Yes	No	Full price	Yes	No	Yes	No.
Getz Prescription Co. (public).	Yes	Yes	do	Yes	No	Yes	No.
Health Insurance Plan of Greater New York (membership).	Yes	No	No charge [2]	Yes	No	Local	Yes.
National Council of Senior Citizens (membership).	Yes	Yes	Full price	Yes	No	Yes	No.
National Retired Teachers Association (membership).	Yes	Yes	do	Yes	No	Yes	No.
Pharmaceutical Services, Inc. (public).	Yes	No	do	Yes	Yes	Yes	No.
United Mine Workers of America Welfare and Retirement Fund (membership).	No	No	No charge	Yes	Yes	No	Yes.
Veterans Administration (beneficiaries).	Yes	No	do	Yes	No	Yes	Yes.
International Ladies Garment Workers Union (members and beneficiaries).	Yes	No	Copayment	Yes	No	Yes	No.

[1] Wide-area telephone service.
[2] No charge if medication is obtained from HIP facility; small charge if medication is obtained from a vendor pharmacy.

The United Mine Workers of America Welfare and Retirement Fund (UMWA) program is termed a "mail-out" program because the prescription order, which bears the patient's diagnosis, is sent directly to the pharmacy by the physician. The medication is then mailed to the patient from one of more than 100 participating community pharmacies and UMWA facilities. The 500,000 members, retired members, and their dependents reside primarily in 10 rural areas in the Appalachian region. UMWA facilities dispense and the welfare and retirement fund pays only for selected chronic-use drugs as prescribed by plan-approved physicians. The fund is supported by a trust contribution of 60 cents per ton of coal mined, soon to be raised to 80 cents per ton.

Pharmaceutical Services, Inc., of Kansas City, Mo., uses a computer-based drug interaction surveillance system in conjunction with a patient profile card service. In an effort to ascertain the validity of questionable prescriptions for schedule II drugs, this company maintains an extensive file of physicians' signatures.

The National Retired Teachers Association and American Association of Retired Persons has 5 million members, less than 10 percent of whom use the pharmacy service. The volume of dispensed prescriptions has reached 6,000 per day at the association's Washington, D.C., operation. In addition, the pharmacy service operates four other mail-order pharmacies in California, Connecticut,

Florida, and Missouri. NRTA-AARP also sells sundries at reduced cost to its patrons, as well as its own brand of over-the-counter drugs—as almost universal practice in this industry.

Direct Drug Service of Washington, D.C., supplies prescription and nonprescription drug products to members of more than 30 organizations, including the National Council of Senior Citizens and the National Farmers Union. Drugs are mailed and the patient billed, or the patient may save 2 percent by prepayment. Direct Drug Service is one of the firms that list prescription drug prices in its catalog. The service began in 1964 through a combined effort of the National Council of Senior Citizens and the Greenbelt Consumer Cooperative.

Health Insurance Plan of Greater New York is a prepaid comprehensive health care plan. Drug benefits are available to members for $1.20 per month for individuals, $2.40 for couples, and $3.60 for families (three or more people, children under 19 years). Prescriptions obtained through in-house facilities are dispensed without additional charge; patients who obtain prescriptions at community pharmacies receive an 80 percent reimbursement after their $25 annual deductible is satisfied.

Federal Prescription Service, Inc., of Madrid, Iowa, is similar to Direct Drug Service. It operates its own mail-order prescription service and also the drug plans for the National Association of Retired Federal Employees, Veterans of World War I, Amvets Drug Plan, American Vocational Association, National Association of Postmasters of the United States, and the National Federation of Federal Employees.

ISSUES REGARDING MAIL-ORDER SERVICES

The practice of mailing prescription drugs has always been accepted as a legitimate and necessary service to the patient when performed by the community-based or hospital pharmacy. However, the advent in the 1950's of high-volume, mail-order firms brought forth a storm of contraversy regarding the ethics of mail-order practice that continues to this day. Investigation has revealed that approximately 20 States have supported litigation against mail-order pharmacies that operate from out-of-State, on the premise that a pharmacist is required by law to obtain a license from the board of that State in which he practices (reference 4 and personal communication of July 12, 1973, from Fred Wegner of Retired Persons Services, Inc.).

The issue of the disruption of the physician-patient-pharmacist relationship is the crux of much of the debate surrounding mail-order programs. More and more, State boards of pharmacy are proposing regulations that prohibit the establishment of a mail-order pharmacy based on the presumed disruption of this relationship. In a recent issue of American Druggist, Kenneth Griswald, chairman of the Judicial Board, American Pharmaceutical Association, stated *(5)*: "It is usually impossible for a pharmacist in a mail-order pharmacy to render to each patient the full measure of his professional ability and to exercise proper professional judgments and skill. He has no personal knowledge of the patient or the prescribing physician on which to base his judgments and since no physician-patient-pharmacist relationship exists, it becomes virtually impossible for a pharmacist practicing in this environment to abide by Sections One and Seven" [of the American Pharmaceutical Association's Code of Ethics].

When one analyzes the current drug dispensing, it is apparent that the typical community-based pharmacy practice is not always able to provide for a true "physician-patient-pharmacist" relationship. The lack of definition of the concept and its select application makes it imperative, therefore, that the relevant professions establish standards of practice that specify the constitutional makeup of this tripartite relationship.

The issue of fraud has also been widely discussed. It is well known that various groups have illegally purchased drugs by mail through bogus prescriptions. The associate general counsel for the National Association of Retail Druggists in a letter to Sentaor Birch Bayh, dated August 7, 1972, stated: "We are confident that any responsible investigation of mail-order practices by Congress, Bureau of Narcotics and Dangerous Drugs, or any other group will demonstrate that widespread use of the mails to deliver drugs subject to abuse contributes to the drug diversion and the nation's drug abuse problems . . . An outright prohibition on the mail-order sale and delivery of drugs subject to abuse is essential and long overdue."

Two months later, John Ingersoll, director of the Bureau of Narcotics and Dangerous Drugs, stated at the annual meeting of the National Association of Retail Druggists that one argument against mail-order pharmacy that concerned BNDD was the diversion of controlled substances. ". . . In response to similar allegations made in 1969, the Bureau conducted an investigation of mail-order pharmacies and concluded at that time: The findings do not lend credence to the suspicion that mail-order prescription firms are a major source of diversion for controlled drugs. On the contrary, the level of compliance with the Drug Abuse Control Amendments of 1965 compares reasonably well with the general run of prescription pharmacies.

"The Bureau is concerned with the relative ease that controlled substances are obtained from all pharmacies. But this problem is not confined to mail-order houses, as shown by a *New York Daily News* survey last spring. Generally, it would appear that drug abusers are more likely to select a retail pharmacy rather than a mail-order pharmacy to attempt to pass a forged prescription. Their needs are of an immediate nature and are more quickly satisfied through a fast purchase. Safety is also a factor. Abusers do not want to give a return address to a mail-order house and prefer doing business with a local pharmacy. The abuser can watch the pharmacist's reaction to a forged script and quickly leave if the pharmacist goes to the telephone . . ."*(6)*.

DISCUSSION

The mail-order prescription drug industry appears to serve a real purpose by supplying the prescribed drug needs of patients who may be invalids, lack transportation, be isolated, or be in need of price savings otherwise unavailable. Further, this mode of practice is probably a permanent institution and will inevitably expand over time.

While the alleged disruption of the "physician-patient-pharmacist" relationship and the potential for fraud in the mail-order industry are two issues worthy of discussion, we wonder whether a motivating issue may be the economic competition that a mail-order operation presents to the local retail pharmacist. There is no doubt that contending forces need to document their positions.

The volume of prescription drugs distributed by mail constitutes only a small portion of the total distribution of drugs. However, public welfare will require adequate standards for this important method of drug delivery. Organized pharmacy is in a position to participate with interested parties in the objective evaluation of practices and the planning of standards for the mail-order prescription drug industry.

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[From the Journal of Contemporary Therapeutics, Hospital Formulary Management, April 1974]

EXHIBIT No. 5

THE RISE OF MAIL-SERVICE PHARMACIES

(By John R. McHugh, B.S., R.Ph., and Fred Wegner, B.A.)

Until 1973, little had appeared about mail-service pharmacies, either in the public or the trade media.

NOTE.—This article is an HFM "invitational paper." John McHugh is president and Fred Wegner is legislative representative of Retired Persons Services, 1750 K St. N.W., Washington, D.C., which serves members of the American Association of Retired Persons & the National Retired Teachers Association.

The detractors of the delivery system reasoned that if no one talked about it, maybe it would go away. And proponents of the system felt that drawing too much attention to it might attract adverse laws and regulations as well.

Last year, however, a number of articles enlightened many more people about mail-service pharmacies. And one even gave them economic status by analyzing and defining them as an "industry." That recognition came from Albert J. Wertheimer and James Knoben, authors of "The Mail-Order Prescription Drug Industry" which appeared in *Health Services Reports*, a publication of the U.S. Department of Health, Education and Welfare. (Editor's note—see page 11.)

A year after their "discovery" is too soon to speculate that an accommodation has been reached between the advocates of mail-service (they prefer that appellation to mail-order) pharmacies and many of the national and state officials of organized pharmacy, principally the National Association of Retail Druggists (NARD) and to a lesser extent the American Pharmaceutical Association (APhA). But a good deal of evidence supports the Wertheimer-Knoben contention that "The mail-order prescription drug industry appears to serve a real purpose of supplying the prescribed drugs needs of patients who may be invalids, lack transportation, be isolated, or be in need of price savings otherwise unavailable," and gives credence to their assertion that ". . . this mode of practice is probably a permanent institution and will inevitably expand over time."

A spokesman for independent pharmacies, Hugh A. Cotton, Associate Dean of the University of Kansas School of Pharmacy, was quickly in print with a feature article, "Can the Community Pharmacist Compete With the Mail Order Prescription Pharmacy?" in the August issue of *Journal of Kansas Pharmacy*. He answered the title's question in the affirmative and forecast a dim future for mail-service pharmacies *provided that* community pharmacies implemented "a pricing formula which is realistic and fair and just to the patient . . . along with the improvement of pharmaceutical services" and passed on "all discounts including cash to the patient." Who would not agree? The begging question remains. "Why doesn't the community pharmacy do so?" Rather than continue legislative and regulatory attempts to put mail-service pharmacies out of business and preserve their high margin of profit, why don't the independents try a bit of old-fashioned economic competition?

Yet, mailing medications is hardly a new concept. Community pharmacists for many years have mailed prescriptions to their customers on vacation or otherwise away from home. Ironically, in an effort to permit this practice to continue, APhA and other national and state pharmaceutical associations and leaders in 1952 were successful in defeating proposed interpretive regulations of the Food and Drug Administration that would have confined medication mailing to a "proximate trade area covering part of an adjacent state or territory," condemning that definition as too restrictive.

No sooner had the FDA backed down on its prescription mailing regulations than another federal agency, the Veterans Administration, began mailing medications to out-patient veterans. By 1963 a majority of eligible veterans were receiving drugs by mail due to an educational campaign waged by the VA which stressed the economy of that method of delivery and the considerable savings to taxpayers.

In the meantime, Western Medical Supply and other pharmacies were principally mailing phenobarbital to epileptics in interstate commerce. The first Retired Persons Pharmacy (formerly NRTA-AARP) was established in 1959 in Washington, D.C., by the National Retired Teachers Association and the American Association of Retired Persons. With the rapid membership growth of those Associations rising to over six million elderly persons, four additional Retired Persons Pharmacies commenced operations in the next 12 years and are located at St. Petersburg, Fla.; Kansas City, Mo.; Long Beach, Calif. and Hartford, Conn.

Because the Retired Persons Pharmacies came into being as the direct consequence of disproportionately high medication expenditures, often for maintenance therapy, among the Associations' elderly members, they were from the outset concerned primarily with two goals: 1) the most economical method of drug delivery, and 2) insistence on the best quality medications. In short, these pharmacies consider themselves to be medication buying agents performing a service on behalf of those member-patients who need or want it.

Price consciousness is a common characteristic of mail-delivery pharmacies—whether they serve members, beneficiaries, or the public. Despite the past 18 months of mounting inflation, Retired Persons Pharmacies lowered prices on three separate occasions.

Still, while price may be a prime reason for elderly members utilizing the Retired Persons Pharmacies, we cannot discount the importance of convenient delivery, NRTA-AARP sponsorship, drug quality assurance, credit, service, or the isolation of some older patients due to chronic illness, lack of transportation, or residential location—be it rural or inner city.

Some mail-service pharmacies make a genuine effort to inform patients about the savings they can achieve if their physicians will prescribe generically. The quality control officer at Retired Persons Pharmacies is responsible for making certain that only the best quality generics are purchased and dispensed, assuring both the pharmacy and its patients of the equivalency of chemically identical products. We believe any pharmacist involved now or in the future in product selection should have his judgment confirmed by some such quality control program.

Just as with most community pharmacies, patient profiles are not now maintained by most mail-service pharmacies, including the Veterans Administration, the largest drug mailing operation, and Retired Persons Pharmacies, which is second largest. While the latter service now provides warning inserts about contraindications, the further practice of clinical pharmacy among mail-delivery services will probably be a collorary function of increasing computerization. The United Mine Workers of America Welfare and Retirement Fund, which serves members, and Pharmaceutical Services, which serves the public, are both well-computerized and maintain patient profiles.

Retired Persons Pharmacies are implementing further innovative steps to benefit their patients. While federal legislation languishes and consumerist appeals fall on deaf ears, these pharmacies are voluntarily moving ahead with a phased consumer action program that includes:

(1) Labeling all prescriptions with the name and strength of the medication;
(2) Placing expiration dates on all time-related drugs;
(3) Including lot and/or control numbers on labels;
(4) Listing all ingredients, active and inactive, on NRTA-AARP brand products; and
(5) Posting prescription prices.

Before the Bureau of Narcotics and Dangerous Drugs' (now the Drug Enforcement Administration) *Project Script* showed community pharmacies more than twice as susceptible to fraudulent prescriptions as mail-service pharmacies, Retired Persons Pharmacies had ceased dispensing virtually all Schedule II drugs and had required telephone verification on those they continued to fill as well as on all amphetamine products dispensed to walk-in patients. Additionally, they had begun a drug verification survey which spot checks controlled substances prescriptions with the practitioner.

The NRTA-AARP legislative program, which is fully supported by the Associations' Pharmacy Service, continues to uphold the consumer's right to a free choice of pharmacy, seeks out-of-hospital drug coverage under Medicare, consumer representation on state boards of pharmacy, and generic prescribing and dispensing with quality controls in federally-aided programs, urges mandatory Rx price posting and permissive Rx price advertising with appropriate regulation, and works for the elimination of state laws and regulations that attempt to prohibit the mailing of prescription medications.

Retired Persons Pharmacies believe their collective activities have made them "a pharmacy with a conscience." Much of what they have managed to achieve, with the valuable support and stimulus of the two Associations they serve, can be done by any other pharmacy—independent, chain, clinical or mail-service.

We believe American consumers want and deserve a diversity of pharmacies to serve their varied needs. And what they want is surely what they will get.

The next witnesses are Mr. Donald Fedder, Mr. Carl Roberts, and Mr. Ronald Williams, all representing the American Pharmaceutical Association.

STATEMENT OF DONALD O. FEDDER, PRESIDENT, ACADEMY OF GENERAL PRACTICE OF PHARMACY, AMERICAN PHARMACEUTICAL ASSOCIATION, ACCOMPANIED BY CARL ROBERTS, ASSISTANT GENERAL COUNSEL AND RONALD WILLIAMS, EXECUTIVE SECRETARY, ACADEMY OF GENERAL PRACTICE OF PHARMACY, AMERICAN PHARMACEUTICAL ASSOCIATION

Mr. ROBERTS. We would like to submit our entire statement for the record. Mr. Fedder will present highlights from that statement so we can help you expedite the hearing this morning.

Senator BAYH. Thank you.

Mr. FEDDER. Mr. Chairman, my name is Donald Fedder. I am a practicing community pharmacist from Baltimore, Md., president of the Academy of General Practice of Pharmacy of the American Pharmaceutical Association, and a trustee-elect of the Association Board of Trustees. APhA is the national professional society of phamacists in the United States. Its membership consist of approximately 40,000 practicing pharmacists, pharmaceutical scientists, and pharmaceutical educators and, in addition, approximately 12,000 pharmacy students. APhA members, of course, are directly and substantially affected by the Comprehensive Drug Abuse Prevention and Control Act of 1970 and I am pleased to present the association views on that legislation.

I am accompanied by Ronald Williams, executive secretary of the Academy of General Practice and Mr. Carl Roberts, our counsel.

Your invitation to testify specified 10 specific questions and issues which you wish us to address. I would like to proceed to these points in order.

1. What can be done to more effectively curb the alarming number of robberies, burglaries, thefts, and assaults directed at pharmacies and those who operate them?

Needless to say, APhA shares the concern of other pharmacy organizations and individual pharmacists concerning the high incidence of criminal activities directed at pharmacies and pharmacists. The association has received numerous reports of such crimes, many of them resulting in serious injury and sometimes even death for the pharmacist victims. Examples are attached hereto as exhibit I. Most of these crimes involve more than efforts to obtain money. Although money is frequently taken, it appears that the prime target for such crimes is the pharmacy inventory of controlled substances.

Although we recognize that we would have no problem if it was capable of easy solution, we do believe that steps can be taken to reduce the incidence of such crimes and are pleased to report that Federal authorities have recently taken at least one of them. DEA has recently adopted a regulation which permits the pharmacist to disperse among his general prescription drug inventory schedule II controlled substances. Previously, all schedule II substances were required to be kept locked in one place where they could be readily obtained by holdup men or burglars. Some pharmacists feel that keeping schedule II substances together in one location involves

less personal risk than dispersal, and they would have the option under the new regulation. However, the weight of pharmacists' opinion seems to favor dispersal and a policy supporting such optional procedure was formally adopted by the APhA House of Delegates at its 1973 annual meeting.

Many pharmacists believe that the new schedule II dispersal regulation will have the effect of reducing face-to-face crimes but they recognize that it may increase the incidence of burglaries. Naturally, we would be pleased from the standpoint of pharmacists' personal safety if the first part of this projection were to prove correct, but we would be most distressed in terms of potential property loss and drug diversion if the second part were also to prove correct. Consequently, we believe that pharmacists will realistically have to reduce controlled substance inventories and take whatever feasible security measures are available to combat burglaries. Although it is too early to gage the effects of the new regultaion, we are hopeful that dispersal of schedule II controlled substances combined with reduction of inventory as recommended by DEA will have a beneficial effect.

APhA also supports legislative efforts to make drug-related crimes against pharmacies and pharmacists a Federal criminal offense. Several bills toward this end have been introduced in the House and Senator Church has introduced S. 2327 toward the same end in the Senate. As everyone generally knows, bank robbery is a specific Federal crime, and we believe this has served as a valuable deterrent to this offense. In our view, the human consequences of criminal drug diversion from pharmacies by robbery and theft are at least as serious as those posed by crimes directed at property alone. We feel the bill as presented should be amended and I would like to call for a voluntary comment there.

Mr. ROBERTS. We would like to add our suggestions to the Church bill to expand it beyond just narcotic controlled substances. It ought to be applied to all controlled substances. I agree with Mr. Rector that there are other technical amendments that have to be made to make it consistent with the act and we would naturally be pleased to offer our support and cooperation in arriving at a good bill. But we certainly support the concept of the Church and similar bills.

Senator BAYH. Thank you.

Mr. FEDDER. Finally on this subject, a requirement for special security measures in pharmacies such as secure prescription departments, alarm systems, and bank-type camera surveillance systems has been widely discussed both in pharmaceutical and regulatory circles. To the best of our knowledge such requirements are still under active consideration by DEA. Such security measures might be instituted voluntarily by a significant number of pharmacists if they were able to afford the extensive costs of such systems. The simple fact, however, is that the average community pharmacist is not able to absorb the cost of such security measures. Consequently, we wish to suggest for your consideration a program of direct grants, tax credits, or other economic incentives to assist pharmacists in obtaining security devices which may be required.

2. "The nature and extent of crimes directed at pharmacies and their impact on society and pharmacy."

Clearly, the impact of all crime is detrimental. This is no less the case when a pharmacy or pharmacist is the victim. The first question we discussed alludes to the types of crimes experienced by pharmacies and pharmacists, but it does not reflect the number of deaths associated with such crimes. Unfortunately, although APhA is aware of individual tragedies involving pharmacists, as illustrated by exhibit I, the association is not able to gather hard data regarding the total number of pharmacy-directed crimes or a statistical breakdown of crimes by type. To the best of our knowledge, the only such data readily available is in the possession of DEA. Whatever the extent of such crime, however, we can state emphatically that it realistically threatens the continued availability of pharmaceutical services in many areas. When, as some have, a pharmacist closes the doors of his pharmacy because he fears for his life or because it is economically impossible for him to continue his practice because of crime, he is not the only loser. Truly it is the community which also suffers, and this problem must be viewed, not merely as a law enforcement problem, but also as a real and substantial public health problem. It is imperative that the potential loss of pharmacist availability not be minimized.

4. "And assessment of the extent to which prescription fraud and mail-order diversion contribute to illicit traffic and abuse of dangerous drugs and recommendations to more effectively curb diversion from both of these sources."

Mr. Chairman, we have attached to this statement as exhibit II a letter to DEA dated August 30, 1973, which addresses this subject matter. The letter presents our basic views on this issue and to it I would simply add the following: APhA has a long-standing policy in opposition to mail-order pharmacy services. While mail-order pharmacy services have a degree of economic impact on community pharmacists, and that would be a sufficient reason to oppose them in the minds of some pharmacists, APhA opposition to mail-order pharmacies is based on the predicate that they represent an inadequate and frequently harmful form of pharmaceutical care, usually to patients for whom direct contact with a pharmacist is most critical. Thus, we do not see that a pharmacist can play a meaningful role in patient care when he does not communicate with the patient.

Although every pharmacist doesn't always have contact with every patient, it is very important that the opportunity exists for the patient to talk to the pharmacist and vice versa. In my own practice, I had the experience just recently where a patient presented a prescription to be filled for an anticholinergic drug, a drug used in gastrointestinal distress. We maintain patient drug profiles on which we record pertinent information regarding a patient's disease state and the drugs he is taking. In this instance, we noted that this patient was being treated by an ophthalmologist at Johns Hopkins for glaucoma, a disease in which the intraocular pressure is elevated, and if given an anticholinergic drug it is possible that this pressure could be dangerously increased. We promptly consulted the prescribing physician, another drug was selected, and a possible harmful drug interaction was averted.

This is the type of meaningful patient-pharmacist-physician contact that we are talking about.

Senator BAYH. May I state that this is an excellent example of the importance of coordinating the role of all those in the chain of delivery of health care, unrelated to the specific problem of abusive substances. It is certainly a significant example.

Mr. FEDDER. As APhA has stated on so many occasions, and as we restate now, the role of the pharmacist goes far beyond any mechanical "count, pour, and label" dispensing of drugs. Now, added to the adequacy of health care problem is the potential for diversion of controlled substances for mail-order sources. We know this is not merely a potential, for the ability to obtain by fraud controlled substances from such sources has been demonstrated both by pharmacists and law enforcement officials. We recognize that drugs have been obtained in the same fashion from community pharmacies, but the difference, in our view, is that the community pharmacist who lives in the community he serves is far more interested in preventing diversion, than is the mail-order pharmacy service whose primary objective is the volume sale of prescription drugs.

It is common practice in many areas, both through Federal arrangements supported by local pharmaceutical associations and through informal arrangements between pharmacists, for warning networks to be established whereby pharmacists inform each other of attempts at drug diversion, identification of known or suspected prescription forgers and thefts or other disappearances of physicians' prescription blanks. What similar activity is undertaken by mail-order pharmacy services? It is our position that the mailing of controlled substances from pharmacy to patient when the patient is not personally known should be prohibited.

5. "What can be done to deal more effectively with the few pharmacists who illegally distribute controlled drugs and to encourage pharmacists to identify the few physicians who improperly or illegally contribute to the traffic and abuse of dangerous controlled drugs?

Mr. Chairman, this point strikes a raw nerve with APhA. Our position always has been and continues to be that any person, including pharmacists or physicians, who engage in criminal activity should be dealt with as criminals. As far as we are concerned such persons should not be permitted to hide behind a veil of professionalism but should be subjected to the penalties for which the law provides.

7. "An assessment of current methods for reporting and compiling diversion statistics and proposals to require a triplicate prescription system for dangerous nonnarcotic drugs."

As to the first point, it is difficult for us to assess the gathering and dissemination of statistical information relating to diversion. To the best of our knowledge, the only purportedly comprehensive information currently available is that gathered from DEA theft report forms (DEA form 106). We understand, however, that the ARCOS system under development by DEA will increase the avail-

ability of such information. We know of no practical means or need for pharmaceutical associations to gather such information.

On the second point of the question, we oppose establishment of any triplicate prescription form system under which pharmacists would be required to forward a copy of the form to a State or Federal regulatory agency. In those few areas where such a system has been instituted, its only measurable result has been an increase in both time and expense for pharmacists and the public and the stockpiling of paper in Government warehouses. We know of no instance in which such a system can be regarded as a "success". On the other hand, we do believe and have urged that control of prescription forms should be increased. This matter is also addressed in exhibit II.

At this time, we would like to suggest for consideration the establishment of a prescription form system much like that for schedule II controlled substances order forms. Specifically, we believe that official, duplicate prescription forms, serially numbered on bank note type paper, which would be ordered by the prescriber, could be of substantial benefit. Under such a system, the prescriber, would retain one copy of the form for his files while the original would be provided the pharmacist by the patient. When necessary, the serial numbers on the form could be confirmed by the pharmacist, and, in addition, the official status and serial number control of such forms could be expected to result in physician concern and control better than that which is exercised with regard to standard prescription for pads now. We believe such a system deserves serious consideration and that it would impose no additional cost factor to the Government since it could be self-financing in the same manner as were schedule II order forms.

9. "The need for more flexibility in the schedules of the 1970 Act."

In our view, there appears to be sufficient flexibility balanced with a requirement for scientific and medical judgment input into the decisions regarding the scheduling of controlled substances under the 1970 act. APhA believes it imperative that this balance be maintained and that controlled substances not be scheduled or rescheduled on the basis of "knee-jerk" reactions. Rather, such decisions can be properly made only on the basis of a full evaluation of the criteria and with the safeguards established by Congress in 1970.

Having said that, we do wish to point out that there is one schedule-related problem which we believe should be corrected. We refer to the necessity of reschduling or initially scheduling controlled substnces in schedule II where the primary objective is to impose production quotas on the controlled substance involved. It appears that production quota motivation has been the primary underlying objective in several control decisions made thus far. These would include amphetamines and the short-acting barbiturates. We emphasize that we are not critical of the decision to limit production of these controlled substances. Rather, our concern is that the necessity for utilizing schedule II to activate the production quota mechanism also carries with its restrictions on prescribing and dispensing which are costly to the public and which may be unnecessary in a given case.

I might add that I am a member of the board of directors of a wholesale drug company. It has come to my attention just this past week, that the three major wholesalers in the Baltimore area have increased the prices they charge for all schedule II controlled drugs. The basis for this increase is the increase cost of handling these drugs and an across the board increase of the nature of 5 percent was imposed. This is a very real cost that must be passed on to the consumer.

Specifically, we refer to the written prescription and no refill requirements applicable to schedule II controlled substances. It may well be that production of a particular controlled substance should be limited, but at the same time, in terms of the abuse problem associated with that controlled substance, schedule III, IV or V controls generally may be adequate. The logical solution to the problem, we think, is to expand the Attorney General's production quota authority so that it will be applicable to all controlled substances without regard to their schedule. In this way, rational production limitation decisions can be implemented without their becoming entangled in unnecessary prescribing, dispensing and record-keeping requirements.

10. "The need for a formal procedure to assure that the views and experience of professional pharmacists are considered in the development of Federal drug control decisions."

Mr. Chairman, our recent and current experience demonstrates that DEA is willing to listen to pharmacy viewpoints and to consider them in arriving at its regulatory decisions. Particularly, we are pleased with the informal "working committee" established to provide meaningful DEA-pharmacy liaison. We believe the efforts of this working committee have been undertaken in good faith, have been productive, and have focused on reasonable and rational results from both the regulatory and professional practice standpoints.

As an example of the cooperation we have received from DEA, we would cite the problem we had experienced with inconsistencies between published DEA regulations and advance press releases announcing the forthcoming regulations. Attached hereto as exhibit IV is a letter to DEA dated November 26, 1973, which summarized the problem. We bring this to your attention not to open old wounds, but to illustrate the responsiveness of DEA to the problem. As a result of this letter, a meeting was held, the problem discussed, and commitments made by DEA aimed at eliminating the problem. We have every reason to believe that these commitments will be honored.

It is no secret that during the development of the 1970 Act APhA had difficulty in obtaining serious consideration of pharmacy viewpoints. That situation has clearly turned around. We believe that DEA and APhA have developed a mutual respect for the other's responsibilities and problems. Thus, at this time, it would not seem necessary to establish any formal mechanism beyond the one already available, rulemaking under the Administrative Procedure Act, to assure the consideration of pharmacy viewpoints. If an additional formal mechanism were created, we certainly would not object to it and would be pleased to participate in it. In the present climate,

however, such a procedure would not seem to be required. If the climate changes, you can be assured you will be among the first to know.

Mr. Chairman, the pharmacist clearly does not practice in "the best of all possible worlds." Specific problems remain and improvements in the system can and should be made. We have tried to recommend improvements which we believe are both feasible and reasonable from the standpoint of both law enforcement objectives and health care objectives. By and large, we are satisfied with our relationship with DEA and intend to devote our efforts to mutually beneficial efforts with that agency. We are particularly pleased that the limited evidence which is available supports our contention that pharmacists are conscientiously seeking to fulfill their responsibilities under the Comprehensive Drug Abuse Prevention and Control Act of 1970. We are confident that these efforts by the profession will continue.

Thank you.

Senator BAYH. Thank you very much, gentlemen. We appreciate your contribution, and if it is the same with you, we could submit those questions in writing and thus permit you to go about your way and for us to terminate our hearing sometime before 2 o'clock we appreciate it very much. Your contribution has been very helpful and we look forward to having the response to the questions.

Mr. FEDDER. Thank you very much.

Senator BAYH. Thank you for being with us. We appreciate it.

[Mr. Fedder's prepared statement is as follows:]

PREPARED STATEMENT OF THE AMERICAN PHARMACEUTICAL ASSOCIATION

Mr. Chairman, members of the subcommittee, my name is Donald Fedder. I am a practicing community pharmacist from Baltimore, Maryland, President of the Academy of General Practice of Pharmacy of the American Pharmaceutical Association, and a Trustee-elect of the Association Board of Trustees. APhA is the national professional society of pharmacists in the United States. Its membership consists of approximately 40,000 practicing pharmacists, pharmaceutical scientists and pharmaceutical educators, and, in addition, approximately 12,000 pharmacy students. APhA members, of course, are directly and substantially affected by the Comprehensive Drug Abuse Prevention and Control Act of 1970 and I am pleased to present the Association views on that legislation.

Your invitation to testify specified ten specific questions and issues which you wish us to address. I'd like to proceed to these points in order.

1. *What can be done to more effectively curb the alarming number of robberies, burglaries, thefts and assaults directed at pharmacies and those who operate them?"*

Needless to say, APhA shares the concern of other pharmacy organizations and individual pharmacists concerning the high incidence of criminal activities directed at pharmacies and pharmacists. The Association has received numerous reports of such crimes, many of them resulting in serious injury and sometimes death for the pharmacist victims. Examples are attached hereto as Exhibit I. Most of these crimes involve more than efforts to obtain money. Although money is frequently taken, it appears that the prime target for such crimes is the pharmacy inventory of controlled substances.

Although we recognize that we would have no problem if it was capable of easy solution, we do believe that steps can be taken to reduce the incidence of such crimes and are pleased to report that federal authorities have recently taken at least one of them. DEA has recently adopted a regulation which permits the pharmacist to disperse among his general prescription drug inventory Schedule II controlled substances. Previously, all Schedule II substances were required to be kept locked in one place where they could be readily obtained by hold-up men or burglars. Some pharmacists feel that keeping Schedule II substances together in one location involves less personal risk than dispersal, and they would have that option under the new regulation. However, the weight of pharmacist opinion seems to favor dispersal and a policy supporting such an optional procedure was formally adopted by the APhA House of Delegates at its 1973 Annual Meeting.

Many pharmacists believe that the new Schedule II dispersal regulation will have the effect of reducing face-to-face crimes but they recognize that it may increase the incidence of burglaries. Naturally, we would be pleased from the standpoint of pharmacist personal safety if the first part of this projection were to prove correct, but we would be most distressed in terms of potential property loss and drug diversion if the second part were also to prove correct. Consequently, we believe that pharmacists will realistically have to reduce controlled substance inventories and take whatever feasible security measures are available to combat burglaries. Although it is too early to gauge the effects of the new regulation, we are hopeful that dispersal of Schedule II controlled substances combined with reduction of inventory as recommended by DEA will have a beneficial effect.

APhA also supports legislative efforts to make drug-related crimes against pharmacies and pharmacists a federal criminal offense. Several bills toward this end have been introduced in the House and Senator Church has introduced S. 2327 toward the same end in the Senate. As everyone generally knows, bank robbery is a specific federal crime, and we believe this has served as a valuable deterrent to this offense. In our view, the human consequences of criminal drug diversion from pharmacies by robbery and theft are at least as serious as those posed by crimes directed at property alone.

Finally, on this subject, a requirement for special security measures in pharmacies such as secure prescription departments, alarm systems and bank-type camera surveillance systems has been widely discussed both in pharmacy and regulatory circles. To the best of our knowledge such requirements are still under active consideration by DEA. Such security measures might be instituted voluntarily by a significant number of pharmacists if they were able to afford the extensive costs of such systems. The simple fact, however, is that the average community pharmacy is not able to absorb the cost of such security measures. Consequently, we wish to suggest for your consideration a program of direct financial assistance to pharmacists in the form of direct grants, tax credits, or other economic incentives to assist pharmacists in obtaining security devices which may be required.

2. *"The nature and extent of crimes directed at pharmacies and their impact on society and pharmacy."*

Clearly, the impact of all crime in detrimental. This is no less the case when a pharmacy or pharmacist is the victim. The first question we discussed alludes to the types of crimes experienced by pharmacies annd pharmacists, but it does not reflect the number of deaths associated with such crimes. Unfortunately, although APhA is aware of individual tragedies involving pharmacists, as illustrated by Exhibit I, the Association is not able to gather hard data regarding the total number of pharmacy-directed crimes or a statistical breakdown of crimes by type. To the best of our knowledge, the only such data readily available is in the possession of DEA. Whatever the extent of such crime, however, we can state emphatically that it realistically threatens the continued availability of pharmaceutical service in many areas. When, as some have,a pharmacist closes the doors of his pharmacy because he fears for his life or because it is economically impossible for him to continue his practice because of crime, he is not the only loser. Truly, it is the community which also suffers, and this problem must be viewed not merely as a law enforcement problem but also as a real and substantial public health problem. It is imperative that the potential loss of pharmacist availability not be minimized.

3. *"The impact of the 1970 Act on the diversion and traffic of legitimately produced and distributed dangerous drugs."*

The information available to APhA indicates that enforcement efforts directed at diversion of drugs produced for legitimate, therapeutic purposes are having a positive effect overall. The establishment of production quotas for

some controlled substances, about which we will have more to say in a moment, is clearly a sensible approach to the problem. So long as legitimate therapeutic needs are met, the less there is produced, the less there is to divert to illicit channels of distribution. Also, information available from DEA seems to indicate that increased security measures at the manufacturing and wholesale distribution levels are proving effective. To the extent this is correct, it might tend to explain increased efforts to criminally obtain controlled substances at the pharmacy level. This effect has been foreseen both by pharmacists and law enforcement authorities. The issue is how to deal with the problem.

4. *"An assessment of the extent to which prescription fraud and mail order diversion contribute to illicit traffic and abuse of dangerous drugs and recommendations to more effectively curb diversion from both of these sources."*

Mr. Chairman, we have attached to this statement as Exhibit II a letter to DEA dated August 30, 1973, which addresses this subject matter. The letter presents our basic views on this issue and to it I would simply add the following. APhA has a long-standing policy in opposition to mail order pharmacy services. While mail order pharmacy services have a degree of economic impact on community pharmacists, and that would be sufficient reason to oppose them in the minds of some pharmacists, APhA opposition to mail order pharmacies is based on the predicate that they represent an inadequate and frequently harmful form of pharmaceutical care, usually to patients for whom direct contract with a pharmacist is most critical. Thus, we do not see that a pharmacist can play a meaningful role in patient care when he does not communicate with the patient.

As APhA has stated on so many occasions, and as we restate now, the role of the pharmacist goes far beyond any mechanical "count, pour and label" dispensing of drugs. Now, added to the adequacy of health care problem is the potential for diversion of controlled substances from mail order sources. We know this is not merely a potential, for the ability to obtain by fraud controlled substances from such sources has been demonstrated both by pharmacists and law enforcement officials. We recognize that drugs have been obtained in the same fashion from community pharmacies, but the difference, in our view, is that the community pharmacist who lives in the community he serves is far more interested in preventing diversion, than is the mail order pharmacy service whose primary objective is the volume sale of prescription drugs.

It is common practice in many areas, both through federal arrangements supported by local pharmaceutical associations and through informal arrangements between pharmacists, for warning networks to be established whereby pharmacists inform each other of attempts at drug diversion, identification of known or suspected prescription forgers and thefts or other disappearances of physicians' prescription blanks. What similar activity is undertaken by mail order pharmacy services? It is our position that the mailing of controlled substances from pharmacy to patient when the patient is not personally known should be prohibited.

5. *"What can be done to deal more effectively with the few pharmacists who illegally distribute controlled drugs and to encourage pharmacists to identify the few physicians who improperly or illegally contribute to the traffic and abuse of dangerous controlled drugs?"*

Mr. Chairman, this point strikes a raw nerve with APhA. Our position always has been and continuous to be that any person, including pharmacists or physicians, who engage in criminal activity should be dealt with as criminals. As far as we are concerned such persons should not be permitted to hide behind a veil of professionalism but should be subjected to the penalties for which the law provides.

The sore point with APhA is the apparent unwillingness of many state licensing agencies to impose appropriate sanctions on pharmacists or physicians caught in such situations. We are not talking here about technical violations involving record keeping or occasional errors in professional judgment. What we are referring to is the unwillingness of some such agencies to close up what pharmacists know to be the few pharmacy sources of drug diversion or to revoke licenses of physicians abusing their prescribing privileges. For example, it has been common knowledge among pharmacists in some areas that a small number

of pharmacies have operated as "syrup shops" dispensing quantities of exempt narcotic cough preparations far in excess of reasonable medical need. If such situations are known to local pharmacists and even are brought to the attention of APhA, why are the pharmacies and pharmacists not the subject of appropriate enforcement efforts by boards of pharmacy? Why are medical licensing agencies similarly derelict? Happily, from our standpoint, DEA is taking enforcement action against such pharmacies and also against physicians involved in significant controlled substances violations. We wish to publicly acknowledge that fact and to commend DEA for its even-handed approach to enforcement of the act. Over the years, pharmacists have complained that enforcement efforts have been directed against them while physicians have been ignored. From those enforcement actions published in the *Federal Register* over the past several months, we must say that this presently is not the case. We are also pleased that DEA enforcement statistics, attached as Exhibit III, confirm our view that pharmacists are not the basic problem.

6. *"The merit of requiring verification of identity and initialling of prescriptions by pharmacists."*

The previously referenced letter attached as Exhibit II addresses itself to this question, and I will not comment further on it.

7. *"An assessment of current methods for reporting and compiling diversion statistics and proposals to require a triplicate prescription system for dangerous non-narcotic drugs."*

As to the first point, it is difficult for us to assess the gathering and dissemination of statistical information relating to diversion. To the best of our knowledge, the only purportedly comprehensive information currently available is that gathered from DEA theft report forms (DEA Form 106). We understand, however, that the ARCOS system under development by DEA will increase the availability of such information. We know of no practical means or need for pharmaceutical associations to gather such information.

On the second point of the question, we oppose establishment of any "triplicate" prescription form system under which pharmacists would be required to forward a copy of the form to a state or federal regulatory Agency. In those few areas where such a system has been instituted, its only measurable result has been an increase in both time and expense for pharmacists and the public and the stockpiling of paper in government warehouses. We know of no instance in which such a system can be regarded as a "success." On the other hand, we do believe and have urged that control of prescription forms should be increased. his matter is also addressed in Exhibit II.

At this time, we would like to suggest for consideration the establishment of a prescription form system much like that for Schedule II controlled substances order forms. Specifically, we believe that official, duplicate prescription forms, serially numbered on bank note type paper, which would be ordered by the prescriber, could be of substantial benefit. Under such a system, the prescriber would retain one copy of the form for his files while the original would be provided the pharmacist by the patient. When necessary, the serial numbers on the form could be confirmed by the pharmacist, and, in addition, the official status and serial number control of such forms could be expected to result in physician concern and control better than that which is exercised with regard to standard prescription form pads. We believe such a system deserves serious consideration and that it would impose no additional cost factor the government since it would impose no additional cost factor to the government since it could be self-financing in the same manner as are Schedule II order forms.

8. *"The need to make the 1970 Act infraction data more accessible to state pharmacy boards in order to facilitate appropriate disciplinary or license revocation decisions."*

To the best of our knowledge, there is no "infraction data" which is not accessible to state pharmacy boards. As we have pointed out, if there exists a problem, it appears to be the unwillingness of some state boards to make appropriate use of such data when it is obtained or made available to them. As we have also stated in connection with prior Controlled Substances Act testimony, there is no evidence that pharmacists are responsible for a significant number of Controlled Act violations or for drug diversion. That fact has been confirmed by DEA. Nonetheless, we believe that any serious violations of the

law, no matter how few in number, must be dealt with vigorously. The failure of law enforcement officials to take forceful action in appropriate cases merely serves to penalize those pharmacists who make a conscious effort to live up to their professional and legally imposed responsibilities. Mr. Chairman, I wish to emphasize that we are not suggesting here that state licensing agencies or other law enforcement officials should engage in harrassment of pharmacists or physicians over what are essentially minor technical violations of the Act. We are addressing ourselves to serious criminal activities.

9. *"The need for more flexibility in the schedules of the 1970 Act."*

In our view, there appears to be sufficient flexibility balanced with a requirement for scientific and medical judgment input into the decisions regarding the scheduling of controlled substances under the 1970 Act. APhA believes it imperative that this balance be maintained and that controlled substances not be scheduled or rescheduled on the basis of "knee-jerk" reactions. Rather, such decisions can be properly made only on the basis of a full evaluation of the criteria and with the safeguards established by Congress in 1970.

Having said that, we do wish to point out that there is one schedule-related problem which we believe should be corrected. We refer to the necessity of rescheduling or initially scheduling controlled substances in Schedule II where the primary objective is to impose production quotas on the controlled substance involved. It appears that production quota motivation has been the primary underlying objective in several control decisions made thus far. These would include amphetamines and the short-acting barbiturates. We emphasize that we are not critical of the decision to limit production of these controlled substances. Rather, our concern is that the necessity for utilizing Schedule II to activate the production quota mechanism also carries with it restrictions on prescribing and dispensing which are costly to the public and which may be unnecessary i na given case. Specifically, we refer to the written prescription and no refill requirements applicable to Schedule II controlled substances. It may well be that production of a particular controlled substance should be limited, but at the same time, in terms of the abuse problem associated with that controlled substance, Schedule III, IV or V controls generally may be adequate. The logical solution to the problem, we think, is to expand the Attorney General's production quota authority so that it will be applicable to all controlled substances without regard to their schedule. In this way, rational production limitation decisions can be implemented without their becoming entangled in unnecessary prescribing, dispensing and record-keeping requirements.

10. *"The need for a formal procedure to assure that the views and experience of professional pharmacists are considered in the development of federal drug control decisions."*

Mr. Chairman, our recent and current experience demonstrates that DEA is willing to listen to pharmacy viewpoints and to consider them in arriving at its regulatory decisions. Particularly, we are pleased with the informal "working committee" established to provide meaningful DEA-pharmacy liaison. We believe the efforts of this working committee have been undertaken in good faith, have been productive, and have focused on reasonable and rational results from both the regulatory and professional practice standpoints.

As an example of the cooperation we have received from DEA, we would cite the problem we had experienced with inconsistencies between published DEA regulations and advance press releases announcing the forthcoming regulations. Attached hereto as Exhibit IV is a letter to DEA dated November 26, 1973, which summarized the problem. We bring this to your attention not to open old wounds, but to illustrate the responsiveness of DEA to the problem. As a result of this letter, a meeting was held, the problem discussed, and commitments made by DEA aimed at eliminating the problem. We have every reason to believe that the commitments will be honored.

It is no secret that during the development of the 1970 Act APhA had difficulty in obtaining serious consideration of pharmacy viewpoints. That situation has clearly turned around. We believe that DEA and APhA have developed a mutual respect for the other's responsibilities and problems. Thus, at this time, it would not seem necessary to establish any formal mechanism beyond the one already available, rule-making under the Administrative Procedure Act, to assure the consideration of pharmacy viewpoints. If an additional formal

mechanism were created, we certainly would not object to it and would be pleased to participate in it. In the present climate, however, such a procedure would not seem to be required. If the climate changes, you can be assured you will be among the first to know.

Mr. Chairman, the pharmacist clearly does not practice in "the best of all possible worlds." Specific problems remain and improvements in the system can and should be made. We have tried to recommend improvements which we believe are both feasible and reasonable from the standpoint of both law enforcement objectives and health care objectives. By and large, we are satisfied with our relationship with DEA and intend to devote our efforts to mutually beneficial efforts with that agency. We are particularly pleased that the limited evidence which is available supports our contention that pharmacists are conscientiously seeking to fulfill their responsibilities under the Comprehensive Drug Abuse Prevention and Control Act of 1970. We are confident that these efforts by the profession will continue.

EXHIBIT I

DRUGSTORE SLAYING VICTIM—"A KIND AND GENTLE MAN"

(By Grayson Mitchell)

His wife of 23 years, Katherine, spoke of his "kindness" and "compassion."

She talked about what a "good man" Herman B. Bretler had been throughout his 60 years, about how "the Maker in Heaven had cut up the pattern when he was born."

Herman B. Bretler died shortly before 11 p.m. Tuesday after being shot in the head and chest during a robbery attempt at the Hillcrest Heights drugstore where Bretler worked as a pharmacist.

The other employee told police Bretler was in the rear of the Drug Mart store at 2334 Iverson Pl. when the shots from the small caliber handgun rang out. Second later, police said, the gunman fled through the front door and Bretler was found slumped behind the pharmacy counter, wounded.

He died before a Maryland State Police helicopter could carry him to a hospital emergency room.

It was all so incongruous, his widow said, for a man so "gentle and kind" to have his life taken away so violently.

"Herman was the kind of man who would go out of his way to help somebody. He was the kind of guy you'd like to be around all the time," recalled his brother-in-law, James Biller.

He had never talked of dying or of being scared, said Mrs. Bretler. He had been working in drugstores, dealing with the public, since he was a 12-year-old boy growing up in Northwest Washington.

"Herman was brave. If some suspicious guys ever came into the store he'd just go up to them to 'get out of here or I'll call the police'," Mrs. Bretler said.

She said in the 30 years her husband had sold medicines he had never been robbed. There never even was a close call.

Bretler loved working in drugstores. There had been periods in his career, according to his widow, when he mixed pills and stirred formulas from sun-up to sundown.

Herman Bretler worked his way through the old College of Pharmacy at George Washington University from wages he earned working parttime and summers as a clerk in an apothecary shop. He graduated in the class of 1931.

In 1948, Bretler had saved enough money to open his own drugstore on Pennsylvania Avenue in Southeast Washington. His widow recalled that she was "the one who wrote all the bills because Herman was bad about keeping up with money," she recalled.

They sold the business in 1957, she said, because "all the headaches and responsibility were getting too much." In later years, she said, he worked for the Metro Drugstore chain in Upper Marlboro and Waldorf and liked being the employee instead of the boss.

Six months ago, when most of his friends were retiring, Bretler went to work for Drug Mart, working three nights and two days a week.

Mrs. Bretler said that they couldn't live on monthly Social Security checks, so her husband had to keep working.

The Bretlers moved from Washington about 10 years ago to a ranch house in Temple Hills. The Bretlers had no children together, but Bretler had a daughter by a previous marriage who lives in Chicago.

The members of the Prince George's County-Montgomery County Pharmaceutical Association, an organization to which Bretler belonged for more than 10 years, announced yesterday it was offering a $1,000 reward for the apprehension of Bretler's killer.

RESOLUTION

Whereas, The number of Drug Store Robberies and Burglaries in Philadelphia has become a daily occurance.

The number of Drug Stores closing in Philadelphia has decreased the number of such stores from 1400 to 525.

There have been seven pharmacists murdered during the course of their professional activities.

A critical shortage of pharmaceutical services may face the citizens of Philadelphia causing a health hazard.

The cause of such crimes of violence is directly related to Federally controlled Substances of the Federal Controlled Substances Act of 1970 (Public Law 9-513) : Now, therefore be it

Resolved, That the Philadelphia Association of Retail Druggists on behalf of the Pharmacists of the United States does hereby request The Congress of The United States to enact Legislation amending the Controlled Substances Act to make it a Federal Crime to commit or attempt to commit a robbery or a burglary or any other act of violence of a Pharmacy registered with the Federal Bureau of Narcotics and Dangerous Drugs in the United States and its Territories.

EXHIBIT II

AMERICAN PHARMACEUTICAL ASSOCIATION,
Washington, D.C., August 30, 1973.

KENNETH A. DURRIN,
Acting Chief,
Compliance Investigation Division,
Drug Enforcement Administration,
U.S. Department of Justice,
Washington, D.C.

DEAR MR. DURRIN: The American Pharmaceutical Association, the national professional society of pharmacists, has reviewed the discussion draft of proposed changes in 21 CFR 306 which would attempt to deal with the diversion of legitimately produced controlled substances through the mechanism of forged, stolen, or altered prescription orders, and the following comments are offered.

Quantification of the Problem—Although APhA is as eager to solve the problem of diversion as is the Drug Enforcement Administration, we feel that any proposed remedial action must reflect an equitable balance between the extensiveness of the problem being attacked and the time, effort and expense required to implement corrective measures. In this case, DEA has failed to demonstrate that the problem of diversion through fraudulent prescription orders is in fact a significant one, particularly when weighed against the total numbers of controlled substances dispensed entirely legitimately through the nation's pharmacies. We feel that DEA is entirely unjustified in promulgating regulations that will be an unnecessary burden on the pharmacist, the patient, and the prescriber, based primarily on the results of Project Script, which in no way quantified the prevalence of prescription fraud. At such time that such definitive proof of a wide spread problem is brought forth, APhA would be the first to cooperate in any reasonable program necessary to combat the problem.

Besides its obvious failure to quantify the problem, Project Script suffers from a number of research deficiencies that seriously detract from its credibility; these deficiencies are presented in Addendum A.

Effect on the Patient—Besides the obvious embarrassment and harassment which many patients would feel when asked for identification, particularly those personally known by their pharmacists, the proposed regulations could have serious effects on patient care and the availability of medication. It is not uncommon for a patient in need of a controlled substance to be unable because of his illness to procure the medication himself, and the agent he employs may either not carry the required identification or its verification would be meaningless. For example, patients often send children for their medication, and in other cases, may use persons unknown even to themselves, such as taxi drivers or delivery boys. Of what value is it to the pharmacist to verify the identification of a purported agent if he has no way of assuring that that person is indeed acting on behalf of the patient? Certainly, patients must continue to be able to obtain medication in this manner, and no DEA regulation should interfere with the patient's medical care by impeding the delivery of controlled substances to authorized agents of bona fide patients.

In addition, it is not at all unlikely that many occasions would arise when none of the proposed vertification procedures could be employed, at night or on weekend, for example; in these not infrequent cases, the regulations as proposed would dictate that the patient be deprived of his medication until such time as verification procedures could be completed. In addition, there can be little doubt that the resultant burdens on the pharmacist would eventually result in higher medication costs to the patient.

Effect on the Prescriber—There is no question but the proposed regulations would result in a significant increase in the number of telephone calls from pharmacists received by physicians, the vast majority of which would prove needless. Not only would this divert a significant portion of the time of the prescriber and his staff from their patient care duties, but it would also tend to influence the prescriber's practice patterns to the degree that he might prescribe a less effective drug than a controlled substance which is the drug of choice merely because of the inconvenience and disruption of his practice brought about by the requirements of the proposed regulations.

Effect on the Pharmacist—The regulations as proposed would add yet another time-consuming administrative burden on the pharmacist, who is already assuming a significant amount of paperwork in conforming to the requirements of the Controlled Substances Act, the Poison Prevention Packaging Act of 1970, the Food, Drug and Cosmetic Act, and various state and local laws and regulations. As DEA has regularly pointed out in the past, the pharmacist is fully willing to cooperate in eliminating the diversion of controlled substances and has consistently demonstrated that willingness. However, there is a limit to the amount of added police and bookkeeping duties that he can assume and still provide economical and comprehensive pharmaceutical service to the patient. The professional recognizes its responsibility to subject itself to *reasonable* regulation of its responsibilities in the control and distribution of controlled substances, but that regulation must not become so unnecessarily intense and burdensome as to adversely affect the pharmacist's practice.

Even if identification verification were readily accomplished, when multiplied by the total number of prescription orders for controlled substances dispensed daily in the average pharmacy, the total time required would be substantial and would have a significant effect on the cost of operation. The increased cost becomes an even greater factor when the additional time required for maintaining and consulting a signature file or phoning each prescriber is considered.

Effect on the Problem—APhA has serious questions about the effectiveness of the proposed regulations in curbing the problem toward which they are directed. It is obvious that documents of identification can be forged or altered as easily as can prescription orders. In addition, the requirement for such documents would undoubtedly result in a black market and all its attendant problems, as well as an increase in crime involving theft of such documents. A pharmacist presented with stolen or forged documents would have no way of disproving their authenticity short of establishment of a verification system for verification documents. It is enlightening to note that the requirement for the presentation of identification has not been effective in keeping youths under the legal age from obtaining alcoholic beverages.

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Even if authentic identification were presented, this would not ensure that the prescription order were authentic. There would be nothing to prevent a person from using proper identification to obtain medication for a nonexistent patient or prescribed by a nonexistent physician.

We should have learned long ago that regulatory and enforcement actions do not solve the underlying problems causing drug abuse; drug users intent upon obtaining a supply merely change their *modus operandi* as their currently-utilized source dries up.

Alternatives to the Regulations—Finding the regulations in the discussion draft to be an excessive burden on the pharmacist, the patient and the prescriber in light of the lack of documentation of the extensiveness of the problem and the low degree of relief that could be expected, the American Pharmaceutical Association urges that they not be proposed and offers the following alternatives for consideration by DEA:

1. Tighter controls should be imposed on the printing, distribution and use of prescription order blanks. Printers producing such blanks should be required to assure that they are being ordered legimately by the prescriber or his agent. In conjunction with this requirement, the provision of prescription order blanks, whether or not preprinted with a prescription order, to a prescriber by another party, such as a drug manufacturer or pharmacist, should be prohibited. DEA, either through regulation or an intensified educational campaign, should seek to ensure that prescribers implement and maintain security measures to prevent prescription order forms from falling into the hands of possible fraud perpetrators.

2. The Drug Enforcement Administration, in cooperation with the organizations of pharmacy and the prescribing professions, should undertake an intensive educational campaign to a) sensitize practitioners to the problem of diversion through the use of fraudulent prescription orders, b) inform them of the various fraud modes utilized, and c) inform them of methods which may be utilized in their own practices to detect and prevent fraudulent prescription orders through the normal process of self-regulation and ethical practice .A concurrent effort should be instituted by DEA to intensify enforcement of existing laws and regulations pertaining to fraudulent prescription orders, including a special effort to sensitize state and local enforcement agencies to the problem and encourage their active cooperation in curbing it.

3. DEA should concurrently conduct additional studies which would a) *quantify* the extent and magnitude of the fraudulent prescription order problem, and b) measure the effectiveness of the educational and enforcement campaign described above.

At the time the Controlled Substances Act regulations were being developed, the American Pharmaceutical Association stated emphatically its behalf that any regulations promulgated must be reasonable and not unnecessarily burdensome to the pharmacist if they were to be understood and observed by practitioners. This necessity still holds true regarding the proposed changes in 21 CFR 306; if pharmacists, the vast majority of whom are already doing a creditable job in monitoring and preventing the illegal diversion of legitimate drugs, view any particular regulation as being unreasonable or excessive, they cannot be expected to lend their wholehearted support to its implementation. Moreover, neither this Association nor any other organization will find it easy to lend assistance to DEA in implementing unnecessary and overly burdensome regulations in the face of adverse member reaction. Over-regulation, with the additive negative effect of insufficient enforcement capability at the national, state and local levels, will have further serious effects on the credibility of both the Drug Enforcement Administration and the Controlled Substances Act. Pharmacist disenchantment with government regulation is already at the highest level observed by APhA since passage of the Act.

We have been encouraged recently by the apparent willingness of the Drug Enforcement Administration to cooperate with and seek the advice of organized pharmacy in combatting problems about which we are all concerned. However, if DEA merely uses these opportunities to announce preconceived plans to the profession, rather than as an effective mechanism for mutually arriving at suitable solutions to problems, the involvement of organized pharmacy cannot be expected to continue. No organization can be put in the posture of seemingly being a party to the promulgation of regulations which are unreasonable and burdensome to its members when, in fact, its views have not received fair consideration in the decision-making process.

Sincerely,

WILLIAM S. APPLE,

Enclosure:

Addendum A

A CRITIQUE BY THE AMERICAN PHARMACEUTICAL ASSOCIATION OF "PROJECT SCRIPT: A STUDY OF PRESCRIPTION FRAUD VULNERABILITY

Conducted by the Bureau of Narcotics and Dangerous Drugs, U.S. Department of Justice, 1973

The forward to the above study states that ". . . it was incumbent upon the Bureau to *definitively* (emphasis added) investigate prescription fraud vulnerability as a preliminary step to proposing remedial actions." *Webster's Seventh New Collegiate Dictionary* defines "definitive" as:

1. Serving to provide a final solution,
2. Authoritative and apparently exhaustive,
3. Serving to define or specify precisely, or
4. Fully differentiated or developed.

Project Script certainly displays none of the above characteristics. To the contrary, the study suffers from research methodological deficiencies to the point where it should not be used by BNDD to formulate policy. These methodological deficiencies include:

1. No information is presented as to how the sample size of 256 was determined. There are appropriate statistical procedures that could have been used, but apparently in this study, the sample size was determined arbitrarily. Additionally, the study does not specify the number of community pharmacies involved in the study. Although one might infer from the body of the report that 128 were included, an examination of Appendix A raises the strong possibility that the number was in fact only sixteen! There is also no recognition of the fact that prescriptions are dispensed by *pharmacists*, not pharmacies; the number of pharmacists, rather than the number of pharmacies, would have been more reliable and definitive data.

2. Page 3 indicates that with both community pharmacies and mail-order houses, past offenders were excluded from the sample. Thus, a realistic picture of the situation is not presented. It may be that if the sampling procedure were not subjected to this tampering, mail-order houses would not have appeared in such a favorable light when compared to community pharmacies.

3. Page 3 further states that community "pharmacies were preselected by field agents in the locality designated according to personal knowledge." The reader should have been informed of the criteria used to make this selection. Apparently, random sampling was not used, and thus bias obviously could have been introduced into the study.

4. Page 3 also indicates that "mail-order houses were randomly selected from a list suggested by the (National) Association of Boards of Pharmacy and similar lists." The exact lists should have been identified. Further, information should have been provided as to how the random selection was accomplished, *e.g.*, table of random numbers or computer generation of random numbers. It is probable that in actuality, systematic (every nth item) rather than true random sampling was used.

5. No statistical tests were performed to determine if the sample was representative of the population. Thus, the findings cannot be projected to the population.

6. Appendix A reveals that the variables were not randomized across trials. For example:

a. All the pharmacies in Detroit were in the suburbs (or the same pharmacy was used for all trials),

b. All the pharmacies in Chicago were of the low volume type (or the same pharmacy was used for all trials), and

c. The distribution of specific drugs, attire, and fraud modes, etc., followed patterns, *i.e.*, they were not randomized. For example: Trial No. 1—Desoxyn; Trial No. 2—Seconal; Trial No. 3—Phenobarbital; Trial No. 4—Robitussin A/C;

Trial No. 5—Desoxyn; Trial No. 6—Seconal; Trial No. 7—Phenobarbital; and Trial No. 8—Robitussin A/C.

7. No documentation or intuitive observations were offered as to why the variables of prescription volume, geographic area, attire, etc., were thought to be influential in prescription fraud vulnerability.

8. The analysis was fragmented in that only two variables at a time were analyzed. Through the use of such statistical models as general path analysis, Boudon path analysis, and the Colemen model, more than two variables could have been analyzed simultaneously. This would have yielded more substantial information.

9. Since most of the variables were not influential in predicting prescription fraud vulnerability suggestions should have been offered as to possible significant variables to be investigated in future studies.

EXHIBIT III.—ACTIONS AGAINST PRACTITIONERS AND PHARMACISTS

Arrests	Calendar year 1972	1973
Practitioners (M.D., D.O., D.D.S., etc.)	27	39
Pharmacists	13	24
Total	40	63

ACTIONS AGAINST REGISTRATIONS—CALENDAR YEAR 1973

	Revocations	Denials	Voluntary surrenders
Practitioners	33	19	99
Pharmacists	19	5	15

EXHIBIT IV

AMERICAN PHARMACEUTICAL ASSOCIATION,
Washington, D.C., November 26, 1973.

JOHN R. BARTELS, ESQ.
Administrator,
Drug Enforcement Administration,
U.S. Department of Justice,
Washington, D.C.

DEAR MR. BARTELS: I am writing to bring to your attention serious "communications" problems arising out of two recent DEA regulatory actions. I refer to the control of methaqualone and rescheduling of amobarbital, secobarbital and pentobarbital, and hasten to point out that I am not criticizing the substance of these regulatory actions, but rather the manner in which they were publicized.

On September 27, 1973, there was a DEA press conference regarding methaqualone in which you released the statement attached hereto as Attachment I. In its second paragraph, your statement indicated that:

"Notice of intention to require Federal control of this drug will be published in the "Federal Register" and *the controls will be effective in 30 days. When this action takes effect*, it means methaqualone will come under the same controls and restrictions as such drugs as cocaine, morphine, codeine, methadone, methamphetamine, and amphetamine." (Emphasis added).

As one would expect, and as was undoubtedly intended, your statement was widely and promptly reported in both the lay press, drug trade and pharmacy publications.

Publication of the methaqualine regulations in the "Federal Register" did not actually occur until October 4, 1973. When published, the regulations rendered the quoted portion of your September 27 statement incorrect in that they

actually made different controls and requirements for methaqualone effective on six different dates. Our particular concern to APhA was the fact that written prescription order and prescription renewal requirements under Schedule II were made applicable for methaqualone on October 4, 1973, the very day they were published in the "Federal Register", with absolutely no lead time for APhA or other associations to make these requirements known to pharmacy practitioners. Moreover, in this instance, the requirements regarding prescriptions were not even specifically delineated in the October 4 order, but had to be determined by a process of interpretation and elimination. DEA found it necessary to publish a clarification of the methaqualone prescription requirements in the "Federal Register" on October 17, 1973, confirming the October 4 effective date in direct conflict with your statement on September 27.

In the barbiturate situation, a DEA press release is again at the heart of the problem. The order rescheduling amobarbital, secobarbital, and pentobarbital was published in the "Federal Register" on November 13, 1973. (Again, in this instance, different controls and requirements become applicable on several different dates. However, the barbiturate order delineated specifically the date upon which Schedule II prescription requirements becom applicable, granting more than 30 days as lead time for these requirements to be made known to pharmacy practitioners, a welcome improvement over the methaqualone procedure).

Analysis of the barbiturate order and existing regulations makes clear that amobarbital, secobarbital, and pentobarbital, alone, or in combination with each other or any other controlled substance are to be rescheduled in Schedule II. The order is also clear that these substances when combined with other non-controlled substances remain in Schedule III at this time and, further, that combination products containing these substances which have been previously excepted (even under the Drug Abuse Control Amendments of 1965) are not affected by the order. Thus, the legal situation is made clear in this instance by the "Federal Register" publication, which brings us to barbiturate press release.

The press release in question was "For Immediate Release—9:00 AM, Tuesday, November 13, 1973". Consequently, it was available for use prior to the time the "Federal Register" of the same date would reach most subscribers, and certainly prior to the time a careful analysis of the "Federal Register" order could be accomplished by interested parties. Nonetheless, we understand why, from DEA's standpoint, timing of the "Federal Register" publication and notification to the press must reasonably coincide. But, this practical requirement makes it all the more imperative that DEA press releases not mislead those who will be effected by DEA action, either actively through misstatement or passively by omission of critical information. Unfortunately, the barbiturate press release is misleading through omission; it is attached hereto as Attachment II.

Since no dates are stated in the press release, it creates the impression that all Schedule II controls for the three barbiturates became effective on November 13, 1973.

In discussing amobarbital, secobarbital, and pentobarbital and listing trade names for four drug products, the press release creates the impression that only the trade name drug products listed are to be transferred to Schedule II. This impression is reinforced by the failure of the press release to make specific mention of combination drug products containing the referenced substances.

As I am sure you recognize, Mr. Bartels, pharmacy practitioners, (and for that matter, other health care practitioners) do not review the "Federal Register". On the other hand, pharmacy practitioners and other health care practitioners do read the daily newspapers and press sources addressing themselves to their particular professional interests. The press, therefore, can serve as a most effective means of communicating DEA actions and requirements to practitioners. By the same token, however, the press can become a most effective means for frustrating DEA intent and actions by unwittingly creating false impressions among their audience. In the methaqualone and barbiturate situations, we believe this has been the result and that it was preordained by DEA through the press releases in question.

Within the past several months, we have been pleased to see evidence that DEA is intersted in improving communications with practitioners and their

associations. I would suggest that further improvement in communications could result were contemplated regulatory actions, such as those discussed herein, routinely reviewed with interested associations in advance of their releaes to the press, so that factual and interpretative problems might be minimized.

Please be assured that the points I am making are intended as constructive criticism aimed at increasing the effectiveness of DEA, associations, and practitioners. These comments are offered in the hope that corrective action can and will be taken to avoid recurrences of similar situations.

I can assure you, that APhA will be most happy to continue to make available to DEA staff consultation on such matters. Without solution of the problems I have been discussing, I would project only further unnecessary confusion and, most importantly, less than optimum effectiveness of controls under the Controlled Substances Act.

I would be pleased to receive your reaction to this letter at your earliest convenience.

Sincerely,

WILLIAM S. APPLE.

Senator BAYH. Our last panel of witnesses today, led by Mr. Joe Schwemin, president of the National Association of Boards of Phaamacy, accompanied by Mr. C.E. Barnnett, chairman of the executive committee, Mr. Karl Marquardt, Chairman of the Bureau of Law Enforcement, NABP, and Mr. Larry Ulrich, chairman of the Committee on Institutional Pharmacy, who coincidentally happens to be from the State of Indiana, and—perhaps I should say—not coincidentally.

I apologize to you again because of the inconvenience of our voting today.

STATEMENT OF KARL MARQUARDT, CHAIRMAN OF BUREAU OF LAW ENFORCEMENT, NATIONAL ASSOCIATION OF BOARDS OF PHARMACY, ACCOMPANIED BY JOE SCHEWEMIN, PRESIDENT, C. E. BARNETT, CHAIRMAN OF EXECUTIVE COMMITTEE, AND LARRY ULRICH, CHAIRMAN, COMMITTEE ON INSTITUTIONAL PHARMACY, NABP

Mr. MARQUARDT. Senator Bayh, I am Karl Marquardt, executive secretary of the Wisconsin Pharmacy Examining Board and chairman of the National Association of Boards of Pharmacy, NABP, Bureau of Law Enforcement. I am accompanied by Mr. Joe Shwemin, president ,NABP and secretary, Oklahoma State Board of Pharmacy; Mr. C. E. Barnett, Chairman NABP executive committee and secretary, Idaho Board of Pharmacy; and Mr. Lawrence Ulrich, member of the Indiana Board of Pharmacy and chairman of the NABP Committee on Institutional Pharmacy.

The NABP is an association comprise of boards of pharmacy from each of the 50 States, the District of Columbia, and the Territory of Puerto Rico. In addition to providing for interstate reciprocity and examination service for pharmacist licensure, the association fosters legislative change and improved drug law enforcement by cooperating with state national, and international agencies and associations having similar objective.

You have requested that NABP express its views regarding drug-related crime, diversion of legally manufactured drugs to illicit channels, prescription fraud and other relevant issues on the adequacy

of Federal drug control legislation. Your request dated March 8, was recieved by NABP on March 12. A copy of the request with a cover letter was sent by NABP to secretaries of all State boards of pharmacy, asking for their responses to the issue which you raised.

Although our statement attempts to reflect the views of most boards of pharmacy throughout the country, it could have been more inclusive if additional time was available.

Senator BAYH. I am hopeful we can go ahead and take advantage of your expertise as we look for ways to examine whether the present law is operating as we had designed. I don't know of any group in a position to bring more expertise than the organization you represent. So if we could have continuing communication in the future, we would appreciate that very much.

Mr. MARQUARDT. Thank you, Senator. We will cooperate with you.

Senator BAYH. I appreciate you cooperating by being here and in the content of your testimony. That is very helpful to us, but when we get to working out the specifics of what we should do and whether there should be changes in the law or by trying to convince those in charge of issuing the administrative edicts that maybe that is the better way to go, we would like to be able to draw on your expertise if we could, please.

Mr. MARQUARDT. We will be very willing.

Senator BAYH. Please continue. I apologize for my necessary absence.

Mr. MARQUARDT. This statement today is a composite view of many boards of pharmacy to the respective issues included in your invitation to testify at today's hearing. The responses follow a restatement of the question or issue.

1. What can be done to more effectively curb the alarming number robberies, burglaries, thefts, and assualts directed at pharmacies and those who operate them.

Armed robberies, burglaries, thefts and assaults in connection therewith to obtain controlled substances have become a national plague. If these crimes against pharmacist and pharmacies were made a felony offense, the incidence woud undoubtedly decrease. Furthermore, the criminal justice system under which apprehended indiviuals are tried for these crimes does not appear to be an effective deterrent. When low low bail is set for those apprehended or leniency shown in sentencing by the courts, the perpetrators of these crimes are soon back "on the streets" committing the same offenses. Penalties for violations of criminal statutes should also have mandatory minimum sentences rather than discretionary sentences, since the latter frequently result in leniency and probationary sentencing.

Other things which might be done to curb the increased number of burglaries include: Finacial assistance to local law enforcement agencies for the specfic purpose of better after-hours protection of pharmacies; installation of various types of adequate alarms with some system of Federal financial assistance since this measure would create a financial burden on many small businesses; require controlled substances to be packaged by manufacturers in smaller sizes so that a pharmacy's inventory is minimal; and encourage pharmacies to stock limited quantities of controlled substances so that amounts obtainable through crime would not warrant committing the crime.

2. The nature and extent of crimes directed at pharmacies and their impact on society and pharmacy.

Although no hard data on the number of crimes against pharmacies is presently available from the NABP, all boards reported an increased incidence in recent years. This would indicate an effective law enforcement effort on illegally manufactured and distributed drugs and a consequent "drying up" of street sources. Addicts will then turn to legally manufactured substances possessed by pharmacies and clinics. The most prevalent crime involving controlled substances is burglary, with armed robbery, thefts, and assault in connectio therewith following closely. Fear and apprehension of being criminal targets has many pharmacies to close or curtail hours of service, and discontinue emergency night prescription service. This has an obvious impact on the health and welfare of the public. These crimes, of course, result in extensive financial loss to the pharmacy in terms of the cost of the drugs involved, repair of damages to property, increased insurance costs, and investment in alarms and other protective systems, all of which eventually must be borne by the public. Therefore, the impact on society is substantial, even to the point of inaccessibility of pharmacy services in some areas.

3. The impact of the 1970 act on the diversion and traffic of legitimately produced and distributed dangerous drugs.

The 1970 Controlled Substances Act has a significant impact on reducing diversion and traffic of legally manufactured drugs. This, in combination with effective enforcement in illicit drug distribution areas, is a primary cause of the increase in pharmacy burglaries and roberies. Although pharmacies are a source of some diversion along with diversion by employees of manufacturers and distributors, the recordkeeping requirements have essentially made it more difficult to accomplish without detection. Several reporting State boards of pharmacy indicated the practice of some wholesale distributors are questionable in ascertaining the eligibility of propective buyers to purchase controlled substances. Many unlicensed practitioners have been found in possession of controlled substances which are obtained from wholesalers who obviously did not question the credentials of the persons ordering the drugs.

Although current regulations restrict complimentary sampling of controlled substances to written request of practitioners; provisions should be enacted to only make them available directly from the manufacturer's principal place of business, rather than through sales representatives.

One loophole in the 1970 act is the absence of a statutory or regulatory restriction on the quantity of controlled substances which can be prescribed or dispensed. States have indicated that physicians are writing prescriptions for larger amounts of schedule II controlled substances so they aren't "bothered" for refills. Several examples are prescriptions for meparidine, methylphenidate, and dextroamphetamine in quantities ranging from 500–1000 tablets or capsules. Recent rescheduling of amobarbital, pentobarbital, and secorbarbital in schedule II has resulted in similar prescribing practices for these drugs. Therefore, the adoption of quantity limitations on prescribing and dispensing controlled substances is respectfully recommended

for the committee's consideration. A provision similar to that proposed by the Drug Enforcement Administration in 37 F.R. 15933, August 8, 1972, might be an appropriate course of action to follow.

4. An assessment of the extent to which prescription fraud and mail-order diversion contribute to illicit traffic and abuse of dangerouse drugs and recommendations to more effectively curb diversion from both of these sources.

The contribution of mail-order deversion and prescription fraud to ability, attempted to answer the question: "How easy is it to perpetrate a prescription fraud?" There were many aspects of the study which call into question its validlty, all of which were pointed out to DEA not only by NABP, but other professional associations representing concerned individuals as well. In an attempt to follow up the study in an education for volunatry compliance effort, NABP's Bureau of Law Enforcement requested additional data on Project Script be sent to the States involved in the study, but access to the information was denied.

Before prescription fraud can be remedied, data on its prevalence must be quantified. Possible remedies might include a Federal triplicate perscription requirement for schedule II drugs. Most boards of pharmacy are also opposed to the mailing of any controlled substances prescriptions, not simply because of possible diversion, but primarily because of public health concerns. Controlled substances, in the best interests of the patient, should be prescribed and dispensed in a setting which allows direct consultation between any of the involved parties, that is physician, patient, and pharmacist. That relationship is broken and at best, strained, when controlled substances are dispensed by mail-order pharmacies.

5. What can be done to deal more effectively with the few pharmacists who illegally distribute controlled drugs and to encourage pharmacist to identify the few physicians who improperly or illegally contribute to the traffic and abuse of dangerous controlled drugs?

The problem can be dealt with most effectively by the respective State licensing boards. However, a seldom used provision of the act is 21 U.S.C. 824, which permits unilateral Federal denial, revocation, or suspension of a DEA registration. Also, practitioners found guilty of illegal distribution or dispensing activities must not be shown leniency in administrative or criminal prosecutions for violations. Too frequently leniency is shown when the defense pleads "you are taking away a persons's livelihood."

Most pharmacists are not reluctant to identify physicians or other prescribers who improperly or illegally contribute to the traffic and abuse of controlled substances. If a pharmacist is assured of his anonymity as an informant, and the information is only used for the appropriate agency to build its case, this type of information should be readily available. If local law enforcement agencies point out to the pharmacist his corresponding responsibility to insure that a prescription is issued in the usual course of professional practice, pharmacists will be encouraged to identify errant practitioners.

An additional effective method of curbing illegal distribution by pharmacists and physicians would be the establishment of a Diversion Investigative Unit (DIU) in all States, as has been done on a

pilot basis in Texas and Michigan. I understand this has been expanded to one additional State, Alabama, in 1973, and there are plans for adding up to seven more States with investigative units.

The DIU is an independent unit comprised of representatives from various State agencies as well as the Federal Drug Enforcement Administration. The State DIU concentrates primarily on licensed health care practitioners such as pharmacists, physicians, dentists, veterinerians, nursing homes, nurses, and hospitals who or which may be involved in illegal diversion activities. The cases can be tried in local, State, or Federal courts or before the respective licensing board, or both. In Michigan and Texas the DIU has proven to be a very effective addition to the drug law enforcement program.

Local compliance efforts are also assisted by conducting drug accountability audits. If the audit shows no evidence of diversion by the pharmacy, it serves a further purpose of assisting investigators in constructing compilations of physicians' prescribing habits, which may indicate that a particular physician is not issuing prescriptions for controlled substances in the usual course of his professional practice. Such information can be forwarded to boards of medical examiners for appropriate action against the practitioner.

6. The merit of requiring verification of identity and initialing of prescriptions by pharmacists.

Requiring verification of identity of the patient on the prescription document has dubious merit. Most drug abusers, pushers, and persons who deal in illicit traffic of controlled substances have many sets of identification, including but not limited to driver's licenses with their photographs on them. Initialing the prescription for verification of identity would accomplish very little and the whole process would be time consuming for all controlled substances prescriptions. The procedure would doubtless have a degrading effect on the professional image of pharmacy and not be an effective deterrent to prescription fraud.

The identity of the pharmacist who dispensed not only a controlled substance prescription, but any prescription drug, is good professional practice and no doubt is already done by most pharmacists or is required by State law or regulation. The NABP therefore supports initialing of prescriptions by pharmacists.

7. An assessment of current methods for reporting and compiling diversion statistics and of proposals to require a triplicate prescription system for dangerous nonnarcotic drugs.

In most States the current methods for reporting and compiling diversion statistics consist of manual reporting systems. Until it can be handled by electronic data processing, compilation of this information is very impractical. Perhaps the Drug Enforcement Administration's Automation of Reports and Consumated Orders System (ARCOS) could be expanded to include dissemination of any orders for controlled substances from any registered manufacturer or distributor to the State licensing agencies for purposes of correlating this data with records maintained by the dispensing pharmacy. In this way diversion could be more readily detected and appropriate action taken against violating practitioners.

Responses to proposals to require triplicate prescriptions for controlled substances have been varied. Several States have already enacted a State triplicate prescription system for all schedule II substances. Those which have, indicate it has been the biggest deterrent to diversion of controlled substances into the illicit market of any measures which could have been taken. If automated systems are available for tabulating data from the third copy filed with the State agency, the agency is readily able to ascertain possible violations of the law. Those States which object to a triplicate prescription system do so on the grounds that the amount of work involved in such a procedure is not justified by the benefits which would be derived from it. Furthermore, it is contended that such a system places an undue restriction on the practice privileges of the physician and pharmacist. If a Federal triplicate prescription system is enacted for schedule II controlled substances, provisions should be made for filing composite automated reports of the third copy with the State licensing agency.

8. The need to make the 1970 act infraction data more accessible to State boards in order to facilitate appropriate disciplinary or license revocation decisions.

Although most States have entered into a memorandum of understanding with the Drug Enforcement Administration, infraction data uncovered by DEA compliance investigations is not routinely disseminated to the appropriate State licensing agencies. However, most boards of pharmacies have a good working relationship and cooperate with, and exchange information on a mutual basis with district, regional and national DEA officials. To facilitate State license suspension or revocation, infraction data should be routinely reported to the board of pharmacy where this data involved pharmacists or pharmacies. In addition, when Federal administrative action to suspend or revoke a DEA registration is not contemplated, DEA should file a complaint based on their investigation with the appropriate State board so that suspension or revocation proceedings may be initiated at the State level.

9. The need for more flexibility in the schedules of the 1970 act.

Most States which have passed the Uniform Controlled Substances Act have sufficient authority to add to, delete from, or reschedule any substances. These States have not indicated a need for greater flexibility in the schedules of the 1970 Controlled Substances Act, either Federal or State. There was some indication, however, that an unreasonably long period of time occurs before action is taken to add or reschedule substances, e.g. methaqualone to Schedule II. Since the act provided that substances may be added based on a potential for abuse, the actual evidence of abuse need not be as strong before scheduling of a substance occurs. An additional suggestion was made that any amendments to the Controlled Substances Act might include consideration for a Schedule VI, to include all prescription legend drugs, but exempt these drugs from the inventory recordkeeping requirements.

10. The need for a formal procedure to assure that the views and experience of professional pharmacists are considered in the development of Federal drug control decisions.

The National Association of Boards of Pharmacy and its Bureau of Law Enforcement concur in the necessity for establishing a formal advisory committee comprised of practitioners in the health care professions, including pharmacists, to assure consideraion of the views and experience of the respective members of the professions represented. The advisory committee should consist of practicing professional pharmacists with representation from one of each of the DEA regional areas. In addition, we would urge that the NABP Bureau of Law Enforcement be a part of any plan to gain views from the profession. The latter representation would provide liaison between the DEA and the members boards of pharmacy affiliated with NABP.

Mr. Chairman, we appreciate the opportunity to participate in these hearings to develop improvements in the drug control legislation first enacted in 1970.

We understand the time constraints imposed on this hearing and will, at your discretion, either submit responses in writing to questions which you will forward to us or respond to any questions that you may have at this time.

Thank you very much.

Mr. RECTOR. Thank you very much. I would like to reiterate Senator Bayh's apologies. I think he indicated earlier in the day, that we have no control whatsoever over the votes that will be coming up on the floor. We wish oftentimes that we did, and again apologize for the inconvenience of the hearing room and the scheduling. It was a last minute change which we had no control over.

I think if you all are willing we could proceed with a few questions. Is that consistent with your schedules?

Mr. MARQUARDT. Surely.

We would be happy to. I might add that both Mr. Barnett and Mr. Schwemin have had broadened experiences in their responsibilities other than just serving as secretaries of the board of pharmacy in their respective States. At an earlier time they were more involved with the total drug enforcement program as directors of their State bureaus of drug control. So they can respond to your questions, both from the standpoint of regulating legitimate and legal trafficking as well as the enforcement problems of illegal trafficking of drugs of abuse.

Mr. RECTOR. I think it would be particularly helpful to get that proper perspective on some of the issues commented on today.

I have noted some questions, and I will start with an interesting observation that you have made with regard to the act and the requisites for rescheduling a drug. You have indicated that it could be added on the basis of potential for abuse and that actual evidence of abuse is not requisite for rescheduling. I think you made specific reference to methaqualone. We would urge you to bring this to the attention of Mr. Bartels, the Administrator of DEA, who on that specific point at a hearing we held on February 25, differed with the Senator's view. The Senator's view is consistent with yours, and it was with regard to the scheduling decision of the shorter-acting barbiturates. They argued that because there was slight evidence of

actual abuse of the several pharmacologically similar barbiturates, not too widely known, they had no basis under their statute to reschedule. However, there have been other instances, Ritalin® and Preludin® which were rescheduled on a prophylactic or precautionary basis. It would be particularly helpful for you to bring your views on this point to their attention.

Mr. MARQUARDT. I think that we will be very willing to do that. I also believe that Senator Bayh's position, which is consistent with ours in this respect, does have support from an administrative review court to which one of the manufacturers of methaqualone appealed the decision to add it to Schedule II. I believe that administrative court decision supported the same viewpoint that substances can be added to or rescheduled, based on their abuse potential, because this is what the 1970 Act provides, and actual evidence of abuse need not be as strong or compelling before the addition of substances is considered.

Mr. RECTOR. If we are referring to the same opinion by the same administrative judge, we are referring to the methaqualone decision of this past fall?

Mr. MARQUARDT. Right.

Mr. RECTOR. I think the judge did refer to the prophylactic basis. In the context of controlling the other similar barbiturates Bartels said that he didn't want to risk losing the precedent that was established in that case. That is just the opposite of what a good lawyer would argue in a case where you had administrative history and clear decision. That is why I think it would be helpful if you would bring your views on that point to their attention.

Mr. MARQUARDT. We will be happy to do so.

Mr. RECTOR. We also were not happy with the delay. Senator Bayh often speaks to that issue. Its unfortunate that it takes what he characterizes as a "body count" or incredible statistics of death and fatalities before you can prick the interests of some of the regulators to move in the control areas, whereas on the other hand if they had some foresight they could have nipped this in the bud.

You probably get the impression that we have been involved in more than one instance in attempts to persuade the agencies to act prudently.

In regard to what has been referred to as the Church bill, I think you indicated support perhaps for mandatory minimum penalties in lieu of the standard penalties. We passed last April Senator Bayh's amendment that would provide mandatory penalties for non-addicted high level drug traffickers. It wasn't specifically related to pharmacists. It was related to the French Connection kind of trafficking case. We would be particularly interested in following up on that suggestion.

I think similarly with regard to statutes, whether criminal or administrative on the State level. Is there support for mandatory provisions with regard to suspension or perhaps criminal penalties for the few unethical pharmacists?

Mr. MARQUARDT. Well, most States have authority to proceed administratively against those whom they license by suspending or revoking their license. They are given broad discretionary authority,

and to my knowledge there are very few States which say that for such an infraction there is a mandatory minimum sentence of "X" number of days or months suspension of his license.

I do believe that in most instances it is a broad discretionary authority to proceed against the individual on a complaint filed with the licensing board or the board takes action on its own motion. They do have broad sentencing authority, ranging all the way from private censure or reprimand to permanent revocation of the license of the individual.

Many States also cannot proceed against the individual until such time as the violator has been convicted in a criminal court, and they need that as prima facie evidence before being able to proceed administratively against his or her license.

Mr. SCHWEMIN. We don't really have that law. As a matter of fact, we don't proceed against a license while it is in litigation either, because whatever decision we make, if we make one pretty hard one side picks it up and says look what his peers say. As a matter of course we stay out of it until litigation is finished, including a man's avenues of appeal.

Mr. RECTOR. What about instances where perhaps administrative action would be more appropriate than litigation and criminal prosecution. In other words, a number of Senators and others suggest that with regard to lawyers and doctors and other professionals there is a substantial role to be played by associations that represent these groups and the State agencies or associations and boards that regulate their conduct, rather than waiting until there is a criminal prosecution and then on the outcome of that case take some kind of administrative action? Are there any moves in the various States to develop something in that regard?

Mr. SCHEWEMIN. I don't think most States don't take the criminal action into consideration. The board hearing is usually held on the basis of evidence, not the fact—unless, of course, it is a felony. Most laws have in there—you can revoke or suspend on felonies. But I believe most of the laws go ahead and take action regardless of litigation. I believe you do, don't you, Jim?

Mr. BARNETT. Yes, we proceed against the practitioners' controlled substances registration. This has been very effective.

Mr. RECTOR. Over the past year and a half we conducted hearings with regard to problems that had arisen with doctors who under the guise of methadone detoxification treatment were actually illegally trafficking in methadone. For example, the notorious Dr. Moore here in the District and other examples around the country, and as few as they are, they can cause a great deal of difficulty. What are the States doing about these cases?

Mr. ULRICH. In Indiana and Iowa, like so many other States, have the statutes that say a felony conviction in criminal court is prima facie evidence. We had a working relationship with the Department of Justice, with DEA that when we investigate a case and take suit we do not take action until their case is complete. Part of the problem is we do not take action under our Controlled Substances Act primarily but under the Professional Pharmacist Practicing Act. The problem we are having is the court drags cases out

with the Department of Justice. We have one now pending for 15 months and this place is still open and doing business and yet they keep telling us to hold until we get our case taken care of. The place is in operation for 15 months. We have what we think is enough evidence to move against him yet we are holding because of their procedures over there.

Mr. RECTOR. What could be done to remedy a situation like that?

Mr. ULLRICH. I don't know, other than working out an arrangement. If they will take him under the Controlled Substances Act then we will go ahead and issue our formal hearing under the Professional Practices Act. The only problem you run into is we recommend the man's license be taken away, his attorneys take that back and say the State authorities have done such and such and taken his livelihood and what in fact are you going to do when in fact they have criminal grounds for criminal prosecution. In many cases this jeopardizes their case and that is why they don't want us to do it.

Mr. RECTOR. Do you think moving these types of cases into a priority posture on the Federal docket would assist in dealing with the kind of problem you mention?

Mr. SCHWEMIN. Our problem really is from an enforcement standpoint as a court problem, particularly district judges that—we have documented proof, same people calling the same pharmacy two or three or four times, the same judge turns them loose every time. We just finished an investigation and we know who it was before we started because he was already out on bond and at least three counties, four counties in the State and under investigation in another county. This man—he is still going to be out. We arrested him but I am sure he will be out in the next 2 or 3 days again. This is our problem.

Mr. RECTOR. Did that case involve someone who had fraudulently obtained drugs?

Mr. SCHWEMIN. Yes, forged prescriptions, robberies, identifying himself as a physician, things like this.

Mr. RECTOR. I would gather that a substantial part of the problem is really a question of law enforcement priorities. We run into this whenever we start talking about law enforcement or control action with regard to nonillicit drugs. There seems to be a definite preference among law enforcement authorities to pursue vigorously cases involving heroin or cocaine or marihuana. On the other hand, with items such as amphetamines, even barbiturates, which are equally, if not more dependency prone than even heroin, there tends to be a less than vigorous attitude about pursuing these kinds of cases. It spills over into the judiciary and the State enforcement boards and the prosecutors and what have you. I think that the pharmacy boards and various professional societies probably do have an obligation in an educational fashion to try to deal with that imbalance of attitude when it comes to enforcement of drug control laws.

Mr. SCHWEMIN. Mr. Marquardt alluded to the fact Mr. Barnett and I have been in the street traffic, I am not sure if Cliff—we are still in it, we still work the street, and it is a big problem.

Mr. RECTOR. Is that a fairly accurate reflection? The way I have characterized it?

Mr. BARNETT. Your on the street investigator, the quick release pattern of many States now—we have over 4,000 files of what we call rap sheets and mug shots in our files, and it will show where someone was given a sentence of 4 years and released again in less than a year for the same crime. So it is a revolving door syndrome, in and out doing the same thing over and over again and 75 to 80 percent of them are repeaters, keep doing the same thing.

Mr. RECTOR. Is part of that solely the reflection of the judicial attitudes about the kinds of criminal conduct that we are dealing with?

Mr. BARNETT. I don't know what the reason behind it is, but they are returned out very rapidly and go back to doing the same thing.

Mr. RECTOR. There were several comments today about the efficacy of the triplicate prescription system. I think the representatives from the National Association of Retail Druggists characterize it as amounting to probably not much more than a pain in the neck, and some others spoke more favorably of it. I would like to hear about the experience in Idaho and supplemental to that, New York, where they have just initiated a similar system there, and Illinois.

Mr. BARNETT. We have had a system in Idaho since 1967 that has been very successful in our State, and we apply it only to schedule II substances. It is controlled by the board of pharmacy. We issue the prescription, serials and issued in a series of 100 prescriptions at a time. We have the physicians' signature on file and keep track of what numbers are issued to him and so forth. This information comes back to us monthly from the pharmacy. He sends one back. The physician keeps one copy in his book and we get the other copy back. We code this information and run it through a computer and we can come up with a listing of the physicians and what they prescribed or go on the basis of what the patient got and so on. We have been able, through this method, to pinpoint the addict pushers or the physicians who are overprescribing these substances.

Rather than go into the long story about it, I am going to send Senator Bayh, if you think this is in order, a complete breakdown with the forms and the whole material, because we assisted in New York getting this program in order and we have also had numerous requests as far away as Australia. They wrote to us and wanted a complete workup. It is highly successful and we can show you on the printouts how successful that has been.

I want to make one thing clear. We don't recommend a Federal triplicate prescription program. There are many, many reasons why I would be opposed to this, and I will point that out in the letter.

Mr. RECTOR. I think we would be interested in receiving as detailed as possible narrative of the experiences in Idaho, and as well as a critique of your view with regard to the proposal to have establish a Federal triplicate prescription service. We have talked with people in Pennsylvania, New Jersey, New York, and Ohio about this. There is some consideration of this in Senate bill, I believe 307, out in Ohio. Eventually people will start raising the question of a national system. Conflict among the States will provide more impetus for it, eventually we will hear more and more commentary about the interstate problem and then the next logical thing to do is to

suggest a national triplicate prescription service. So it would be quite helpful for us to have both those kinds of information.

Also, do you have any materials available on a national basis as to actions taken by State pharmacy boards in the area of suspensions and revocation of professional pharmacists in the particular States?

Mr. BARNETT. Well, I think this record that was one of the exhibits in the APhA is actually material garnered from the State boards. That is not action by DEA. They merely collected the information and put it out. We don't have, I don't think, on the national—in our national office I don't think we have too much material on that because we have never gone into collecting that.

Mr. RECTOR. The material that was in their statement, correct me if I am mistaken, but I recall that it referred to the number of robberies, breakins, did I overlook something that specified the administrative action that had been taken with regard to suspensions?

Mr. BARNETT. I think, if I recall reading their's, I think it was exhibit 3. Each district calls the boards in their particular district each month and asks what suspensions or revocations they have had, and this is reported to them and they compile this information.

Mr. RECTOR. Exhibit 3 did you say?

Mr. BARNETT. Right, under actions against registrants.

Mr. RECTOR. I am familiar with that. So that would reflect the picture nationally with regard to all the various State boards?

Mr. BARNETT. I think that refers specifically to the Controlled Substances Act and not for other reasons.

Mr. RECTOR. That would reflect all the activity or action taken under the various agreements the States have taken with regard to the professionals?

Mr. SCHWEMIN. We collect on a yearly basis—every year the office of the national board sends to all States and the District of Columbia and Puerto Rico letters on actions that all boards have taken. The information will probably be in there someplace only on scheduled items, but you would just have to dig it out. In this the compilation includes all revocations.

Mr. RECTOR. So that is not as readily available as the DEA information?

Mr. SCHWEMIN. No sir.

Mr. RECTOR. I recently was apprised of printout data that is available from DEA. They have considerable information on their computers indicating the number of break-ins, burglaries, thefts, instances that relate to pharmacies, manufacturers, and retailers. We were wondering whether that information is available to the boards and to your organization, and perhaps you could speak with regard to the organizations who testified earlier today. Of course, if it is not, we would seek to facilitate it being made available to you all?

Mr. BARNETT. In our State we never try to obtain it because we require the same information, so we that information, whether they would furnish it back to us from DEA, I don't know.

Mr. MARQUARDT. There is a Federal reporting requirement for any loss or theft of control substances by whatever means, and that information has to be reported to the regional offices of the DEA.

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It will vary from State to State as to whether there is an analoguous State requirement.

Idaho does. We in Wisconsin do require that the individuals report that same information to the State offices, but I think it might be helpful for DEA, maybe on a quarterly basis, to publish that information to the States concerned, since they have it on data processing and it would perhaps be more accurate information than that which the States might have, simply because they have this computer capability.

Mr. RECTOR. They were aware that the information they have is in fact based on the reporting requirements of the 1970 Act, but a number of individuals had expressed concern that it was not being made available to them in their region or in other endeavors that they would be interested in. The States have to provide the information, but if you are in Idaho perhaps you would like to know what officials are experiencing in New Mexico or Mississippi or Pennsylvania or what have you.

As you recall, during consideration of the 1970 Act there was considerable controversy as to requiring separate record-keeping for certain controlled drugs, and one of the interesting aspects of Schedule II is that separate recordkeeping is required. We are particularly interested to learn whether this has been of any assistance to law enforcement in various States. The fact that you have access to records that pertain solely to controlled schedule II drugs as opposed to having to search records which intermingled those on amphetamines with toothpaste and aspirin should be of assistance to auditors and investigators.

Mr. MARQUARDT. That is very different to our compliance at State level. Those records as to schedule II receipts and distributions are kept separately. It is much easier to do an audit than if these records were comingled with other types of prescriptions for both schedule III and IV or noncontrolled drugs dispensed by that pharmacy. It's just a real timesaving measure, and it points out to the practitioner on a daily basis the responsibilities which he has. He is more aware of his responsibilities and the prescriber's for safeguarding the use of that drug and is continually reminded of the fact that these are drugs of abuse.

Mr. ULRICH. I think one of the problems in Indiana is the only time we can see those records is when we go into a store to do an audit, and on many occasions DEA, having a copy sent to the, they get a paper trail ahead of us and we get a call we are going into such and such a drugstore, send a man over, and it is an hour's notice. We don't have an inspector. Four and a half people, so we are lucky to make it twice a year. To conduct an indepth audit we would have to supply more than one individual. In many cases they are sitting there filing through Schedule II forms and they get a handle on things much faster than we do.

Second, we have had unreasonable cooperation from border States. We have had several occasions where we have written and asked them for invoices or purchases for certain stores and we will check them and they as much as told us to go jump in the lake. If we wanted them they would come and lay them out on the table and we could look them over.

Mr. RECTOR. What could we do to facilitate your access to that kind of thing? What could we do to assure that DEA would respond to that kind of request?

Mr. SCHWEMIN. I might allude to that, and I am not sure, I haven't talked to the other men.

Do you get the copy of the narcotics schedules items?

Mr. BARNETT. The order form?

Mr. SCHWEMIN. The order form. I don't think all States do, but we do, and this is a big help. This is exactly what he was saying. The DEA people are certainly—I am not knocking them any, but they are not as familiar with the locations, so we can't take an order form and tell whether this is a reasonable amount for this location and week. We have picked up several people merely by the fact they have given us those forms. We get a copy of everything that is ordered up, regardless of where it is ordered from, if a physician orders it, dentist, veterinarian, whatever. It is of great deal of help to us.

Mr. RECTOR. Are you supplied the order forms on a monthly basis?

Mr. SCHWEMIN. Yes, every 30, 60 days.

Mr. RECTOR. We were talking this week with officials in Pennsylvania who had just broken up a ring involving in excess of 35 individuals who were passing forged prescriptions to a multiple number of pharmacists in the inner city in Philadelphia. They had obtained more than 40,000 tablets of Dilaudid. It was selling in the street for $20 a tablet. So we are talking about a considerable value on the street, in excess of $800,000 over a several month period of time. Under their scheme their printer makes up prescriptions and with the name of a doctor who was practicing in the community. They had a phone number that coincided with a phone they had covered. They were able to obtain in excess of $800,000 in illicit drugs.

Because of the reporting system that had been initiated in Philadelphia, the enforcement people were able to identify a number of these individuals. The net result was the elimination of this rather substantial illegal activity in Philadelphia.

That kind of thing, the monthly reporting scheme, appears very attractive to members of this committee. But, on the other hand, quite often, whenever you talk about that kind of reporting scheme or triplicate scheme, questions of confidentiality and questions regarding the doctor-patient relationship are raised that are also of considerable interest to the members of the committee. We are wondering what experiences the various States have had when those kinds of concerns are raised with regard to identifying patients and sometimes with regard to identifying the fact—that "X" patient is taking "Y" drugs.

Mr. MARQUARDT. Mr. Barnett, do you want to speak to that because you do have a triplicate prescription where the patient would be identified on the third copy filed with your office.

Mr. BARNETT. We have never had any question raised, particularly because I think we do handle them very confidentially. This information is not given to anyone outside our office unless there is actually a criminal violation or something. Since we handle these

administratively through their own licensing board, since it is a psysician we take the evidence of the violation to the licensing board and then we cooperatively handle the problem. So it is not like a court case or something where the patient's name would be bandied about, or if it happens to be a drug pusher and we have evidence that he does this, we also go further than this and try to make buys and this type of thing. So use it as an enforcement tool in those cases. So the information it not readily available to anyone except in our office or the particular licensing board.

Mr. RECTOR. You haven't had that kind of problem. I know in New York as they have implemented their new system, which is similar to Idaho's, they have had that problem. They are still involved in litigation. I think some of the doctors in New York State and perhaps the State Association were concerned that there would be a breach of the confidential relationship between doctor and patient.

Mr. BARNETT. I anticipate they have three or four doctors who don't like the system and I anticipate they will probably bring this up as a result of New York experiences.

Mr. RECTOR. I have a couple of other questions.

You mentioned that in various States unlicensed dealers were receiving controlled substances. I wish you could elaborate on unlicensed dealers, the type of operations they are involved in, not naming individuals, but characterizing these individuals; and secondly, identify to the extent possible, the source of the supply for unlicensed dealers.

Mr. MARQUARDT. I think I would like to have Mr. Barnett respond to that question because he is personally aware of it and can address himself to the issue you raised without identifying individuals.

Mr. BARNETT. We have a group of people in our State known as nature-paths and I understand they are licensed in some States but not Idaho. We have arrested over 20 of these people and they have all been in possession of controlled substances. Most of the companies that they have received these from are not what I would call ethical companies, but apparently they did not check to see whether these people were licensed to receive these products and did not have a registration unmber requirement. Where some of the companies or the practitioners, if I can call them that, got their supplies is unknown to us. They wouldn't disclose where they had gotten them. They didn't have the records to indicate where they had received them from.

Mr. RECTOR. We would be interested, to know whether a mail order house had supplied control items to such so-called—or I guess, in fact, practitioners

Mr. BARNETT. We are in litigation on one of these people now. We are attempting to find out where they have obtained these products, but we haven't had much luck yet.

Mr. RECTOR. You commented on the distribution of samples and raised the question about the proper conduit for that and raised questions about whether or not a sales person should be distributing samples; am I correct?

Mr. MARQUARDT. Right.

Mr. RECTOR. Could you elaborate on why you would recommend that that intermediate party be eliminated from the process. Is there some problem associated with sales people dispensing samples to practitioners?

Mr. BARNETT. I would like to briefly respond to that, also.

We have recently had a case where a detail man for one of the companies was arrested for not only selling samples but also taking control substances from drugstores and selling them to other people. So it is our feeling that if the detail men or the company representatives did not have these products they couldn't sell them, which is being done. They repackaged them and sold them to anyone that wanted to buy them.

Mr. RECTOR. Were they being sold to an illicit market or licit market?

Mr. BARNETT. Illicit market. Through a bar, usually.

Mr. RECTOR. In the last several years during the course of our hearings a number of questions have been raised about pharmaceutical sales persons. Recently California passed a statute that would prohibit the unsolicited distribution of samples so that a physician would have to solicit distribution. The medical society in California supported that approach. Other people have recommended a State licensing scheme that would bring to the attention of the proper authorities within a State the activities of such sales people in terms of identifying them, the association that they are working for, and in some instances I think the suggestions would have included reporting on drugs that were dispensed and the amount.

Mr. BARNETT. Well, many of the ethical companies now require that the physician or practitioner request by writing when he wants samples, and they have to keep close track of these, and if the detail man delivers them he has to keep a record of this.

I think what we were suggesting, it seems to us it would be just as easy if he requested these in writing for the manufacturer to send them directly to the physician rather than to make another entry and go through the procedure.

I might, along that same line, we instituted that the physician must sign when he receives them. The reason we did this, we had more than one case where we assumed that the physician was distributing drugs illegally. He was getting them from a detail man. Of course, when we confront them with this and go to court he says he didn't and the detail man says he did. We had no proof one way or the other. This was our primary reason for instigating this.

But I agree the sampling of drugs should certainly come only from the wholesaler. One thing, the detail man, he handles these drugs all the time and I don't really believe that some of them, even though they are honest, really realize the abuse they have. He doesn't have the security that he should. He locks them in his car or maybe he just leaves them in the back seat. They have had any number of cases like this where they have been stolen out of automobiles. If he locks them in the trunk you have a heat problem which deteriorates the drug.

Mr. RECTOR. That would be helpful if the association has any records of that typ of activity. It would be helpful if we could

receive them and review the various cases from States around the country——

Mr. ULRICH. I would like to comment on registration and licensing. We had a salesman involved with control substances, but what he was doing in a particular store which was in bad credit with his company and he wanted to maintain the level of credit with that store and ordering large quantities through another store and bootlegging them to the other store and selling them to him out of the petty cash fund. There were no records. These were dumped out of the bottles and transported in a bag, maybe 15 or 20,000 tablets in a bag. We didn't have any handle on the salesman. However, he did appear before the board and about the only means we used to discipline him was if we heard any further reports we would go to the home office of the company.

But we really don't have any legal way of handling this particular problem. We did with the pharmacists, but not with the salesman.

Mr. RECTOR. Can you identify the community where that happened without causing any difficulty?

Mr. SCHWEMIN. It is in the northern part of the State.

Mr. RECTOR. If there is some problem we could say in the northern part of Indiana. I would be interested as to whether it was rural or urban?

Mr. ULRICH. Two rural communities.

Mr. RECTOR. A lot of people have the misimpression that when we talk about abuse of drugs—whether it is classic illicit heroin or cocaine or marihuana or really the more typical would be the amphetamines and barbiturates—people have gotten the impression it is just a problem of the inner city or a problem of the adjacent suburbs. I think it is important to inform people that all around the country, rural, urban, suburban and the like, communities are being confronted with these substances. You all probably have more expertise in that regard than we do.

There was a comment about restricting the quantity of control substances on the State level. I believe Massachusetts and one or more other States have put controls of that nature—I don't know if it is across the board on Schedule II items or what the scope of it is in Massachusetts, but—similar proposals have been made to us. In reflecting on such a proposal, how do you respond to the claim that you are likely to increase the cost anywhere from, who knows 50 to maybe even 100 percent for the consumer.

Mr. ULRICH. How was it determined that the cost would be increased?

Mr. RECTOR. This isn't our argument. The argument is made to us quite often that by limiting the quantity and thereby limiting number of dosage units that person could obtain, say in a 1-month period, you are going to necessitate additional visits to a practitioner which would incur expense; and second, it is the case that if you buy in volume you can make a better deal.

Mr. ULRICH. If I can respond, in our area of practice a 100 dosage units is usually the best, quote, price. Larger volumes very seldom do you get any additional break in the price.

The idea of returning visits to the physician could be very nicely handled if the individual physician felt like this individual needed—or he did not want to see him for 6 months, if he would give him a month's supply of a various drug, no matter what schedule, and then give him easily several post-dated prescriptions at intervals—if he takes one a night, a hundred nights, whatever it takes, rather than giving him a quantity of say 500. This happened very nicely with methylphenidate for hyperactive children. Most generally where you have small children you also have very possibly larger children and with a quantity of that particular drug available the mere safety factor alone is one thing and the ability of older children or babysitters get into the cabinet and find 500, they could take a 100 and not even miss them.

Mr. RECTOR. I think we tend to agree with your commentary. I was just mentioning there are other points of view and it is good to get a balanced discussion of those kinds of questions.

We have found several years ago in other investigations that methylphenidate is not only a problem with the older children or other siblings or even perhaps a parent in a family that have abused it, but in Seattle, and in Portland, there was considerable evidence of very young grade school youngsters and grammar school, third, four, five, sixth grade who were not only orally abusing it, but were shooting it up. So you have the additional problem of what intravenous approach would entail. You had an awful situation with kids who were allegedly getting it from school nurses. A child in third grade would go to the school nurse and get 20 or 30 tablets because they were ostensibly a hyperactive child. In most instances there had been no diagnosis of hyperactivity whatsoever. The child had been jumpy and the nurse had given the child a vial of tablets and that started the whole stairstep of events which led to the tragic deaths of 13 youngsters.

Mr. ULRICH. The other thing that is pertinent, I don't believe they know at what point in time that hyperactive child becomes a normal individual, and then you get the effects of taking a stimulant. I don't think the company can give you any set age level at which time this does not occur.

Mr. RECTOR. I had one last question with regard to the impact of the production quotas that we were involved in obtaining on the amphetamines. It has been almost 2 years now since the production was rather substantially reduced and again reduced this year. I think it is close to 95 percent reduction over the production levels of 1971. What has been the impact in the various States of that reduction?

Mr. MARQUARDT. I think the legally manufactured amphetamines have not been diverted as readily to illicit channels of distribution. They were manufactured in the United States, in some instances shipped across the border into Mexico and found their way back into the street market here in the United States again. I think all the testimony given today has pointed out the fact that pharmacies have become the target for violent crimes, and drugs sought are not only narcotics but amphetamines. That is one impact of the quotas imposed on amphetamines. This has been our experience in the urban

area of Wisconsin. It is not only been the narcotic drugs in schedule II that are sought, but also the amphetamine type substances.

Mr. RECTOR. I think the statistics we commented on today indicated nearly half the drugs lost through theft of pharmacies and other registrants are either amphetamines or barbiturates. I guess you are saying they have been effective but it is perhaps a double-edged sword. The controls have been effective because now abusers and pushers are looking to drugstores for their amphetamines rather than a street corner pusher; is that correct?

Mr. MARQUARDT. That has been our experience in Wisconsin. I think perhaps some of the other persons——

Mr. RECTOR. What about Indiana?

Mr. ULRICH. I notice in the urban area of Indianapolis many physicians stopped prescribing amphetamines. However, there still continues to be a few physicians who continue to use amphetamines and their practice has grown. I notice that we are getting a larger volume of prescriptions from these people and they are largely amphetamines. The clientele spread over maybe 200 or 300 physicians is now centered within maybe 15 to 30.

Mr. SCHEWEMIN. The production quotas as well as the scheduling of different drugs, I don't think there is any doubt has helped. I wasn't too much of an advocate when it started, but it certainly has helped. There is just no doubt about it. How far it will help I don't know. Of course, we talked about it when they were talking about scheduling these drugs. We knew at the time or anticipated that you would have a great upsurge in the burglaries and the thefts in the pharmacies. You don't change these people. You only change their habit.

Mr. RECTOR. Gentlemen, thank you for appearing before us today. Your testimony is of great value to the subcommittee in assisting us evaluate the affects of the CSA regulations on your profession.

[Mr. Marquardt's prepared statement is as follows:]

PREPARED STATEMENT OF KARL W. MARQUARDT RERRESENTING THE NATIONAL ASSOCIATION OF BOARDS OF PHARMACY

Mr. Chairman and members of the committee, I am Karl W. Marquardt, Executive Secretary of the Wisconsin Pharmacy Examining Board and chairman of the National Association of Boards of Pharmacy (NABP) Bureau of Law Enforcement. The NABP is an association comprised of boards of pharmacy from each of the 50 states, the District of Columbia and the Territory of Puerto Rico. In addition to providing for interstate reciprocity and examination services for pharmacist licensure, the Association fosters legislative change and improved drug law enforcement by cooperating with state, national, and international agencies and associations having similar objectives.

I am accompanied by Mr. Joe Schwemin, Pres., NABP and Secretary, Oklahoma State Board of Pharmacy; Mr. C. E. Barnett, Chairman NABP Executive Committee and Secretary, Idaho Board of Pharmacy; and Mr. Lawrence Ulrich, member of the Indiana Board of Pharmacy and Chairman of the NABP Committee on Institutional Pharmacy.

You have requested that NABP express its views regarding drug related crime, diversion of legally manufactured drugs tot illicit channels, prescription fraud and other relevant issues on the adequacy of federal drug control legislation. Your request dated March 8 was received by NABP on March 12. A copy of the request with a cover letter was sent by NABP to secretaries of all state boards of pharmacy, asking for responses to the issues which you raised.

Although our statement attempts to reflect the views of most boards of pharmacy throughout the country, it could have been more inclusive if additional time was available.

This statement is the composite view of many boards of pharmacy to the respective issues included in your invitation to testify at today's hearing. The responses follow a restatement of the question or issue.

1. What can be done to more effectively curb the alarming number of robberies, burglaries, thefts and assaults directed at pharmacies and those who operate them?

Armed robberies, burglaries, thefts and assaults in connection therewith to obtain controlled substances have become a national plague. If these crimes against pharmacists and pharmacies were made a federal felony offense, the incidence would undoubtedly decrease. Furthermore, the criminal justice system under which apprehended individuals are tried for these crimes does not appear to be an effective deterant. When low bail is set for those apprehended or leniency shown in sentencing by the courts, the perpetrators of these crimes are soon back "on the streets" committing the same offenses. Penalties for violation of criminal statutes should also have mandatory minimum sentences rather than discretionary sentences, since the latter frequently result in leniency and probationary sentencing.

Other things which might be done to curb the increased number of burglaries include: financial assistance to local law enforcement agencies for the specific purpose of better after-hours protection of pharmacies; installation of various types of adequate alarms with some system of federal financial assistance since this measure would create a financial burden on many small businesses; require controlled substances to be packaged my manufacturers in smaller sizes so that a pharmacy's inventory is minimal; and encourage pharmacies to stock limited quantities of controlled substances so that amounts obtainable through crime would not warrant committing the crime.

2. The nature and extent of crimes directed at pharmacies and their impact on society and pharmacy.

Although no hard data on the number of crimes against pharmacies is presently available from the NABP, all boards reported an increased incidence in recent years. This would indicate an effective law enforcement effort on illegally manufactured and distributed drugs and a "drying up" of street sources. Addicts wil then turn to legally manufactured substances possessed by pharmacies and clinics. The most prevalent crime involving controlled substances is burglary, with armed robbery, thefts and assault in connection therewith following closely. Fear and apprehension of being criminal targets has caused many pharmacies to close or curtail hours of service, and discontinue emergency night prescription service. This has an obvious impact on the health and welfare of the public. These crimes, of course, result in extensive financial loss to the pharmacy in trems of the cost of the drugs involved, repair of damages to property, increased costs, and investment in alarms and other protective systems, all of which eventually must be borne by the public. Therefore the impact on society is substantial, even to the point of inaccessibility of pharmacy services in some areas.

3. The impact of the 1970 Act on the diversion and traffic of legitimately produced and distributed dangerous drugs.

The 1970 Controlled Substances Act has had a significant impact on reducing diversion and traffic of legally manufactured drugs. This, in combination with effective enforcement in illicit drug distribution areas, is a primary cause of the increase in pharmacy burglaries and robberies. Although pharmacies are a source of some diversion along with diversion by employees of manufacturers and distributors, the record keeping requirements have essentially made it more difficult to accomplish without detection. Several reporting state boards of pharmacy indicated the practice of some wholesale distributors are questionable in ascertaining the eligibility of prospective buyers to purchase controlled substances. Many unlicensed practitioners have been found in possession of controlled substances which are obtained from wholesalers who obviously did not question the credentials of the person ordering the drugs. Although current regulations restrict complimentary sampling of controlled substances to written requests of practitioners, provisions should be enacted to only make them available directly from the manufacturer's principal place of business,

rather than through sales representatives. One loop-hole in the 1970 Act is the absence of a statutory or regulatory restriction on the quantity of controlled substances which can be prescribed or dispensed. States have indicated that physicians are writing prescriptions for larger amounts of schedule II controlled substances so they aren't "bothered" for refills. Several examples are prescriptions for meperidine, methylphenidate, and dextroamphetamine in quantities ranging from 500-1000 tablets or capsules. Recent rescheduling of amobarbital, pentobarbital, and secobarbital into schedule II has resulted in similar prescribing practices for those drugs. Therefore, the adoption of quantity limitations on prescribing and dispensing controlled substances is respectfully recommended for your consideration. A provision similar to that proposed by the Drug Enforcement Administration in 37 F.R. 15933 (Aug. 8, 1972) might be an appropriate course of action to follow.

4. An assessment of the extent to which prescription fraud and mail order diversion contribute to illicit traffic and abuse of dangerous drugs and recommendations to more effectively curb diversion from both of these sources.

The contribution of mail order diversion and prescription fraud to illicit drug use is of increased significance since the illegal market for drugs is not as open as it once was. Of the two, the fraudulent prescription is the more serious problem, and both mail order and community pharmacies alike become the victims of such forgeries. The DEA "Project Script", a 1973 study of prescription fraud vulnerability, attempted to answer the question: "how easy is it to perpetrate a perscription fraud?" There were many aspects of the study which call into question its validity, all of which were pointed out to DEA not only by NABP, but other associations representing concerned individuals as well. In an attempt to follow up the study in an education for voluntary compliance effort, NABP's Bureau of Law Enforcement requested additional data on Project Script be sent to the states involved in the study, but access to the information was denied. Before prescription fraud can be remedied, data on its prevalence must be quantified. Possible remedies might include a federal triplicate prescription requirement for schedule II drugs. Most boards of pharmacy are also opposed to the mailing of any controlled substances prescriptions, not simply because of possible diversion, but primarily because of public health concerns. Controlled substances, in the best interests of the patient, should be prescribed and dispensed in a setting which allows direct consultation between any of the involved parties, i.e. physician, patient and pharmacist. That relationship is broken and at best, strained, when controlled substances are dispensed by mail order pharmacies.

5. What can be done to deal more effectively with the few pharmacists who illegally distribute controlled drugs and to encourage pharmacists to identify the few physicians who improperly or illegally contribute to the traffic and abuse of dangerous controlled drugs?

This problem can be dealt with most effectively by the respective state licensing boards. However, a seldom used provision of the Act is 21 USC 824, which permits unilateral federal denial, revocation or suspension of a DEA registration. Also, practitioners found guilty of illegal distribution or dispensing activities must not be shown leniency in administrative or criminal prosecutions for violations. Too frequently, leniency is shown when the defense pleads "you are taking away a person's livelihood".

Most pharmacists are not reluctant to identify physicians or other prescribers who improperly or illegally contribute to the traffic and abuse of controlled substances. If a pharmacist is assured of his anonymity as an informant, and the information is only used for the appropriate agency to build its case, this type of information should be readily available. If local law enforcement agencies point out to the pharmacist his corresponding responsibility to ensure that a prescription is issued in the usual course of professional practice, pharmacists will be encouraged to identify errant practitioners.

An additional effective method of curbing illegal distribution by pharmacists and physicians would be the establishment of a Diversion Investigative Unit (DIU) in all states, as has been done on a pilot basis in Texas and Michigan. The DIU is an independent unit comprised of representatives from various state agencies as well as the federal Drug Enforcement Administration. The state DIU concentrates primarily on licensed health care practitioners such as pharmacists, physicians, dentists, veterinarians, nursing homes, nurses and hospitals who may be involved in illegal diversion activities. The cases can be

tried in local, state, or federal courts or before the respective licensing board, or both. In Michigan and Texas the DIU has proven to be a very effective addition to the drug law enforcement program.

Local compliance efforts are also assisted by conducting drug accountability audits. If the audit shows no evidence of diversion by the pharmacy, it serves a further purpose of assisting investigators in constructing compilations of physicians' prescribing habits, which may indicate that a particular physician is not issuing prescriptions for controlled substances in the usual course of his professional practice. Such information can be forwarded to boards of medical examiners for appropriate action against the practitioner.

6. The merit of requiring verification of identify and initialing of prescriptions by pharmacists.

Requiring verification of identify of the patient on the prescription document has dubious merit. Most drug abusers, pushers, and persons who deal in illicit traffic of controlled substances have many sets of identification, including but not limited to driver's licenses with their photographs on them. Initialing the prescription for verification of identity would accomplish very little and the whole process would be time consuming for all controlled substances prescriptions. The procedure would doubtless have a degrading effect on the professional image of pharmacy and not be an effective deterrant to prescription fraud.

The identity of the pharmacist who dispensed not only a controlled substance prescription, but any prescription drug, is good professional practice and no doubt is already done by most pharmacists or is required by state law or regulation. The NABP therefore supports initialing of prescriptions by pharmacists.

7. An assessment of current methods for reporting and compiling diversion statistics and of proposals to require a triplicate prescription system for dangerous non-narcotic drugs.

In most states the current methods for reporting and compiling diversion statistics consist of manual reporting systems. Until it can be handled by electronic data processing, compilation of this information is very impractical. Perhaps the Drug Enforcement Administration's Automation of Reports and Consumated Orders System (ARCOS) could be expanded to include dissemination of any orders for controlled substances from any registered manufacturer or distributor, to the state licensing agencies for purposes of correlating this data with records maintained by the dispensing pharmacy. In this way diversion could be more readily detected and appropriate action taken against violating practitioners.

Responses to proposals to require triplicate prescriptions for controlled substances have been varied. Several states have already enacted a state triplicate prescription system for all schedule II substances. Those which have, indicate it has been the biggest deterrent to diversion of controlled substances into the illicit market of any measures which could be taken. If automated systems are available for tabulating data from the third copy filed with a state agency, the agency is readily able to ascertain possible violations of the law. Those states which object to a triplicate prescription system do so on the grounds that the amount of work involved in such a procedure is not justified by the benefits which would be derived from it. Furthermore, it is contended that such a system places an undue restriction on the practice privileges of the physician and pharmacist. If a federal triplicate prescription system is enacted for schedule II controlled substances, provisions should be made for filing composite automated reports of the third copy with the state licensing agency.

8. The need to make the 1970 Act infraction data more accessible to state pharmacy boards in order to facilitate appropriate disciplinary or license revocation decisions.

Although most states have entered into a memorandum of understanding withthe Drug Enforcement Administration, infraction data uncovered by DEA compliance investigations is not routinely disseminated to the appropriate state licensing agencies. However, most boards of pharmacies have a good working relationship and cooperate with, and exchange information on a mutual basis with district, regional and national DEA officials. To facilitate state license suspension or revocation, infraction data should be routinely reported to the board of pharmacy where this data involves pharmacists or pharmacies. In addition, when federal administrative action to suspend or revoke a DEA registration is not contemplated, DEA should file a complaint

based on their investigation with the appropriate state board so that suspension or revocation proceedings may be initiated at the state level.

9. The need for more flexibility in the schedules of the 1970 Act.

Most states which have passed the Uniform Controlled Substances Act have sufficient authority to add to, delete from, or reschedule any substances. These states have not indicated a need for greater flexibility in the schedules of the 1970 Controlled Substances Act. There was some indication, however, that an unreasonably long period of time occurs before action is taken to add or reschedule substances, e.g. methaqualone. Since the Act provided that substances may be added based on a potential for abuse, the actual evidence of abuse need not be as strong before scheduling of a substance occurs. An additional suggestion was made that any amendments to the Controlled Substances Act might include a schedule VI, to include all prescription legend drugs, but exempt these drugs from the inventory record keeping requirements.

10. The need for a formal procedure to assure that the views and experience of professional pharmacists are considered in the development of Federal drug control decisions.

The National Association of Boards of Pharmacy and its Bureau of Law Enforcement concur in the necessity for establishing a formal advisory committee comprised of practitioners in the health care professions, including pharmacists, to assure consideration of the views and experience of the respective members of the professions represented. The advisory committee should consist of practicing professional pharmacists with representation from one of each of the DEA regional areas. In addition, we would urge that the NABP Bureau of Law Enforcement be a part of any plan to gain views from the profession. The latter representation would provide liaison between the DEA and the member boards of NABP.

Mr. Chairman, we appreciate the opportunity to participate in these hearings to develop improvements in the drug control legislation first enacted in 1970. My colleagues, whom I have introduced at the beginning of this statement, have had considerable experience not only as secretaries of boards of pharmacy, but also as directors of state bureaus of drug control. In the latter capacity they have had the responsibility for street drug enforcement activities, as well as the administration and enforcement of state narcotic and controlled drug laws.

It has been a please to provide this information for you and we will be pleased to respond to any questions you and members of the committee may have.

[Additional materials of the National Association of Boards of Pharmacy submitted for the record are marked "Exhibit Nos. 6–8" and are as follows:]

EXHIBIT No. 6

THE NATIONAL ASSOCIATION OF BOARDS OF PHARMACY, CHICAGO, ILL.

ORGANIZATION AND PURPOSES

By way of background information, the NABP was established in 1904 as a non-profit Association. Membership in the Association at the present time includes 56 licensing authorities which are as follows: 50 states, the District of Columbia, the territory of Puerto Rico, the commonwealth of the Virgin Islands and the Canadian provinces of British Columbia, Manitoba, Alberta and Ontario.

The constitution and by-laws of the Association designate active and associate member states. Forty-nine boards, who are members of the Association, actively participate in the reciprocal exchange of licenses, which is the major funciton of the Association. All associate members (7) participate in activities of the Association (committee projects, meetings, etc.) with the exception of exchanging licenses.

The Association functions under a Constitution and By-laws agreed to by its member boards and through a series of committees which give advice to the Association on matters pertaining directly to the objectives as outlined in the constitution and to the problems of Boards of Pharmacy. The Association is directed by an administration office and an executive committee composed of seven members.

The average board of pharmacy in the United States is made up of 5 members, usually appointed by the Governor of the state. This varies somewhat from state to state; however, the Association has approximately 300 members who are also members of the official state agency.

These administrative agencies are the licensing bodies which certify those persons who are deemed fit to practice pharmacy. They also supervise the distribution of drugs which are outlined by the Pharmacy Practice Act of each participlar state or jurisdiction. These agencies are empowered to exercise disciplinary measures for the practicing pharmacist as outlined in the Pharmacy Practice Act of each state.

It should also be noted that in 6 states, the Board of Pharmacy enforces the narcotic laws and in a number of other states, the Board has a dual or even a primary responsibility for the enforcement of the Dangerous Drug Acts. In all states, the Board of Pharmacy licenses outlets (pharmacies) of distribution for drugs and medicines.

In general, these licensing agencies are supported mainly by fees from the profession and for licensing outlets (pharmacies). Appropriations above fees collected are established by the legislature of some states to subsidize additional law enforcement work that may be performed by these Boards.

INFORMATION SOURCE

The Association office stands as a source of reliable, consultive information to pharmacists, national and state associations, boards of pharmacy, government agencies (federal and state), and to foreign graduates seeking licensure in the United States.

Information provided is of a wide variety but basically pertains to licensure, reciprocity, examinations, legal aspects of the practice of pharmacy, census and licensure data, state pharmacy practice acts, internship programs (national and state), individual information about a specific pharmacist, legislative reporting reference service, resources of state boards of pharmacy, manpower studies, and other aspects relative to education, licensure, practice of pharmacy, and distribution of drugs. NABP often acts as a coordinator of information between boards of pharmacy and federal and state government agencies.

NABP BOARDS OF PHARMACY MANAGEMENT STUDIES

As a regular part of the boards of pharmacy Secretaries workshop, the Association examines new methods of management, office procedures, technique, personnel management, new equipment, etc., in an effort to increase the efficiency of the board of pharmacy office and field operations. In addition, management articles written by leaders in busness, education, and government are forwarded to board secretaries periodically or are published in the NABP QUARTERLY.

ANNUAL CONVENTION

This meeting feautres topics of current interest to boards of pharmacy members and secretaries. It demonstrates new techniques in management, law enforcement, examination materials and procedures, in addition to reviewing the annual activities of the Association, hearing from Executive Committee personnel and staff. Reports of various standing and special committee as well as delegate reports are presented.

BOARD MEMBERS AND SECRETARIES SEMINARS

This service, scheduled to begin in 1970, will be a part of each year's district meeting. It will provide information to board members that has been funneled from the national office to district and state levels. Special problems in the Association will be treated in depth. At the same time it will serve as a sounding board for members where they may voice opinions about Association activities or present specific problems they may be experiencing in their state.

DIRECTORY OF MEMBERS

A part of each annual PROCEEDINGS, this information is a Who's Who in boards of pharmacy affairs. The Directory is kept up to date and is made available upon request.

BLUE RIBBON COMMITTEE ACTIVITIES

In 1967 a Blueprint Committee was established to prepare a Taxonomy for the preparation of a standardized examination for licensure in pharmacy. In 1968 a Blue Ribbon Committee was convened and, as a result, several thousand test items were screened, after which selected questions in four categories were placed in the NABP standardized licensure examination. This service will be available to boards of pharmacy in June 1969.

BULLETIN SERVICE

Information of special interest to board members, secretaries, deans of colleges of pharmacy, and state association secretaries is prepared in a bulletin and mailed throughout the year. At various times these are also sent to board counsel for each board. This information may be contained in the form of a news release relating certain information relative to court cases, national and state legislative happenings, etc.

CERTIFICATION OF PHARMACISTS TO STATES

As set forth in the NABP CONSTITUTION, the purpose of the Association is to provide for interstate reciprocity based upon a uniform minimum standard of education and uniform legislation; to improve the standards of pharmaceutical education, licensure and practice by cooperating with State, National and International Agencies and Associations having similar objects.

The Association, therefore, acts as a clearing house for applications of pharmacists seeking licensure in another state. Through a special form determination is made of the eligibility of the applicant, after which his education, internship, and examination records are screened, as well as his practice record. All states where the applicant has been licensed are checked. Any information gathered is forwarded to the board of pharmacy where the applicant wishes to transfer his license. The Association Suspension and Revocation File is also screened to determine whether or not the applicant has ever been disciplined.

INFORMATION FOR FOREIGN GRADUATES

Th NABP receives numerous requests from persons throughout the United States and foreign countries requesting information about the registration of pharmacists from other lands. The Association maintains a complete file on current procedures for absorbing foreign pharmacists through licensure in the various states. An up-to-date letter of information is forwarded to all foreign graduates requesting information in relation to licensure in the United States. Through this "Foreign Graduate Information Letter" boards of pharmacy, colleges of pharmacy, state and national associations have been made aware of the requirements for licensure of a foreign graduate.

The Association participates in a continuing joint committee with the American Association of College of Pharmacy whose member colleges, in most instances, screen foreign graduate credentials prior to examination and licensure.

SURVEY OF BOARDS OF PHARMACY CAPABILITIES

Every three years the Association publishes the results of a survey of boards of pharmacy budgets, receipts, personnel, and laboratory facilities. Although individual states are not indicated, the results of this survey provides a comparative picture in terms of all of the aspects of a board of pharmacy's operation and capabilities. As a matter of information, the results of this survey are made available to the profession of pharmacy and to state and federal government agencies.

CENSUS AND LICENSURE DATA

This survey gives important information on pharmacy manpower in each state of the United States. First published in 1942, it is one of the only continuous surveys available. The NABP is considered to be one of the prime resources for manpower information in pharmacy in this country.

SURVEY OF PHARMACY LAWS

The SURVEY is published each legislative year. It continually updates information on board secretaries, narcotic law enforcement, pharmacists on boards of health. Other requirements for licensure and reciprocity in pharmacy are also included.

A review of the various practice acts is a part of the publication. Administrative agencies in each state, membership of boards, commissions or committees for pharmacy in each state, specific information relative to the operating procedures of state boards, requirements for reciprocal licensure, requirements for original licensure as a pharmacist, information on uniformity of drug and narcotic laws, as well as conditions for suspension and revocation of licenses by boards of pharmacy, licensure requirements for drug distribution, and the Associations' recommendation relative to minimum standards of technical equipment and stock for a pharmacy, including the reference library of a pharmacy are some of the subjects covered.

A revision of this SURVEY is now underway.

A file containing all state pharmacy acts and regulations is maintained in the NABP office. The Committee on Institutional Pharmacy also maintains a file on all state laws concerning the distribution of drugs in institutions.

COLLEGES AND SCHOOLS OF PHARMACY IN THE UNITED STATES AND PUERTO RICO

This publication is an historical account of the various programs in pharmaceutical education offered in American and foreign colleges of pharmacy. It was first published in 1948. This booklet contains information relative to the establishment of and control of universities or colleges that house a college of pharmacy.

SUSPENSION AND REVOCATION OF PHARMACY LICENSES

As a routine service to boards of pharmacy, the NABP compiles a list of pharmacists whose licenses were either suspended or revoked by a board of pharmacy from July 1 of one year to June 30 of the following year. A current file is also kept concerning all licenses which have been suspended, revoked; and information pertaining to other disciplinary measures taken by a board. During the regular screening process for all applications submitted, these are reviewed.

This information is made available to all boards screening individuals who apply for licensure by examination or by reciprocity.

LEGISLATIVE REPORTING SERVICE

As a service to state boards of pharmacy members who are interested in state legislation in other jurisdictions, the NABP provides a reporting service concerning bills introduced in state legislatures. The legislation is then followed by the board secretary to determine its fate. The Committee on Legislation presents a final report on legislation to the convention each year.

LEGAL SERVICE—FORUM

The Association maintains legal counsel who assists boards of pharmacy members and secretaries with various legal problems; however, boards maintain counsel on an outside basis or through the office of the attorney general in their state. The NABP Legal Forum is composed of a number of attorney generals who serve state boards of pharmacy as counsel. These attorneys meet under the direction of NABP counsel to discuss problems relating to pharmacy laws, regulations, and administration of the practice acts in the states in order to assist boards by giving recommendations and guidance in drafting legislation or in administrative procedures and regulations in the future.

One of the first problems which the Forum concerned itself with was the ability of a board of pharmacy to remove from practice a pharmacist mentally incapable of practicing dur to senility, etc.; physically or mentally incapacitated. In recent years practitioners are maintaining their license in good standing for a continued length of time. Not all of these persons are physically or mentally able to protect the health and welfare of the citizens they serve.

SCHOOL FOR BOARD INSPECTORS

In 1968 the Association committed itself to establish a continuing education program for board inspectors and secretaries through a grant from the National Pharmaceutical Council.

The first School for Board Inspectors in the United States was held at Temple University in January, 1969. The curriculum and guidelines for the school were prepared by Dr. Sidney H. Willig, Director of the Drug Law Unit of the University. These were approved by the Bureau of Narcotics and Dangerous Drugs, Justice Department, and the Food and Drug Administration.

Future plans for conducting additional schools are being made. In 1968 or 1970 a school is to be held at the University of Georgia, Athens, Georgia. Other sites in the north central and west will be considered for future schools.

NABP SPEAKERS' BUREAU

For several years the Association has provided speakers to a number of state pharmaceutical association conventions. The speakers explain the purposes and objectives of the Association, call attention to the national program of internship training, and give a general overall view of the services and activities provided through the NABP.

BUREAU OF LAW ENFORCEMENT

The Bureau shall have pertinent information pertaining to enforcement measures (effective and ineffective) throughout the United States. Such information shall be made available at regular NABP annual meetings or by special reports to be mailed to member boards.

It should offer counselor service to member boards seeking information to be used in improvement of enforcement programs at the state level. The Bureau desires to cooperate with national and state associations in the health field and the law enforcement area in curbing the flow of drugs from legitimate channels into illicit traffic.

Bureau shall cooperate with the Executive Director in setting up workshops or similar programs to deal with control and enforcement matters thereby contributing to a plan for further protection of public health.

SPECIAL LIAISON ACTIVITIES

Permanent Task Force Liaison Unit with the Bureau of Narcotics and Dangerous Drugs, Justice Department and Food and Drug Administration.

Contacts with Social Security Administration, Public Health Service, and state law enforcement and health agencies.

Special committee on Subprofessional Personnel for Pharmacy with the American Pharmaceutical Association, American Association of Colleges of Pharmacy, and American Society of Hospital Pharmacists.

Ad hoc Committee to Study and Make Recommendations on the Licensure of Foreign Graduates Seeking Licensure in the United States (this Committee was formed in 1968 at the suggestion of NABP).

Association representatives act as consultants with federal and state government agencies, bureaus, etc. each year. For example, NABP was invited to consult and comment concerning drafting of the proposed "Controlled Dangerous Substances Act of 1969" by the Bureau of Narcotics and Dangerous Drugs. NABP accepted the invitation and representatives participated in discussion of a model state omnibus dangerous substances bill.

NABP coordinates its activities in conjunction with other national associations in the profession of pharmacy. From time to time Committee personnel are requested to attend scientific, law enforcement or other informative meetings to gather material which pertains directly to the Committee's responsibilities. Information is then disseminated to members of the Committee for background material. Much of this information is contained in the Committee's yearly report to the annual convention of the Association.

ASSOCIATION PUBLICATIONS

The following are made available, in most instances, free of charge to the profession and to members of state boards of pharmacy. They are published primarily for members of NABP:

1. Proceedings—the annual NABP "yearbook" containing a complete summary of the annual meeting and committee activities for the year
2. Survey of Pharmacy Law—see this caption heading
3. Licensure Statistics and Cenus of Pharmacy—see "Census and Licensure Data", page 6. This publication is also published in reprint form
4. Constitution and Bylaws.
5. Colleges and Schools of Pharmacy in the United States and Puerto Rico—see this caption heading, page 7
6. Roster of Board Members—see "Directory of Members", page 4
7. List of Accredited Colleges of Pharmacy—published by the American Council on Pharmaceutical Education; distributed by NABP to Association members, foreign graduates, students, and other interested persons
8. NABP Indicator—This publication is now and written especially for students in the 74 accredited colleges of pharmacy in the United States and Puerto Rico. Its purpose is to communicate with students in the interest of the objectives of the Association, to bring needed information relative to acquiring and maintaining licenses as pharmacists. The Association has an obligation to all pharmacists to see that they may transfer their licenses freely at any time that they choose during their professional careers.
9. So You're a New Board Member—a manual as indicated by its title, this publication was prepared with the new board member in mind. It is being written by the Association President and is now in draft form. During the coming year the Association plans to consult various committees and members in the interest of reinfining and perfecting the MANUAL in order to present it at the forthcoming annual meeting in Washington, D. C. in 1970.

REPRINTS OF NABP PUBLICATIONS

1. Chapter 13, Pharmacists", reproduced from "State Licensing of Health Occupations", published by the Public Health Seervice (the NABP assisted in the compilation of data contained in this document). This reprint is distributed free of charge.
2. "Licensure Statistics and Census of Pharmacy", a reprint from the yearly PROCEEDINGS, and distributed free of charge
3. "Model Core Curriculum" and "Drug Abuse: A Course for Educators", although not NABP publications, are distributed without charge

NABP Quarterly—Released four times each year, this publication contains board news of interest about board members and secretaries, rules and regulations of boards of pharmacy that are promulgated by boards, legislation considered in various states, regulations stemming from federal government activities, roster of boards of pharmacy secretaries, and a thorough summary of court decisions in the areas of public health, welfare, education, and licensing.

Pharmacy Preceptors Guide—Since 1964 the Association has funded, printed, and distributed this GUIDE for perceptors who train interns qualifying for licensure in pharmacy. In general, all states require one year's experience gained under the supervision of a registered pharmacist. In an effort to stimulate the quality of the various state programs, the NABP, combined with the AACP Internship Committee, prepared the copy for the GUIDE and later funded and distributed this publication.

In 1969 the Association took the necessary steps to screen all national and state associations in pharmacy, as well as boards of pharmacy personnel, in the interest of revising the GUIDE. This revision is in progress.

To date 30,000 copies of the GUIDE have been distributed.

Examination Manual—This publication contains basic test information as to differences between educational and licensure testing and a complete taxonomy of education and testing objectives as set by the Blueprint and Blue Ribbon Committees of the Association under the auspices of the NABP Advisory Committee on Examinations. This Manual is particularly helpful to board members who write their own test items. Much in demand, it is distributed widely upon request to colleges of pharmacy and to NABP members. All new members of the Association are mailed a copy.

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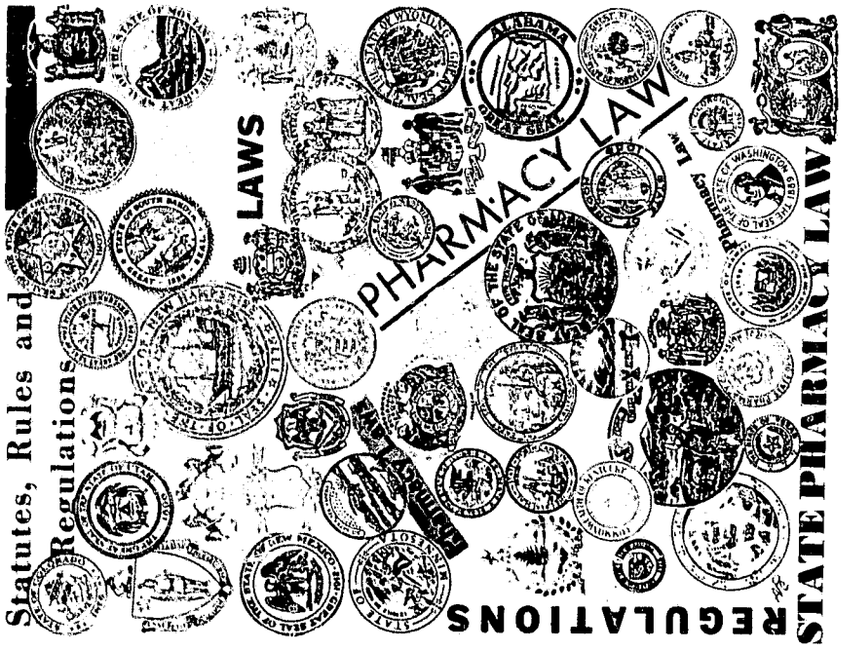
EXHIBIT NO. 7

NATIONAL ASSOCIATION
OF BOARDS OF PHARMACY

SURVEY OF PHARMACY LAW JULY 1, 1973



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SURVEY OF PHARMACY LAWS
Revised to July 1, 1972
NATIONAL ASSOCIATION OF BOARDS OF PHARMACY

Each of the 50 states, the District of Columbia and the Territory of Puerto Rico, have statutory provisions which regulate the practice of pharmacy. Other professions and occupations which are regulated and licensed by all states are: accountants, architects, attorneys, chiropodists, dentists, dental hygienists, embalmers, engineers, nurses (registered), nurses (licensed practical), optometrists, osteopaths, physicians, teachers and veterinarians, making a total of fourteen. Twenty-one health professions are regulated and licensed by at least one state.

Administration of the pharmacy laws is vested in a state board of pharmacy composed of licensed practitioners whose qualifications, appointment, compensation, administrative functions and length of term of office are tabulated for each state in the charts which follow. Additional charts in this Survey are separated under three headings: Organizational Law, Licensing Law and Drug Law. The charts are submitted with a series of footnotes which are intended to serve as sources of reference providing information which is most frequently requested of this Association.

The National Association of Boards of Pharmacy (NABP) acts as intermediary for licensure by reciprocity. In every state, the board recommends or issues a license after a successful examination or review of credentials forwarded by the NABP.

Board functions include the issuance of temporary licenses or permits in 16 states, annual renewal or registration required

in all except six states—all of which have biennial renewal. The general statutory powers granted to a board of pharmacy through their state laws viz. inspection procedures, reporting violations, preferring charges and assisting prosecution, as well as suspension and revocation prerogatives are generally provided in all state pharmacy acts and may be taken for granted. California, Kansas, Florida, Ohio and New Jersey have requirements of Continuing Education (in some form) that must be fulfilled for extended licensure.

Fees for examination range from $10 to $75. Fees for license renewal range from $2 in Puerto Rico to $50 in Alaska and California. In 13 states the board is financed from fees deposited in the state board account, in 15 states from a special account in the state treasury and the remaining from appropriations and general revenue.

OPENING DATES OF STATE LEGISLATURES—1974

Alabama	Jan. 15	Montana	Jan. 3
Alaska	Jan. 10	Nebraska	Jan. 4
Arizona	Jan 10	Nevada	. . . .
Arkansas	Jan. 8	New Hampshire	Jan. 5
California	Jan. 3	New Jersey	Jan. 11
Colorado	Jan. 5	New Mexico	Jan. 18
Connecticut	Feb. 9	New York	Jan. 5
Delaware	Jan. 11	North Carolina	Jan. 1
Florida	Apr. 4	North Dakota	Jan. 3
Georgia	Jan. 10	Ohio	Feb. 2
Hawaii	Jan. 19	Oklahoma	Jan. 4
Idaho	Jan. 10	Oregon	. . . .
Illinois	Apr. 10	Pennsylvania	Jan. 4
Indiana	Jan.	Puerto Rico	Jan. 10
Iowa	Jan. 10	Rhode Island	Jan. 4
Kansas	Jan. 11	South Carolina	Jan. 11
Kentucky	Jan. 4	South Dakota	Jan. 16
Louisiana	May 8	Tennessee	Jan 8
Maine	Jan.	Texas	Jan.
Maryland	Jan. 9	*Utah	Jan. 10
Massachusetts	Jan. 5	Vermont	Jan.
Michigan	Jan. 12	Virginia	Jan. 12
Minnesota	Jan. 2	Washington	Jan. 10
Mississippi	Jan. 4	West Virginia	Jan. 12
Missouri	Jan. 5	Wisconsin	Jan. 1
		Wyoming	Jan. 9

*Meets biennially, odd years.

ORGANIZATIONAL LAW

I. BOARD ACTIVITIES

	First Enactment	Board Year	Publishes Annual Report	Reprints of Laws and Regulations Available	Number of Examinations Annually	Nature of Present Act [1]
Alabama	1931	A	No	Yes	3	C
Alaska	1935	B	No	Yes	G	C
Arizona	1903	B	Yes	Yes	2	C
Arkansas	1891	B	Yes	Yes	2	C
California	1891	B	No	Yes	3	C
Colorado	1867	B	No	Yes	2	C
Connecticut	1881	C	Yes	Yes	3	C
Delaware	1883	B	Yes	Yes	1	C
Dist. of Columbia	1906	B	No	Yes	4	C
Florida	1889	B	Yes	Yes	2	C
Georgia	1881	B	No	Yes	2	C
Hawaii	1945	B	No	Yes	2-G	C
Idaho	1889	B	No	Yes	2-G	C
Illinois	1881	A	Yes	Yes	3	C
Indiana	1899	B	Yes	Yes	2-G	C
Iowa	1880	B	Yes-E	Yes	2	C
Kansas	1885	F	No	Yes	3	C
Kentucky	1874	A	Yes	Yes	2-G	C
Louisiana	1888	A	Yes	Yes	3	C
Maine	1877	B	Yes	Yes	1	C
Maryland	1902	B	Yes	Yes	2	C
Massachusetts	1885	B	Yes	Yes	2-G	C
Michigan	1885	B	No	Yes	3	C
Minnesota	1885	B	Yes-E	Yes	2	C
Mississippi	1892	B	Yes	Yes	1	C
Missouri	1881	B	Yes	Yes	3	C
Montana	1895	B	Yes	Yes	2-3	C
Nebraska	1887	B	No	Yes	2	C
Nevada	1901	B	No	Yes	3	C
New Hampshire	1875	B	No	Yes	2-G	C
New Jersey	1877	B	Yes	Yes	3-G	C
New Mexico	1889	B	Yes	Yes	2 G	B
New York	1884	I	Yes	Yes	2	C
North Carolina	1881	F	Yes	Yes	2	C
North Dakota	1887	B	Yes	Yes	2	C
Ohio	1884	B	Yes	Yes	2	C
Oklahoma	1899	B	Yes	Yes	2	C
Oregon	1891	B	Yes	Yes	1	C
Pennsylvania	1887	B	Yes	Yes	2-G	C
Puerto Rico	1927			Yes		C
Rhode Island	1875	B	Yes	Yes	2-G	C
South Carolina	1876	B	Yes	Yes	3	C
South Dakota	1890	B	Yes	Yes	2	C
Tennessee	1893	B	Yes	Yes	2	C
Texas	1907	D	Yes	Yes	3	C
Utah	1892	B	No	Yes	1	C
Vermont	1894	A	No	Yes	2	C
Virginia	1886	A	Yes	Yes	2	C
Washington	1891	C	No	Yes	2-G	C
West Virginia	1881	B	Yes	Yes	2	C
Wisconsin	1882	C	Yes	Yes	3	C
Wyoming	1888	A	Yes-E	Yes	3	C

FOOTNOTES:

A—Jan. 1 to Dec. 31
B—July 1 to June 30
C—June 1 to May 31
D—Sept. 1 to Aug. 31
E—Biennial
F—May 1 to April 30
G—At discretion of the Board
H—July 2-July 1
I —April 1-March 31

[1]Compulsory (C) — Only persons holding a license are permitted to practice the occupation, and unlicensed persons are prohibited from working in the field. Some laws and regulations do include exceptions which may invalidate compulsory provisions.

II. ADMINISTRATIVE AGENCIES

	Designation (See Footnotes)	Board Members	Examining Committee of Pharmacists	Boards or Committee Appointed by	Rules and Regulations Made by	Licenses Issued by	Licenses Revoked by
Alabama	B	5		K	A	A	A
Alaska	A	5	5	K	A	A	A
Arizona	B	5		K	B	B	B
Arkansas	B	5		K	B	B	B
California	BQ	8•	7	K	B	B	B
Colorado	BU	5		K	B	B	B
Connecticut	CS	6		K	C	C	C
Delaware	B	5		K	B	B	B
Dist. of Columbia	AT	5		L	AL	A	AL
Florida	A	5		K	A	A	A
Georgia	BR	5	5	K	B	B	B
Hawaii	BU	5	5	K	U	B	B
Idaho	B	4		K	B	B	B
Illinois	BD	7	7	M	BD	D	D
Indiana	A	5	5	K	A	A	A
Iowa	V	3	3	K	E	E	P
Kansas	B	5		K	A	A	A
Kentucky	A	5		K	A	A	A
Louisiana	B	19		K	B	B	B
Maine	F	5		K	F	F	F
Maryland	A	5		K	A	A	A
Massachusetts	GW	5•		K	GN	G	G
Michigan	AX	5	5	K	A	A	A
Minnesota	B	7••		K	B	B	B
Mississippi	B	5		K	B	B	B
Missouri	AI	5		K	A	A	A
Montana	B	3	4	K	B	T	B
Nebraska	HN	3	3	N	HN	N	N
Nevada	B	5		K		A	A
New Hampshire	C	5		K	A	C	C
New Jersey	AY	7••		K	C	A	A
New Mexico	A	5		K	A	A	A
New York	IA	15	15	O	I	I	IO
North Carolina	A	5		K	A	A	A
North Dakota	B	5		K	B	B	B
Ohio	B	8		K	B	B	B
Oklahoma	B	5		K	B	B	B
Oregon	B	5		K	B	B	B
Pennsylvania	BZ	5	5	K	B	B	B
Puerto Rico	B	5		K	A	A	A
Rhode Island	AN	5		M	A	A	A
South Carolina	A	7		K	A	A	A
South Dakota	B	3		K	B	B	B
Tennessee	AN	6		K	B	B	B
Texas	B	6		K	B	B	B
Utah	AD	5	5	K	A	D	D
Vermont	A	5		K	B	D-1	B
Virginia	B	5		K	A	A	A
Washington	B	5•	5	K	B	B	B
West Virginia	A	5		K	A	A	A
Wisconsin	VX	5		K	V	V	V
Wyoming	B	3		K	B	B	B

FOOTNOTES:

All examinations given by Board or Examining Committee of Pharmacists.

A—Board of Pharmacy
B—State Board of Pharmacy
C—Commission of Pharmacy
D—Dep't of Registration
D-1-Department of Human Resources and approval of Board
E—State Pharmacy Examiners
F—Board of Commissioners of Pharmacy
G—Board of Registration in Pharmacy
H—Board of Examiners in Pharmacy
I—Dep't of Education
J—Dep't of Insurance and Banking
K—Governor of State
L—District Commissioners
M—Director of Dep't
N—Dep't of Health
O—Board of Regents
P—Court Proceedings only
Q—Dep't of Professional and Vocational Standards (Calif.—Dept. of Consumer Affairs)
R—Sec'y of State
S—Dep't of Consumer Protection
T—Bureau of Occupations and Professions (Mt. - Dep't of Professional and Occupational Licensing)
U—Dep't of Regulatory Agencies
V—Board of Pharmacy Examiners
W—Dep't of Civil Service and Registration
X—Dep't of Licensing and Regulation
Y—Dep't of Law and Public Safety
Z—Dep't of State
• —1 Member a layman
•• —2 Laymen Members

III. MEMBERSHIP OF BOARDS, COMMISSIONS AND COMMITTEES

	QUALIFICATIONS FOR					COMPENSATION	
	Resident of State	Years of Practice as R.Ph.	Member State Ph. Association	Graduate Recognized College of Pharmacy	Term Length in Years	Per Diem	Expense Incurred
Alabama	A	10	A	A	5	$ 25.	F
Alaska	A	3			5	35.	
Arizona	A	10			5	30.	F
Arkansas	A	5	A		5	20.	F
California	A•				4	25.	F
Colorado	A	10			5	25.	F
Connecticut	A	10			6	500.C	F
Delaware	A		A	A	5	25.	F
Dist. of Columbia		5			3	25.	F
Florida	A	5			4	35.	F
Georgia	A	5			5	25.	F
Hawaii	A	5		A	4		
Idaho	A	5		A	3	25.	F
Illinois	A	5		A	5	25.	F
Indiana	A			A	4	25.	F
Iowa		5			3	40.	F
Kansas	A	5	A		3	35.	F
Kentucky	A	5			5	50.	F
Louisiana	A	5			6	35.	F
Maine	A		A	B	5	25.	F
Maryland	A	5	A	A	5	20.	F
Massachusetts	A•	10			5	1050.C	F
Michigan	A	5			5	25.	F
Minnesota	A••	5			5	35.	F
Mississippi	A	5	A	A	5	20.	F
Missouri					5	50.	F
Montana	A	5		B	3	15.	F
Nebraska	A	5		A	3	15.	F
Nevada	A	5			4	25.	F
New Hampshire	A	10			3	30.	F
New Jersey	A••	5			5	25.	F
New Mexico	A	8			5	20.	F
New York	A	5		A	5	35.	F
North Carolina	A		A		5	15.	F
North Dakota	A		A	A	5	20.	F
Ohio	A			A	4	58.	F
Oklahoma		5	A	A	5	15.	F
Oregon	A	5		B	5	20.	F
Pennsylvania	A	10		A	6	30.	F
Puerto Rico	A	5			4	15.	F
Rhode Island	A	5		A	3	500.C	F
South Carolina	A	3	A	A	6	16.50	F
South Dakota	A		A		3	30.	F
Tennessee	A	10	A	B	6	50.	F
Texas	A	5		B	6	25.	F
Utah	A	5		A	5	15.	F
Vermont	A	5			5	15.	F
Virginia				A	5	25.	F
Washington	A•	5		A	4	25.	F
West Virginia	A			A	5	10.	F
Wisconsin	A	5			5	25.	F
Wyoming	A	5			6	17.G	F

FOOTNOTES:

A—Required of all.
B—Required of majority.
C—Annually.
D—Fixed by director.
E—Expires with term of governor.
F—In addition to per diem.
G—Wyoming $22 out of state.
• One member a layman.
••Two laymen members

LICENSING LAW

IV. QUALIFICATIONS FOR LICENSURE

Laws in all states, including the District of Columbia and Puerto Rico, require applicants for licensure to be; 1) of good moral character; 2) 21 years of age (Please note exceptions in Table V—Requirements For Examination and Registration) 3) have graduated from an accredited college of pharmacy and 4) have passed an examination given by the board. With the exception of Rhode Island, (which requires no practical experience), most states require student candidates for licensure to have a record of practical experience or internship training acquired under the supervision and instruction of a licensed practitioner.

All states that grant licensure by reciprocity, the District of Columbia and Puerto Rico, require that a pharmacist who applies for licensure shall furnish evidence of having acquired a license by examination in a state that grants licensure by reciprocity. It is necessary that this license be in good standing, as this license is the basis for transferring the license to other reciprocal states.

There are no states which issue original licenses to assistant pharmacists. Examination and issuance of new certificates has been abolished in all states, but certificates previously issued and now in effect may be renewed in the following states: Alabama, Colorado, Connecticut, Delaware, Illinois, Indiana, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Minnesota, Mississippi, Montana, New Jersey, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Virginia, West Virginia, Wisconsin, and Puerto Rico.

V. REQUIREMENTS FOR EXAMINATION AND REGISTRATION—A-B-C

(For former requirements in lieu of college prerequisite, see Requirements for Reciprocal Licensure.)

	Personal qualifications		Education and experience		
	*Age	Citizenship 1-2	H.S. Graduation Since	Graduate College of Pharmacy since*	Prior Practical Experience
Alabama	21	x	1927	1927	1 Yr F
Alaska S	19	x	1955	1955	R-S
Arizona	none	xx		1935	1 Yr. F
Arkansas	21	x	1925	1936	1 Yr. F-H
California L	18		1928	1928	1 Yr. F
Colorado	21	x	1929	1929	1 Yr. F-H-M
Connecticut	21	x	1923	1925-D	1 Yr. F-H-M
Delaware	21		1927	1949-H	1 Yr. F-L
Dist. of Columbia	21		1928	1928	1 Yr.
Florida	21	xx	1928	1928	1 Yr. F-H-M
Georgia	21	x	1927	1934-D	1 Yr.
Hawaii K-L	18			1945	1 Yr.
Idaho	21		1925	1967	1 Yr.
Illinois	21	xx	1920	1917-D	1 Yr. M
Indiana	21		1923	1920	6 Mo. M-F-H-U
Iowa	21	x	1925	1917	6 Mo. F-M
Kansas	21		1921	1929	1 Yr.
Kentucky	18	x	1926	1924	F-M-1600 hrs.
Louisiana	21	xx	1926	1928	1 Yr. F
Maine	21	x	1927	1931	1 Yr. E
Maryland	21		1926	1920	1 Yr. F-S
Massachusetts	21	x	1948	1948-D	1 Yr.
Michigan	18	xx	1924	1938	1 Yr. F-H-M
Minnesota	21	x	1920	1929-D	F - 9 mos.
Mississippi	21	xx	1921	1921-D	None F-H
Missouri	21		1923	1937	1 Yr. F-N
Montana		x	1926	1939	1 Yr. F
Nebraska M	21	xx	1920	1942	1500 hours F
Nevada	21	xx	1914	1948	1 Yr. H
New Hampshire	18	x	1927	1939-D	1 Yr. F
New Jersey K	21	xx	1923	1920	1 Yr. F-H-M-P
New Mexico K	21		1935	1935	1 Yr. F-M
New York	21	xx	1925	1905	6 Mo. F-H

REQUIREMENTS FOR EXAMINATION AND REGISTRATION—A-B-C (cont.)

(For former requirements in lieu of college prerequisite, see Requirements for Reciprocal Licensure.)

	Personal qualifications		Education and experience		
	Age	Citizenship 1-2	H.S. Graduation Since	Graduate College of Pharmacy since*	Prior Practical Experience
North Carolina	21		1922	1922	1 Yr. F-H-M
North Dakota	21		1913	1915	1 Yr. F-M
Ohio L	21	xx	1920	1915-D	1500 hrs. F-M
Oklahoma	21		1921	1923	1 Yr. F-H-M
Oregon	18		1919	1922-D	1 Yr. H-M
Pennsylvania	21		1925	1906	1 Yr. M
Puerto Rico	21		1927	1927	6 Mo.
Rhode Island	18	Q	1910	1910	S
South Carolina	21	x	1918	1918	1 Yr. S-M-R
South Dakota	18		1927	1933	9 Mos. F
Tennessee	18	xx	1919	1930	F-P-S
Texas K	21	x	1926	1934	1 Yr. H
Utah	21		1925	1927	1 Yr.
Vermont	21	x	1929	1956	1 Yr. E
Virginia	21	x	1922	1922	1 Yr. F-M-T
Washington	18	xx	1914	1914-D	1 Yr. F-H-M
West Virginia	21	x	1923	1923	1 Yr. F-H-M
Wisconsin	18	xx	1926	1927-D	1 Yr. F-H-M
Wyoming	21	xx	1925	1936	1 Yr.

(Five-year program required for graduation in all colleges.
Six year program offered by several colleges).

1 State residence of 1 year is required in Hawaii and 90 days in Utah.
A reference attesting to good moral character is required in all States;
Physical examination is required in New Jersey and South Dakota.

2 x = full citizenship. xx = full citizenship or legal declaration of intention.

FOOTNOTES:

A—Examination required in all states
B—Legal age required in all states
C—Good moral character required of all applicants (not mentioned in statute of fifteen states)
D—Exemptions provided for apprentices, assistants or those having experience at that time.
E—Experience must be in community pharmacy (hospital pharmacy experience not accepted).
F—Experience must be obtained in either hospital pharmacy or retail pharmacy licensed by the Board.
G—Credit allowed for experience in hospital pharmacy not to exceed one-half time required.
H—Some experience must be acquired after graduation. (N.Y.—all experience must be acquired after graduation)
J—$7.50 of annual fee renewal applied to Internship Commission
K—Examination subjects specified in law
L—Passing grade specified in law. In Tennessee as determined by the Board
M—Intern registration required to validate experience
N—Apprentice registration permitted (optional)
O—Experience subsequent to graduation after 1939
P—Experience subsequent to graduation after 1936
Q—Failure to secure citizenship within six years automatically annuls license. California seven.
R—Alaska—540 of total 1500 must be completed after graduation. (S. C.—at least 500).
S—1500 hours.
T—6 mos. in Virginia only.
U—Ind.—Structured externship program.

CONTINUED

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VI. REQUIREMENTS FOR INITIAL STATE LICENSURE OF PHARMACISTS

	Examination		Exam-ination Fee	Initial Certifi-cate Fee	Annual Fee Renewal-3
	Written	Practical			
Alabama	x	x	$25.-2	None	$10.
Alaska S	x	x	50.	$20.	50.A
Arizona	x	x	50.	10.	15.
Arkansas	x	x	25.	5.	10.
California	x	x	75.	15.	50.A-7***
Colorado	x	x	35.	10.	10.
Connecticut	x	x	50.	None	15.
Delaware	x	x	30.	10.	10.
Dist. of Columbia	x	x	40.	10.	10.
Florida	x	x	100.	None	25.-7***
Georgia	x	x	25.	None	5.
Hawaii	x	x	37.50	None	12.
Idaho	x	x	50.	None	20.
Illinois	x	x	35.	None	5.
Indiana	x	x	50.	None	15.A-7*
Iowa	x	x	50.	None	15.
Kansas	x	x	50.	None	15.-7***
Kentucky	x	x	50.	None	20.
Louisiana	x	x	35.	None	15.
Maine	x	x	35.	None	5.
Maryland	x	x	40.	None	15.A
Massachusetts	x	x	25.	None	10.A
Michigan	x	x	25.	25.	5.
Minnesota	x	x	50.	20.	20.-7**
Mississippi	x-1	x	15.	50.	25.
Missouri	x	x	25.	None	20.
Montana	x	x	25.	None	15.
Nebraska	x	x	65.	None	10.
Nevada	x	x	50.	10.	10.-7*
New Hampshire	x	x	25.	None	25.
New Jersey	x	x	35.	None	15.-7*
New Mexico	x	x	50.	5.	20.-6
New York	x	x	40.	None	15.A

VI. REQUIREMENTS FOR INITIAL STATE LICENSURE OF PHARMACISTS (Cont'd)

	Examination		Exam-ination Fee	Initial Certifi-cate Fee	Annual Fee Renewal-3
	Written	Practical			
North Carolina	x	x	25.	None	15.
North Dakota	x	x	25.	None	10.
Ohio	x	x	75.	None	13.75-7***
Oklahoma	x	x	20.	None	20.-7**
Oregon	x	x	45.	None	20.
Pennsylvania	x	x	15.	20.	2.50
Puerto Rico			10.	10.	2.
Rhode Island	x	x	25.	None	5.
South Carolina	x	x	35.	None	4.
South Dakota	x	x	25.	5.	25.
Tennessee	x	x	35.	15.	15.
Texas	x	x	20.	None	15.
Utah	x	x	15.	None	5.
Vermont	x	x	35.	5.	5.
Virginia	x	x	50.	None	10.
Washington	x	x	20.	20.	15.-7**
West Virginia	x	x	50.	5.	15.
Wisconsin	x	x	55.	5.	21.-4
Wyoming	x	x	25.	None	15.

A. Biennially

B. Triennially

1-No examination is required for graduates of the University of Mississippi (to practice in Mississippi only.)

2-Non-resident fee $50

3-Average renewal fee $14.90

4-$11.00 of renewal for Internship Program.

5-Non-resident fee $10.

6-N.M. resident active pharmacist; non-resident active and inactive $15.

7-Continuing Education required for relicensure.

*Effective during 1974

**Effective during 1975

***Effective now

VII. REQUIREMENTS FOR RECIPROCAL LICENSURE

(See Requirements for Examination and Registration)

	Temporary Permit to Qualified Applicants	*Fee for Reciprocity	Special Requirements	Equivalent Requirements in Prior State	Former Requirements in Lieu of Present College and Experience Requirements
Alabama	No	$50.	EH	A	Prior to 1927 four yrs. exper., two yrs. H.S. after 1919. Two yrs. exper. required of two-yr. graduates.
Alaska	Yes	25.	C	B	Prior to 3-29-55 five yrs. exper.
Arizona	No	125.	E-F	A	Prior to 6-20-35 four yrs. exper., credit allowed for actual time in college.
Arkansas	Yes	50.	C-F	A	Prior to 7-1-36 four years exper. Two yrs. H.S. after 1923.
California					No Reciprocity.
Colorado	No	150.	E-H	A	Prior to 5-26-29 four yrs. exper.. credit allowed for time in college. Legal exper. prior to 5-26-29 exempts from H.S. and college until 5-26-34.
Connecticut	No	50.	C-H-F-I	A	Prior to 1-1-25 four yrs. exper. Two yr. grads. must have two yrs. exper. Apprentices in 1921 exempt from college.
Delaware	No	50.	C-F	A	Prior to 3-30-27 four yrs. exper., credit allowed for time in college up to two years.
Dist. of Columbia	No	50.	C-F	A	Prior to 3-4-28 four yrs. exper. two yr. grads. must have three yrs. exper.
Florida					No Reciprocity.
Georgia	Yes	50.	C	A	Prior to 6-1-34 three yrs. exper. Credit allowed for time in college.
Hawaii					No Reciprocity.
Idaho	Yes	75.	C-E-H	A	—Prior to 4-14-30 four yrs. exper. Two yrs. college and two yrs. exper. thereafter. Four yrs. college and one yr. exper. after 5-1-39.
Illinois	No	50.	C-H-F	A	Prior to 7-1-17 four yrs. exper. credit up to two yrs. allowed for time in college. Legal exper., prior to 7-1-17 exempts from college. No deadline date.
Indiana	No	100.	C-F	A	Prior to 1-1-20 four yrs. exper. Credit up to two yrs. allowed for time in college. Exper. recorded prior to 7-1-23 exempts from college 1-1-41.
Iowa	No	75.	C-D-F-H	B	Prior to 7-1-17 four years exp. apprentices and assistants registered prior to 1-1-17 exempt from college to 7-1-24. After 7-1-17 two years college and two years experience. After 7-4-36 four year grad. recog. college.
Kansas	No	60.	C	A	Prior to 5-28-29 four yrs. exper. Credit allowed for time in college.
Kentucky	Yes	75.	C-E-F	A	Prior to 7-1-24 four yrs. exper. two yrs. H.S. credit allowed for time in college.
Louisiana	No	100.	C-E	A	Prior to 1-1-28 four yrs. exper. Credit allowed for actual time in college up to three yrs. See footnote K.
Maine	No	25.	C	A	Prior to 6-19-31 four yrs. exper. Credit allowed for time in college. Six months exper. prior to 6-19-31 exempt from college to 6-19-36.
Maryland	No	50.	C-H-F	A	Prior to 6-1-20 four yrs. exper. Credit allowed for time in college. Four yr. course after 1936.
Massachusetts	No	50.	H-I	A	Prior to 1-1-48 four yrs. exper. Credit allowed for actual time in college.

REQUIREMENTS FOR RECIPROCAL LICENSURE (Cont.)

(See Requirements for Examination and Registration)

	Temporary Permit to Qualified Applicants	*Fee for Reciprocity	Special Requirements	Equivalent Requirements in Prior State	Former Requirements in Lieu of Present College and Experience Requirements
Michigan	No	50.	E-F-I	B	Four yrs. exper. prior to 1-1-29. Two yrs. col. thereafter. Four yrs. col. after 1-1-38. No exper. for 4-yr. grads prior to 7-1-55.
Minnesota	No	100.	F-H-E	A	Prior to 4-23-19 four yrs. exper. Credit allowed for time in college. Two yrs. college and two yrs. exper. required after 4-23-19. Graduation after 3-28-29. Exper. prior to 4-23-19 exempts to 3-28-37.
Mississippi	Yes	50.	C	A	Prior to 1-1-21 4 years experience graduate thereafter.
Missouri	No	100.		A	Prior to 9-1-37 four yrs. exper. Credit allowed for time in college. One yr. H.S. after 8-1-13, two yrs. after 8-1-20, four yrs. after 8-1-23.
Montana	Yes	50.	C	A	Prior to 3-17-39 four yrs. exper. Credit allowed for time in college. Graduation thereafter.
Nebraska	No	100.	C-F	A	Prior to 1-1-42 four yrs. exper. Credit up to two yrs. allowed for time in college. One yr. college required after 1-1-30.
Nevada	Yes	100.	E	B	Five yrs. exper. prior to 1-1-48.
New Hampshire	No	50.	C	A	Prior to 1-1-39 four yrs. exper. Credit allowed up to two yrs. for time in college.
New Jersey	No	50.	E-F-H	A	Prior to 1920 four yrs. exper. Credit allowed up to two yrs. for college work. 4 yr. course compulsory for matriculants after 1-1-32.
New Mexico	No	100.	A-E-F-M	B	Prior to 5-20-35 three yrs. exper. Credit allowed for time in college. Legal exper. prior to 11-20-34 exempt from college to 5-20-40.
New York	No	40.	B-C-E-F	B	Prior to 1-1-04 four yrs. exper. Credit allowed for time in college. Two yrs. college, 4 yrs. exp. after 1-1-04. Three yrs. college after 1-1-28. Four yrs. college, 1 yr. exp. after 6-1-41.
North Carolina	Yes	25.	N-C-D-E	A*	Prior to 1-1-18 four yrs. exper. Credit allowed for time in college. One yr. college after 1-1-18. Graduation after 1-1-22.
North Dakota	Yes	50.	C-F	A	Prior to 1-1-30 two yrs. college and two yrs. exper. Prior to 1-1-15 four yrs. exper. Credit allowed for time in college.
Ohio	No	150.	B-E	A	Prior to 8-26-15 four yrs. exper. Credit if a graduate allowed for actual time in college. Four yrs. apprenticeship prior to 7-1-17 exempts from college. No exper. for 4-yr. grads 1932-45.
Oklahoma	No	50.	C	A	Prior to 7-15-23, four yrs. exper. Credit allowed up to two yrs. for time in college. One yr. of college required after 7-18-21. Assistants prior to 1-1-22 exempt.
Oregon	Yes	60.	E	A	Prior to 1921 four yrs. exper. Credit allowed for time in college. One yr. college required 1-1-21, two yrs. 1-1-22, three yrs. 7-1-25, four yrs. for matriculants after 7-1-30.
Pennsylvania	No	75.	C-H-F	A	Prior to 1-1-06 four yrs. exper. Matriculants after 1906, two yrs. college and four yrs. exper.; after 1925, three yrs. college and two yrs. exper.; after 1932, four years college and one yr. exper. Two yrs. H.S. after 1920, 3 yrs. H.S. after 1923.
Puerto Rico	No	100.	E	B	Prior to 3-12-27 four yrs. exper.
Rhode Island	No	50.	C-F-H-I	A	Prior to 1-10-10 three yrs. exper.

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REQUIREMENTS FOR RECIPROCAL LICENSURE (Cont.)

(See Requirements for Examination and Registration)

	Temporary Permit to Qualified Applicants	*Fee for Reciprocity	Special Requirements	Equivalent Requirements in Prior State	Former Requirements in Lieu of Present College and Experience Requirements
South Carolina	No	20.	C	A	Prior to 7-1-18 three yrs. exper. Credit allowed for time in college. Ten yrs. exper. exempts from college 3-1-25 to 1-1-33.
South Dakota	Yes	50.	G-F	A	Prior to 7-1-31 three yrs. exper. Credit allowed for time in college, or graduated and one yr. exper. Four yrs. college after 7-1-33.
Tennessee	No	100.	E-F	B	Prior to 1-1-41 four yrs. exper. Credit allowed up to two yrs. for time in college.
Texas	No	100.	H	A	Prior to 6-12-34 four yrs. exper. Credit allowed up to two yrs. for time in college. Apprentices prior to 6-14-30 exempt from college if registered prior to 6-12-34.
Utah	No	15.	C	A	Prior to 7-1-27 four yrs. exper. Credit allowed up to two years for time in college. Two yr. course compulsory for all after 1-1-27.
Vermont	No	35.	C	B	Four yrs. exper. prior to 6-30-56.
Virginia	Yes	100.	N-C-F-H	A	Prior to 4-1-22 four yrs. exper. Credit allowed up to two yrs. for time in college. After 4-1-22 graduation, no exper. After 7-1-43 graduation and one yr. exper.
Washington	No	75.	E-H-F	A	Prior to 6-13-63—2 year graduate and 2 years of experience or 3 year graduate and 1 year exper.
West Virginia	No	50.	B-E-F	A	Prior to 1-1-23 four yrs. exper. Credit allowed for time in college.
Wisconsin	No	100.	G-F-H-E	A	Prior to 8-1-27 five yrs. exper. Credit allowed for time in college. Two yrs. H.S. after 1920.
Wyoming	Yes	50.	C-E	A	Prior to 7-1-36 four yrs. exper. One yr. credit allowed for time in college.

FOOTNOTES:

Basic rule for reciprocity: An applicant must have had the legal qualifications at the time of examination and registration in the state from which he applies which would AT THAT TIME have enabled him to qualify for examination and registration in the state to which he applies for reciprocal registration.

Personal appearance before board or some member general requirement in all states.

Failure in examination usually a bar to reciprocal registration in the same state later.

A—Qualifications at time of original registration must be equivalent to requirements for examination and registration at that time. (N.C. qualifications at time of application must be equivalent to requirements for registration at that time)
B—Standards at discretion of the board.
C—Examination discretionary — usually none other than oral.
D—Practical examination given when "F" is waived.
E—Examination in jurisprudence.
F—Pharmacists who have not been licensed one year are not eligible to be licensed by reciprocity.
G—"F" requirement applicable to licensees from states that impose that qualification for reciprocal licensure.
H—Photographs, identification and special forms furnished by state in addition to official NABP application.
I—Residence or employment in state to which application is made, required of applicants.
J—"F" is waived for applicants from states that do not require.
K—Only persons licensed after 7-28-48 must be graduates.
L—Charges same fee as reciprocating state.
M—"F" may be waived if internship is comparable to internship requirements of New Mexico.
N—Board may only issue a temporary license for first year. Must complete 85 hr./mo. practice requirement for one year.

*Illinois, Iowa and Colorado, $10.00; Alabama, Arkansas, Dist. of Columbia, Georgia, Idaho, Louisiana, Minnesota, Mississippi, Missouri, New Mexico, North Dakota, Tennessee, Washington and Wisconsin, $5.00; Ohio $4.50; New York, Delaware, Indiana and Kentucky $3.00; New Hampshire, Nebraska $2.00; Kansas $1.25; all other states $1.00.

VIII. REVOCATION PROCEEDINGS

	Specified in Statute	Written Notice Required	Statement of Charges Furnished	Hearing Required	Issuance of Subpoenas	Court Review or Retrial
Alabama	A	A	A	A	B	C
Alaska	A	A	A	A	C	C
Arizona	A	A	A	A	B	C
Arkansas	A	A	A	A	B	C
California	A	A	A	A	A	B
Colorado	A			A	B	B
Connecticut	A	A	A	A	B	C
Delaware	A	A	A	A		E
Dist. of Columbia	A	A	A	A	A	C
Florida	A	A	A	A	A	A
Georgia	A	A	A	A	A	A
Hawaii	A	A	A	A	A	A
Idaho	A	A		A		E
Illinois	A	A	A	A	B	C
Indiana	A	A	A	A	B	C
Iowa	A	A	A	A		E
Kansas	A	A	A	A		C
Kentucky	A	A	A	A		C
Louisiana	A	A	A	A	B	C
Maine	A	A	A	A	B	E
Maryland	A	A	A	A		C
Massachusetts	A	A	A	A	B	C
Michigan	A	A	A	A	B	
Minnesota	A	A	A	A	B	C
Mississippi	A	A	A			C
Missouri	A			A		D
Montana	A	A	A	A		C
Nebraska	A	A	A	A	B	C
Nevada	A	A	A	A	B	B
New Hampshire	A			A		C
New Jersey	A	A	A	A		C
New Mexico	A	A	A	A	B	C
New York	A	A	A	A	B	
North Carolina	A	A	A	A		C
North Dakota	A	A	A	A		C
Ohio	A	A	A	A	B	C
Oklahoma	A	A	A	A	C	C
Oregon	A	A	A	A	B	C
Pennsylvania	A	A	A	A	C	C
Puerto Rico	A	B	A	A	A	B
Rhode Island	A	A	A	A	A	A
South Carolina	A	A	A		B	B
South Dakota	A			A		C
Tennessee	A	A	A	A	A	C
Texas	A	A	A	A	A	C
Utah	A	A	A	A	A	C
Vermont	A	A		A		C
Virginia	A	A	A	A	A	C
Washington	A	A	A	A	A	C
West Virginia	A	A	A	A	A	C
Wisconsin	A	A	A	A	B	C
Wyoming	A	B	B	A	C	C

FOOTNOTES:

A—Yes.
B—May do so.
C—Provided for.
D—Appeals to Governor or Attorney General.
E—Original proceedings in court only.

IX. ISSUANCE AND RENEWAL OF LICENSES

	Examination	Issuance of licenses: Initial and renewal	Issuance of licenses: Temporary[2]	Issuance of licenses: To foreign educated	License suspension	License revocation	License renewal[1]: Expiration date[3]	License renewal[1]: Mailing date
Alabama	x	x			x	x	Dec. 31	Dec.
Alaska	x	x	x		x	x	June 30	Apr.
Arizona	x	x			x	x	June 30	May
Arkansas	x	x	x		x	x	Dec. 31	Dec.
California	x	x		x[4]	x	x	Oct. 31[5]	Sept.
Colorado	x	x			x	x	July 1	May
Connecticut	x	x			x	x	Mar. 31	Feb.
Delaware	x	x			x	x	Dec. 31	Oct.
Dist. of Col.	x	(6)			x	x	Feb. 28	Dec.
Florida	x	x	x		x	x	June 20	Feb.
Georgia	x	x			x	x	Dec. 31[7]	Dec.
Hawaii	x	x	x		x	x	Dec. 31	Nov.
Idaho	x	x	x	x		x	June 30	May
Illinois	x	(6)		(6)	(6)	(6)	Jan. 31	Nov.
Indiana	x	x			x	x	June 30[7]	May
Iowa	x	x			x	x	June 30	Apr.
Kansas	x	x			x	x	June 30	May
Kentucky	x	x	x		x	x	Dec. 31	Dec.
Louisiana	x	x			x	x	Dec. 31	Dec.
Maine	x	x			x	x	June 30	June
Maryland	x	x			x	x	Dec. 31[7]	July
Massachusetts	x	x			x	x	Dec. 31[7]	Oct.
Michigan	x	x			x	x	June 30	May
Minnesota	x	x			x	x	Mar. 4	Feb.
Mississippi	x	x	x		x	x	Apr. 30	Mar.
Missouri	x	x			x	x	June 30	June
Montana	x	x	x-2		x	x	June 30	May
Nebraska	x	(6)			(6)	(6)	Jan. 1	Nov.
Nevada	x	x	x		x	x	May 30	March
New Hampshire	x	x			x	x	Dec. 31	Nov.
New Jersey	x	x			x	x	Dec. 31	Nov.
New Mexico	x	x			x	x	June 30	May
New York	x	(6)		(6)	(6)	(6)	Dec. 31[7]	Oct.
North Carolina	x	x		x[8]		x	Dec. 31	Nov.
North Dakota	x	x	x	x	x	x	Feb. 28	Feb.
Ohio	x	x			x	x	Sept. 15	July
Oklahoma	x	x			x	x	June 30	May
Oregon	x	x	x		x	x	June 30	Apr.
Pennsylvania	x	x		(11)	x	x	Sept. 30[7]	July
Puerto Rico	x	x			x	x	July 1	June
Rhode Island	x	x		x	x	x	June 30	June
South Carolina	x	x			x	x	June 30	June
South Dakota	x	x	x		x	x	Sept. 30	Sept.
Tennessee	x	x			x	x	Dec. 31	Dec.
Texas	x	x			x	x	Jan. 1	Nov.
Utah	x	(6)	(6)		(6)	(6)	Dec. 31	Oct.
Vermont	x	x			x	x	Dec. 31[5]	Dec.
Virginia	x	x	x		x	x	Dec. 31	Nov.
Washington	x	x			x	x	May 31	Apr.
West Virginia	x	x			x	x	June 30	May
Wisconsin	x	x			x	x	May 31	Mar.
Wyoming	x	x	x		x	x	Dec. 31	Nov.

[1] Renewals are annual unless otherwise specified.
[2] Temporary licenses or permits are issued to qualified applicants pending examination or completion of reciprocity procedures. In Florida, temporary permits are issued to interns.
[3] Excludes grace period.
[4] Licenses are issued only after review of foreign transcripts by a dean of a recognized school of pharmacy and his statement that such training is equivalent to the standards of the recognized school of pharmacy. (Calif.—Foreign graduates may take examination if board establishes that their education is equivalent to education from accredited U.S. College of Pharmacy)
[5] Biennial, odd years.
[6] The board or committee recommends to the department which has this function.
[7] Biennial, even years. In Washington, A-L even years and M-Z odd years.
[8] Licenses are issued only to graduates of the University of Havana who meet all other requirements for licensure.
[9] Triennial from date of issuance.
[10] Under review
[11] Upon examination

X. FINANCIAL PRACTICES OF STATE BOARDS

	Fees charged by board: Examination[1]	Fees charged by board: Reciprocity	Fees charged by board: Renewal[10]	Method of financing the board: State board account	Method of financing the board: Special fund in State treasury	Method of financing the board: State general revenue fund
Alabama	$25[2]	$50	$10	x		
Alaska	50[7]	25[7]	50			x
Arizona	50	125	15		x	
Arkansas	25	50	10	x		
California	75	....	50[3]			
Colorado	35	150	15		x	
Connecticut	50	50	15			x
Delaware	30	50	10			x
District of Columbia	50	50	5			x
Florida	100	....	25		x	
Georgia	25	50	5			x
Hawaii	37.50	....	12			x
Idaho	50	75	20		x	
Illinois	35	50	5			x
Indiana	50	100	15[3]			x
Iowa	50	75	15			x
Kansas	50	60	15		x	
Kentucky	50	75	20		x	
Louisiana	35	100	15	x		
Maine	35	25	5		x	
Maryland	40	50	15[3]			x
Massachusetts	10	50	10[3]			x
Michigan	25	50	5			x
Minnesota	50	100	20		x	
Mississippi	15	50	25	x		
Missouri	25	100	20		x	
Montana	25	50	15		x	
Nebraska	65	100	15		x	
Nevada	50	100	10	x		
New Hampshire	25	50	25	x		
New Jersey	35	50	15			x
New Mexico	50	100	20[7]			x
New York	40	40	15[3]			x
North Carolina	25	25	15	x		
North Dakota	25	50	10	x		
Ohio	75	150	13.75			x
Oklahoma	20	50	20	x	x	
Oregon	30[5]	60	20		x	
Pennsylvania	15	75	5[3]			
Puerto Rico	10	100	2			x
Rhode Island	25	50	5			x
South Carolina	35	20	4	x		
South Dakota	25	50	25	x		
Tennessee	35	100	15			x
Texas	20	100	15	x		
Utah	15	15	5			x
Vermont	35	35	5			
Virginia	50	100	10			x
Washington	20	75[1]	15			x
West Virginia	50	50	15			x
Wisconsin	55	100	21		x	
Wyoming	25	50	15[9]		x	

[1] Includes fees for application and initial license where such fees are applicable.
[2] Nonresident examination fee is $50.
[3] Biennial renewal.
[4] Triennial renewal.
[5] Includes a $1 identification fee.
[6] Additional license fee.
[7] New Mexico renewal inactive fee $15; Non-resident active fee $15.
[8] Average renewal fee $14.90.

DRUG LAW

XI. LICENSURE REQUIREMENTS FOR DRUG DISTRIBUTION

	Pharmacy Permit Required	New Permit Fee	Annual Fee Renewal-R	Minimum Standards of Equipment Required	Pharmacy Inspected Annually	Outlets Other than Pharmacies Licensed to Sell Packaged Drugs Saleable Drugs	Outlets Other than Pharmacies Licensed to Sell Packaged Drugs Annual Fee
Alabama	Yes	$50. A	$25.	x	x	K	No
2 Alaska	Yes	50.	2.	x			No
*1, 2 Arizona	Yes	50. A	50.	x	x	K-L	$25.
Arkansas	Yes	25. B	25.	x	x	K	No
1, 2 California	Yes	50. B	50. D	x	x	K	5.
Colorado	Yes	100.	35.	x	x	L	25-10
1, 2 Connecticut	Yes	200. E	50.	x	x	K-L	20.-40.
1 Delaware	Yes	25.	25.	x	x	K	No
Dist. of Col.	Yes	15. A	15.	x	x		15.
Florida	Yes	50.	25. F	x	x	K	No
1 Georgia	Yes	25.	15.	x	x		No
1 Hawaii	Yes	18.	18.	x	x		18.
2 Idaho	Yes	50. A	50.	x	x		4.-10.-25.
Illinois	Yes	10.	10.	x	x		No
Indiana	Yes	25. B	10.	x	x	K-L	No
2 Iowa	Yes	25.	25.	x	x		50.
1, 2 Kansas	Yes	30. B	10.	x	x		8.-15.
Kentucky	Yes	25. A	25.	x	x		No
Louisiana	Yes	40. A	40.	x-o	x	N	No
Maine	Yes	100.	100.	x	x	K	100.
1, 2 Maryland	Yes	40. B	20.	x	x	K	No
1, 2 Massachusetts	Yes	35. B-P	35.	x	x	L	No
Michigan	Yes	15. B	15.	x	x	K-L	No
1, 2 Minnesota	Yes	35. A	35.	x	x		No
Mississippi	Yes	25. A	25.	x	x	L	No
Missouri	Yes	100. A	20.	x	x		No
Montana	Yes	20. A	20.	x	x		5
Nebraska	Yes	100. B	50.	x	x	K	No
1, 2 Nevada	Yes	50. B	25.	x	x		No
New Hampshire	Yes	100. A	50. A	x	x		No
1, 2 New Jersey	Yes	100. G	25.	x	x	K	No
1, 2 New Mexico	Yes	60. A	60.	x	x	K	No
1, 2 New York	Yes	60. F	25.	x	x	L	5
North Carolina	Yes	50. A	25.	x	x	K-L	No
North Dakota	Yes	50. A	50.	x	x		3.H
1, 2 Ohio	Yes	27.50	27.50	x	x	K-	No
1, 2 Oklahoma	Yes	35. B	35.	x	x	K	No
1, 2 Oregon	Yes	25. B	15.	x	x	L	8.
1, 2 Pennsylvania	Yes	50. B	5.	x	x	K	No
Puerto Rico	Yes	3. A	3.	x	x	K	
1, 2 Rhode Island	Yes	20. A	10.	x	x	K-	No
South Carolina	Yes	15. A	10.	x	x	K	No
South Dakota	Yes	50.	50.	x	x	K-L	6.
1, 2 Tennessee	Yes	20. A	20.	x	x		20
1, 2 Texas	Yes	25.	25.	x	x		No
1, 2 Utah	Yes	5.	7.50	x	x	K	No
Vermont	Yes	10. A	10.	x	x	K-L	No
1, 2 Virginia	Yes	25. A	25.	x	x		No
1, 2 Washington	Yes	65. AH	10. HS	x	x	K-L	15.
1 West Virginia	Yes	50. F	25.	x	x		No
1, 2 Wisconsin	Yes	85. A	45.	x	x	L	15
Wyoming	Yes	50.	50.	x	x		No

FOOTNOTES:

*1 — License required to manufacture drugs.
2 — License required to wholesale drugs.
A — Not transferable.
B — Transfer fee same.
C — Transfer fee $1.00
D — Transfer fee $5.00
E — Transfer fee $15.00
F — Transfer fee $25.00
G — Transfer fee $50.00
H — Plus $10 for prophylactic fee
I — Only to dealers located remote from a pharmacy.
K — Drugs saleable designated by law, Arizona $25.00 annual patent and proprietary permit; N. M., all proprietary OTC except controlled substances in Schedule V.
L — Drugs saleable designated by Board, Arizona $5.00 lifetime general dealer permit.
M — Examination given applicants.
N — Louisiana Bd. Health License products of Mfg.
O — Minimum standards of equipment designated by Board except in Louisiana where it is by law.
P — Massachusetts permit fee—biennial
R — Average renewal fee $28.00
S — Additional $10.00 — Controlled Substances Act

XII. STATE DRUG RESTRICTIONS

	Model Food and Drug Act Enacted	Dangerous Drug Law	Controlled Substances Act	Uniform Scheduling
Alabama		x·m		
Alaska		x		
Arizona	x	x		
Arkansas		x	x·o	Yes
California	x	x	x	Yes
Colorado	x	x		
Connecticut	x	x	x	
Delaware	xx	x	r	
Dist. of Columbia	a	x		
Florida	x	x	x	Yes
Georgia		x·m		
Hawaii	r	r	r	r
Idaho		x·m	x·p	Yes
Illinois	x·m	x·m	x·p	Yes
Indiana	x	x	x·p	Yes
Iowa	x	x	x·p	Yes
Kansas		x·m	x·m	
Kentucky	x		x	R
Louisiana	x	x·m	x·p·r	
Maine		x		
Maryland	x	x·m	x·s	Yes
Massachusetts		x		
Michigan			x	A
Minnesota			x·p	
Mississippi		x	x·p	Yes
Missouri	x	x·n		
Montana	x	x		
Nebraska		x	x·t	Yes
Nevada	x	x	x·p	Yes
New Hampshire		x·m	x	Yes
New Jersey	x·k	x·m	x·r	Yes
New Mexico	x	x	x·p	Yes
New York	x		x	
North Carolina	x	x·n	x·u	No
North Dakota		x·m	x·v	Yes
Ohio	x	x		
Oklahoma	x·k	x·m	x·w	Yes
Oregon	x·l	x		
Pennsylvania	x	x·n	Yes	
Puerto Rico		x	x	
Rhode Island	x	x·n		
South Carolina		x·m	x·r	Yes
South Dakota		x·m	x·w	No
Tennessee	x	x	x·p	Yes
Texas	x	x	x	
Utah		x	x·y	No
Vermont		x	x	
Virginia	x		x·p	Yes
Washington	x		x·p	Yes
West Virginia		x·m	x·p	Yes
Wisconsin		x	x	Yes
Wyoming		x	x·w·p	Yes

FOOTNOTES:

A — Same as federal regulations permit.
I — Applicable to foods only.
K — State enabling act permits enforcement of federal act.
L — Paregoric sales limited to prp. containing 25% paregoric.
M — Uniform
N — Dangerous Drug Law including stimulants and hallucinogenics.
O — Narcotic and Toxic Substances Control Commission
P — Board of Pharmacy
Q — Department of Law Enforcement
R — State Board of Health
S — Department of Health and Mental Hygiene
T — Bureau of Examining Boards
U — State Drug Authority
V — State Laboratories Department
W — Commissioner of Narcotics and Dangerous Drugs Control
Y — Attorney General

XIII. MINIMUM STANDARD OF TECHNICAL EQUIPMENT AND STOCK

Stock of Drugs

Approved by N.A.B.P. (See 1934 and 1962 Proceedings)

The stock of drugs should include such U.S.P., N.F., and other commonly used chemicals, drugs, and preparations sufficient to compound ordinary prescriptions as indicated by experience in the community where the pharmacy is located.

Reference Library

The U.S.P. and Supplements.
The National Formulary.
The Dispensatory.
New and Non-official Remedies.
(All of the above books to be of the latest editions.)
A Medical Dictionary.
A treatise on each of the following subjects.
Materia Medica & Therapeutics.
General Chemistry.
Botany and Pharmacognosy.
Practice of Pharmacy.
A book or books of reference covering the subjects of:
Toxicology—Compounding.
Incompatibilities—Arithmetic.
Copies of Federal and State Laws governing pharmacy.
Upon inspection these books should be indelibly stamped with an identifying serial number.
Other books recommended are works on—
Bacteriology—Endocrinology—
Vitamin Therapy—Bio-Chemistry—
First Aid—Pharmaceutical Law—
Economics—History of Pharmacy—
A copy of each of Merck's Index and Modern Drug Encyclopedia with supplements.
American Hospital Formulary Service of American Society of Hospital Pharmacists.
Introduction to the Practice of Pharmacy—A Guide for Preceptors and Interns.

Technical Equipment

The necessary equipment for dispensing and compounding should include:

Graduates—capable of accurately measuring volumes from 5 cc. to at least 500 cc.
Mortars and Pestles—Glass—at least one
—Porcelain—at least two assorted sizes
Wedgewood—at least three assorted sizes
Spatulas—Steel—at least three assorted sizes
—non-metallic—at least two assorted sizes
Funnels—at least three assorted sizes
Stirring rods—glass or rubber
Test Tubes—assorted sizes
Pill Tile
Ointment Slab
Tripod
Water Bath
Bunsen Burner or Alcohol Lamp
Ring Stand and Rings
Corks—assorted sizes
Filter Paper
Litmus Paper
Powder Papers—pervious and impervious
Evaporating Dishes
Percolator
Sieves
Empty Capsules—various sizes
Ointment Jars—various sizes
Collapsible Tubes—various sizes
Tablet Triturate Mold
Towels
Flasks
Prescription Files
Poison Record Book and Narcotic Record Book
Homeopathic Vials
Bottles—clear glass, amber glass—necessary sizes
Labels
Boxes—Capsule and Powder
Thermometer—for measuring temperature from Zero to 250 degrees centigrade
Scales and Balances—for bulk, medium, and light weighing at least one of which must be sensitive to ½ grain
Weights—apothecary and avoirdupois from ½ gr. to 1 lb. metric from 0.02 Gm. to 1 Kg.

Space and Fixtures

The stock, library and equipment should be housed in a suitable, well lighted and ventilated room or department with clean and sanitary surrounding devoted primarily to the com-

pounding of prescriptions, the manufacture of pharmaceutical preparations, and the operations necessary to determine strength and purity of medicines. The space should be equipped with necessary counters, tables, drawers, shelves and storage cabinets; a sink with hot and cold water, or some facilities for heating water, and proper sewerage outlet; poison cabinet, narcotic drug cabinet; and refrigerator storage equipment of a reasonable capacity. There must be facilities for sterilizing solutions and containers as well as facilities for the proper cleaning of premises, equipment and utensils.

NOTE: Requirements in all states do not conform to minimum recommendations, in all respects. In some states it is not mandatory for pharmacies to have any reference texts or special equipment to weigh, measure, compound, dispense and store drugs. Very few states do not require all or more than the above listed reference texts, equipment and facilities.

BUDGETS, RECEIPTS, PERSONNEL and LABORATORY FACILITIES OF STATE BOARDS OF PHARMACY

BUDGETS, RECEIPTS, PERSONNEL AND LABORATORY FACILITIES OF STATE BOARDS OF PHARMACY

Following our practice of making a periodic report relating to the budgets, receipts and personnel staffs of the boards of pharmacy, a questionnaire was addressed to the Boards in the 50 states, the District of Columbia and Puerto Rico during 1972. Forty-two (42) state boards, including Puerto Rico, responded and returned the questionnaire.

Thirteen (13) of the 42 boards reported that they are self-sustaining—that the state legislatures appropriate no funds to these boards. Twenty-seven (27) of the 42 boards reported that they are sustained by additional legislative appropriations or that their budgets are approved by the state legislature, and two (2) of the boards did not report on this item.

Of the 27 boards sustained by legislative appropriations:

14 reported budgets less than revenue collected
7 reported budgets more than revenue collected
3 reported budgets equal to revenue collected
3 did not report their budgets

BOARDS OF PHARMACY ANNUAL BUDGETS

38 reporting

$ 5,000 to $ 10,000	1 Board
$ 10,000 to $ 14,000	2 Boards
$ 15,000 to $ 20,000	1 Board
$ 20,000 to $ 30,000	1 Board
$ 30,000 to $ 35,000	2 Boards
$ 35,000 to $ 40,000	0 Boards
$ 40,000 to $ 50,000	2 Boards
$ 50,000 to $ 60,000	2 Boards
$ 60,000 to $ 65,000	0 Boards
$ 65,000 to $ 70,000	1 Board
$ 70,000 to $ 75,000	3 Boards
$ 75,000 to $ 80,000	2 Boards
$ 85,000 to $105,000	7 Boards
$105,000 to $115,000	2 Boards
$115,000 to $145,000	3 Boards
$145,000 to $160,000	1 Board
$160,000 to $185,000	0 Boards
$186,000 to $190,000	2 Boards
$191,000 to $215,000	2 Boards
$216,000 to $240,000	1 Board
$765,000	1 Board
No Budget	2 Boards
Average Annual Budget	$105,000
Median Annual Budget	$ 87,000

ANNUAL RENEWAL FEES

Annual Renewal Fee	Number of States 1969-70	1971-72
$50.00	1	1
25.00	1	4
20.00	4	7
21.00	0	1
17.50	1	1
17.00	1	0
15.00	8	13
13.75	0	1
10.00	16	11
7.50	1	1
5.00	12	9
4.00	1	1
3.33	1	0
3.00	1	0
2.50	2	1
2.00	1	1
1.50	1	1
	52	52
Total for 52 states	$555.83	$692.25
Average per state	$ 10.68	$ 13.31
Median fee per state	$ 10.00	$ 13.75

19 states increased their fee from 1969-70 to 1971-72; 33 states retained the same annual renewal fee; none showed a decrease in the annual renewal fee.

BOARD SECRETARIES

Full-time Secretary	28 states
Part-time Secretary	11 states
Voluntary Secretary	2 states
Not reporting	11 states

Of the full-time secretaries, 9 are permitted to perform other than board duties and obtain additional income by doing so. 17 full-time secretaries are not permitted to perform outside duties; 1 state reported "not defined" and 1 state did not report on this particular question. Of the 11 part-time secretaries, 9 are permitted to hold outside jobs for additional income; 1 may not have outside employment, and 1 state did not report on this item.

SALARIES OF SECRETARIES

Full-time Secretaries: (28 reporting)
Range: $ 8,520 to $25,500
Average: $15,647
Median: $15,612

Part-time Secretaries: (7 reporting)
Range: $ 500 to $ 6,000.
Average: $ 3,343
Median: $ 4,000

FULL-TIME SECRETARIES' SALARIES

$ 8,520	1	$15,612	1
10,500	1	15,948	1
11,052	1	16,000	1
11,728	1	16,537	1
12,000	1	17,000	1
12,300	1	17,700	1
12,500	1	18,000	2
12,720	1	18,200	1
12,844	1	18,500	1
14,040	1	18,951	1
14,400	1	20,000	2
15,000	1	25,500	1
15,576	1	Unknown (part of joint budget)	1

PART-TIME SECRETARIES' SALARIES

$ 500	2
1,000	1
4,000	1
5,400	1
6,000	2

One (1) part-time secretary reported "no" salary; 1 receives a per diem for each meeting attended; 2 states did not report on this particular question.

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OFFICE ASSISTANTS EMPLOYED BY FULL-TIME SECRETARIES

Of the 28 states reporting, 1 employs 25; 1 employs 10; 1 employs 7; 2 employ 6; 1 employs 5; 3 employ 4; 8 employ 3; 6 employ 2; 3 employ 1;1 employs "none" and 1 state did not report.

OFFICE ASSISTANTS EMPLOYED BY PART-TIME SECRETARIES

Of the 11 states reporting, 1 employs 5; 1 employs 3; 3 employs 2; 1 employs 1; 2 employ 1 full-time and 1 part-time assistant; 2 employ 1 part-time only.

BOARD OF PHARMACY INSPECTORS

*2 Boards engage no inspectors
5 Boards engage 1 inspector
2 Boards engage 1 inspector part-time
7 Boards engage 2 inspectors
2 Boards engage 2 inspectors part-time
8 Boards engage 3 inspectors
5 Boards engage 4 inspectors
2 Boards engage 5 inspectors
1 Board engages 6 inspectors
3 Boards engage 7 inspectors
1 Board engages 9 inspectors
1 Board engages 13 inspectors
1 Board engages 14 inspectors
1 Board engages 15 inspectors
1 Board has 10 inspectors available on call

*Of the two Boards which do not employ inspectors, in one the Secretary functions as the inspector and in the other the Board Members do the inspecting.

Of the 40 boards which reported that they engage inspectors, 27 reported that the inspectors are pharmacists; 7 reported that their inspectors are not pharmacists; 1 state reports 1 inspector a pharmacist and 2 are non-pharmacists; 1 state shows one inspector a pharmacist and 3 non-pharmacists; 2 states report 2 inspectors are pharmacists and 1 a non-pharmacist; 1 state shows 2 inspectors as pharmacists and 3 non-pharmacists; 1 state engages 2 pharmacist inspectors and 7 non-pharmacists.

24 Boards reported that their inspectors have civil service status, and 17 reported that their inspectors do not have civil service status. 35 states indicated that their inspectors have retirement benefits, and 7 reported no such benefits; 1 state did not report on civil service status.

1 state reported that the board secretary is the inspector; 1 state uses the board members as inspectors; 8 state boards reported that board members may be inspectors; 3 reported that board members occasionally function as inspectors; 29 state boards reported that board members do not function as inspectors.

Of the 27 boards reporting that all of their inspectors are pharmacists, additional necessary qualifications were listed as follows:

6 boards do not require any additional qualifications
1 board requires investigative and general experience
2 boards require two years experience as pharmacist
4 boards require three years experience as pharmacist
1 board requires qualifications as set by state
2 boards require graduation from police academy
2 boards require one year experience in drug law and some experience as law officer
3 boards require "on-the-job" training
6 boards did not report on this question

Of the 7 boards which reported that their inspectors are not pharmacists, 2 listed requirement of investigative education and experience; 1 board listed "requirements as specified" and 4 did not reply to this item of additional requirements.

Of the 27 boards reporting that their inspectors are all pharmacists, 13 reported that this is required by state law; 12 that it is a rule or regulation of the board; 1 reported "required by Department of Health" and one did not report on this item.

Of the 27 reporting that their inspectors are pharmacists, 19 stated that the salaries of inspectors are comparable to other pharmacists; 7 that the salaries are not comparable to other pharmacists and 1 did not report on this item.

The amount of training needed to become an inspector ranges as follows:

2 report "no special training required"
2 boards reported 4 weeks to 3 months
7 boards reported "on-the-job" training (specified no time)
12 require BNDD and NABP school attendance
2 reported "peace officer training course" required
2 did not report on this question

The average number of inspections assigned to each inspector annually appeared as follows:

7 boards reported "no set number"
2 less than 100 each
6 100 to 200
6 250 to 400
7 500 to 800
3 1,000 to 1,500
3 assign 1,500 to 1,680
1 "all stores to be inspected once a year"
1 "all stores to be inspected twice during year"
16 states did not report on this question

INSPECTORS MEET WITH BOARDS

28 require inspectors to meet with the board
12 do not require inspectors to meet with the board
1 requires when necessary
11 did not respond to this question

COOPERATION WITH FDA AND BNDD

36 boards indicated that their inspectors cooperate 100% with the Food and Drug Administration and with the Bureau of Narcotics and Dangerous Drugs; 4 reported cooperation when necessary to discuss matters of mutual concern; 2 reported "seldom" or "very little" and 10 did not reply to this question. At the present time 44 states function under Memorandums of Understanding with BNDD. They assist Federal Agencies in the enforcement of the Controlled Substances Act for community and hospital pharmacies.

USE OF OUTSIDE AGENCIES

Of the 42 boards which submitted replies to the questionnaire, the use of outside agencies is as follows:

5 frequently
7 when needed
6 occasionally
4 rarely or very little
5 for search warrants only
15 none

CHECK-UP ON FIELD WORK

39 boards reported that they use some form of check-up on field work; 13 boards did not respond to this question. As to use of laboratory facilities, the 39 boards reported as follows:

7 used Board of Health labs
5 College or other School of Pharmacy labs
4 Department of Agriculture
15 State Police Crime labs
5 FDA offices
2 BNDD facilities
1 Local facilities

EXHIBIT NO. 8

LICENSURE STATISTICS, CENSUS

Acknowledgement is given to Mr. Fred T. Mahaffey, Miss Blanche Rutledge of N.A.B.P., Mr. Sheldon Starr and the National Center for Health Statistics, Department of Health, Education and Welfare, for their assistance in preparing the statistical information on the following pages.

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LICENSURE STATISTICS AND CENSUS OF PHARMACY

NATIONAL ASSOCIATION OF
BOARDS OF PHARMACY, INC.
77 WEST WASHINGTON STREET
CHICAGO, ILLINOIS 60602

Information on census and licensure data for pharmacy is published in the following series of tables and is gathered through the cooperation of the secretaries of state boards of pharmacy in 50 states, the District of Columbia, the Commonwealth of Puerto Rico and the Virgin Islands. Licensure data included relates to the calendar year January 1, 1972, to December 31, 1972. Census data includes totals as of January 1, 1973.

There are a few omissions in the data, indicated by blanks.* These are due to the inability of some boards to gather and compile the range of information requested. However, we believe that the information made available through these tables presents a sufficient amount of data to make totals and percentages significant for the pharmacy profession as a whole. In the paragraphs preceding each table, we have attempted to interpret the figures shown in that particular table.

Totals are shown at the top of each column, and we believe the headings used accurately indicate the information presented in each column. Footnotes at the bottom of some of the tables will be helpful in interpreting the data.

***The symbol—indicates no report given.**
The symbol 0 indicates an actual "none to report."

TABLE NO. 1

LICENSURE DATA

TABLE NO. 1 lists the total number of registrations, a breakdown into "total resident in each state (in practice and out of practice)" and the number of pharmacists who reside "outside of the state" in which they are licensed. The last column shows resident pharmacists per 100,000 population in each state and the country as a whole.

Pharmacist registrations as of January 1, 1973, numbered 191,247, and include persons who are licensed in one or more states—some with as many as nine registrations. When those who have out-of-state addresses are excluded, the number drops to 145,374, which is the most accurate approximation we have of persons trained in pharmacy. When pharmacists who have not renewed their licenses, and thus are no longer active, are eliminated, this figure drops to 132,899 active pharmacists.

In relation to population there are 62 pharmacists, in practice, per 100,000 population. This 1973 rate is slightly lower than that of a year ago—63.2 in 1972.

Table 1. Pharmacist registrations according to residence and activity status and ratio of pharmacists to population: January 1, 1973

Location	*Total registrations	Pharmacists resident in State			Pharmacists Out of State	Resident pharmacists in practice per 100,000 population 1/
		Total	In practice	Not in practice		
TOTALS	191,247	145,374	132,899	12,475	45,873	62.0
Ala.	2,674 2/	2,477	2,301	176	197	66.7
Alaska	188	121	96	25	67	29.5
Ariz.	2,881	1,393	1,171	222	1,488	60.2
Ark.	1,821	1,311	1,098	213	510	55.5
Calif.	14,626	13,639	12,485	1,154	987	61.0
Colo.	3,412	1,953	1,631	322	1,459	69.2
Conn.	2,507 2/	2,235	2,105	130	272	68.3
Del.	537	282	259	23	255	45.8
D.C.	1,555	625	570	55	930	76.2
Fla.	6,310	4,750	4,370	380	1,560	60.2
Ga.	4,572	3,730	3,280	450	842	69.5
Hawaii	343	268	268	-	75	33.1
Idaho	1,429	583	510	73	846	67.5
Ill.	9,720 2/	6,634	6,163	471	3,086	54.8
Ind.	5,573	3,732	3,276	456	1,841	61.9
Iowa	3,076	1,821	1,635	186	1,255	56.7
Kansas	2,347	1,739	1,482	257	608	65.6
Ky.	2,527	2,047	1,789	258	480	54.2
La.	3,186	2,471	2,411	60	715	64.8
Maine	789	526	520	6	263	50.5
Md.	3,210	2,585	2,372	213	625	58.5
Mass.	7,083	5,511	5,021	490	1,572	86.6
Mich.	6,549	5,965	5,585	380	584	61.5
Minn.	3,413	2,553	2,367	186	860	60.8
Miss.	1,609	1,249	1,186	63	360	52.4
Mo.	4,610	3,288	2,682	606	1,322	56.4
Mont.	846 2/	531	447	84	315	62.2
Nebr.	2,196	1,259	1,012	247	937	66.4
Nev.	3,311	345	330	15	2,966	62.6
N.H.	674	415	355	60	259	46.0
N.J.	5,890	4,763	4,024	739	1,127	54.6
N.Mex.	1,181	640	607	33	541	57.0
N.Y.	18,325	14,420	14,076	344	3,905	76.6
N.C.	2,967	2,464	2,204	260	503	42.3
N.Dak.	1,355	489	447	42	866	70.7
Ohio	8,524	7,648	7,274 3/	374	876	67.5
Okla.	3,131	2,253	2,173	80	878	82.5
Ore.	2,267	1,540	1,368	172	727	62.7
Pa.	12,081 2/	11,404	10,559	845	677	88.5
P.Rico	1,133	1,133	1,066	67	-	39.6 4/
R.I.	1,257	710	549	161	547	56.7
S.C.	1,932	1,545	1,509	36	387	56.6
S.Dak.	901	480	463	17	421	68.2
Tenn.	3,541	2,609	2,477	132	932	61.4
Tex.	8,759	7,144	6,418	726	1,615	55.1
Utah	1,366	812	769	43	554	68.3
Vt.	869	232	225	7	637	48.7
Virginia	2,968 2/	2,335	2,065	270	633	43.3
Virgin I.	-	-	-	-	-	-
Wash.	3,738	2,838	2,507	331	900	72.8
W.Va.	1,227	793	743	50	434	41.7
Wis.	3,477	2,789	2,394	395	688	53.0
Wyo.	784	295	205	90	489	59.4

1/ Total Civilian Resident Population, Current Pop. Reports, U.S. Bur. of Census, Series P-25, No. 500
2/ As of January 1, 1972
3/ Estimated
4/ Total Civilian Resident Population, estimated by U.S. Bur. of Census for Puerto Rico, July 1, 1972, Series P-25

Table 2. Type of practice of pharmacists by States: January 1, 1973

Location	Total licensed in State	In practice						Not in practice
		Total in practice in State	Community pharmacy			Hospital pharmacy	Manufacturing	Teaching, government and other pharmaceutical capacities
			Total in community practice in State	Owner	Employee			
TOTALS	145,374	132,899	109,113	46,118	62,995	13,310	5,237	5,239	12,475
Ala.	2,477 1/	2,301	1,933	810	1,123	230	23	115	176
Alaska	121	96	80	13	67	8	8	-	25
Ariz.	1,393	1,171	867	223	644	217	32	55	222
Ark.	1,311	1,098	965	459	506	104	13	16	213
Calif.	13,639	12,485	10,860	5,539	5,321	1,065	360	200	1,154
Colo.	1,953 1/	1,631	1,312	376	936	198	46	75	322
Conn.	2,235 2/	2,105	1,595	707	888	265	208	42	130
Del.	282	259	209	69	140	30	7	13	23
D.C.	625	570	463	74	389	57	20	30	55
Fla.	4,750	4,370	3,728	1,454	2,274	358	35	249	380
Ga.	3,730	3,280	2,477	1,344	1,133	195	336	272	450
Hawaii	268	268	190	60	130	49	21	8	0
Idaho	583 1/	510	444	173	271	28	23	15	73
Ill.	6,634 2/	6,163	5,046	1,980	3,066	889	193	35	471
Ind.	3,732	3,276	2,620	886	1,734	338	231	87	456
Iowa	1,821	1,635	1,181	579	602	164	77	213	186
Kansas	1,739	1,482	1,309	715	594	119	30	24	257
Ky.	2,047	1,789	1,452	623	829	189	55	93	258
La.	2,471	2,411	2,189	950	1,239	110	52	60	60
Maine	526	520	494	150	344	15	4	7	6
Md.	2,585	2,372	1,866	403	1,463	236	97	173	213
Mass.	5,511	5,021	4,057	1,664	2,393	411	267	286	490
Mich.	5,965	5,585	4,787	1,996	2,791	608	151	39	380
Minn.	2,553	2,367	1,704	771	933	254	41	368	186
Miss.	1,249	1,186	892	477	415	231	25	38	63
Mo.	3,288	2,682	2,212	943	1,269	326	144	-	606
Mont.	531 1/	447	374	215	159	51	9	13	84
Nebr.	1,259	1,012	826	381	445	97	65	24	247
Nev.	345	330	292	88	204	25	5	8	15
N.H.	415	355	303	135	168	43	6	3	60
N.J.	4,763	4,024	3,585	1,792	1,793	163	227	49	739
N.Mex.	640	607	517	217	300	64	12	14	33
N.Y.	14,420	14,076	10,670	2,732	7,938	1,647	731	1,028	344
N.C.	2,464	2,204	1,889	820	1,069	241	39	35	260
N.Dak.	489	447	336	198	138	76	20	15	42
Ohio	7,648	7,274 2/	5,906	2,534	3,372	975	255	138	374
Okla.	2,253	2,173	1,859	676	1,183	99	121	94	80
Ore.	1,540	1,368	1,154	428	726	149	19	46	172
Pa.	11,404 1/	10,559	8,848	4,919	3,929	739	697	275	845
P.Rico	1,133	1,066	967	317	650	17	30	52	67
R.I.	710	549	428	97	331	87	15	19	161
S.C.	1,545	1,509	1,397	562	835	68	12	12	36
S.Dak.	480	463	410	129	281	23	19	11	17
Tenn.	2,609	2,477	2,072	919	1,153	243	82	80	132
Tex.	7,144	6,418	5,268	2,312	2,956	697	172	281	726
Utah	812	769	625	244	381	68	33	43	43
Vt.	232	225	211	101	110	14	-	-	7
Virginia	2,335 1/	2,065	1,540	612	928	179	37	309	270
Virgin I.	-	-	-	-	-	-	-	-	-
Wash.	2,838	2,507	1,985	1,191	794	351	70	101	331
W.Va.	793	743	659	254	405	65	7	12	50
Wis.	2,789	2,394	1,882	720	1,162	423	53	36	395
Wyo.	295	205	178	87	91	17	2	8	90

1/ As of January 1, 1972
2/ Estimated

TABLE NO. 2

CENSUS DATA

TABLE NO. 2 indicates the "types of practice of resident pharmacists in practice as of January 1, 1973."

About 109,113 of the active pharmacists practice in community pharmacies. In our data, hospital pharmacies account for 13,310 pharmacists. Pharmacists employed by manufacturers and wholesalers account for 5,200; teachers in colleges of pharmacy, government and other personnel make up the balance of 5,200.

As a general rule, the number practicing in community pharmacies is higher in those states that have small populations and a small number of pharmacists.

Pharmacists who are employed in community pharmacies slightly outnumber those who are owners, partners or stockholders. As shown in Table 2, 46,118 of the 109,113 pharmacists practicing in community pharmacies are owners or partners while 62,995 are employees. This represents a slight decrease in ownership from a year ago.

TABLE NO. 3

CENSUS DATA

TABLE NO. 3 breaks down the number of resident pharmacists in practice, in the country as a whole and in each state into the number of male and female pharmacists (indicating the percentage of female) and the "professional education" of pharmacists in practice. The last column lists by state the percentages of those who have completed four, five or six years of college education.

Puerto Rico leads in female pharmacists with 56.2 per cent. The proportion of pharmacy students who are women is increasing and has now reached 10.3 per cent. This increase should soon be reflected with a larger number of female pharmacists in active practice. A little more than seven out of ten pharmacists have four, five or six years of post-high-school education.

Table 3. Sex and education of resident pharmacists engaged in practice: January 1, 1973

Location	Resident pharmacists in practice	Sex			Professional education				Percent with 4, 5 or 6 years education
		Male	Female	Percent female	4, 5, or 6 years	3 years	2 years	Non-graduate	
TOTALS	132,899	119,379	13,520	10.3	97,637	15,481	13,366	6,415	73.5
Ala.	2,301[1]	2,154	147	6.4	2,176	32	49	44	94.6
Alaska	96	66	30	31.3	80	1	3	12	83.3
Ariz.	1,171	1,062	109	9.3	863	48	104	156	73.7
Ark.	1,098	1,063	35	3.2	920	23	55	100	83.8
Calif.	12,485	11,585	900	7.2	8,585	2,500	1,200	200	68.8
Colo.	1,631	1,435	196	12.0	783	100	166	582	48.0
Conn.	2,105[1]	2,027	78	3.7	1,516	219	215	155	72.0
Del.	259	242	17	6.6	159	34	22	44	61.4
D.C.	570	457	113	19.8	410	96	41	23	71.9
Fla.	4,370	4,086	284	6.5	3,413	328	397	232	78.1
Ga.	3,280	3,067	213	6.5	2,585	174	210	311	78.8
Hawaii	268	225	43	16.0	202	25	11	30	75.4
Idaho	510	425	85	16.7	446	34	20	10	87.5
Ill.	6,163[1]	5,596	567	9.2	4,407	783	579	394	71.5
Ind.	3,276	2,906	370	11.3	2,850	189	172	65	87.0
Iowa	1,635	1,471	164	10.0	1,342	11	254	28	82.1
Kansas	1,482	1,347	135	9.1	877	73	237	295	59.2
Ky.	1,789	1,640	149	8.3	1,505	92	162	30	84.1
La.	2,411	2,013	398	16.5	1,951	185	165	110	80.9
Maine	520	465	55	10.6	229	32	38	221	44.0
Md.	2,372	2,084	288	12.2	2,091	214	66	1	88.2
Mass.	5,021	4,619	402	8.0	3,389	889	362	381	67.5
Mich.	5,583	4,980	605	10.8	4,696	120	704	65	84.1
Minn.	2,367	2,152	215	9.1	2,025	153	143	46	85.6
Miss.	1,186	1,047	139	11.7	976	58	103	49	82.3
Mo.	2,682	2,392	290	10.8	1,590	306	376	410	59.3
Mont.	447[1]	408	39	8.7	366	42	25	14	81.9
Nebr.	1,012	926	86	8.5	691	133	130	58	68.3
Nev.	330	317	13	3.9	230	0	0	100	69.7
N.H.	355	330	25	7.0	284	28	5	38	80.0
N.J.	4,024	3,674	350	8.7	2,744	722	499	59	68.2
N.Mex.	607	554	53	8.7	384	34	31	158	63.3
N.Y.	14,076	13,283	793	5.6	7,404	3,252	3,364	56	52.6
N.C.	2,204	1,973	231	10.5	2,013	74	62	55	91.3
N.Dak.	447	384	63	14.1	382	51	14	0	85.5
Ohio	7,274[2]	6,206	1,068	14.7	5,943	618	713	0	81.7
Okla.	2,173	2,002	171	7.9	1,635	104	202	232	75.3
Ore.	1,368	1,154	214	15.6	1,223	80	47	18	89.4
Pa.	10,559[1]	9,559	1,000	9.5	6,937	2,386	1,046	190	65.7
P.Rico	1,066	467	599	56.2	986	44	21	15	92.5
R.I.	549	461	88	16.0	434	110	5	0	79.1
S.C.	1,509	1,406	103	6.8	1,224	9	214	62	81.1
S.Dak.	463	386	77	16.6	382	27	36	18	82.5
Tenn.	2,477	2,088	389	15.7	1,861	192	145	279	75.1
Tex.	6,418	5,780	638	9.9	5,031	269	557	561	78.4
Utah	769	708	61	7.9	665	35	26	43	86.5
Vt.	225	215	10	4.4	136	12	22	55	60.4
Virginia	2,065[1]	1,685	380	18.4	1,811	145	58	51	87.7
Virgin I.	-	-	-	-	-	-	-	-	-
Wash.	2,507	1,819	688	27.4	2,126	213	108	60	84.9
W.Va.	743	676	67	9.0	625	57	55	6	84.1
Wis.	2,394	2,134	260	10.9	1,875	125	127	267	78.3
Wyo.	205	178	27	13.2	179	0	0	26	87.3

1/ As of January 1, 1972
2/ Estimated

Table 4. Age distribution of resident pharmacists engaged in practice: January 1, 1973

Location	Resident pharmacists in practice	Number by age (in years)						Percent	
		Under 30	30-39	40-49	50-59	60-64	65 and over	Under Age 30	Age 65 and over
TOTALS	132,899	27,004	32,294	28,473	22,553	11,434	11,141	20.3	8.4
Ala.	2,301[1]	522	892	647	127	58	55	22.7	2.4
Alaska	96	38	21	18	8	3	8	39.6	8.3
Ariz.	1,171	142	194	318	226	131	160	12.1	13.7
Ark.	1,098	186	316	270	137	38	151	16.9	13.8
Calif.	12,485	3,995	2,397	2,435	2,410	849	399	32.0	3.2
Colo.	1,631	186	287	405	357	189	207	11.4	12.7
Conn.	2,105[1]	341	600	499	223	202	240	16.2	11.4
Del.	259	28	83	44	56	22	26	10.8	10.0
D.C.	570	77	135	115	139	63	41	13.5	7.2
Fla.	4,370	516	1,398	1,027	704	354	371	11.8	8.5
Ga.	3,280	679	1,010	722	442	200	227	20.7	6.9
Hawaii	268	9	103	65	55	21	15	3.4	5.6
Idaho	510	123	174	120	42	28	23	24.1	4.5
Ill.	6,163[1]	1,288	1,399	1,116	1,035	592	733	20.9	11.9
Ind.	3,276	547	820	752	580	470	107	16.7	3.3
Iowa	1,635	341	410	318	251	116	199	20.9	12.2
Kansas	1,482	325	281	288	245	163	180	21.9	12.1
Ky.	1,789	369	470	408	269	105	168	20.6	9.4
La.	2,411	895	524	430	310	132	120	37.1	5.0
Maine	520	50	104	94	115	53	104	9.6	20.0
Md.	2,372	492	720	410	425	175	150	20.7	6.3
Mass.	5,021	773	1,265	1,049	1,206	387	341	15.4	6.8
Mich.	5,585	1,418	1,480	1,016	984	397	290	25.4	5.2
Minn.	2,367	427	567	437	425	261	250	18.0	10.6
Miss.	1,186	284	292	253	133	85	139	23.9	11.7
Mo.	2,682	530	523	507	526	406	190	19.8	7.1
Mont.	447[1]	57	109	134	70	35	42	12.8	9.4
Nebr.	1,012	297	206	197	133	142	37	29.3	3.7
Nev.	330	34	65	65	72	40	54	10.3	16.4
N.H.	355	70	102	67	37	35	44	19.7	12.4
N.J.	4,024	853	683	930	755	602	201	21.2	5.0
N.Mex.	607	95	119	121	111	72	89	15.7	14.7
N.Y.	14,076	1,808	3,453	2,873	2,654	1,704	1,584	12.8	11.3
N.C.	2,204	438	617	572	354	95	128	19.9	5.8
N.Dak.	447	134	104	87	65	36	21	30.0	4.7
Ohio	7,274[2]	1,280	1,804	1,695	1,280	429	786	17.6	10.8
Okla.	2,173	671	481	445	291	202	83	30.9	3.8
Ore.	1,368	204	354	339	240	113	118	14.9	8.6
Pa.	10,559[1]	2,144	2,291	1,943	2,101	1,056	1,024	20.3	9.7
P.Rico	1,066	185	255	346	164	31	85	17.4	8.0
R.I.	549	111	103	136	101	33	65	20.2	11.8
S.C.	1,509	460	367	361	178	78	65	30.5	6.5
S.Dak.	463	55	141	93	70	41	63	11.9	13.6
Tenn.	2,477	431	671	593	383	168	231	17.4	9.3
Tex.	6,418	1,521	1,555	1,444	804	426	668	23.7	10.4
Utah	769	81	261	238	88	33	68	10.6	8.8
Vt.	225	53	40	55	32	16	29	25.6	12.9
Virginia	2,065[1]	450	553	502	306	122	132	45.0	13.2
Virgin I.	-	-	-	-	-	-	-	-	-
Wash.	2,507	286	707	714	426	201	173	11.4	6.9
W.Va.	743	166	169	178	82	43	105	22.3	14.1
Wis.	2,394	498	563	517	306	170	340	20.8	14.2
Wyo.	205	41	56	65	20	11	12	20.0	5.9

1/ As of January 1, 1972
2/ Estimated

TABLE NO. 4

CENSUS DATA

In TABLE NO. 4 we find age data of "resident pharmacists in practice" followed by the percentage of those under 30 years of age and those 65 years or more. These two groups represent 29 per cent of the resident pharmacists in practice.

According to the age distribution of pharmacists, approximately 20.3 per cent are under 30 years of age and 8.4 per cent are 65 or older. How reliable this information is cannot be determined. Some of the states reported considerably different distributions in earlier accounts. Given sound statistics on age, we might be able to apply survival rates as part of the projection on the future supply of pharmacists and ascertain whether the younger pharmacists are practicing in urban communities rather than in rural areas.

TABLE NO. 5

CENSUS DATA

TABLE NO. 5 shows that about 55,776 community pharmacies are operated by some 109,113 pharmacists. Of the 109,113 pharmacists who reported, 12.7 per cent of them practice in one-person outlets, while of the 34,490 outlets which reported, 27.4 per cent are manned by one pharmacist. These figures are, of course, based upon only the statistics available from the states which reported.

Information on the number of community pharmacies (including chain outlets) and hospital pharmacies has also been supplied by the state boards of pharmacy, who are the licensing agencies for those outlets. However, in some states, the board of health or some other agency licenses hospital pharmacies, thus leading to an understatement of the number. The number of hospitals with pharmacies attended by a registered pharmacist given in the **Guide** issue of the **Journal of the American Hospital Association** differs considerably from some of the statistics presented here.

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Table 5. Pharmacists in community pharmacies and in hospital pharmacies by size of staff: January 1, 1973

Location	Community pharmacies: Total pharmacists	Community pharmacies: Total pharmacies	Community pharmacies: Total Community pharmacies	Community pharmacies: Number of Outlets: Independent Outlets	Community pharmacies: Number of Outlets: Chain (6 or more) Outlets	Hosp. pharmacies: Total pharmacists	Hosp. pharmacies: Total pharmacies	No. Community Pharmacies Serviced by: 1 pharmacist	2 or 3 pharmacists	4 or more pharmacists	Percent of pharmacists in 1-person outlets	Percent of outlets with 1 pharmacist
TOTALS	109,113	55,776	50,662	39,998	10,604	5,174	13,310	13,873	17,828	2,817	12.3[2/]	27.3[3/]
Ala.	1,933[2/]	1,065	964	845	119	101	230	422	416	126	21.8	43.8
Alaska	168	96	53	44	9	3	8	25	25	3	11.1	47.2
Ariz.	867	468	401	251	147	67	217	99	234	69	11.4	24.7
Ark.	965	611	590	540	50	21	106	306	269	15	11.7	51.9
Calif.	10,860	4,909	4,252	3,325	927	635	1,065	1,386	2,207	659	12.8	32.6
Colo.	1,312	640	583	497	86	97	196[2/]	-	-	-	-	-
Conn.	1,599[2/]	774	736	639	129	0	260[2/]	162	488	98	11.6	23.7
Del.	263	151	136	102	34	15	30	43	88	5	20.6	11.6
D.C.	1,728	161	145	69	76	16	57	-	-	-	-	-
Fla.	2,477	2,154	1,967	1,186	781	167	395	897	1,003	77	25.8	45.1
Ga.	2,477	1,530	1,628	1,195	433	100	135	670	673	88	27.0	26.9
Hawaii	190	115	79	60	19	16	49	-	-	-	-	-
Idaho	224	122	99	68	31	3	28	79	109	21	17.8	37.8
Ill.	5,668[2/]	2,938	2,701	2,017	684	23	283	889	847	1	-	-
Ind.	2,620	1,355	1,222	786	436	133	338	338	867	30	12.4	12.6
Iowa	1,181	716	707	607	100	9	116	325	292	30	54.4	32.5
Kansas	1,309	626	585	517	68	41	159	196	277	14	22.5	50.3
Ky.	1,452	846	796	646	150	56	189	294	447	10	30.8	56.3
La.	2,189	1,115	1,044	850	194	82[2/]	110	342	563	143	15.6	51.6
Maine	266	225	225	153	72	0[2/]	15	169	56	0	31.2	75.1
Md.	1,866	779	734	491	243	45[2/]	236	31	661	39	1.8	4.6
Mass.	4,057	1,565	1,565	1,210	355	0[2/]	611	-	-	-	-	-
Mich.	4,787	1,961	1,961	1,322	639	312	1,041	248	1,137	576	5.2	12.6
Minn.	1,704	841	721	535	186	113	254	352	450	39	20.6	41.9
Miss.	812	369	286	172	114	38	231	386	328	7	20.2	51.5
Mo.	2,772	1,272	1,151	916	235	123	326	455	671	85	32.9	55.4
Mont.	370[2/]	290	222	192	30	68	91	166	91	15	28.1	51.5
Nebr.	1,189	626	556	410	146	63	97	232	283	15	15.0	55.6
Nev.	376	196	196	152	44	20	12	18	94	8	6.2	75.1
N.H.	313	132	132	93	39	0[2/]	43	31	94	12	10.2	21.6
N.J.	3,587	1,633	1,577	1,341	236	113[2/]	163	-	-	-	-	-
N.Mex.	517	286	260	234	26	26[2/]	64	124	125	11	24.0	-7.7
N.Y.	10,670	4,776	4,558	3,865	693	168	1,847	-	-	-	-	-
N.C.	1,889	1,289	1,141	852	289	148	341	583	485	68	31.1	51.5
N.Dak.	316	205	166	82	84	16	76	85	78	6	35.3	38.7
Ohio	5,806	2,784	2,106	1,422	684	678	935	723	1,156	175	11.6	25.0
Okla.	1,898	861	815	701	115	27	99	204	543	65	11.0	44.4
Oreg.	1,154	591	514	437	77	77	149	228	292	34	15.8	-
Pa.	8,645[2/]	3,435	3,186	2,545	641	249	733	-	-	-	-	95.6
P.Rico	967	814	771	766	5	20	87	737	32	2	76.2	71.0
R.I.	428	253	253	199	54	44	68	49	153	31	11.4	21.1
S.C.	1,197	686	654	536	118	53	23	190	424	20	13.6	-
S.Dak.	270	264	211	193	18	59	243	-	-	-	-	-
Tenn.	2,072	1,382	1,221	1,015	206	161	284	1,157	1,540	143	22.0	40.7
Tex.	5,268	2,086	2,040	2,235	665	246	68	-	-	-	-	-
Utah	621	275	231	180	51	5	14	56	56	5	20.4	41.3
Vt.	211	159	156	141	15	100	179	53	470	21	26.9	45.8
Virginia	1,540[2/]	1,086	906	568	338	-	-	415	-	-	-	-
Virgin I.	-	-	-	-	-	-	-	-	-	-	-	51.9
Wash.	1,985	1,033	953	820	133	80	351	495	481	47	2.4	52.5
W.Va.	659	373	343	292	51	30	65	180	161	2	32.9	67.0
Wis.	1,882	1,059	945	810	135	130	427	620	293	12	12.9	47.5
Wyo.	174	99	93	79	14	0	17	47	47	5	26.4	

1/ Based on 1,470 pharmacies in 43 locations
2/ Based on 13,823 out of 68,487 pharmacists in 43 locations
3/ Based on 13,883 out of 35,490 pharmacies in 43 locations
4/ As of January 1, 1972
5/ Pharmacists employed in hospital pharmacies not licensed by State Board of Pharmacy
6/ Does not include U.S. Government, VA, USPHS or Military Hospitals

Table 6. Licensure of pharmacists: Calendar Year 1972

Location	Applicants for examination	Licenses Issued: Applicants Failed	By examination	By reciprocity	By reinstatement	Total	Licenses recalled: By death	By suspension or revocation	Net licenses
TOTALS	7,397	1,025	6,372	2,219	258	8,849	1,211	1,575	4,961[1/]
Ala.	76[2/]	0	76	28	-	104	-	-	-
Alaska	2	0	2	18	3	23	0	20	3
Ariz.	66	6	60	130	3	193	26	45	122
Ark.	69	0	69	31	2	102	26	19	57
Calif.	655	139	516	0	-	516	126	179	211
Colo.	79[2/]	9	70	103	92	265	45	191	29
Conn.	57[2/]	1	56	29	2	87	-	-	-
Del.	9	1	8	18	0	26	0	11	15
D.C.	10	0	10	16	1	27	3	1	23
Fla.	438	25	413	0	-	413	54	3	356
Ga.	217	37	180	77	2	259	33	2	224
Hawaii	51	6	45	0	-	45	1	10	34
Idaho	39[2/]	5	34	13	6	53	4	32	17
Ill.	419[2/]	85	334	120	0	454	-	-	-
Ind.	153	12	141	56	4	201	35	0	166
Iowa	172	18	154	29	8	191	46	239	(94)
Kansas	66	3	63	86	2	151	26	15	110
Ky.	119	14	105	54	4	163	27	39	97
La.	146	5	141	31	4	176	4	66	106
Maine	29	1	28	32	1	61	8	1	52
Md.	111	10	101	83	1	185	48	1	136
Mass.	184	9	175	21	19	215	0	5	210
Mich.	213	12	201	74	2	277	73	2	202
Minn.	108	13	95	31	4	130	43	21	66
Miss.	105	9	96	31	3	130	7	4	119
Mo.	134[2/]	1	133	64	1	198	40	156	2
Mont.	26[2/]	1	25	14	0	39	11	38	(10)
Nebr.	135	2	133	17	3	153	18	37	98
Nev.	205	17	188	21	3	212	6	65	141
N.H.	38	0	38	23	1	62	3	35	24
N.J.	110	12	98	122	1	221	-	1	270
N.Mex.	43	0	43	50	5	98	30	55	13
N.Y.	670	380	290	47	3	340	-	7	333
N.C.	165	37	128	19	18	165	38	-	127
N.Dak.	69	2	67	6	0	73	9	12	52
Ohio	275	10	265	91	0	356	90	25	241
Okla.	130	12	118	17	21	156	29	81	46
Oreg.	68	5	63	45	3	111	26	15	70
Pa.	352[2/]	8	344	60	10	414	-	0	-
P.Rico	68	6	62	2	0	64	-	0	64
R.I.	51	0	51	5	0	56	21	0	35
S.C.	67	4	63	31	5	99	15	0	84
S.Dak.	26	0	26	10	-	36	7	-	29
Tenn.	129	5	124	78	1	203	28	2	173
Tex.	385	25	360	122	2	484	104	13	367
Utah	40	7	33	15	-	48	-	-	-
Vt.	37	1	36	28	1	65	7	0	58
Virginia	170[2/]	29	141	90	15	246	23	39	184
Virgin I.	-	-	-	-	-	-	-	-	-
Wash.	160	3	157	54	-	211	-	-	-
W.Va.	59	4	55	34	1	90	10	5	75
Wis.	171	33	138	34	-	172	50	60	62
Wyo.	21	1	20	9	1	30	11	23	(4)

1/ "No reports" indicated by (-) show that sixteen states have no accurate method of recording "Licenses issued by reinstatement" or of "Licenses recalled by death and/or suspension or revocation." For purposes of this Table we have based "Net licenses" upon a total of 7,531 licenses issued in 46 locations.

2/ As of January 1, 1972

TABLE NO. 6

LICENSURE DATA

TABLE NO. 6 lists information pertaining to "licensure of pharmacists for the calendar year, 1972." In that year, 7,397 applicants applied for examination and 6,372 were licensed by examination. A total of 4,961 "net" licenses were added to the profession. The difference between this figure and the number licensed by examination is the attrition rate due to death, loss of license for nonpayment, revocation or suspension and persons who have left the profession for other reasons. The "net" figure suffers from inaccuracy due to a lack of reports from some states. In 10 states there was no report of deaths, and in 8 states no report of suspensions or revocations. It is obvious that this will result in some inaccuracy.

The table shows 2,219 pharmacists licensed by reciprocity. This figure differs from the NABP list of persons who reciprocated. The NABP list shows 2,603 persons having reciprocated. The difference lies in varied methods of reporting. The NABP list at the back of the 1973 Proceedings is based on coupons returned from the states confirming the reciprocal procedure.

The table also shows that state boards reinstated 258 licenses that had been withheld for nonpayment, revocation or suspension, with 9 states not reporting and 14 states reporting no reinstatements.

*See foot-note at the bottom of Table #6.

TABLE NO. 7

ASSISTANT PHARMACIST LICENSURE DATA

TABLE NO. 7 gives the number of assistant pharmacist licenses that have been retained in good standing by renewal. Those assistants who hold valid licenses number 1,718.*

None of the states presently issue original licenses to assistant pharmacists. Those states which have abolished the issuance of new certificates but continue to renew previously issued assistant pharmacist licenses are: Alabama, Colorado, Connecticut, Delaware, Illinois, Indiana, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Minnesota, Mississippi, Montana, New Jersey, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, South Dakota, West Virginia, Wisconsin and the Virgin Islands. There are no outstanding certificates in states not mentioned.

Table 7. Assistant pharmacists according to residence and activity status: January 1, 1973

Location	Total	Registrations			
		Residence		Activity status	
		Outside of State	Within State	Active	Inactive
TOTALS	1,718	330	1,388	1,357	361
Ala.	147	1	146	146	1
Colo.	165	158	7	7	158
Conn.	-	-	-	-	-
Del.	12	2	10	10	2
Ill.	299	0	299	296	3
Ind.	6	2	4	2	4
Kansas	185	34	151	158	27
Ky.	1	1	0	0	1
La.	38	-	38	38	-
Maine	52	4	48	48	4
Md.	1	0	1	0	1
Mass.	72	32	40	40	32
Minn.	11	4	7	2	9
Miss.	52	1	51	45	7
Mont.	45	19	26	26	19
N.J.	3	1	2	0	3
N.C.	15	0	15	9	6
N.Dak.	3	3	0	0	3
Ohio	1	0	1	1	0
Okla.	170	42	128	128	42
Ore.	2	0	2	1	1
Pa.	52	0	52	52	0
P.Rico	235	0	235	235	0
R.I.	28	6	22	14	14
S.C.	67	6	61	61	6
S.Dak.	1	0	1	1	0
Virgin I.	-	-	-	-	-
W.Va.	16	2	14	10	6
Wis.	39	12	27	27	12

[Subsequently Mr. C. E. Barnett, chairman of the executive committee of the National Association of Boards of Pharmacy, and executive secretary of the Idaho Board of Pharmacy submitted materials on the State of Idaho's Triplicate Prescription Program. This material is marked "Exhibit No. 9" and is as follows:]

EXHIBIT No. 9

IDAHO BOARD OF PHARMACY,
BOISE, IDAHO, *April 3, 1974*

HON. BIRCH BAYH,
U.S. Senate,
Washington, D.C. 20510

DEAR SENATOR BAYH: Enclosed you will find information regarding Idaho's Triplicate Prescription Program.

You will recall I pointed out in my testimony that any triplicate prescription program should be limited to schedule II substances and administered on a state level. In order to have a smooth working triplicate prescription program, the state must have the backing of the medical and pharmaceutical professions. In other words, the administrating agency must encourage voluntary compliance and work through the various licensing agencies for enforcement purposes.

We appreciate the opportunity you provide for us to testify and if we may be of any further assistance to you at any time, please do not hesitate to call on us.

Sincerely yours,

C. E. BARNETT, R.PH.,
Executive Secretary, Idaho Board of Pharmacy.

IDAHO BOARD OF PHARMACY

The Idaho Board of Pharmacy has administered the triplicate prescription program since 1967, and have substantially curtailed the movement of controlled substances into the illicit market. Physicians and pharmacists have become much more responsible in the prescribing and dispensing of controlled substances.

During the 1972-73 fiscal year, we had approximately 100,000 triplicate prescription copies returned to our office for coding and data processing. This will probably double with the addition of other substances to Schedule II.

All practitioners licensed to prescribe and dispense controlled substances are registered under the Controlled Substances Act by the Idaho Board of Pharmacy.

Triplicate prescription forms are issued in books of 25, 100 blanks to an order to physicians, dentists, podiatrists, osteopaths, veterinarians. These blanks are serially numbered and are used only by the practitioner to whom they have been issued. The pharmacy, once each practitioner to whom the have been issued. The pharmacy, once each month, forwards copies of all triplicate prescription blanks to the Board office where they are coded for data processing.

IDAHO STATE BOARD OF PHARMACY
Suite 3 Imperial Plaza, 200 No. 3rd
Boise, Idaho 83702

Office Use Only
Receipt No.
Registration No.

APPLICATION FOR CONTROLLED SUBSTANCES REGISTRATION

NAME _____ Please type or print

ADDRESS: _____ Street Number

_____ City State Zip

( ) Pharmacist
( ) Practitioner _____ specify MD, DDS, DVM, etc.
FEE: $5.00
Professional License #
Federal Registry #
DUE: JULY 1

DATE OF APPLICATION _____ Signature of Applicant

CERTIFICATION OF EXEMPT OFFICIAL

(a) Name of Government _____ U.S., State, City, County

(b) Function:
( ) Purchase ( ) Administer ( ) Procure ( ) Dispense
( ) Research

Date Signature of Certifying Superior Title

WARNING: Chapter 27, Section 37-2717 I.C. states that any person who knowingly furnishes false or fraudulent information in this application is subject to imprisonment for not more than four years, a fine of not more than $30,000 or both.

IDAHO STATE BOARD OF PHARMACY
IDAHO BUREAU OF DRUG CONTROL
Suite 3 Imperial Plaza, 200 No. 3rd
Boise, Idaho 83702

Office Use Only
Receipt No.
Registration No.

APPLICATION FOR CONTROLLED SUBSTANCES REGISTRATION

NAME _____ Please type or print

ADDRESS: _____ Street Number

_____ City State Zip

_____ Signature of Applicant

( ) Manufacturer $50.00
( ) Distributor $25.00
( ) Analytical Lab $ 5.00
( ) Researcher $ 5.00
Date of Application
Fed. Registry #
State Registry #
DUE: July 1

CERTIFICATION OF EXEMPT OFFICIAL

(a) Name of Government _____ U.S., State, City, County

(b) Function:
( ) Purchase ( ) Adm. ( ) Analysis ( ) Research

Date Signature of Officer Title

WARNING: Chapter 27, Section 37-2717 I.C. states that any person who knowingly furnishes false or fraudulent information in this application is subject to imprisonment for not more than four years, a fine of not more than $30,000 or both.

Name _____ 221114

℞ Street City Date



Dr.

Take Both Copies to Pharmacist
Idaho Bureau of Drug Control
Reg. No.

Street
City

Mr. RECTOR. I think the Senator referred to the balloon concept today, you push it in one place and its pops out the other.

One reason for the production quota is it could have a prevention function in the sense that maybe some medicine cabinets would no longer be inordinately stocked with amphetamines. We all know quite often a child's introduction to drug abuse is through the family medicine cabinet and quite often it is jampacked with controlled substances and parents and others responsibility in the home are not all that attentive as to what is happening with regard to the medicine cabinet. We thought by cutting back on the production of amphetamines that introducdtion of a child to drug abuse could be nipped in the bud.

I would like to apologize again, as the Senator indicated, for the inconveniece today, and his inability to stay throughout the entire hearing.

I would appreciate receiving the various materials that we have mentioned and perhaps we will have some supplementary questions. Of course, if you have anything additional to offer for the record we will be more than happy to include it in the final printed volume on the hearings.

I would like to thank you again. The hearing is adjourned until further call of the Chair.

[Whereupon, at 2:45 p.m., the Committee was adjourned, subject to the call of the Chair.]

APPENDIX

Additional Statements and Articles supplied for the record

APPENDIX 1

[From the Congressional Record, Oct. 3, 1973]

PHARMACISTS FIGHT AGAINST DRUG ABUSE

Mr. BAYH. Mr. President, during my 3 ears as chairman of the Juvenile Delinquency Subcommittee, I have conducted an intesive investigation into the diversion, traffic and abuse of legitimately produced narcotic and nonnarcotic drugs.

Not drugs illicitly grown in Turkey and refined in France. Not drugs grown and refined in Asia's Golden Triangle. But dangerous drugs produced legitimately within our own borders.

We have found that far too many people hold to the traditional, but archiac "hard" drug—heroin cocaine—"soft" drug—produced for legitimate medical purposes—rationale. This unfortunate distinction has served to perpetuate the belief that so-called "soft" drugs, such as amphetamines, barbiturates and methaqualone, involve little risk to the abuser. As many subcommittee witnesses, particularly the former abusers, made abundantly clear, nothing could be further from the truth.

Casual attitudes, the failure of all concerned to put polydrug abuse in proper perspective—they outnumber heroin abusers 17 to 1—and a readily available supply are intimately linked with the current abuse and extent to which persons, particularly our youth, are becoming dependent on these drugs.

Diversion from legitimate channels occurs at all levels of distribution. This includes thefts, employee pilferage, unauthorized sales and in some instances excessive and even unlawful prescribing and dispensing. Quite often the feared and despised "pusher" is a family's own medicine cabinet.

Our earlier success withthe amphetamines, the recent decision on methaqualone and what I hope will be prompt action on the short-acting barbiturates are important steps in limiting the diversion of legitimately manufactured drugs to illicit purposes.

Yet before we truly "turn the corner on drug abuse" we must enlist the support of all concerned, from Federal officials to school teachers, from doctors to prosecutors, from drug companies to former addicts, to do their part to combat a major health and criminal problem reaching its tragic tenacles into all corners of American lift.

Pharmacists have a special role to fill in the battle against drug traffic and abuse.

As officials crack down on illegitimate drugs, abusers direct their efforts at the legitimate sources of abusable medicines, in particular pharmacies. During fiscal year 1973 thefts of controlled substances stolen from distribution channels rose by 15 percent—from 2,974 in the first half of the year to 3,408 in the second half. During the same year thefts from pharmacies rose from 57 percent of the total during the first half of the year to 77 percent during the second half. Night break-ins accounted for 70 percent of the total thefts reported, with armed robbery being the second most utilized method at 17 percent of the total.

A far less visible, but apparently equally important source of diversion is prescription fraud. Concern with the alleged ease with which prescription frauds can be perpetrated provided the impetus for the recent Bureau of Narcotics and Dangerous Drugs study "Project Script—A Study of Prescription Fraud Vulnerability." To acquire an estimate of the vulnerability, 256-prescription frauds were attempted over a 2-month period. The attempts were evenly divided among retail pharmacies and mail-order prescription firms. Among the variables involved were modes of fraud, drugs, geographic area, urban location, prescription volume and perpetrator dress mode. Detailed reports were made

by the trained criminal investigators who acted as fraud perpetrators. The results indicated that if a fraud perpetrator attempts common prescription fraud involving representative drugs from Controlled Substances Act schedules II through V, the retail pharmacy will honor the prescription 56 percent of the time.

Fraudulent prescriptions for schedule II methamphetamine tablets were honored significantly less than were the drugs in schedule III, IV, and V, but one has a fairly even chance of obtaining secobarbital—"reds"—and phenobarbital through a forged prescription or even by use of a bogus prescription. Few of these diversions are detected and reported as thefts.

Another common practice involves an abuser who visits numerous physicians and complains of the same relevant ailment. From each doctor, the abuser requests and receives a prescription. These prescriptions are then filled and refilled at numerous pharmacies. Thus the abuser or dealer is often able to obtain large quantities of prescription drugs without being detected or the diversion reported.

Pharmacists, indeed, have a special role to play in the fight against drug traffic and abuse. Through educational efforts they can help to promote the legitimate use of medicine which when abused presents a danger to the abuser and the community. Through efforts to self-police careless or unethical colleagues and physicians who are sources of diversions they can combat the illegitimate use of these drugs.

The September 1973 issue of Pharmacy Times entitled "The Pharmacists Drug Abuse Manual," reflects a commitment to fight against drug abuse and a recognition of the vital role that these practitioners can play in that fight. This type of voluntary effort is a credit to the professional and a service to the public. I recommend it to my colleagues and others concerned with drug abuse.

Mr. President. I ask unanimous consent for the text of Dr. Irving Rubin's editorial and accompanying advice for pharmacists, physicians, and patients to be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

[The material referred to follows:]

LET'S WIPE OUT THE ILLEGITIMATE USE OF DRUGS!

Today, drug abuse (with its crime-related side effects) is probably the nation's No. 1 problem. Unlike skyrocketing prices, you can't put a "freeze" on drug abuse in an attempt to solve its complexities.

And that's why the editors of PHARMACY TIMES are highly pleased that this issue is cosponsored by the U.S. Drug Enforcement Administration. This new federal agency is gathering momentum in its attack on the drug abuse problem. In doing so, DEA seeks the active help of the nation's pharamacists.

Essentially, the drug abuse problem entails the follow 2 areas:

(1) The illegitimate use of *legitimate* medicinal products;

(2) The illegitimate use of *illegitimate* drugs.

These 2 areas are related as follows: A drug abuse officials crack down on illegitimate drugs, abusers direct their efforts at the legitimate sources of abusable medicines—*pharmacies*.

As a pharmacist, you can help in *both* of these areas. To do so, admittedly, takes time. However, your help is *urgently* needed. Moreover, the illegitimate use of *any* drug *re-emphasizes* your responsibility to see to it that medicines are used *properly*.

This issue of Pharmacy Times provides the ammunition to help you help our nation in its battle against drug abuse. Won't you help—*now?*

IRVING RUBIN, R.Ph.,
Editor, Pharmacy Times.

TWENTY WAYS TO IMPROVE SECURITY IN YOUR PHARMACY

Improvement in the physical security of the community pharmacy occurs at several different levels. The cost and effectiveness of this security increase—as the means become more sophisticated. Some scurity methods can be as simple as eliminating the weak spots in physical security which invite illegal entry

(i.e., broken windows, door panels, or poor locks). Cluttered counters, aisles, and drug storage areas also invite the loss of drugs by customers pilferage. Caution in employee hiring practices can help to eliminate theft and illegal activities by unscrupulous personnel.

The pharmacist is encouraged to take those steps that are within his means to improve the security of his (or her) community pharmacy. He may receive additional help by contacting the nearest Regional Office of the Drug Enforcement Administration.

A GUIDE TO SECURITY

The following 20 methods are offered as a guide to help the community pharmacist improve the physical security of his establishment:

(1) Stock minimal quantities of controlled drug substances.

(2) Limit access to drug storage areas.

(3) Leave lights on within the pharmacy after hours. Light up the store exterior at night in order to discourage robberies.

(4) Provide windows and doors with intrusion detection devices (contact switches, electrical lacing).

(5) Install tamper-proof locks.

(6) Install silent (hold-up) alarms for use during operating hours.

(7) Install space protection alarm devices within the pharmacy—for use after operating hours.

(8) Install bars, break-resistant glazing materials, metal shields, metal gates, or screens over exterior openings.

(9) Connect the alarm systems to a central protective agency station by means of a supervised line.

(10) Alarm interior "party" or common walls (with an adjacent establishment).

(11) Use mirrors or closed circuit television for surveillance of aisles and drug storage areas.

(12) Practice proper control of the keys to the pharmacy.

(13) Don't accumulate large sums of money or large quantities of controlled substances.

(14) Request a police escort for after-hour prescription calls.

(15) Practice the "buddy system" at opening or closing times.

(16) Make sure that the pharmacy is free of customers *before* it is locked up at night.

(17) Be cautious of last-minute customers.

(18) Don't become a "soft touch" for dispensing questionable prescriptions.

(19) Don't resist an armed hold-up.

(20) Invite frequent police patrols of the area at irregular intervals.

TWELVE TIPS FOR PRESCRIBERS OF CONTROLLED DRUGS

(1) Keep your prescription blanks in a safe place where they can't be stolen easily. Minimize the number of Rx pads in use.

(2) Write Rxs for Schedule II drugs in ink or indelible pencil or use a typewriter. They must be *signed* by the physician.

(3) Write out the actual amount prescribed *in addition* to giving an arabic number or roman numeral—in order to discourage alterations in written prescriptions.

(4) Avoid writing prescriptions for large quantities of controlled drug products unless you *absolutely* determine that such quantities are necessary.

(5) Maintain only a minimum stock of controlled drugs in your medical bag.

(6) Take your medical bag with you when you're away from your automobile or lock it in the trunk.

(7) Be cautious when a patient tells you that another physician had been prescribing a controlled drug product for him. Consult the physician or the hospital records—or else examine the patient thoroughly and decide for yourself if a controlled drug product should be prescribed.

(8) Prescription blanks should only be used for writing prescriptions—and not for notes or memos. A drug abuser could easily erase the message, and use the blank to forge a prescription.

(9) Never sign Rx blanks in advance.

(10) Maintain an accurate record of controlled drug products you have dispensed—as required by the Controlled Substances Act of 1970 and its regulations. However, you may administer medication to a patient in the course of your normal professional practice without maintaining any record.

(11) Assist the pharmacist when he telephones you to verify information about a prescription you may have written. A corresponding responsibility rests with the pharmacist who dispenses the prescription.

(12) Phone the nearest office of the Drug Enforcement Administration to obtain or to furnish information. Your call will be held in the strictest confidence.

EIGHT IMPORTANT SUGGESTIONS FOR PATIENTS ABOUT PROPER DRUG USAGE

Patients should be advised to consult their family physician and pharmacist with respect to proper drug usage.

As a further help, here are 8 suggestions—directed at the patient.

Do not use anyone's prescription medication, except your own (i.e., those prescribed for you by your physician).

Do not haphazardly use or combine nonprescription drug products with prescription medications.

Store all medicines out of the reach of children—as a safety measure.

Do not again use prescription medication for a condition which you feel is similar to the one for which it was originally prescribed by your physician.

Take your prescription medication only as directed by your physician. It is just as important not to underdose yourself as it is not to overdose yourself.

Flush down the toilet all prescription medication not in current use.

Keep your prescription medication in its original container. Do not transfer it to other bottles or mix it together with other medications in one bottle.

Read the directions and precautions which accompany non-prescription products.

(Pharmacists can reprint or mimeograph these suggestions, and provide the informationto their patrons--as a professional and public service.)

[The preceding material is concluded.]

APPENDIX 2

[From the Congressional Record, Aug. 2, 1973]

By Mr. CHURCH:

S.2327. A bill relating to acquiring of certain narcotics by force, violence, or intimidation. Referred to the Committee on the Judiciary.

FEDERAL PENALTY FOR THE ROBBERY OR ATTEMPTED ROBBERY OF A CONTROLLED SUBSTANCE FROM A PHARMACY

Mr. CHURCH. Mr. President, on a January evening in 1972, Mr. Kent Dean, the owner-manager of Dean's Drug Center in Lewiston, Idaho, received a telephone call from a man who claimed that he was in need of some medicine for his sick child. Dean agreed to meet the man at his store, and Mrs. Dean and their two children accompanied him. When the alleged customer arrived, he was wearing a gas mask and carrying a brown paper bag containing a homemade bomb. It was not medicine for a sick child, but rather amphetamines and syringes he demanded. In the awful aftermath, a young Lewiston police officer lost his life, and two other officers were injured.

This tragic episode is not an isolated case in the files of drug store crimes. The increased use of narcotic drugs--coupled with the high cost of these drugs on the black market and the poor quality of the street product—have resulted in the rising incidence of drug store robberies. It is not uncommon now to learn of pharmacists wearing bullet-proof vests to work or hiring armed guards to police the premises. In an article that appeared in the Washington Post earlier this year, several pharmacists stated that they have reverted to keeping guns within easy reach, in addition to installing added alarm measures.

The increase in this type of burglary is frightening. Boston, Mass., reported 138 such robberies in 1972, with about 100 of the city's 208 pharmacies hit. Sixteen of 20 drugstores in Boston's Roxbury section have closed because of the high crime rate.

In Georgia, drug store robberies and burglaries are occurring at the rate of one a day. In 1968 there were not more than 10 robberies of this type, but in 1972 there were 312 and during the first three weeks of 1973, 26 were reported. In my own State of Idaho, the burglarizing of drug stores has reached unprecedented proportions.

The recognition of this problem leads me to introduce legislation which would impose a Federal penalty for the robbery or attempted robbery of a controlled substance from a pharmacy. My bill would provide for a maximum fine of $5,000 and/or 10 years imprisonment for persons acquiring drugs covered by the Controlled Substance Act from a pharmacy by force, violence, or intimidation.

In addition to serving as a tool for the crackdown on this type of crime, my bill would allow local law officers to enlist the aid of Federal authorities on drugs and to draw upon their expertise. I am hopeful that Congress will act favorably on this legislation before we witness the loss of other lives—and the eventual forced-closing of many more pharmacies across the Nation. The druggists and pharmacists are dedicated professionals who dispense the necessary medicines and drugs which, when used with proper precaution, save millions of lives each year. We should now offer them this added protection to insure that we are not deprived of their vital service.

Mr. President, I ask unanimous consent that the text of this bill, along with an article from the Lewiston Tribune, an article from the Washington Post, and a listing of recent Idaho pharmacy hold-ups compiled by the Idaho Board of Pharmacy, be printed at this point in the RECORD.

There being no objection, the bill and material were ordered to be printed in the RECORD, as follows:

[The material referred to follows:]

34-066 O - 74 - 15

S. 2327

"Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That chapter 103 of title 18, United States Code, is amended by adding at the end thereof the following new section:

"§2118. ROBBERY OF PHARMACY AND INCIDENTAL CRIMES.

"(a) Whoever, by force and violence, or by intimidation, takes or attempts to take, from the person or presence of another, any material, compound, mixture or preparation containing any quantity of a narcotic controlled substance set forth in a schedule of controlled substances under the Controlled Substances Act and belonging to, or in the care, custody, control, management, or possession of any pharmacists, shall be fined not more than $5,000 or imprisoned not more than ten years, or both.

"(b) Whoever takes and carries away, with intent to steal or purloin, any material, compound, mixture or preparation containing any quantity of a narcotic controlled substance set forth in a schedule of controlled substances under the Controlled Substances Act and belonging to, or in the care, custody, control, management, or possession of any pharmacists, shall be fined not more than $5,000 or imprisoned not more than five years, or both.

"(c) As used in this section, the term—

"(1) 'pharmacists' means any person registered in accordance with the Controlled Substances Act for the purpose of engaging in commercial activities involving the dispensing of any controlled substance to an ultimate user pursuant to the lawful order of a practitioner;

"(2) 'dispensing' shall have the same meaning as that provided under section 102 (10) of the Controlled Substances Act;

"(3) 'practitioner' shall have the same meaning as that provided under section 102 (20) of the Controlled Substances Act;

"(4) 'controlled substance' shall have the same meaning as that provided under section 102 (6) of the Controlled Substances Act."

SEC. 2. The section analysis of chapter 103 of title 18, United States Code, is amended by adding at the end thereof the following new item:

"2118. Robbery of pharmacy and incidental crimes.".

DRUGSTORE HOLDUPS UP SHARPLY IN UNITED STATES

(By Celia J. Doremus)

David Brothers says some of his fellow pharmacists wear bullet-proof vests to work.

"It's a tough way to run a business," he said.

Brothers, who owns the Blue Hill Pharmacy in Boston's orchestra section, was robbed of money or drugs eight times in the past year. He and two competitors on the same street have clipped into pay for armed guard on duty from 3 p.m. to 7 p.m.

"These robbers have never manhandled me," he said, "but I give them what they want."

Drugstore robberies have become an increasing problem in urban areas, across the nation. In many of these holdups, the objective is narcotics and other drugs.

Pharmacists, who are licensed to distribuate lifesaving drugs to the public, are rapidly becoming the targets of addicts and narcotics pushers, in cities from Boston to San Francisco.

"There is no question that theft and holdups are a serious problem in the Commonwealth of Massachusetts," said Romulus Denicola, secretary of the Massachusetts State Board of Pharmacy. He said persons who hold up drugstores "are either drug addicts or pushers, and they are a different type. They are desperate."

Boston reported 138 such robberies in 1972, with about 100 of the city's 203 pharmacies hit. At least 80 per cent of the robberies were for control substances (narcotics and dangerous drugs).

Several drugstores in Boston's Roxbury section are employing armed guards to keep open, Denicola said. "If the guards don't show up, the stores don't open."

He said that 16 out of 20 drugstores in Roxbury have closed because of the high crime rate. This "leaves that section devoid of adequate pharmaceutical accommodations," he added.

The story repeats around the country.

Atlanta's chief drug inspector, Joe Weldy, said drugstore robberies and burglaries in Georgia, the Southeast pharmacy distribution center, occur at a rate of one a day. He said in 1968 there were not more than 10 robberies of this type, but in 1972 there were 312 and during the first three weeks of 1973, 26 were reported.

In cities such as Pittsburgh and Los Angeles, drugstores have gone out of business because of the rash of holdups.

And in many cities druggists are using a variety of devices to protect themselves and their stores—with differing results.

San Francisco pharmacist David Bonelli, 53, has double-barred doors, cross bars on the vents, a wire screen over the window, a new safe and a sonic alarm system. However, last Dec 7, someone poked through a side wall and escaped without touching off the alarm.

In Pittsburgh, Robert Botser, owner of a pharmacy in the Carrick-Brentwood area, said he locks most of his narcotics in a safe and in drawers in the store.

At the University Pharmacy in Spokane, Wash., all the drugs are locked up and a security agency handles safekeeping. One clerk said, "There is no way in—unless they want to blow up the sides of the building."

Ken Schaefer, manager of Cosmopolitan Drug Store in Chicago, said, "We limit the quantities of narcotics on hand so we are never a really big and attractive target.

"There are so many different types of drugs and so many buyers for them that it is impossible to operate a store and keep the drugs somewhere else, like at a police station.

"There are three druggists under me and each is armed with a .38 pistol. I carry a .38 and another smaller gun.

"We are all psychologically prepared to use them because drug addicts run rampant around here. We also have a good alarm system, but no matter what you do, when they want what you've got, they're going to find a way to get it."

In Spokane, Paul Picket, manager of East Mission Pharmacy, keeps a hand gun in his desk drawer.

"Ive got this place wired in pretty good," Picket said. He said his store has not been robbed since he installed a burglar alarm. "They have hit all around us since I put in my system."

Robert Pattison, 57, a pharmacist near the low-income Fillmore district of San Francisco, has been robbed twice and is dubious about guns.

"I expect to be held up again," he said, "and I don't know of any form of real protection. If you use a pistol, I doubt if you will come out alive."

Dave Cohen, owner of the West Bridgewater Pharmacy in West Bridgewater, Mass., said the answer is not alarms. He said the problem is with the judicial system.

"The police are disgusted because they bring these cases in and some are even thrown out of court," Cohen said.

Many druggists agreed the courts are merely "giving the offender a slap on the wrist and saying go home and be a good boy."

In Chicago, druggist Schaefer said the federal Food and Drug Administration should be stronger in the drug fight.

"City police here are ill-equipped to do the job. What they need is officers who know more about drugs. Police often come in here with tablets they've found on a suspect and they don't know what they've got."

Albert Sherman, president of the Boston Association of Retail Druggists, had a different iden about the police.

"We have received remarkable cooperation from the city and state police regarding the problem of drugstore robberies," he said.

Sherman, who owns the Charles River Pharmacy in Boston, said the association was responsible for instituting the Boston police department drugstore surveillance square last March, which minimized the increasing holdup problem in Boston.

"The problem still exists but the police cannot be everywhere," Sherman said. "As long as the quality of narcotics on the streets is poor, the junkies will continue to turn to the drugstores for drugs."

Court Told Bomb-Carrier's Note Demanded Drugs, Vials, Syringes

(By Jack Marshall)

A 26-year-old Lewiston man was bound over to Second District Court by Magistrate Eli B. Ponack yesterday after a preliminary hearing on a charge of first-degree murder in the bomb death of a Lewiston policeman last Thursday.

Fred W. Hokenson, 2029 Powers Ave., sat silently with no visible signs of emotion as four witnesses called by Nez Perce County Prosecutor Roy E. Mosman recalled events leading up to the bomb blast at Dean's Drug Center, 1624 Main St., which killed Ross D. Flavel during an alleged robbery attempt.

NOTES FOUND

Kent Dean, owner-manager of the drug store, testified that two notes were presented during the alleged robbery attempt and had gone unnoticed until Friday morning when Lewiston police and a team of Federal Bureau of Investigation and Tobacco, Tax and Firearms agents began a detailed investigation.

Dean said that on Friday morning he returned to the store, which had been boarded up during the night because many of the windows and glass doors had been shattered by the blast, and found the notes. "One of the notes was laying on a pop cooler and the other was on the floor directly beneath it," he said.

On one note Dean recalled scratchy printing which he said read, as near as he could recall, "Give me all your amphetamines, meth-amphetamines, methadone, vials, some syringes and all your money." The other note read "Don't try anything. I've got a bomb and my partner has your family. Don't try to be a hero."

Mosman said the notes have been sent to the FBI laboratory at Washington, D.C., for fingerprint checks.

Mrs. Dean testified she was behind the drug counter and first noticed the intruder when he appeared behind a pop machine to the right of the pharmacy counter. She said he was wearing a gas mask and holding a brown paper sack under his right arm with his hand clutched over it. He said, "Don't anyone move and no one will get hurt. I have a bomb," she testified.

At that point, she said, her husband, who had been sitting in a chair in front of the drug counter "rushed toward the man and put his arms around him." They strugled and Dean pulled and pushed the man toward the rear door, she said.

During the struggle, Dean told her to call the police and to get a gun he kept in the pharmacy. She said she called the operator to get the police and watched the struggle by leaning out over the counter. She also looked for the revolver, but could not find it right away, she said.

Dean told her it was behind a pediatrician's reference book and she found it.

"I then went to the back of the store where I could see three arms and hands sticking out with a knife in one of them," Mrs. Dean said. "I asked who had the knife. Kent said, 'I do.' I had the revolver cocked and let the hammer down then."

The police arrived in about two minutes, she said: "I stepped over the man's feet (who was pinned to the floor by Dean in front of the rear exit) and opened the door for the officer." She said Flavel then arrived and she let him in.

Mosman then asked about the contents of the paper bag.

"I saw what looked like an Eveready battery," Mrs. Dean said. "It was red and blue anyway like they are. It had two terminals on top. I saw three cylinders in the sack that I thought in my mind to be sticks of dynamite."

Hokenson sat at the defense table with his court-appointed attorney, Owen L. Knowlton, and Manderson Miles, a University of Idaho law student from Oklahoma City, Okla.

She said Flavel went to the sack. At about that time, she said, the man on the floor said, "You only have 30 seconds. I set the fuse."

"Flavel went over, bent down and picked up the sack and turned slightly. He said something that I didn't completely hear and the word bomb. I turned and ran for my children.

Mosman asked what happened next.

She said, "It went off—There was an explosion."

Mosman then called Lewiston patrolman Thomas E. Saleen who had a small scratch above his left eye, showing evidence of the injuries he received during the explosion.

Saleen said he was standing at the window of Flavel's patrol car at 14th and Main Sts. when the call from the dispatcher about the robbery attempt was received. He said Flavel responded to the call and that he ran to his patrol car, which was parked nearby, and left for the scene.

He said he drove his car up on the sidewalk in front of Bullwinkle's, a tavern next to Dean's Drug, and peered through the front window at the drug store for two or three minutes.

"I could see someone through the window and I tapped on the window," he testified. "Mrs. Dean let me in. She had a revolver and I asked if it was involved in the robbery attempt. She said that it was hers," he said.

Saleen said he went to the back of the store and saw someone with something over his head lying on the floor. Flavel and Dean were struggling with the man. Saleen helped put handcuffs on him.

He said he recalled telling Flavel to get the patrol car and back it to the back door of the store, "I had a knee on the back of the subject's neck, holding him down," he said. "I looked for Mr. Dean. He was by the prescription counter. I called him over and asked him some questions about what had happened." He said Dean mentioned something about a bomb.

SAYS JOKE MENTIONED

"The subject said something about it was a joke, there wasn't any bomb, the joke was on us," Saleen said. "Then Ross (Flavel) returned."

"Dean pointed out the paper sack," Saleen said. "Flavel jumped around to the sack and bent over it. He lifted up a corner of the sack. I could see wiring and some sticks of dynamite. He started to pull wires out of the sack. I told him not to do it because it might explode."

Saleen said the subject on the floor said, "It wouldn't do any good now. I set the time delay."

"I jumped up and started dragging the subject out the door," Saleen said. The bomb exploded.

Mosman asked Saleen what he experienced during the blast.

"I felt myself fly through the air. I hit the floor east of where I was standing," he said. "I was at the back of the store when officer Whittington arrived."

Lewiston police Cpl. Henry Whittington was next on the stand. He testified he was blown down as he approached the rear door and that he saw Saleen stagger from the smoke and radioed for an ambulance and assistance. He said he returned to the store and went in to search for Flavel. Upon entering the store, he said, he saw a man lying about three to five feet inside, wearing a gas mask.

Mosman asked Whittington if the man was in the court room.

Whittington pointed to Hokenson.

Whittington said he continued to look for Flavel and found him 10 to 15 feet from the rear door.

Mosman asked about the condition of Flavel. Whitting answered, "Badly multilated."

Whittingtor said both legs were gone and his left arm appeared to be gone—he indicated the part from the forearm down. He said he had no way of knowing whether Flavel was alive at the time. He said he believed him to be dead.

List of Recent Idaho Pharmacy Hold-ups

July, 1970. Rockland Pharmacy. Break-in. Took entire stock of Amphetamines.

August, 1970. Lorton Drug Store, Cambridge. Large amount of controlled substances, two typewriters, a television set, money, cigarettes.

September, 1970. Bi-Rite Drug, Sandpoint. Break-in. B & O Superettes (1 gr. Opium), Demerol, etc. was taken.

November, 1970. Dixon's Drug Store, Rathdrum. Night break-in. Taken: large quantity of Phenobarbital, Nembutal, Seconal, Darvon and other drugs.

March, 1971. Hy-Way Drug in Idaho Falls. Entry was made via the roof. Taken was a large quantity of Seconal, Desoxyn, Dexamyl, Desbutal and Dexedrine.

April 12, 1971. Seely Super Thrift. Parma. Night burglary. Taken a large quantity of Cocaine Hydrochloride, Dolophine, Morphine Sulfate, and Numorphan.

April 19, 1971. Owl Drive In, Lewiston. Night break-in. Taken: Eskatrol.

April 18, 1971. Katz Pharmacy, Idaho Falls. Night break-in. Taken was Nembutal, Seconal, Desbutal, Dezerex, Desoxyn, Dicumeral and Diamax.

May 4, 1971. Red Cross Pharmacy, Kendrick. Taken: Demoral, APC w/Demerol, Codeine Phosphate,Dolophine, Leritine, Mepergan, Tethadone, Morphine Sulfate, Numorphan, Opium Tinc., Percodan and Perc. Demi.

May 11, 1971. Osco Drug, Pocatello, Taken: large quantity of Biphetamines, Desoxyn, Dexampyl, Dexedrine, Doriden, Nembutal, Ritalin, Tuinal, Seconal and other drugs.

May 10, 1971. Perkin's Pharmacy, Lewiston. No drugs, just money.

April 23, 1971. Ketchum Drug, Ketchum. Burglar hid in store until after closing. A quantity of narcotics and other drugs were stolen as well as empty gelatin capsules, syringes and needles.

June 3, 1971. Owl Drug, Lewiston. Large quantity of Dexedrine.

June 5, 1971. Skaggs Drug Center, Nampa, Dilaudid taken.

June 5, 1971. Red Cross Pharmacy, Kendick, Darvon, Phenobarbital and TH&C taken.

June 14 and June 17. ISU College of Pharmacy. Large quantity of stimulant and depressant drugs taken in these two burglaries.

June 12, 1971, Super-Save Drugs, Pocatello. Early morning break-in. Taken: Desbutal and Desoxyn.

June 25, 1971. Super-Save, Pocatello. Taken: Desbutal and Desoxyn.

August, 1971. Owl Drug, Lewiston, Night break-in. Taken: Dexedrine, Dexamyl.

August 21, 1971. Arnell Pharmaceutical Center, Blackfoot. Large quantity of Demerol, Desarex, Desbutal, Desoxyn, Dexedrine, Nembutal, Placidyl, Ritalin and Tuinal.

September 1, 1971. Arnell Pharm. Center, Blackfoot. Large quantity of Demerol, Desarex, Desbutal, Desoxyn, Dexedrine, Numbutal, Placidyl, Ritalin and Tuinal.

October 14, 1971. Armed robbery. Sherman Drug, Coeur d'Alene. Pharmacist forced to give robber large quantity of Dexedrine and Biphetamines.

October 25, 1971. Owl Drug Drive In, Lewiston. Night break-in. Taken: quantity of Emperin Compound #1, #2, #3, #4.

November 1971. White Pine Pharmacy, Potlatch. don't have a list of stolen drugs.

November 5, 1971. Rockland Pharmacy, American Falls. Taken, entire stock of Amphetamines.

December 7, 1971. Irwin Drug, Grangeville. no drugs taken. just money.

December 30, 1971. Sav Mor Drug, Twin Falls Taken: Desbutal, Desoxyn, Nembutal.

December 30, 1971. Johnson Sav On Drug, Twin Falls. Taken: Quantity of Nembutal, Desoxyn, Desbutal.

December 30, 1971. Don Wilson Skyline Drug, Idaho Falls. Quantity of Dexedrine, Dexamyl and Desoxyn and Nembutal taken.

January, 1972. Rockland Pharmacy, American Falls. Entry gained through front door. Taken was disposable syringes and needles and some controlled substances. Woman thief apprehended.

January 4, 1972. Crowley Pharmacy, Twin Falls. Quantity of Nembutal taken.

January 4, 1972. Johnson Sav On Drug, Twin Falls, 800 Ritalin tabs.

January 29, 1972.. Halliwell Drug, Pocatello. Taken: 1100 Carbrital FS.

February 8, 1972. Magic Valley Drug, Inc., Twin Falls. Quantity of Desbutal and Desoxyn taken.

March 19, 1972. Osco Drug, Twin Falls. Taken: Large quantity of Desbutal and Desoxyn.

March 23, 1972. Don Wilson Skyline Drug, Idaho Falls. Quantity of Mebaral, Nembutal, Phenobarital, Bontril and Benadryl.

April 7, 1972. The Prescription Shop, Couer d'Alene. Large quantity of controlled substances taken: Dolophine, Pehaphen, Morphine Sulfate, Codeine, Demerol, etc.

April 14, 1972. White Pine Drug, Potlatch. Night burglary. Taken: Benzedrine, Amphetamine, Dexamyl, Demerol, Dexedrine, Eskabarb, Obedrin.

June, 1972. White Pine Pharmacy, Potlatch. Attempted burglary.

August, 1972. White Pine Pharmacy. Potlatch. Another attempted burglary.

August, 1972. Maag Prescription Center, Pocatello. Night break-in. Taken: Phenobarbital, Nembutal, Tuinal, needles and other drugs.

September, 1972. Owl Tri State Drug, Lewiston. $600 worth of drugs. No list.

October, 1972. Halliwell Drug Co. Pocatello. Break-in burglary. No list.

October 19, 1972. Cook Drug, Pocatello. Forced entry from adjoining building. Taken: Ritalin, Nembutal, Morphine Sulfate, Desoxyn, Dexedrine, Dilaudid.

January, 1973. McCreery Drug, Jerome. Night break-in. Very large quantity of controlled substances taken: Nembutal, Equanil, Darvon, Phenaphen w/Codeine, Carbrital, Cocaine, Demerol, Meperegan, Percobarb, Morphine Sulfate, Perc. Dimi, Biphetamines, Dextro-ampetamines.

January 7, 1973. Dixon's Drug, Rathdrum. Taken: Dexamyl, Ritalin, Eskatrol, Leritine, Obedrin-LA, Percodan, Biphetamines, Preludin, syringes and needles.

January, 1973. Rod's Drug, Orofino. 2500 pills. (not known what).

January 29, 1973. Kamiah, Drug, Kamiah. Opium, Tinc. Opium, Tuinal, Seconal, springes and needles taken.

February 10, 1973. Amos Idaho Drug, Boise. Davron and other drugs taken.

July 21, 1973. Halliwell Drug Company, Pocatello. Large quantity of Desarex, Desbutal, Desoxyn, Dexendrine, Morphine, Ritalin, Nembutal, and other drugs taken. Night break-in.

APPENDIX 3

DEPARTMENT OF JUSTICE,
Washington, D.C., December 17, 1973.

HON. JAMES O. EASTLAND,
Chairman, Committee on the Judiciary,
U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to your request for the views of the Department of Justice on S. 2327, a bill to amend Chapter 103 of title 18 of the United States Code by adding a new section "relating to acquirnig of certain narcotics by force, violence or intimidation."

The bill would amend Chapter 103 of title 18 of the United States Code by adding a new Section 2118 thereby creating a new Federal violation by making it a Federal offense to rob or attempt to rob any person of a narcotic drug belonging to or under the care of a registered pharmacist. The penalty for such a violation would be not more than 10 years imprisonment and/or a fine of not more than $5,000. In addition, the proposed legislation would make it a Federal offense to steal narcotic drugs belonging to or under the care of a registered pharmacist. The penalty for the theft of narcotic drugs would be not more than 5 years imprisonment and/or a fine of not more than $5,000. The proposed legislation places no monetary restriction on the value of narcotic drugs taken and would require no proof of interstate travel to commit the offense or to transport the drugs after they are taken.

This legislation would require Federal responsibility in an area which traditionally has been considred a State and local police function. In this respect providing collateral jurisdiction to Federal law enforcement officers in this area could encourage local police organizations to abdicate their law enforcement responsibilities at a time when the Government has been attempting to de-emphasize Federal involvement in local matters.

Although Federal involvement in this area would help solve some pharmacy robberies and thefts and perhaps contribute some deterrence value, there is little reason to believe that Federal officers could handle such investigations more effectively than State and local police organizations. The success of stopping offenses of this type and apprehending violators depends on the capacity of the police to respond quickly to either capture the violators in the commission of the offense or in locating witnesses before they leave the scene. Since Federal law enforcement agencies have limited manpower and do not have the facilities to respond immediately to offenses of this type, we believe it would be best for the States to retain full jurisdiction.

We should add too, that the legislation would require considerable increases in Federal law enforcement personnel. In fiscal year 1973, there were reported to the Drug Enforcement Administration 4,410 nighttime break-ins, 1,057 robberies, 221 employee thefts, 108 pilferages, and 588 miscellaneous theft-type losses from pharmacies in the United States. The Drug Enforcement Administration estimates that it would require approximately 15 agent man-days to fully investigate the average pharmacy robbery and at least 5 agent man-days to investigate the other type of criminal offenses resulting in loss of narcotic drugs from pharmacies. Based on these figures, the proposed legislation would require the employment and training of an additional force of approximately 176 law enforcement officers and supporting personnel at an annual estimated cost of $4,800,000.

The Department, therefore, recommends against enactment of the bill.

The Office of Management and Budget has advised that there is no objection to the submission of this report from the standpoint of the Administration's program.

Sincerely,

PATRICK M. MCSWEENEY,
Acting Assistant Attorney General.

APPENDIX 4

STATEMENT OF THE AMERICAN ASSOCIATION OF COLLEGES OF PHARMACY

(Submitted by Charles W. Bliven, Executive Secretary—April 12, 1974)

The American Association of Colleges of Pharmacy is the only educational organization representing the nation's 73 accredited colleges and schools of pharmacy. The schools employ approximately 2500 full-time and part-time faculty members to teach more than 28,700 students.

The Association is pleased to submit this statement in reply to your request letter of March 8. Because the Association does not normally compile or maintain information which would specifically answer the ten questions submitted in your letter, several faculty members who are known for their expertise in drug abuse matters were consulted in the preparation of this statement. The faculty members consulted were: E. Roy Hammarlund, Ph.D.; Professor of Pharmacy, University of Washington; Marc G. Kurzman, J.D., Assistant Professor and Assistant Director, Drug Information and Education Program, University of Minnesota; George R. Spratto, Ph.D., Associate Professor of Pharmacology, Purdue University; and Melvin R. Weinswig, Ph.D., Associate Dean and Professor of Pharmacy, University of Wisconsin.

Replies from these faculty members indicated that answers to the ten questions were largely matters of opinion inasmuch as pharmacy schools do not maintain data files on drug-related crimes. Several suggestions were made which may be of assistance to the Subcommittee in assessing the Comprehensive Drug Abuse Prevention and Control Act of 1970, and the statement comments on these suggestions.

The educational activities of pharmacy schools have included significant emphasis on drug abuse prevention, both in the control of drugs by the pharmacists and in the education of the public on the use of drugs. Examples of the drug abuse educational activities carried on by pharmacy schools are available in a report prepared by the Association for the Drug Enforcement Administration. A copy of the report, "Drug Abuse Education in Pharmacy Schools" is attached.[1]

The Association would emphasize the need for Federal support and participation in programs to maintain the pharmacists' knowledge of drug abuse control and drug abuse prevention regulations and educational techniques. The newly formed 15-member Controlled Substances Advisory Committee at the Food and Drug Administration should provide some improvement in the dialogue between pharmacists and the regulatory system. The progress of this Committee should be watched carefully by the Subcommittee. Prevention and education efforts in pharmacy schools deserve additional support from the National Institute of Drug Abuse and other Federal agencies.

The Association suggests that the Subcommittee encourage the development of programs which will provide a broader interface between patients and pharmacists. Abuse of drugs and the diversion of drugs is only a part of the problems related to drugs. The faculty consultants believe that the impact from the misuse of drugs is probably greater than the impact from drug abuse or crimes directed at pharmacists. The common impact factors and the interrelation between misuse and crime should be the subject of Federally supporter research.

The Association believes that greater patient contact in which pharmacists provide more drug use information will, in the long run, affect the drug abuse problem.

Professional organizations and State licensing organizations should be encouraged to enforce firmly State laws and regulations. In addition to this

[1] This report may be found in the files of the Subcommittee to Investigate Juvenile Delinquency.

activity, our faculty consultants have suggested establishment of local controlled substances review boards. These would consist of physicians, pharmacists and others who handle controlled drugs, meeting periodically to review anonymous reports from their peers concerning any irregular prescribing or dispensing of controlled drugs. Drug utilization reviews will eventually be an activity of the Professional Service Review Organization which is now being established by the Department of Health, Education and Welfare. The anonymous reporting feature and the fact that these review boards would be made up of health professionals who know one another may assist tremendously in the elimination of improper or illegal drug distribution.

One Association consultant has suggested that less conspicuous identification of controlled substances would increase the burglars' difficulty in identifying these controlled products.

The Association appreciates this opportunity to submit this statement. The officers and staff stand ready to be of further service to Chairman Bayh and the members of the Subcommittee.

APPENDIX 5

NEBRASKA PHARMACEUTICAL ASS'N, INC.
Lincoln, Nebr., March 27, 1974.

Hon. BIRCH BAYH,
Chairman,
Subcommittee on Juvenile Delinquency,
Senate Judiciary Committee,
Washington, D.C.

DEAR SENATOR BAYH: This Association wishes to offer several comments to the Subcommittee concerning the Controlled Substances Act. We welcome the opportunity to do so.

Rex C. Higley, R.P., Chief of Nebraska's Bureau of Examining Boards, testified before your Bayh-Hruska hearing in Omaha concerning Methadone. Mr. Higley is probably the most knowledgeable of the pharmacists in the State concerning Pharmacy laws, since enforcement is his responsibility.

It is his belief that the exemption of the physician from keeping as stringent records as the pharmacists must is a mistake. We recognize that the dispensing physician must keep records—but why are all physicians not accountable for their shots and disposition of Controlled Substances?

Mr. Higley's other comment about the Controlled Substance Act is that he sees no reason or circumstance where a mail-order house should be mailing Schedule II Controlled Substances. These are emergency medications for pain. If any patient has a pain problem, the matter should be handled in the local pharmacy.

What possible explanation can there be when a man has a prescription for pain medication for him to mail it to a Veterans Hospital or some mail-order house in Washington, D.C., or Madrid, Iowa, and wait ten days for the prescription to arrive.

I am not being facetious about delivery time. A letter I mailed to Omaha on March 6 had not arrived on March 16, and I do not know if it has yet been delivered. We finally gave up and made a duplicate.

This need for all physicians to be required to keep careful records and the elimination of mailing Scheduled II Controlled Substances are the two needs we see at the present time.

Respectfully,

CORA MAE BRIGGS, *Executive Secretary.*

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APPENDIX 6

TENNESSEE PHARMACEUTICAL ASSOCIATION,

Nashville, Tenn., April 4, 1974.

HON. BIRCH BAYH,
U.S. Senate,
Washington, D.C.

DEAR SENATOR BAYH: On behalf of the pharmacists of Tennessee, may I thank you for your interest in the current problems in the implemention of the Comprehensive Drug Abuse Prevention and Control Act of 1970. The hearings held last week and attended by pharmacists from throughout the country will certainly be beneficial in the consideration of these problems.

Tennessee pharmacists are most interested in legislation that would make crimes of violence involving controlled substances subject to Federal jurisdiction. S-2327 sponsored by Senator Church and HR-9299 sponsored by Representative Jones of Tennessee are most important to all of us. We would hope that the hearings of your subcommittee will result in a favorable endorsement of this legislation.

For the file of your subcommittee, I am enclosing an account of the very harrowing experience of Mr. Wayne Beam of Tullahoma with a would be burglar. The fact that this man followed him to his home and threatened not only his life, but the lives of his children makes the need of such legislation even more important. Also, enclosed for your subcommittee's consideration are a few sheets of clippings of both burglaries and armed robberies that have occurred in Tennessee since January 1974. Now that illicit supplies of the drugs are being curtailed the criminals are moving even more to the rural areas of our state. While local and state law enforcement officers do their best to apprehend the criminals and pharmacists are installing protective devices, the crime rate is ever increasing as the clippings and Mr. Beam's statement attest. Pharmacists in the metropolitan areas have curtailed pharmacy hours and in many of the inner city areas actually have armed guards on duty in the afternoon and evening hours.

We all realize that this legislation will not suppress all of this activity, but it will provide some very much needed assistance from Federal law enforcement officials that presently is not available. As Mr. William Woods of the N.A.R.D. stated at the hearing, the Congress has specifically provided that a person who manufacturers, distributes, dispenses or passes a controlled substance with the intent to distribute it, is subject to the Federal penalties while one who obtains the drugs by violence in a pharmacy is seemingly of no Federal concern. Just as financial institutions who are controlled by the Federal Government have been given some Federal protection, it would appear that pharmacists who are also under just as strict control also need more protection.

May I thank you again for your interest in this problem, and we will be most happy to assist you in any manner in the implementation of this legislation.

Sincerely,

TOM C. SHARP, JR.,
Executive Secretary.

Enclosures.

TULLAHOMA DRUG STORES,
Tullahoma, Tenn.

For the past thirteen years, I have practiced pharmacy in Tullahoma, Tennessee, a community of 15,000 people.

In late November, I closed my store at 8 PM as usual and drove to my home in the city limits of Tullahoma. When I arrived home, my wife was leaving to see a friend. About 10 minutes later, the door bell rang. (I have a door bell on the front, patio, and garage doors.) My daughter, Deborah, who is 14 years old,

went to answer the front door. Finding no one there, she went to the garage door. I was sitting in the den at this time. When she started to the garage door, I got up to follow her since our garage door is seldom used by anyone visiting our home. Deborah opened the garage door after turning on the garage lights and found herself facing a young teenage boy in a ski mask and holding a gun on her. He immediately commanded her to turn off the garage lights. When she paused, he reached into the hall and threw the light switch himself. By this time, I had reached the hallway and could see Deborah standing in the doorway with the garage lights off. When I reached the doorway, I turned on the garage lights again. When I found myself facing the robber with a gun in his hand, I immediately pushed my daughter and 12 year old son out of the doorway. The young man was standing two steps below me in the garage, in the light, since I had turned the lights on again. He first demanded that I turn the lights off. After I had obeyed, he asked for all the money I had brought home from the drug store. He was very excited and seemed nervous as his gun hand was shaking violently. The gun he had was a "Saturday Night Special", 25 Cal. Automatic. His hand was shaking so bad I was afraid the gun would go off accidentally. When I told him I had locked the days receipts in the safe at the store and that I never brought money home from the store, he demanded all the drugs I might have in the house. By this time, I could tell the robber wanted to get out of my garage because he kept looking over his shoulder outside the garage into the darkness. I assumed he had friends waiting on him outside. I told him the only drugs in my house were medicine for my family and that I never kept narcotic drugs at home; that they were also in the safe at the store and that the safe was wired to the police station and would set off an alarm if opened before 8 AM the next day.

By this time, I was feeling more confident and told him he had made a bad mistake by coming to my home and scaring my family and that I would appreciate it very much if he would leave my garage and go on his way. At this time, the robber left the garage.

Even with the descriptions given by myself, my daughter, and my son, the robber was never caught.

I consider myself and my family being very lucky, if the robber had had more experience or if he had used one of my children as a hostage, he could have demanded anything he wanted and would have gotten it. At this time, there had been 33 break-in's in our county into drug stores, doctors' offices, and related places in one month's time.

Respectfully yours,

WAYNE W. BEAM, R.PH.

APPENDIX 7

UNITED MINE WORKERS OF AMERICA,
WELFARE AND RETIREMENT FUND,
Washington, D.C., April 25, 1974.

Hon. BIRCH BAYH,
U.S. Senate,
Old Senate Office Building,
Washington, D.C.

DEAR SENATOR BAYH: Last October 31, we wrote to you evidencing our concerns relative to further restrictive legislation and regulations as to the Controlled Substance Act.

At that time, we informed you of our concern over the activities of a national association of retail druggists (independent drug store owners) that was urging the Committee to adopt an amendment for the Controlled Substance Act (CSA) that would prohibit the distribution and dispensing of any controlled substance prescription through the mails.

Before expressing our position on specific issues that, no doubt, will come before your Senate Subcommittee to Investigate Juvenile Delinquency and its concern over controlled drug legislation, I would like first to present some background material relative to the United Mine Workers Welfare and Retirement Fund and its drug program.

The significant features of the medical care program as it relates to prescription drugs are:

1. The Fund, in existence since 1946, currently serves over 500,000 beneficiaries (miners and their dependents, widows and pensioners).

2. Only drugs of a "maintenance" nature are covered by Fund payment and these are prescribed for long-term or chronic illnesses.

3. While the Fund does use carefully selected community, clinic and hospital pharmacies for the dispensing of medications, a good portion of the pharmacy service is provided by selected "mail-out" pharmacist vendors to beneficiaries in *Indiana, Pennsylvania, West Virginia, Kentucky, Illinois, Missouri and numerous* western states. Many of these vendors are hospitals and clinics as well as community (independent and chain) pharmacies.

4. When "mail-out" pharmacist vendors are utilized, the prescription order of the physician is not, as it customary, given to the patient, but rather is sent by the prescriber, either directly or thru one of our Regional Offices to a designated pharmacy. The physician prescribing must be one on the Fund's list of approved participating physicians. In most instances, the selected pharmacist vendors maintain patient-monitoring of drug usage. Also, at least four pharmacies now use computerized records. These records are most useful for such monitoring purposes as detecting possible duplicate prescription orders, drug interactions, "over" and "under" drug utilization by patients, and in reviewing the prescribing habits of participating physicians. This type of operation, we are certain, because of the built-in controls, is not the type of activity which is cause of concern by your committee as to the diversion problem. Obviously, the effect of any restrictive regulation against a mail-out prescription service would create a severe hardship on our beneficiaries.

It would be almost impossible for us to provide prescription service for our beneficiaries without the "mail-out" part of the program. The biggest users of "maintenance" drugs are the aged and chronically ill, and, therefore, are individuals most likely to have low incomes. Others, as I previously indicated to you, reside in remote rural areas where it is not economically feasible for a pharmacist to locate. In this situation, beneficiaries often cannot afford the cost of transportation to the nearest pharmacy without such a trip making a major dent in an already meager income.

Obviously, because of the above, we must object to any amendment to the Controlled Substance Act that would further hinder the providing of medical care to Fund beneficiaries as would be a prohibition of the mailing of prescriptions or a restriction on the ordinary prescribing patterns of the physician for his chronically ill patients.

We would point out that this type of "mail-out" prescription delivery service have been estimated by HEW[1] at over 17 million prescriptions annually and encompasses such programs as the V.A. Home Pharmacy Program, the AARP-NART prescription programs and others as well as ours, which has been in effect many years.

As to the "specifics" of the present DEA requirements of special concern to us:

1. We object to the recent transfer to Schedule II of hypnotics, sedatives and tranquilizer drugs in that prescription orders for such medications can now no longer be refilled as in the past (up to 5 times within a six month period). We respectfully suggest that the public would be better served by returning these drugs to Schedule III or that these drugs be isolated from narcotics Schedule II drugs as a separate grouping, and "refills" authorized on the "up to 5 times within six month basis" if so indicated by the prescriber.

To force the geriatric and chronically ill patient to return to his physician for a new prescription order each time, in our opinion, is unnecessary and a waste not only of expensive pharmacist's time but also the time of the busy physician who normally, in most instances, does not wish to see such patients more than once every four to six months once the patient's condition has been stabilized such as with cardiacs and hypertensives, arthritics, etc. We feel that such a change would in no way increase the "diversion problem" and would decrease patient inconvenience and costs to the payor regardless of whether he is the patient or a third party payor.

While the problem of diversion, we believe, is nonexistent in our program, because of the fact that the physicians send their prescription orders directly to selected pharmacists or to our Regional Offices, where, in both instances, they are checked as to participating physicians and eligible beneficiaries, we would have no objection to the use of a triplicate prescription order form for the use of physicians for Schedule II narcotic drugs. The advantages to DEA and FDA of such a form, as you know, are many, such as the pinpointing of prescribing practices, drug utilization rate, "over" and "under" drug utilization by patients and the detection of "physician shoppers". It is our understanding that at least one state uses such triplicate forms—(Illinois).

We respectfully bring these matters to the attention of your Subcommittee knowing of the Committee's deep interest in this problem and in the health of the chronically ill including the geriatric and chronically ill patients such as are many of our beneficiaries who reside in remote areas or for other reasons must of necessity resort to "mail-out" drug service programs.

We appreciate greatly this opportunity to once again present our concerns to you and your Committee. We would be pleased to testify if your Committee so desires.

Sincerely,

JOHN NEWDORP, M.D.,
Executive Medical Officer.

[1] See U.S.P.H.S.—Health Service Reports, Nov. 1973, Vol. 88, No. 9 (copy attached).

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U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service

The Mail-Order Prescription Drug Industry

ALBERT I. WERTHEIMER, PhD, and JAMES E. KNOBEN, PharmD

"The mail-order prescription drug industry appears to serve a real purpose by supplying the prescribed drug needs of patients who may be invalids, lack transportation, be isolated, or be in need of price savings otherwise unavailable. Further, this mode of practice is probably a permanent institution and will inevitably expand over time."

Reprinted by Retired Persons Pharmacies
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Serving members of
the National Retired Teachers Association and
the American Association of Retired Persons

The Mail-Order Prescription Drug Industry

ALBERT I. WERTHEIMER, PhD, and JAMES E. KNOBEN, PharmD

THE PRACTICE of mailing prescription and other medications to consumers in the United States probably had its origin in rural America. Before the general availability of the automobile, rural inhabitants often were dependent upon the U.S. mail for delivery of medicines and health supplies from their local pharmacy. This practice was not only a convenience to the consumer, but an essential health service as well—one in which physician, pharmacist, and patient were active participants.

The Veterans Administration has used the mails for distributing medicines to its ambulant patients for many years. This practice was expanded greatly with the return of veterans after World War II and has continued to grow, proving convenient and economical for both parties. In more recent times, the National Retired Teachers Association and American Association of Retired Persons (NRTA-AARP) has been distributing prescription medications to its members through a program that is now a featured service.

As the volume of prescriptions delivered by mail has increased, the practice has come under continuing, and at times critical, surveillance, particularly by organized pharmacy. Because available information to characterize the nature and extent of the mail-order prescription industry has not been collected and scrutinized, we undertook to assemble as much factual information as could be obtained.

Professional organizations and State boards of pharmacy were contacted for the names of firms engaged in high-volume, mail-order distribution of prescription drugs. A list of approximately 60 organizations was compiled. Data were then collected through a combination of personal and telephone interviews from 10 of the larger organizations, using a standard set of questions relating to the data reported in the remainder of this paper. These organizations are responsible for approximately 90 percent of the volume of mail-order prescription drugs in the United States. This report constitutes a profile of the mail-order prescription drug industry as constructed from our study. For purposes of convenience, mail-order prescription suppliers can be classified as follows:

1. Nonprofit government, such as the Veterans Administration drug program, which began in 1946
2. Nonprofit private, such as the NRTA-AARP drug program, which began in 1959
3. For-profit specialized (limited) programs, such as the Western Medical Company, which caters to the drug needs of epileptic patients
4. For-profit, open, public drug programs, such as Pharmaceutical Services, Inc.

Dr. Wertheimer and Dr. Knoben were formerly on the staff of the Pharmacy-Related Programs Branch, National Center for Health Services Research and Development, Health Resources Administration. Dr. Wertheimer is now associate professor, University of Minnesota College of Pharmacy; Dr. Knoben is now at Yale University. Tearsheet requests to Dr. Albert I. Wertheimer, University of Minnesota College of Pharmacy, Minneapolis, Minn. 55455.

General Features of Mail-Order Services

Patients' characteristics. The marketing data of these firms and the kinds of drugs supplied suggest that most mail-order suppliers serve elderly patients with chronic conditions who live in rural areas and use a high volume of prescription drugs.

Services offered. Most of the 60 organizations offer walk-in as well as mail-order service and dispense prescription drugs, nonprescription drugs, and limited sundry items. Many of the organizations dispense and mail Bureau of Narcotics and Dangerous Drugs (BNDD) schedule II (abusable) prescription drugs; however, only the Veterans Administration is allowed by postal regulation to mail narcotic drugs. The National Retired Teachers Association dispenses only two schedule II drugs: Preludin and Ritalin and, in each case, the prescriber is telephoned. Pharmaceutical Services, Inc., dispenses no schedule II-controlled drugs.

Prescription pricing. Mail-order prices are generally competitive with prices prevailing in urban areas; the price advantage in some organizations is approximately 25 percent below the retail price. No uniformity in pricing policy was found; examples of both markup and professional fee pricing mechanisms were encountered. The high volume of prescription orders is an industry-wide trait, necessary to offer the low price. Most organizations distribute a brochure or catalog describing the services offered and listing the prices for nonprescription products. Usually, only those firms in the for-profit category list prescription drug prices in their literature, which is distributed to the public.

Prescription processing and services. To assure themselves of the authenticity of a mailed-in prescription and to protect themselves from legal prosecution, firms usually take special precautions to screen out fraudulent orders. Among the steps they follow are a manual inspection of the prescription order by a pharmacist or specially trained technician, telephone verification in the case of suspected prescription orders, and comparison with known samples of handwriting, if these are available. In membership organizations, the patron's name is checked against the membership roster as an additional security check. The majority of these organizations maintain WATS (wide-area telephone service) lines due to the volume of long distance telephone calls made for verification purposes.

Most firms do not maintain drug-use profiles of patients. Few suppliers perform any drug interaction surveillance or monitoring of patients' drug regimens. Records are kept by all of the firms for purposes of medication refills and financial accounting.

Inquiries from patients are handled in most instances by one experienced person. Correspondence encompasses answers to price requests, answers to clinical questions, notification that a product contains a narcotic agent and must be dispensed locally, answers to inquiries regarding lost or late shipments, as well as need for receipts, special delivery, or the completion of insurance claim forms.

Prescription dispensing. Pharmacists dispense or supervise the drug dispensing operations. They are licensed by the State in which they practice and must, therefore, follow that State's regulations. A limited sampling discloses a ratio of approximately 100 to 150 prescriptions dispensed per pharmacist per working day; most organizations use a large number of technicians in the dispensing process. Ratios varying from one to eight technicians per pharmacist were found. These ratios compare with about 60 prescriptions dispensed per pharmacist per working day in the group medical clinic (*1*) and with about 80 prescriptions per day dispensed in community pharmacies which may employ one to two pharmacists during a given period (2).

Prescription shipping. All organizations attempt to ship medications on the same day that the prescription order is received. Generally 3 to 5 days are required for delivery by mail. The drugs are usually packaged in boxes, which may be marked "medicine," and sent via first- or third-class mail or by the United Parcel Service. United Parcel Service mail delivery is preferred by some organizations because the patient must sign a re-

ceipt, and three attempts to deliver are made prior to the return of the medication to the sender.

The mail-order firms report few losses, thefts, and late deliveries. In a letter dated October 18, 1972, the Better Business Bureau of Metropolitan Washington, D.C., reported that during March through August 1972, 13 inquiries and 11 complaints were made in the category of drugs and medicines, a category that includes all medications purchased from all sources; this total represents only 0.1 percent of the complaint volume.

Prescription volume and drugs dispensed. The market volume of mail-order prescription drugs can only be estimated at best, due to the diverse nature of the industry. Based on our discussions with knowledgeable industry representatives, we estimate that roughly 17 million prescriptions are dispensed annually through mail-order channels, 11 million of these by nonprofit firms and organizations. This volume compares with 155 million prescriptions dispensed by chain pharmacies and 959 million prescriptions by independent community pharmacies in 1971 (3).

The most frequently dispensed mail-order prescription drugs in 1972 for one organization, the National Retired Teachers Association and American Association of Retired Persons, are listed. While the population served by this group is clearly older than the population at large, this list is probably a good approximation of the drugs most frequently dispensed by all the mail-order firms.

Aldactazide
Aldomet, 250 mg
Atromid-S
Butazolidin Alka
Cyclospasmol, 200 mg
D. B. I.-T.D., 50 mg
Diabinese, 250 mg
Dilantin, 100 mg
Diuril, 500 mg
Equanil, 400 mg
Esidrix, 50 mg
Hydrodiuril, 50 mg
Hygroton, 100 mg
Inderal, 10 mg
Indocin, 25 mg
Indocin, 50 mg
Lasix, 40 mg
Librium, 5 mg
Librium, 10 mg
Lomotil, 2.5 mg
Meprobamate, 400 mg
Orinase, 0.5 gm
Pavabid capsules
Peritrate, 20 mg
Premarin, 1.25 mg
Quinidine, 3 gr
Regroton
Tandearil, 100 mg
Thyroid, 2 gr
Tofranil, 25 mg
Tolinase, 250 mg
Valium, 5 mg
Vasodilan, 10 mg

Summary data. The characteristics of selected mail-order prescription drug programs are given in the table. A number of characteristics unique to certain programs are detailed more fully in the subsequent section.

Special Features of Programs

Certain mail-order prescription drug suppliers merit further consideration by virtue of specific characteristics or features in their operation. Programs that have such a special feature are recounted in this section.

The Veterans Administration program is unique in several aspects. It is the only organization currently allowed by postal regulation to distribute narcotics through the mails (that is, by registered mail). In addition, its 28 million veteran beneficiaries (excluding dependents) comprise the largest single group of recipients. In 1972, these veterans acquired 7 million mail-order prescription medications.

Comparison of features of mail-order prescription organizations

Organization and population served	Also sells		Payment	Other services			
	Over-the-counter drugs	Sundries		Walk-in service	Patient profiles	WATS lines [1]	Use outside vendors
Federal Prescriptions Service, Inc. (public)	Yes	No	Full price	Yes	No	Yes	No
Getz Prescription Company (public)	Yes	Yes	Full price	Yes	No	Yes	No
Health Insurance Plan of Greater New York (membership)	Yes	No	No charge [2]	Yes	No	Local	Yes
National Council of Senior Citizens (membership)	Yes	Yes	Full price	Yes	No	Yes	No
National Retired Teachers Association (membership)	Yes	Yes	Full price	Yes	No	Yes	No
Pharmaceutical Services, Inc (public)	Yes	No	Full price	Yes	Yes	Yes	No
United Mine Workers of America Welfare and Retirement Fund (membership)	No	No	No charge	Yes	Yes	No	Yes
Veterans Administration (beneficiaries)	Yes	No	No charge	Yes	No	Yes	Yes
International Ladies Garment Workers Union (members and beneficiaries)	Yes	No	Co-payment	Yes	No	Yes	No

[1] Wide-area telephone service
[2] No charge if medication is obtained from HIP facility; small charge if medication is obtained from a vendor pharmacy.

The United Mine Workers of America Welfare and Retirement Fund (UMWA) program is termed a "mail-out" program because the prescription order, which bears the patient's diagnosis, is sent directly to the pharmacy by the physician. The medication is then mailed to the patient from one of more than 100 participating community pharmacies and UMWA facilities. The 500,000 members, retired members, and their dependents reside primarily in 10 rural areas in the Appalachian region. UMWA facilities dispense and the welfare and retirement fund pays only for selected chronic-use drugs as prescribed by plan-approved physicians. The fund is supported by a trust contribution of 60 cents per ton of coal mined, soon to be raised to 80 cents per ton.

Pharmaceutical Services, Inc., of Kansas City, Mo., uses a computer-based drug interaction surveillance system in conjunction with a patient profile card service. In an effort to ascertain the validity of questionable prescriptions for schedule II drugs, this company maintains an extensive file of physicians' signatures.

The National Retired Teachers Association and American Association of Retired Persons has 5 million members, less than 10 percent of whom use the pharmacy service. The volume of dispensed prescriptions has reached 6,000 per day at the association's Washington, D.C., operation. In addition, the pharmacy service operates four other mail-order pharmacies in California, Connecticut, Florida, and Missouri. NRTA-AARP also sells sundries at reduced cost to its patrons, as well as its own brand of over-the-counter drugs—an almost universal practice in this industry.

Direct Drug Service of Washington, D.C., supplies prescription and nonprescription drug products to members of more than 30 organizations, including the National Council of Senior Citizens and the National Farmers Union. Drugs are mailed and the patient billed, or the patient may save 2 percent by prepayment. Direct Drug Service is one of the firms that ... prescription drug prices in its catalog. The service began in 1964 through a combined effort of the National Council of Senior Citizens and the Greenbelt Consumer Cooperative.

Health Insurance Plan of Greater New York is a prepaid comprehensive health care plan. Drug benefits are available to members for $1.20 per month for individuals, $2.40 for couples, and $3.60 for families (three or more people, children under 19 years). Prescriptions obtained through in-house facilities are dispensed without additional charge; patients who obtain prescriptions at community pharmacies receive an 80 percent reimbursement after their $25 annual deductible is satisfied.

Federal Prescriptions Service, Inc., of Madrid, Iowa, is similar to Direct Drug Service. It operates its own mail-order prescription service and also the drug plans for the National Association of Retired Federal Employees, Veterans of World War I, Amvets Drug Plan, American Vocational Association, National Association of Postmasters of the United States, and the National Federation of Federal Employees.

Issues Regarding Mail-Order Services

The practice of mailing prescription drugs has always been accepted as a legitimate and necessary service to the patient when performed by the community-based or hospital pharmacy. However, the advent in the 1950's of high-volume, mail-order firms brought forth a storm of controversy regarding the ethics of mail-order practice that continues to this day. Investigation has revealed that approximately 20 States have supported litigation against mail-order pharmacies that operate from out-of-State, on the premise that a pharmacist is required by law to obtain a license from the board of that State in which he practices (reference 4 and personal communication of July 12, 1973, from Fred Wegner of Retired Persons Services, Inc.).

The issue of the disruption of the physician-patient-pharmacist relationship is the crux of much of the debate surrounding mail-order programs. More and more, State boards of pharmacy are proposing regulations that prohibit the establishment of a mail-order pharmacy based on the presumed disruption of this relationship. In a recent issue of American Druggist, Kenneth Griswald, chairman of the Judicial Board, American Pharmaceutical Association, stated (5): "It is usually impossible for a pharmacist in a mail-order pharmacy to render to each patient the full measure of his professional ability and to exercise proper professional judgments and skill. He has no personal knowledge of the patient or the prescribing physician on which to base his judgments

and since no physician-patient-pharmacist relationship exists, it becomes virtually impossible for a pharmacist practicing in this environment to abide by Sections One and Seven" [of the American Pharmaceutical Association's Code of Ethics].

When one analyzes current drug dispensing, it is apparent that the typical community-based pharmacy practice is not always able to provide for a true "physician-patient-pharmacist" relationship. The lack of definition of the concept and its select application makes it imperative, therefore, that the relevant professions establish standards of practice that specify the constitutional makeup of this tripartite relationship.

The issue of fraud has also been widely discussed. It is well known that various groups have illegally purchased drugs by mail through bogus prescriptions. The associate general counsel for the National Association of Retail Druggists in a letter to Senator Birch Bayh, dated August 7, 1972, stated: "We are confident that any responsible investigation of mail-order practices by Congress, Bureau of Narcotics and Dangerous Drugs, or any other group will demonstrate that widespread use of the mails to deliver drugs subject to abuse contributes to the drug diversion and the nation's drug abuse problems . . . An outright prohibition on the mail-order sale and delivery of drugs subject to abuse is essential and long overdue."

Two months later, John Ingersoll, director of the Bureau of Narcotics and Dangerous Drugs, stated at the annual meeting of the National Association of Retail Druggists that one argument against mail-order pharmacy that concerned BNDD was the diversion of controlled substances. ". . . In response to similar allegations made in 1969, the Bureau conducted an investigation of mail-order pharmacies and concluded at that time: The findings do not lend credence to the suspicion that mail-order prescription firms are a major source of diversion for controlled drugs. On the contrary, the level of compliance with the Drug Abuse Control Amendments of 1965 compares reasonably well with the general run of prescription pharmacies.

"The Bureau is concerned with the relative ease that controlled substances are obtained from all pharmacies. But this problem is not confined to mail-order houses, as shown by a *New York Daily News* survey last spring. Generally, it would appear that drug abusers are more likely to select a retail pharmacy rather than a mail-order pharmacy to attempt to pass a forged prescription. Their needs are of an immediate nature and are more quickly satisfied through a fast purchase. Safety is also a factor. Abusers do not want to give a return address to a mail-order house and prefer doing business with a local pharmacy. The abuser can watch the pharmacist's reaction to a forged script and quickly leave if the pharmacist goes to the telephone . . ." (6).

Discussion

The mail-order prescription drug industry appears to serve a real purpose by supplying the prescribed drug needs of patients who may be invalids, lack transportation, be isolated, or be in need of price savings otherwise unavailable. Further, this mode of practice is probably a permanent institution and will inevitably expand over time.

While the alleged disruption of the "physician-patient-pharmacist" relationship and the potential for fraud in the mail-order industry are two issues worthy of discussion, we wonder whether a motivating issue may be the economic competition that a mail-order operation presents to the local retail pharmacist. There is no doubt that contending forces need to document their positions.

The volume of prescription drugs distributed by mail constitutes only a small portion of the total distribution of drugs. However, public welfare will require adequate standards for this important method of drug delivery. Organized pharmacy is in a position to participate with interested parties in the objective evaluation of practices and the planning of standards for the mail-order prescription drug industry.

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(3) Prescription drug data summary. Social Security Administration, Washington, D.C., 1972.

(4) Prescription mail-order operations. *In* 1967 secretaries' workshop. Proceedings of the National Association of Boards of Pharmacy, Chicago, 1967.

(5) American Druggist 165: 13, Apr. 17, 1972.

(6) Ingersoll, J.: Address at the annual meeting of the National Association of Retail Druggists, Chicago, Oct. 4, 1972.

APPENDIX 8

AMERICAN SOCIETY OF HOSPITAL PHARMACISTS,
Washington, D.C., May 28, 1974.

Hon. BIRCH BAYH,
Chairman,
Subcommittee to Investigate Juvenile Delinquency,
Committee on the Judiciary,
Russell Senate Office Building,
Washington, D.C.

DEAR SENATOR BAYH: The American Society of Hospital Pharmacists wishes to take this opportunity to provide you with our views on S. 2327 currently pending before the Subcommittee. This measure would amend the Controlled Substances Act of 1970 to provide a Federal penalty for the robbery of narcotic drugs from pharmacies.

The American Society of Hospital Pharmacists is the national specialty society of over 10,000 pharmacists practicing in hospitals and related institutions. The members of ASHU are directly responsible for large inventories of narcotic drugs and other controlled substances maintained by institutional pharmacies. As with any other source, these inventories are attractive to criminals.

We believe the pending legislation is too narrow. For example, the bill only applies to "pharmacies" and the robbery of "narcotic drugs". But hospitals have been robbed and all classes of controlled substances taken. In all probability, attempts will be made in the future. The same applies to practitioners, distributors and other registrants who possess controlled substances. Therefore, we recommend that the bill be amended to apply to any registrant under the Act and to apply to the robbery of any controlled substance whether a narcotic, depressant, stimulant, or other substance as defined in Section 102(6) of the Act.

The need for a solution to the problem of controlled substance robberies is well documented. The Drug Enforcement Administration has released statistics which illustrate an alarming increase in such crimes. Senator Frank Church (D–Idaho) apprised the Congress of the problem in the August 2, 1973 issue of the *Congressional Record*. Pharmacy organizations testifying at oversight hearings on the Comprehensive Drug Abuse and Prevention Control Act of 1970 on March 28, 1974 before the Subcommittee have also reported the experiences of their members with night break-ins, armed robberies and other crimes committed to obtain controlled drugs.

We recognize that Federal criminal sanctions will not totally eliminate controlled substance robberies. However, our recommendations would make the proposal applicable to the specified crimes committed against all registered persons and institutions who lawfully possess any type of controlled substances.

We appreciate this opportunity to provide the Subcommittee with our views on the adoption of additional Federal penalties under the Controlled Substances Act. If further information is required, or questions arise, we would be pleased to respond upon request.

Yours truly,

JOSEPH A. ODDIS,
Executive Director.

APPENDIX 9

PHARMACY TIMES,
Port Washington, N.Y., May 9, 1974.

Hon. BIRCH BAYH,
U.S. Senate,
Washington, D.C.

DEAR SENATOR BAYH: Enclosed is a copy of the May issue of *Pharmacy Times* which just came off the press.

Our front cover strikes the keynote of the issue. This keynote is developed in articles starting on pages 31, 38, 46, and 70.

The issue includes a number of useful ideas which can help with respect to the drug abuse fight. A few examples:

(1) A recommendation is made that the "C" Number be placed at the *rear* of containers, so that in-a-hurry crooks can't quickly identify Controlled Drugs via the front labels—and snatch them up.

(2) A plan—in effect in Massachusetts—assigns a Code No. to all pharmacies. This enables stolen Controlled Substances to be traced back to the pharmacy from which they were taken.

(3) Arkansas pharmacists notify the public (and crooks, too!) via a sign which explains that *minimum* stocks are carried for certain Controlled Substances.

(4) Unscheduled, during-the-day visits by police to retail pharmacies are also helping to cut drug abuse crime.

In our May 1973 issue, we published an article on a special hand stamp for physicians—used at the University of Cincinnati Medical Center to curb drug abuse (see enclosed tearsheets).

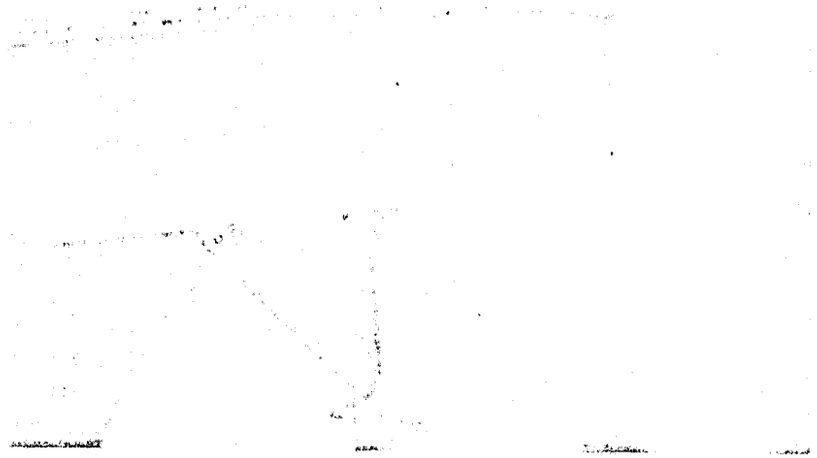
We hope that our May issue will be of help in the fight against drug abuse.

Pharmaceutically yours,

IRVING RUBIN, *R.Ph., Editor.*

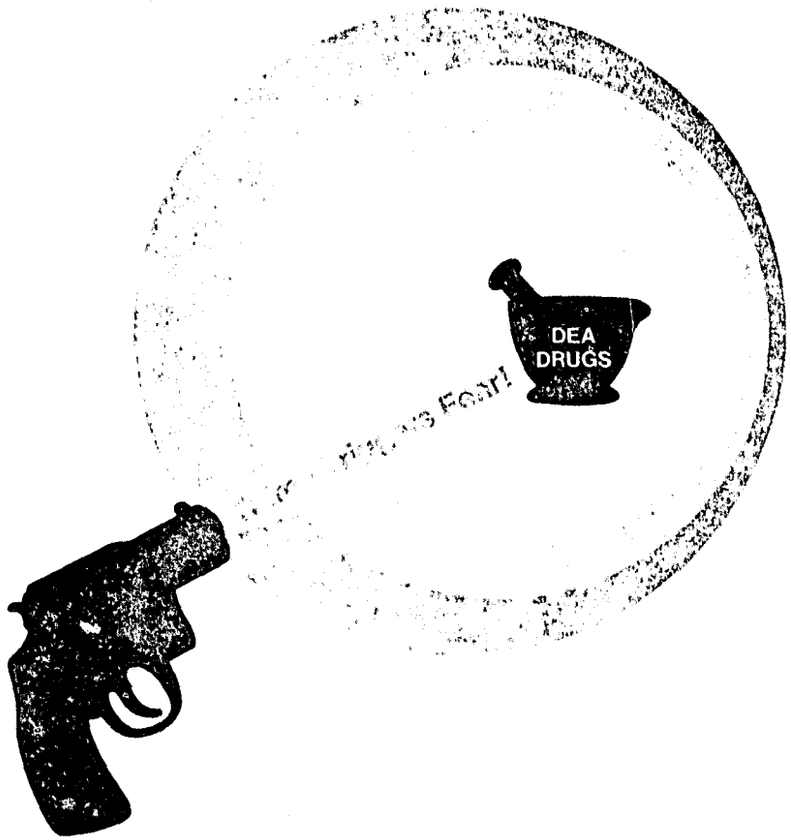
Special Hand Stamp for VIPs Curbs Forged Rx's and Illicit Use of Drugs





Above: A hand stamp is being used by a physician before he signs an Rx for a ENBD drug. The Rx is invalid without the stamp and signature.

Pharmacy Times
MAY 1974



Survey of Drug Crimes in Retail Pharmacies

Only Women Operate This Chain Pharmacy Unit

Continuing Education: The Arthritides

How Pharmacists Try to Protect Themselves Against Drug-Related Crimes

► Serious crime rose by 5% in 1973, the U.S. Justice Department reports. Commenting on the increase in the crime rate, Attorney General William B. Saxbe said: "The criminal plays the odds."

Drug abuse-related crimes in retail pharmacies apparently pay heavy odds, because they have far exceeded the overall crime increase for the year. And drug-related crime is triggering fear among the nation's retail pharmacists.

In an attempt to draw a clear picture of the crime situation as it relates to retail pharmacies, PHARMACY TIMES conducted a survey of the 50 states and the District of Columbia.

A questionnaire—which was recently sent to state pharmaceutical association secretaries—asked these 4 questions:

(1) Did the incidence of drug abuse-related crime in community pharmacies in your state increase, decrease, or remain the same in 1973 as compared with 1972?

(2) Was anyone killed or injured in 1973 as a result of such crimes? If so, how many?

(3) Does the drug abuse-related crime in the state seem to be concentrated in:

Drug-Related Crimes (continued)

large metropolitan areas, suburban communities, or towns & rural areas."

(4) Has any plan or idea been successful in reducing drug abuse related crime in pharmacies? If the answer to this question was yes, the respondents were requested to describe the successful program.

As of the deadline for receiving the filled-out questionnaires, representatives of 32 states and Washington, D.C. had responded with their data or estimates. In most cases, the executive secretary of the state pharmaceutical association answered the questions. In some cases, though, the association forwarded the questionnaire to the state board of pharmacy which had more information.

Of the 38 responses, 26 reported that drug abuse related crime in pharmacies had increased in 1973 over 1972. (Table below)

Respondents from 9 states plus the District of Columbia indicated that the rate for this type of crime had remained about the same in 1973 as it was the previous year. Pharmacy executives from 2 states reported they had no reliable, up-to-date information on drug-related crimes.

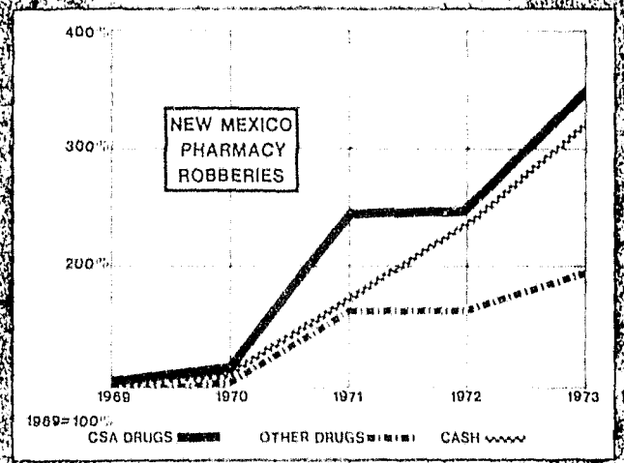
No State Reported Decrease

No state reported that drug abuse related crime decreased in 1973. However, one county in Pennsylvania (the only state to break down the statistics by counties) did report a decline in crime. This decline, though, was not great enough to reverse the overall statistics for the state, which reflect an increase of more than 20%.

A total of 15 respondents reported that one or more persons died as a result of

Drug-Related Crime in Retail Pharmacies, As Viewed by 38 Pharmacy Leaders

Increased Less than 25%	Increased 25% to 49%	Increased 50% to 99%	Increased by 100%	Increased, but Data Not Available	Remained The Same	No Data Available
Alaska	Arizona	Georgia	California	Alabama	Arkansas	Colorado
Connecticut	Idaho	Maine	New Mexico	Illinois	Delaware	New Jersey
Mississippi	Iowa		North Carolina	Indiana	D.C.	
Nebraska	Texas		Ohio	Michigan	Florida	
North Dakota			Oregon	Missouri	Massachusetts	
Pennsylvania				Nevada	Minnesota	
Virginia				New Hampshire	South Dakota	
				Tennessee	Utah	
					Washington	
					Wyoming	



Crime Graph. Statistical data on the increase in pharmacy robberies in New Mexico are depicted on this graph made available by the state pharmaceutical association. The graph clearly shows that the robbery of Controlled Substances is well above the 1969 level.

NOTICE TO THE PUBLIC

PLEASE EXCUSE ANY DELAY IN FILLING YOUR PRESCRIPTIONS FOR ANTI-OBESITY DRUGS. WE HAVE DISCONTINUED STOCKING MANY OF THESE DRUGS DUE TO PRESCRIPTION FORGERIES, BURGLARIES AND ROBBERIES. NARCOTIC STOCK HAS BEEN REDUCED TO A MINIMUM. YOUR UNDERSTANDING OF THIS NEW POLICY WILL HELP ELIMINATE DIVERSION OF THESE DRUGS FOR NON-MEDICAL PURPOSES.

Notice: Provided by the Arkansas Pharmaceutical Association, this 10" by 8" card is displayed in pharmacies throughout the state. The card asks for public understanding with respect to certain Controlled Drugs to eliminate their diversion for non-medical purposes.

Drug-Related Crimes *(continued)*

pharmacy crimes. Not all states had exact figures on the number of deaths, and in some cases it was not the pharmacist who was killed during the crime.

Virginia, for example, reported that several robbers fell victim to their own crimes. In Utah, the list of casualties includes one policeman. In Massachusetts, one pharmacist was killed by robbers and another died later of a heart attack sustained as a result of a robbery. Additionally, 12 states reported injuries due to crimes committed in pharmacies, but few states maintained records on the number of injuries.

Not Confined

Drug abuse-related crime is not confined to metropolitan areas. While 14 respondents said that in their states it was primarily an urban problem, 6 states reported that it is predominantly a problem in small towns and rural areas.

Only 2 states (Conn. & Wash.) reported that this type of crime is concentrated *primarily* in suburban communities. However, Alabama, Delaware, Ohio, and Virginia reported that the problem exists in both large cities *and* suburban communities. A total of 7 respondents explained that it is a pervasive problem, affecting all areas of their states.

The response received from Tennessee explained that, as law enforcement is stepped up in the urban areas, the crime wave drifts to the suburbs, and finally flows out into the rural areas.

Perhaps the most significant aspect of the survey is the variety of comments pharmacy officials made concerning programs that have been successful in combating drug abuse-related crime.

The following letters are typical of the responses received by PHARMACY TIMES:

"Alarm systems in our larger communities (Anchorage and Fairbanks) —that are directly connected to police stations—have resulted in the apprehension of several burglars and an overall decrease in drug abuse-related crime in these areas."

From DAVE SWANSON
Alaska Pharmaceutical Assn.
Anchorage, Alaska

"A special patrol by police, wherein they visit each pharmacy 3 or 4 times daily, has been moderately helpful in combating crime. At each visit, the time is noted on a card which is then signed by both the pharmacist and the policeman.

"In the high crime areas, some pharmacists have hired armed guards or use trained guard dogs."

From LEONARD PERMUT
Mass. State Pharmaceutical Assn.
Boston, Massachusetts

"Early closings, armed guards in pharmacies, and reduced inventories have all contributed somewhat to combating crime in our state."

From TOM C. SHARP, JR.
Tennessee Pharmaceutical Assn.
Nashville, Tennessee

"We advise pharmacists never to answer an emergency call for anyone they don't know, unless they have someone from the police or sheriff's department accompany them.

"In 2 recent break-ins, pharmacists' homes had been burglarized and the keys to their pharmacies stolen and used for entry. As a result, no alarm went off.

"Although emergency telephone numbers are posted at most pharmacies, one pharmacist was criticized recently for not posting his name and address to supplement the telephone number. He responded by saying: 'If I'm going to be threatened with a gun in my pharmacy, it is one matter. But under no circumstances do I intend to publish my home address and involve my wife and family in a potentially dangerous situation.' "

From GRACE E. HANNAN
New Hampshire Pharmaceutical Assn.
Concord, New Hampshire

"An article in *Texas Pharmacy* reports that pharmacists in Amarillo have formed a Crime Prevention Committee to work toward implementation of new techniques in burglary prevention.

"The committee plans to work with law enforcement officials and concerned groups. Methods under consideration involve increased police patrols, the use of more sophisticated electronic surveillance, attack dogs, and armed guards."

From LUTHER R. PARKER
Texas Pharmaceutical Assn.
Austin, Texas

"Security awareness programs sponsored by the state and metropolitan associations have educated pharmacists on protective measures to reduce crime in pharmacies. These programs have also taught pharmacists how to react to ensure their own safety if they find themselves in the position of being a victim of a holdup."

From ROGER W. CAIN
Illinois Pharmaceutical Assn.
Chicago, Illinois

"This association has appealed for stiffer penalties for controlled substances robberies in pharmacies plus greater vigilance of pharmacies by law enforcement personnel. Our appeal was made to President Nixon, the congressional delegation from New Mexico, the governor, our state legislators, the chief of the state police, and the chiefs of all the local police departments in the state.

"This has attracted the attention of the news media. As a result of this news coverage and accompanying support by law enforcement personnel, there has been a sharp drop in the number of pharmacy robberies in the past 6 weeks. This reverses a trend which has seen a 350% increase in drug abuse-related crime since 1969.

"Police departments are working more closely with pharmacists and, in some cases, have installed electronic devices in the pharmacies which automatically alert the police while a robbery is in progress."

From JACK HILLIGOSS
New Mexico Pharmaceutical Assn.
Albuquerque, New Mexico

More ►

Drug-Related Crimes *(continued)*

"In 1971, there were 134 drug abuse-related pharmacy burglaries in Arkansas, 131 in 1972, and 126 in 1973. We have been able to prevent an increase through the installation of alarm systems, maintenance of only minimum stocks of narcotics, and not stocking other abuse drugs.

"We furnish the retail pharmacies in the state with a sign headlined *Notice to the Public* (reproduced on page 33 of this issue).

"Unfortunately, while the increased installation of burglar alarm systems has proved effective against burglaries, it may be the cause of a shift in the drug-related crime picture in the direction of armed robbery."

From WILLIAM G. SMITH
Arkansas Pharmaceutical Assn.
Little Rock, Arkansas

"Recently, $1,500 in controlled substances was taken from a pharmacy located near Greensboro, North Carolina. One day later, police in Atlanta, Georgia, called and reported that they had the drugs. Why? The pharmacist had stamped the name of his pharmacy on the bottle labels. This enabled the pharmacist to identify his unwanted night customers."

From W. J. SMITH
North Carolina Pharmaceutical Assn.
Chapel Hill, North Carolina

"Silent alarms have helped curtail pharmacy break-ins."

From CLIFFORD E. BARNETT
Idaho State Pharmaceutical Assn.
Boise, Idaho

"Our 'alert system' has been very successful in alerting the entire state to forged prescriptions, stolen Rx blanks, and various other abuses. Under this system, each pharmacy received a postcard listing 2 other pharmacies to call. We can alert most of the pharmacies in the state in about 2 hours via this relay system.

"Most of the drug abuse-related crimes in Delaware pharmacies have involved break-ins. These have occurred particularly in shopping center and in highway locations."

From AARON M. LAUTER
Delaware Pharmaceutical Society
Wilmington, Delaware

"Our membership recommends that the labels on the fronts of bottles containing controlled substances *not* indicate that the product is controlled. The controlled ID marking might be placed, instead, on the *back* of the bottle, making it difficult for the thief to find these drugs in a hurry."

From STEWART E. PAQUETTE
Nevada State Pharmaceutical Assn.
Las Vegas, Nevada

"We have been able to hold the line on drug abuse-related crime, because the police are becoming more vigilant and more willing to cooperate with retail pharmacists."

From CHAUNCEY I. COOPER
District of Columbia
Pharmaceutical Association
Washington, D.C.

"Internal movement alarm systems help curb pharmacy break-ins. Also, the Postal Service sells used safes at reasonable prices. Perhaps pharmacists could purchase these safes, and store some controlled drugs in them."

From JOHN E. BURRILL
Maine Pharmaceutical Assn.
Portland, Maine

"Many pharmacies are installing alarm systems. It seems that only those which ring in a police station are worthwhile; unfortunately, these are not available in all areas.

"There is, however, the danger that, when breaking in becomes more difficult, armed robberies will increase. This could result in additional injury and possibly death to the pharmacist."

From HENRY A. SPECKMAN
Oregon State Pharmaceutical Assn.
Salem, Oregon

"The incidence of drug abuse-related crime in the state of Washington remained about the same in 1973 as it was in 1972. This is due, in part, to the education of the pharmacist on how to protect himself.

"Also, the installation of burglar alarms in urban areas has helped to alleviate the crime problem there. However, this has forced drug burglars to attack the suburbs.

"Another measure which has helped to combat drug-related crime is the methadone maintenance program in our state. When addicts are given methadone as part of a program, they don't need to steal and re-sell abuse drugs in order to support their expensive drug habits."

From V. W. SHEPPARD
Washington State Pharmaceutical Assn.
Seattle, Washington

℞ ⇌ OTC

Pharmacy Times'
Continuing Education Series

Experts at the nation's Voluntary Health Associations have written a series of important feature articles—especially for the readers of PHARMACY TIMES. Here are the first 4 articles in this series:

ISSUE	TOPIC
#1 April 1974	Cancer Chemotherapy
#2 May 1974	The Arthritides
#3 June 1974	Diabetes
#4 July 1974	Emphysema

Additional articles in PHARMACY TIMES' Continuing Education Series will be published in future issues. Please watch for them!



'Garrison' Pharmacy: (Photo, left) Attack dogs and (photo, right) retractable drawers in bullet-proof glass are becoming more common—as drug criminals zero in on retail pharmacies.

What You Can Do To Curb Drug-Related Crime in Retail Pharmacies

BY LEONARD STEIN, R.Ph.
Thrift Drugs
Lindenhurst, New York

The Pharmacy is experiencing an unprecedented drug-related crime wave. Reports from all parts of the nation tell of armed robberies, burglaries, brutal assaults, and prescription forgeries.

Pharmacists have a unique problem with respect to crime. The very same reasons that the retail pharmacy has become attractive to customers—easy access and long hours—have made them equally attractive to criminals. In addition, illicit drug traffickers—plagued by "shortages"—have zeroed in on the pharmacy as a prime target for "abuse" drugs as well as cash.

Armed robbery is the most frightening crime that the pharmacist has to contend



'Packing a Rod': Crime has forced this pharmacist to "pack a rod" while dispensing prescriptions.

with. This crime produces the most fatalities, and arouses the most anxiety. Most retail pharmacy holdups are committed with hand guns (over 60%), but knives, axes, and other weapons are also used. In large cities, up to 500 armed robberies in pharmacies are committed yearly. In suburban areas, this type of crime has been rising at an annual rate of 10% to 15%.

The *professional* thief usually has a criminal record, prefers to work as part of a team, and prepares carefully for his crime. Often, an accomplice enters first, ostensibly as a customer. While the clerk is selling a product to the accomplice, the other criminal enters, draws a revolver, and compels the pharmacy's personnel to go to the rear of the pharmacy. Thereupon, the accomplice empties the cash register, and loots the prescription department of "abuse" drugs.

Another common method involves a confederate entering at the moment the pharmacist is confronted with the gun. While his partner covers the pharmacy's personnel, the thief rifles the cash register and forces the pharmacist to show him the location of "abuse" drugs.

The *amateur* thief, on the other hand, usually works alone. He generally has no prior criminal record, and either commits his crime based on impulse or on need, such as a drug habit. He is more dangerous than the professional criminal, because he is easily frightened and—as a result—readily uses his weapon.

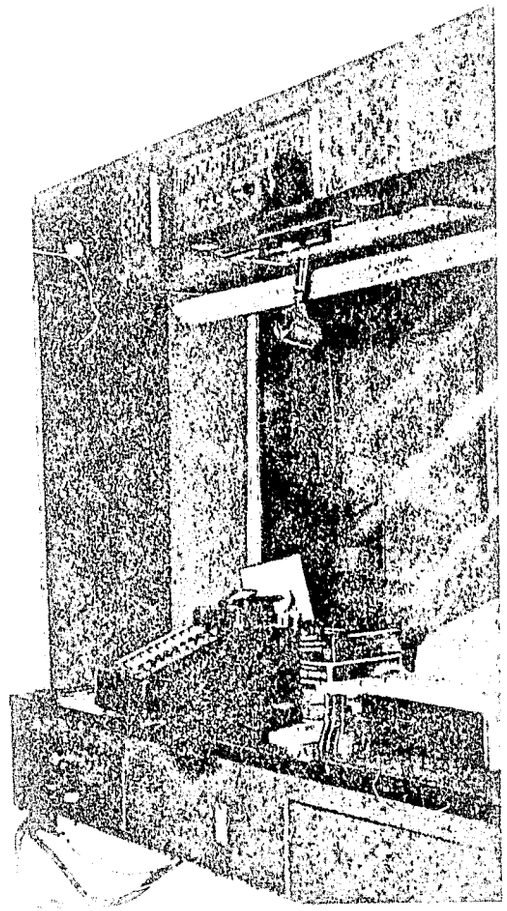
Some years ago, I was held up in my pharmacy. The fear and suspicion engendered by that experience lasted for quite a long time. Indeed, some pharmacists never recover from this traumatic experience—as the growing list of pharmacy closings shows.

Burglary

In addition to holdups, burglary is another crime that menaces the retail pharmacist. A crime of stealth, burglary occurs mostly at night. Again, pharmacies are a prime target because of their twin lures: cash and drugs.

Installation of security hardware—such as electronic alarms and in-store TV coverage of the pharmacy—can make deep inroads into the number of burglaries. All-night lighting, directed alarms connected to a surveillance station, Plexiglas bullet-proof shields, watch dogs, and security patrols have also cut down considerably on burglaries (see photos).

More ►



(continued)

headed by Rep. Robert N. C. Nix (D.-Pa.) and Senator Frank Church (D.-Idaho) to make it a federal crime to commit or attempt to commit a drug-related robbery or a burglary or any other act of violence in a pharmacy.

♦ Help create a national data bank to monitor and record pharmacy crimes. In this way, Pharmacy can dramatize its crime problem—and back it up with facts, statistics, and actual case histories.

As community pharmacists, we must:

♦ Step up the use of our knowledge of drugs in a constructive and educational way. Participation in drug clinics and drug education programs in community schools is desirable.

♦ Support and fight for a better criminal justice system in our localities.

♦ Participate in local activities aimed at preventing and or controlling drug abuse.

Crimes Hamper Health Services

Pharmacists have a common interest in fighting crime. Our objective, to provide quality health services, has been seriously hampered by increased criminal activity. Unfortunately, the general public is relatively unaware of our dilemma. One fact stands out: Unless the crime picture improves dramatically, "Garrison Pharmacy" may tend to become the rule, rather than the exception. We must all work together to meet Pharmacy's biggest challenge! R—OTC



Death of a Pharmacist: The recent robbery murder of pharmacist Al Kurtzweig touched off this mass demonstration in Youngstown, Ohio. Civic and pharmacy leaders called for "jail not bail."

(1) Unclutter your windows. Criminals like to work in privacy.

(2) Arrange to have adequate sales help on the selling floor—*visible to all*. Criminals consider this a major problem.

(3) Maintain good lighting at all times. Criminals prefer to work in poorly-lighted areas.

(4) Disperse your drug supplies throughout the prescription department. The requirement that pharmacists keep all narcotics under lock and key in a single location proved to be a valuable guide for professional criminals. This federal requirement has been rescinded; the option is dispersal.

Keep some cash and abuse drugs hidden and regularly change the hiding place. A criminal may watch you and, over a period of time, he can learn your habits.

(5) Employ a "buddy alarm" system. This device ties in 2 pharmacies (or other stores, offices, etc.) in an area of up to 500 yards. It enables a pharmacist in an emergency situation to activate an alarm secretly in his "buddy's" establishment, so that the "buddy" can summon police.

(6) Never open or close the pharmacy alone. You are most vulnerable at this point, and the criminal knows it.

(7) Exercise special care in opening the pharmacy after hours for emergency service. If you do not know the patron personally, phone the local police and ask that a policeman be on hand when you arrive at the pharmacy to open it.

(8) Be especially alert for trouble during the hour when the police in your area change shifts. Municipal protection is weakest at this time.

(9) Arrange with your local police department to have a policeman drop into the pharmacy at varying, unscheduled times during the day.

(10) Employ as many electronic alarm devices as are economically feasible. This includes direct wires to the police station and to private security agencies. The criminal that is caught by this means serves as an object lesson to others in his trade to be leery of zeroing in on your establishment.



How An Assigned Code Helps the Police Trace Stolen DEA Drugs

BY ALBERT SHERMAN, R.Ph.*
Immediate Past President
Boston Association of Retail Druggists

After the sharp increase in armed robberies and break-ins that occurred in Boston pharmacies during 1972, the law enforcement agencies were able to recover large amounts of controlled substances in their original containers. Criminals who hold up or break into pharmacies are reluctant to transfer these Drug Enforcement Administration (DEA) substances to other containers. DEA drugs have greater "credibility" with their "buyers" when the name and the strength of the drug are listed on the label of the original containers.

A person arrested with DEA drugs can only be charged with possession of a controlled substance, because the container can only be traced to the manufacturer (by the name on the container) or perhaps to the wholesaler through the manufacturers' rec-

*Pharmacist Sherman owns a community pharmacy—Charles River Pharmacy, Boston.



On the Label: The code number assigned to his retail pharmacy is rubber stamped on the label of a DEA controlled product by James Houhoulis, current president of the Boston Association of Retail Druggists. The code number may also be hand marked. A recent suggestion calls for using "invisible" ink that would show up under special (e.g., ultraviolet) lighting

CONTINUED

3 OF 5

Assigned Code (continued)

ords of control numbers—a bad "loophole."

It was my idea—in my position as consultant to the Boston Drug Control Unit as well as president of the Boston Association of Retail Druggists—that we ask each pharmacy in the city to use some identifying markings on Schedule II, III, and IV substances. This would enable enforcement officials to trace a person charged with possession—through such marked containers—to the pharmacy from which the containers were taken. I presented my idea to the Police Commissioner of the City of Boston. He approved it.

It appeared that the best method for Boston would involve a digit system: The first two digits would denote the precinct and the second two digits would denote a particular pharmacy. (Example: My own pharmacy is located in district one. Because I had formulated the system, I assigned myself number one. Hence, the code for Charles River Pharmacy is 01-01.)

A letter was then sent, over the signature of Police Commissioner Robert J. deGrazia, to every one of the 208 community pharmacies and 51 hospital pharmacies (we included the hospitals) in the city, asking them to mark their controlled substance containers with the assigned number. Commissioner deGrazia was most cooperative in this project—in keeping with the spirit of cooperation maintained by law enforcement leaders in Massachusetts and the profession of Pharmacy.

The system worked so well in the first few weeks that the Commissioner of Public Safety of the Commonwealth of Massachusetts requested that each local chief of police, in the other 350 cities and towns in the Commonwealth, request that pharmacies in their towns also mark their controlled substances, by using the Massachusetts Criminal Information Code (MCIC) Letters for the town or city and the digits to denote the pharmacy.

The City of Lynn in the MCIC Code is LYN—and the pharmacies are numbered accordingly. Newton is NTN and Brookline is BRL, etc.

The first week that the system was "active" in the entire Commonwealth, there were 3 drug-related cases that were solved via the code system. In each case, the persons arrested and charged with possession were also identified by the pharmacists who had been held up. Then, these same persons were also charged with armed robbery, attempted murder, etc. (The latter charges are more difficult to beat than a simple possession charge.)

The master list of coded pharmacies is maintained by the Massachusetts State Police, Criminal Investigation Bureau; the citywide (Boston) list is maintained by the Criminal Investigation Division of the Boston Police Department. Each city and each town, naturally, has a copy of the codes for that locale.

During the initial stages of the program (both the Boston pilot program and the statewide program), pharmacists were hesitant about using a code. However, most of them cooperated. Those who are aware of the benefits of the system—namely, the apprehension and virtual conviction of arrested parties—are now enthusiastic about this successful program! ⊨OTC

APPENDIX 10

Statement of Frank D. Breckbill, President, Dangerous Drug Distribution Concerns Associated, Canton, Ohio

Mr. Chairman, members of the committee, As President and on behalf of Dangerous Drug Distribution Concerns Associated, may I express our appreciation in being permitted to appear before this committee.

I am Frank D. Breckbill of Canton, Ohio, an advocate of legislation to tighten the security over distribution of legally manufactured dangerous drugs. My 4 years of effort in this endeavor are known by nearly all Ohio's Boards and Associations in the medical, pharmacy, dentistry, veterinarian and hospital professions; also by the American Medical Association, several subcommittees in Washington and many legislators, both State and Federal.

The Attorney General's bill under study today has several good features to which I subscribe:

1. Closer conformity to the Federal drug law;
2. More realistic and humanistic approach to the marijuana problem;
3. Establishment of Controlled Substances Board involving th ecooperation of each of those professionals entrusted with our health, the health of our welfare recipients and the health and institutionalization of our loved ones.

As with most Federal and State drug legislation to date, few provisions have been made to close the leaks in our distribution system among America's 450,000 drug handlers. Over- and Mis-prescribing physicians and unethical pharmacists presently can not be detected easily, and if so, the case is very difficult to prove. Instead, our laws deal with "after-the-fact", analogous to super highways without guard rails or median strips, or commercial airplanes without FAA inspection. Why not instead just pick up the living accident victims and hospitalize them; bury the dead. Look at the business and opportunity for profit this apathy would generate. Why even try to prevent accidents? Of course, few thinking persons would validate that approach.

Instead, addition of the provisions set forth in SB-307 to the Attorney General's bill would make it a model for Federal law incorporating humanitarian safeguards.

I am pleased to report that partly through the pursuasion of our Association, the triplicate script concept is currently in use in New York State. California has had a workable plan for many years and Idaho and Illinois have implemented a similar plan within the last several years. Both Michigan and Pennsylvania are holding hearings to study the plan.

The concept that all fifty states should adopt triplicate script and peer group review was first advocated by a committee of physicians meeting in New York in 1967. Later their report was widely distributed in a book, "Drug Abuse, a Guide for Physicians". Unfortunately, the plan was not adopted then, and the single, white copy, easily counterfeited, forged, copied and stolen, continued its role in leaking millions—perhaps tens of millions—of dangerous drugs into the illicit market.

Since I am not a professional in either the field of medicine or pharmacy, I heartily recommend your studying expert testimony given before Senator Birch Bayh's committee as recorded in a government publication. "Barbiturate Abuse 1971-1972". There you will grasp the severity of the licit drug disease gripping our nation. Briefly, synthetic psychotropic drugs came into wide use in the mid-fifties and their use skyrocketed as physicians believed a significant, effective and safe nervous system modifier had been found as they listened to the detail men supplied by the pharmaceuticals and read the Madison Avenue ads.

We also not a rise in crime statistics, narcotic violations and health care costs:

Drug sales: Up 4+ times, 1950–70.
Narcotic violations: Up 8 times, 1960–70.
Homicide rates: Up 1.4 times, 1950–70.
Health care costs: Up; from 4.6% of 1950 GNP to 7.4% of 1971 GNP.

There is now an estimated 1,000,000 barbiturate and tranquilizer addicts in the United States and 10,000,000 more on the medical road to dependency and possible addiction. Ohio's rate of expectancy then would be 50,000 addicts and 500,000 dependants. Barbiturate addiction is also proving much more severe and fatal than heroin addiction.

As previously stated, I am not qualified to answer technical questions regarding specific effects of specific drugs on specific individuals. A particular study has shown, however, that 55% of the physicians questioned admitted they are not experts either. Almost daily I hear of mistaken diagnoses and misprescribing. Recent investigations in Cleveland by the Plain Dealer revealed physicians dispensing psychoactive drugs unethically, and even illegally.

Physicians are not the only professional problem: only several weeks ago I was told by a clerk in a juvenile court that two drug stores in his area were selling prescription drugs to certain juveniles without prescriptions. Another pharmacist was fired when the chain store's investigators found $16,000 of pilfered drugs in the man's trunk. He had also mis-filled four known prescriptions and other patients were hurriedly called to verify their prescriptions. The pharmacist was noted by another co-worker to have been "high" at the time, celebrating a football win by his favorite school.

Thousands of patients are doctor and pharmacy shopping either for their own dependency and addiction or for low cost pusher supplies at your cost and mine as taxpayers, insurance payors, victims of accidents and assaults caused by the users, or as grieving friends or relatives of affected lives.

With such sloppy handling of dangerous drugs, the buying out of the Turkish farmer and the apparent control over the Golden Triangle has only minutely reduced America's drug abuse plague. Fifty percent of our crime cost is drug related and 90% of all our drug problems is from illicit use of legally manufactured dangerous drugs.

May I now address my remarks to remedial, positive and preventive action: triplicate script, computer technology and peer group review.

The strongest criticism against computerization of triplicate script has been fear of misuse of data bank information. Just last Saturday President Nixon stated Vice President Ford is to chair a blue ribbon committee to study the problem and make recommendations for legislative action. Most of us would appreciate less unsolicited mail.

The President has reason, however, to be beholden to certain of the health care providers who would lose enormous profits if hospitalizations or drug use were reduced. His re-election campaign coffers were swelled with contributions from pharmaceuticals and hospital supply companies.

But may I make myself perfectly clear when I say, the data bank need never have an identifying number or even a name to make the triplicate script and computer data program effective in detecting unethical practices of many physicians and pharmacists and forcing, beyond reasonable doubt, pharmaceutical accountability.

The DRUGS would be under surveillance—not people!

True, the individual would not have the protection of peer group review of the medicines he is ingesting for a specific illness, nor could we find that hapless individual already dependent and well on the road to addiction, nor the individual who has a probable non-malignant tumor growing in defense of overmedication. Nor could we find pushers who are getting cheap reliable supplies of dangerous drugs.

True, the program could not help these above-named individuals; however, the program would still help—as has been proven in other states—in less prescribing by physicians for borderline cases; and the program would drastically reduce society's drug problems, by providing a means of accounting for nearly every pound of the hundreds of tons of licit dangerous drugs now manufactured yearly. We would hope through an educational program that each patient would ask for the program's assistance in maintaining safe levels of potentially toxic medications, just as they feel a need for Federal inspection of meat, or FAA approved commercial aircraft.

And the physician would be held accountable only to his peer group—and the pharmacist his—not either to the other or to law enforcement. Law enforcement would, however, have an objective and effective tool to make pharmaceuticals more responsible, and if the erring professionals persist in unethical practices, to prosecute effectively.

The Controlled Substances Board as provided for in the Attorney General's bill could be the nucleus of the system which would receive the input data obtained through implementation of triplicate script. Ethical practices of the several professions would be under peer group review while the Mental Health Board studied the drug profiles of those patients who desired that protective feature. (Present Ohio computer readouts have shown that over 200 times the proper dosages have been given some Medicaid and Medicare patients. Hopefully the Welfare Department can share with you the effectiveness and need for computer assistance in alleviating overmedication.)

Input could spot the drugs of abuse in the "embryo stage" before they became a full-grown maimer and killer. It is both interesting and frightening to know that over 1500 separate psychoactive drugs are available, with some types having 50 different manufacturers each. Sopors could have been spotted before Columbus became known as the Sopor capital of the world.

The proposed Board, representing each of the professions, would also be in a position to detect deflecting peers and initiate remedial action before the situation got out of control A physician in Summit County, father of three, may have been spared suicide if he had been warned by his peers in his early practice that being a "nice guy" could lead to severe problems with the law. Perhaps the BNDD would not have had to request that fateful audit.

Have you visited some of our convalescent or nursing homes? Most of the patients are zombies. Nearly all are on some kind of sedation. Have you talked with a loved one afflicted with a touch of paranoia supercharged with an hallucinogen? Have you had a loved one operated on for the removal of an ovary or an adrenal tumor caused at least in part by overmedication? Do you known any of the 6% on kidney machines who are there because of overuse of pain killers?

Subcommittee Members:

Please accept the responsibility for adding the provisions of SB-307 as an amendment to the Attorney General's bill and start this State on its way to preventing drug abuse as well as picking up the casualites. Many conscientious physicians and pharmacists need your help in getting this program operational.

Thank you.

California's Triplicate Prescription System

FOREWARD

Most individuals using narcotics illicitly are criminals first and then addicts. They are well aware that the medicinal narcotics flowing through the normal channels which supply the medical profession constitute a far greater and more permanent supply than illicit trafficking could ever provide. It is axiomatic,

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therefore, that the addict, when cut off by or from his illicit supplier, will turn to the procurement of medicinal narcotics.

They are equally aware that Federal and State laws allow only licensed physicians to prescribe narcotics—a fact which at all times encumbers the physician to the possibility of being the alternate and unwitting supplier of narcotics to gratify addiction.

The constant danger of a physician being victimized and of licit narcotics falling into the hands of the illicit user has long been recognized by California legislators who, over a period of years, have passed a series of laws which have aided both the physician and law enforcement officers.

The Narcotic Act of the State of California provides for control of the distribution of certain narcotic drugs through the use of official triplicate prescription blanks—a system developed in California and subsequently adopted by several other states. Narcotic experts who have conducted studies of this program have been able to see the definite advantages to be derived and have been unanimous in their praise of the system.

AUTHORIZATION

Division 10 of the California Health and Safety Code provides that all narcotics not expected by Section 11166.12 be written on the Official Triplicate Narcotic Prescription Blank. An exception is made to the requirement for the use of triplicate prescriptions in case of a sudden or unforeseen accident, calamity, or epidemic.

Section 11001 of the code describes the narcotics which must be prescribed on the official triplicate narcotic forms. Chapter 3 gives further information on the use of the prescriptions.

PROCEDURE

The prescriptions are issued in boxes of one hundred serially numbered triplicate blanks, four pads of 25 blanks each, upon request and free of cost to practitioners who are registered with the United States District Director of Internal Revenue. The blanks are printed on erasure-proof paper in a "snap-out" form with carbon paper interleaved in each prescription. The boxes are unmarked as to contents and bear only a post office box return address. It is suspected that this may have resulted in some cases in the supply of prescriptions inadvertently being discarded by the receiver, but these few cases are more than compensated for by the fact that thefts from the mails are practically nonexistent.

When a narcotic requiring a triplicate prescription is prescribed, it is prepared on an official blank in triplicate. The prescriber retains a copy for his records; the original with copy attached is given to the patient. When a patient has a prescription filled he gives the original and the copy to the druggist. After filling the prescription the druggist separates original and copy, and endorses the back of the copy, showing the date the prescription was filled, the name of the drug store, and the name of the pharmacist filling the prescription. The druggist retains the original in his files. He sends the duplicate copies of all such prescriptions to the State Bureau of Narcotic Enforcement Headquarters Office in Sacramento at the end of each month.

Personnel at the Bureau's Headquarters office encode and punch the information from the prescriptions onto key punch cards. These cards are subsequently printed on monthly tabulation sheets, copies of which are sent to the Bureau's six Area Offices. These tabulation sheets list the name of the patient, the patient's city of residence, the serial number of the prescription, the narcotic registry number of the prescriber, and the quantity and type of narcotic prescribed.

An examination of these tabulation sheets will uncover irregularities such as forgeries, fraudulent obtaining of narcotic drugs, and thefts of prescription blanks and their misuse by unauthorized persons. It will show if a patient has obtained prescriptions by going from doctor to doctor, if there is a signature of an unregistered physician, and if blanks reported stolen from one person turn up in the hands of another. Such irregularities will form the basis for a complete investigation.

HISTORY AND COST

A triplicate prescription system has been in effect in California since 1940. The number of prescriptions handled each year since that time has pretty much kept pace with the increase in population and the number of doctors practicing within the state.

In 1966, the law was amended to require that Percodan be prescribed on a triplicate narcotic prescription blank and at that time the number of prescriptions handled each month doubled. Currently, we are receiving and processing about 40,000 prescriptions per month.

The total annual cost of this operation including the salaries of three key punch operators and a clerk typist, machine rental, cost of prescriptions and postage is around $46,000 per year. This cost is broken down as follows:

Salaries	$24,000
Machine rental and operating expenses	15,000
Printing	5,000
Postage	2,000

VALUE

Through the simple process of a serially numbered prescription, with duplicate mailed to the Bureau of Narcotic Enforcement, there is afforded a control of legal supplies of narcotics—inhibiting their transfer into illicit channels while adding no obstacle to free use of the prescription by the prescribed and no burden upon the pharmacist, other than the requirement that once a month he send all of his duplicates to the Bureau in a single mailing envelope.

At the same time, the tissue triplicate copy of the prescription, remaining in the physician's pad of blanks, is a ready-made inventory record which is required not only by State law but by Federal regulations as well.

The advantages derived from the Triplicate Prescription System may be summarized as follows:

a. It prevents the doctor from becoming unknowingly a supplier of narcotics to addicts.

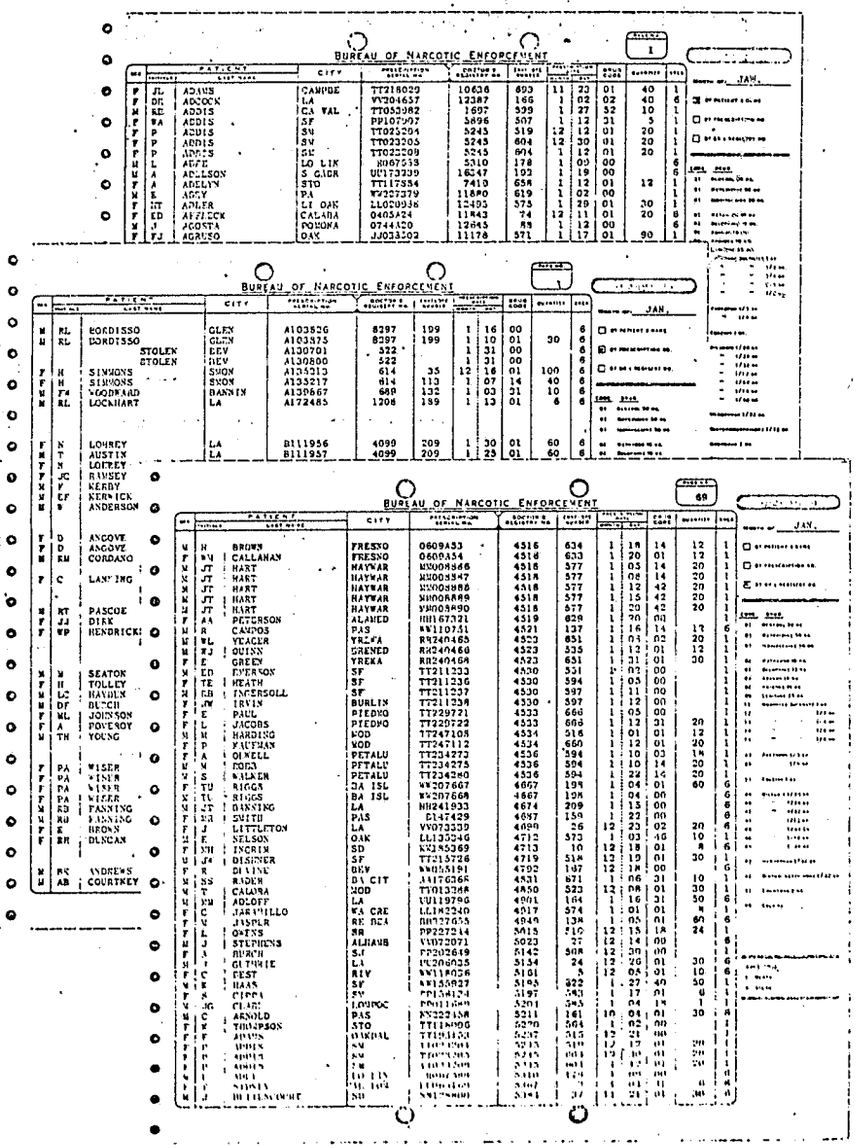
b. It provides the doctor with a ready-made record of narcotics prescribed by him.

c. It assists in the recovery of medical bags and other equipment stolen from the doctor by an addict.

d. It is a law enforcement tool providing vital information needed by law enforcement to initiate an investigation.

Each year Agents of the Bureau of Narcotic Enforcement make arrests of individuals who, in their attempts to obtain narcotics, have altered or falsified prescriptions which were issued to them in good faith by members of the medical profession. Without the triplicate narcotic prescription system, these arrests would not have been possible and the prescribing physicians, unknowingly, would have been the main source of supply for many addicts.

MONTHLY
NARCOTIC PRESCRIPTION
LISTINGS



CANTON, OHIO, *February 6, 1973.*

Memo to: The Hon. John Gilligan, Governor

DEAR GOVERNOR GILLIGAN: There is now much expert testimony and evidence documented in Washington and New York State indicating America's most serious drug problem—by 90%—is the overuse, misuse and illicit use of *legitimately* manufactured dangerous drug substances in the first instance. This drug problem is costing American thousands of lost lives each year, millions of lost production man hours and billions of dollars in industrially unproductive police protection, pusher incarceration, addict rehabilitation, overdose and toxic hospitalizationsand misguided drug education. There is no price tag on America's fears, tensions and griefs which are unparalleled in any other "civilized" country in the world. Might-have-been foreign tourists pass up violent America on their junkets. Tokyo has 1/200 the crime rate of New York City and 1/225 the drug arrests and entire London has only 1/5 the murders per year as the city of Cleveland, Ohio. Little wonder Japan's steel and cars undersell ours, or many industrial products of England, Germany and including most recently gunboats of Israel. To their price tags have not been added the percentage of unproductive dollars in crime costs, excess hospitalizations, and other allied parasitic dangerous drug related expenditures. Unfortunately, fighting drug abuse has become a major business enterprise, adding significantly to our GNP, a false yardstick in world competitive economics.

Up to the present documentation of facts, news media emphasis and resulting billions of dollars expended to fight drug abuse has been placed on illicit marijuana, clandestinely manufactured hallucinogens and imported heroin. Comparison poundages alone reflect a maximum 12 tons of heroin usage yearly versus 125 tons of barbiturates. Only recently have Senate investigations ripped off the sugar-coated sheep's clothing from pills, capsules and tablets to expose a hideous synthetic wolf—far more menacing, debilitating and crime inducing than even heroin.

Please examine carefully the following list of legally manufactured causes of social ills and their computer aid alleviation:

Sources of illicit drug use, overuse	*Computer detection and alleviation*
1. Forged and altered prescriptions	1. Uniform State-supplied and not easily counterfeited.
2. Pill pushing doctors	2. Peer group surveillance and subsequent fines, loss of license and possible incarceration.
3. Side selling pharmacists	3. Board of Pharmacy inventory control.
4. Doctor hopping patients	4. Easy and effectual detection of present "hoppers" and a deterrent to future "would trys."
5. Inadvertent over-medication from the same or several physicians.	5. Rising patients' toxic level detected by expert pharmacists' supervision.
6. Possible adverse or incompatible medications from the same or several physicians.	6. Again, expert pharmaceutical opinion.
7. Emergency admittances to hospitals or physicians offices.	7. Dangerous drug profile of patient obtained within minutes from computer source for effective diagnosing aid.
8. Sloppy distribution from manufacturer to intended ingestor through 450,000 handlers.	8. Efficient surveillance throughout complete chain of distribution.
9. Present overproduction requirements to meet legitimate demands.	9. Much less chance for black market or abuse diversion while still meeting legitimate medical needs.
10. Interns beginning prescribing practice.	10. Hospital chief of staff review together with peer group review.

An Assistant Chief Counsel of BNDD has personally expressed interest in meeting with Columbus professionals for the purpose of discussing the following:

1. Ohio's acceptance of Uniform Drug Code;

2. State computer tie-ins with Federal Bureau; and
3. Hearing about committee of professionals capable of exercising peer group surveillance and detection and follow-up of pushers, abusers and inadvertent dependers.

Since New York plans to implement their triplicate prescription computer plan in May, it would seem an opportune time for Governor Gilligan to personally meet with Governor Rockefeller for the purpose of bi-partisan cooperation in encouraging uniform prescription computer control in all the other states for the full effectiveness of controlling dangerous drug substances. It appears that the Federal Government in the past has either been misinformed or bought off and it is now imperative the states take direct action to protect their citizens. Only pressure from the various states can offset the forces of the powerful affected lobbies.

Third person payors in the form of Medicaid and Medicare have been vehicles for untold millions of health dollars being spent needlessly most conned by vendors and hypochondriacs. Some states are near bankruptcy. Workmen's Compensation and insurance health plans are also seriously overused by opportunists.

Peer group health surveillance and closed dangerous drug distribution computerization appears to be minimal steps for Government's intervention in the health fraud gripping our society. Possibly, for competition and study purposes, the State should seriously consider running a modified type national health program—hospitals, nursing homes, salaried doctors—similar to the Army for Medicaid and Medicare patients. If unproductive, emotionally debilitating costs such as crime, needless hospitalization, ambulance runs, lost production man hours, etc., continue to rise disproportionately to our standard of living, the trade deficit and welfare roles will mount, taxes will rise unbearably and even more serious social problems erupt and bury our once fine society.

FRANK D. BRECKBILL.

[From American Druggist Merchandising, Oct. 1, 1973]

OPERATING UNDER "TOUGHEST" DRUG LAW . . .

(By Gloria Zaludek)

The toughest, most aggressive drug-control law in the country—effective April 1, 1973 in New York state—are producing violently mixed reactions among pharmacists.

A spot survey by ADM indicates strong disagreement on the value of the stricted regulations and on their possible outcome.

Following is a sample of the divergent reactions statewide to the laws, which may prove a model for other states' legislation.

"I find the changes have affected our operation almost to no extent," says the owner of Martin Rein Pharmacy, Kenmore.

Mr. Rein says of his neighborhood pharmacy in a small plaza near Buffalo, "The new requirements fall into our normal operating procedures. We've always cautioned our clients when we refill their prescription for the last time. Now, we just do it more often.

"In my estimation, pharmacists understand the need for the stricter regulations, are complying, and conveying the message to their customers."

KEY CHANGES IN NEW YORK STATE'S DRUG LAWS

1. Many drugs considered highly abusable have been reclassified and added to the list of controlled substances: amphetamines, such as dexedrine, Preludin and Ritalin previously were not controlled, for example. Now they are on Schedule II.

Recently the City of New York proposed that 19 more drugs be treated as Schedule II because of their abuse potential. (Rulings should come this month on the first three such drugs: Doriden, Noludar, and Placidyl.)

2. All Schedule II substances must be prescribed by the physician on an official New York State triplicate form distributed by the state Department of Health. Formerly the doctor's own prescription blank sufficed—even for narcotic drugs. No copies of the prescription were made or filed.

With the new triplicate-form system, the pharmacist receives the first (original) and third copies. He retains the original for 5 years. (Previously only narcotics were filed and retained for 2 years.)

The pharmacist must file the copy with the State Bureau of Narcotic Control by the 15th of the month following the prescription date.

3. No prescription for controlled substances can exceed a 30-day supply, as taken in accordance with the prescribing physician's instructions. An unlimited supply could have been prescribed in the past.

4. All Schedule II through Schedule V substances are to be dispensed on a special orange label which also bears one or both of the following legends: "Controlled substance: Dangerous unless used as directed."

"Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."

Or when applicable, "This prescription is not refillable. Need a new written prescription from your physician."

Formerly, in contrast, no special colored labels were necessary. For a narcotic substance only, the pharmacist added, "This prescription cannot be refilled."

Joseph Hoffman, J & S Drugs, Glendale, says he "finds the new laws very easy to live by." He feels the responsibility of explaining them to patients rests with the pharmacists and "I believe we are filling that need. Our clients are informed about the status of their prescription—we offer to phone their physician if there's a question. They seem to agree that stricter laws are necessary and will definitely benefit everybody," Mr. Hoffman said.

"Everytime new laws or regulations are passed, they touch off a wave of violence" says Moe Gartner of the Bronx Medical Arts Pharmacy.

He feels that pharmacists are most vulnerable; unprotected in their stores, they are in jeopardy if they refuse to fill a prescription. "Yet as street sources for drugs dry up," he explains, "addicts are turning to a prime source—the pharmacy."

Dan Michaelson, M & W Pharmacy, Brooklyn, discusses a different problem he has in enforcing the new laws.

"We service a heavily geriatric population. Believe me, it's difficult to explain to people on long-range treatment that they'll have to return to their physicians more often for prescriptions. They resent the added transportation and office fees."

Anthony DiNicola mentioned several positive aspects of the stricter laws. His pharmacy, Atlantic Chemists of Freeport, Long Island, services "an average, middle-class neighborhood of about 8,000." He says he notices a more judicious drug-prescribing and drug-using attitude in the community.

"And we headed off any comfusion among our customers by alerting them beforehand to the coming changes."

He said he and his colleagues (4 pharmacists, 3 students) printed circulars quoting the new law and explaining its changes. They gave them to all customers and discussed them when possible. They also stuffed them into monthly statements for two months "since our pharmacy has a substantial charge account business. Problems never materialized," he said.

Ernest Wyre refers to the transition to stricter laws as "a nuisance. Special forms, if not completed properly by a physician, can delay our filling a prescription. It could mean a serious delay for those who need vital drugs."

But he says the new laws have changed prescribing habits of many doctors. In his Lenox Terrace Drug Store, Manhattan, he says he sees a "drastically reduced number of prescriptions for controlled substances. For instance, instead of scripting for codeine—and filling out added forms—doctors are more often writing for Darvon."

In Westchester County, Sal J. Rubino says he has noted an upsurge in robberies in the past few weeks in an area he describes as middle- to high-income.

He feels there is "an absolute connection between the theft increases and the orange labels now placed on controlled drugs.

"These labels show the sub-culture new addictive drugs they weren't aware of before," he explained, "and makes the drugs easier to spot in purses, medicine cabinets, and pockets.

"Also, the new labels seem to confuse and scare the public. One of my clients said she used to take meprobamate. But the orange label frightened her—'that's a dangerous drug,' she said—so she simply stopped taking it. How many others will be fearful and ignore therapeutic drug prescriptions?"

A Syracuse pharmacist cites his growing concern over one of the "obligations" of the new laws. Now pharmacists must report doctors who fail to submit within 72 hours a written script for a substance prescribed over the phone.

"Do you imagine that if I turn in a physician more than twice. I'd ever have a decent professional relationship with him again? Anyway, that 'obligation' should be theirs, not ours." he said.

A pharmacist in Binghamton asked. "What good a triplicate prescriptions? Anybody can easily visit two different doctors, use assumed names and take the prescriptions to two different pharmacies. No cross-reference is possible. The law creates extra work, and truly doesn't serve medical professionals or the consumer."

From a suburb of Albany, a pharmacist in a heavy-traffic area says most objections to the stricter regulations come from physicians and dentists. "They're up in arms. They don't like the closer scrutiny of their prescribing methods," he says. "And the extra forms they must purchase and use have caused a few doctors in my area to refuse to comply. They've stopped writing prescriptions."

Joseph Tumelty of the Pharmaceutical Society of the State of New York summed up the over-all reactions he received from pharmacists: "There is definitely a dichotomy.

"On the one hand, many believe that the laws help curb drug abuse. Fewer narcotics are being prescribed and addictive drugs are harder to come by.

"Also on the positive side, pharmacists see the opportunity of strengthening communications with their clients. By explaining to them the implication of the new laws, and the import and seriousness of certain drugs, they show their continuing community concern.

"Perhaps their position can be stated thus: since so many people are worried about drug abuse, it's well for pharmacy to lend the fight."

Mr. Tumelty continued, "Now we must consider the other side of the argument. And I must say, more pharmacists seem to be crossing over to this side of the fence.

"They feel that drying up the sources of hard drugs on the street is leading to more attacks on pharmacies.

"Another effect of the stricter legislation has been to alter the nature of some of the crimes. That is, someone caught with heroin receives a Class A felony charge—life imprisonment. 'Might as well carry a gun—same charge,' he reasons.

"And since plea bargaining is no longer possible, criminals refuse to inform on their contacts as they once did to lessen their sentence."

Mr. Tumelty added, "In New York state we're only beginning to feel the effects of the new legislation. It's premature to judge the effectiveness."

DANGEROUS DRUG DISTRIBUTION CONCERNS ASSOCIATED,
Canton, Ohio, December 11, 1973.

MR. JOHN R. BARTEL, JR.,
Drug Enforcement Agency,
Washington, D.C.

DEAR MR. BARTELS: Hopefully your bureau is in the position of implementing a 50-state triplicate script plan for closing up the distribution loopholes whereby licitly manufactured drugs are getting into illicit use.

It had been both my hope and endeavor that cooperation between the medical health care society and your Department could work cooperatively toward the solution of our nation's number one drug problem. However, after reviewing attempts at legislation by various states, it appears that this cooperation will not be possible.

By the implementation of a drug counting system only, the following benefits would still accrue to our society:

1. A complete production and inventory surveillance of each dangerous drug manufactured;
2. Ability of your Department to monitor high use hospitals and out patient facilities;
3. Detect physicians who are continuing extensive drug therapy through prescribing from schedules III and IV;

4. Monitor nursing homes, many of which are overutilizing mood altering medicines;
5. Detect pharmacists that may be selling without benefit of doctor's bona fide prescription for all scheduled drugs;
6. Begin tabulating hot areas of high over-the-counter use of dangerous drugs;
7. Complete accountability by pharmaceuticals of all dangerous drug substances, whether distributed under schedules II, III, IV or V.

This plan could be put into effect nationwide without disturbing the patient-physician confidentiality, since neither the social security number nor the individual's name would be on the computer copy under the plan.

Since you are working with mechanics only rather than personalities, the plan should not have resistance from the Civil Rights protectors or the mass media as there is NO infringement on the individual's rights. It would be a benefit to the public if the plan could be expanded to include physician peer group surveillance and drug profile review by pharmacists, in that

1. toxic reactions could be detected as drugs were prescribed by different physicians or dentists or other health care professionals to the same individual;
2. individuals who have inadvertently become dependent on medications could be detected and warned of impending life threatening problems;
3. unethical or misinformed physicians could be more easily detected through reading the drug profiles of their individual patients;
4. patients of nursing homes and hospitals would have better protection from misdiagnostic or overutilization of mood altering drugs.

It is understandable in light of recent events that the news media would look suspiciously on any attempt of the Government to further computerize our private lives and activities. It is a sad commentary, however, to bury the benefits of health care computerization in deceit and distrust of special interest groups who are benefitting by the overutilization of chemicals.

If any one group is forcing the Government into socialized medicine more than another, it is our health care vendors. Your careful attention and consideration to this recommendation is most appreciated.

Sincerely,

FRANK D. BRECKBILL.

PROPOSED PLAN FOR MONITORING LEGALLY PRESCRIBED ABUSED DRUGS

1. Patient contacts physician.
2. Physician determines an abused drug is required for medication.
3. If patient is unknown or record not in physician's file, physician's secretary requests positive identification of patient, preferably driver's license, and also requests social security card.
4. Social Security number and name as it appears on Social Security card is carefully noted on prescription with other standard prescription data.
5. Prescription is then given to patient.
6. Patient goes to pharmacy of his choice and presents prescription.
7. Pharmacist requests Social Security card for correlation of name and number.
8. Pharmacist requests patient sign multiple-type OCR form and then dispenses medication.
9. Pharmacist prepares Optical Character Reader form at his convenience, but preferably within 24 hours, and forwards one copy of form in postage-free envelope to Computer Complex. Other copies of form can be forwarded to required agencies (Medicaid, insurance, Medicare, etc.) for payment.

The following information is carefully noted on numerical form:

(a) Social Security Number.
(b) Patient's name, identical to Social Security card name.
(c) Physician's license number.
(d) Pharmacist's license number.
(e) Drug number.
(f) Quantity of drug prescribed and dosage.
(g) Number of refills.
(h) Insurance and/or Welfare data (price not carried to monitoring copy).

DANGEROUS DRUG DISTRIBUTION CONCERNS ASSOCIATED,
Canton, Ohio, January 15, 1974.

MR. TOM A. NUNZIATO,
Assistant Attorney General,
Columbus, Ohio

DEAR MR. NUNZIATO: In this manner I wish to thank you for soliciting my opinions regarding the Attorney General's proposed drug legislation. Your willingness to seek comments from outside the usual scope of professionals suggests a cooperative effort in dealing with America's number one health and crime problem. The following five features of the Bill are of particular benefit:

1. Closer conformity to the Federal drug law which, hopefully, will be expanded soon to include preventive as well as punishment features;
2. More realistic and practical approach to the marijuana problem;
3. More equitable and just treatment for both pushers and victims (hopefully unethical pharmaceuticals, pharmacists and physicians and their victims will also soon be more easily identificable);
4. Establishment of Controlled Substances Board involving the cooperation of those professionals entrusted with our health;
5. The continuing provision for the Board of Pharmacy's surveillance of licit drugs (hopefully computer technology can be implemented for their use in this preponderous job).

As with most drug legislation to date, there have been few provisions made to close the leaks in the drug distribution system or methods of detecting intentional or unintentional overprescribing. At least four states now have triplicate script generating computer data covering Schedule II drugs. Drugs in Schedules III, IV and V are also abusable and potentially deadly. Senate Bill 307 awaiting hearings in the Health & Education Committee provides a completely closed monitoring system.

The need for triplicate script was noted and advocated by some of America's most brilliant medical men meeting in New York City in 1967. The American Medical Association has distributed hundreds, perhaps thousands, of its paperback, "Drug Dependence, A Guide for Physicians" which outlines the plan in general terms on pages 158 and 159. Our nation would have less drug abuse problems today if their recommendation had become law in 1968.

The Controlled Substances Board provision of the Attorney General's bill may be that Committee which could function as the data collector. Each of the professional Boards would have relevant objective data for detecting their unethical members. The Mental Health Board could detect individuals dependent upon tranquilizers and pain killers before they actually became addicted. Preventive health care could become a reality.

According to Senator Birch Bayh's lengthy and in-depth investigation, licit drugs are causing our society ten times the number of problems of illicit drugs. A million adults are now addicts and another ten million are on their way to dependency and possible addiction.

Some welfare patients have been prescribed dosages over 20 times the recommended safe amount. Welfare Director Bates can verify the accuracy, effectiveness and need for computerization to help this often unintended overmedication.

Triplicate script might have prevented the drug overdose death reported in the Plain Dealer on January 10th. Triplicate script and computerization could effectively reduce the Cambridge State Hospital problem reported in yesterday's Plain Dealer.

As a result of my numerous contacts here in Ohio as well as other states and Washington, D. C., I am convinced that only through legislation can peer group surveillance be implemented. Resistance from within the professions and especially from the pharmaceutical companies is much too great for even conscientious Boards to overcome. I am also convinced the various Boards realize this urgent need to implement triplicate script and data collection.

May I meet with the Attorney General's Steering Committee to share more intimate information and recommendations?

Sincerely,

FRANK D. BRECKBILL.

APPENDIX 11



The Controlled Substances Act of 1970

...a BNDD manual for the

Pharmacist

January 1973



Prepared by
Office of Scientific Support
The Bureau of Narcotics and Dangerous Drugs
Washington, D.C.

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Important Definitions

The term "Act" means the Controlled Substances Act and/or the Controlled Substances Import and Export Act

The term "pharmacist" means any pharmacist licensed by a State to dispense controlled substances, and shall include any other person (e.g., pharmacist intern) authorized by a State to dispense controlled substances under the supervision of a pharmacist licensed by any such State.

The term "dispenser" means an individual practitioner, institutional practitioner, pharmacy or pharmacist who dispenses a controlled substance.

The term "person" includes any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity.

The term "registrant" means any person who is registered pursuant to the Act.

The term "readily retrievable" means that certain records are kept by automatic data processing systems or other electronic or mechanized record-keeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.

The term "prescription" means an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription).

Application of State Law and Federal Law

Nothing in this pamphlet shall be construed as authorizing or permitting any person to do any act which he is not authorized or permitted to do under other Federal or State laws. In addition, none of the policy and information in this pamphlet may be construed as authorizing or permitting any person to do any act which he is not authorized or refuse to meet any requirements imposed under the regulations published in the most recent publication of Title 21, Chapter II, of the Federal Register.

Schedules of Controlled Substances

The drugs that come under jurisdiction of the Controlled Substances Act are divided into five Schedules. They are as follows:

Schedule I

Drugs in this Schedule are those that have *no* accepted medical use in treatment in the United States. Some examples are Heroin, Marihuana, LSD, Peyote, Mescaline, Psilocybin, Tetrahydrocannabinols, Ketobemidone, Levomoramide, Racemoramide, Benzylmorphine, Dihydromorphine, Morphine methylsulfonate, Nicocodeine, Nicomorphine, and others.

Schedule II

Drugs in this Schedule include those formerly known as "Class A Narcotics," and, in addition, the amphetamines and methamphetamines. The drugs phenmetrazine (Preludin) and methylphenidate (Ritalin) are also in this schedule.

Some examples of narcotic drugs in this Schedule are:

Opium
Morphine
Codeine
Percodan (oxycodone)
Pantopon
Cocaine
Percobarb
Edrisal with Codeine
Dilaudid (dihydromorphinone)
Numorphan (oxymorphone)
Dolophine (methadone)
Demerol (meperidine)
Leritine (anileridine)
Mepergan (meperidine)
Levodromoran (racemorphan)
Alvodine (piminodine)

Some examples of amphetamine drugs in this Schedule are:

Benzedrine
Dexedrine
Dexamyl
D.A.S.
Bamadex
Dex-sule
Eskatrol
Phantos
Obolip
Dexobarb
Amvicel
Obocell
Biphetamine

Some examples of methamphetamine drugs in this Schedule are:

Syndrox
Desoxyn
Norodin
Obedrin
D.O.E.
Desbutal
Methedrine
Ambar

Schedule III

Drugs in this Schedule include those formerly known as "Class B Narcotics."

Some examples are:

Empirin with Codeine	Tussionex
A.S.A. with Codeine	Phenaphen with Codeine
Codempiral #2	Hycomine
Tylenol with Codeine	Soma with Codeine
Hycodan	Donnagesic #1
	Paregoric.

In addition to the above narcotic drugs, the following are some examples of non-narcotic drugs in Schedule III.

Noludar (methyprylon)	Seconal (secobarbital)
Chlorhexidol	Tuinal (amobarbital & secobarbital)
Alurate	
Doriden (glutethimide)	Nembutal (pentobarbital)
Carbrital	Butisol (butabarbital)
Amytal (amobarbital)	Fiorinal

All amphetamine and methamphetamine combination products not listed in Schedule II, are in Schedule III as of January 1, 1972, and are subject to Schedule III requirements.

Schedule IV

Some examples of drugs in this Schedule are:

Barbital		Methohexital	
Phenobarbital		Methylphenobarbital	
Noctec		Beta-Chlor (chloral betaine)	
Felsules	(chloral hydrate)	Placidyl (ethchlorvynol)	
Kessodrate		Equanil	
Somnos		Miltown	(meprobamate)
Valmid (ethinamate)		Kesso-Bamate)	
Paraldehyde		Petrichloral	

The drugs Librium and Valium are now being reviewed by the courts to determine if they are to be included as Controlled Substances. If so, they will be placed in Schedule IV.

Schedule V

Drugs in this Schedule include those drug preparations formerly known as "exempt narcotics," such as the cough syrups containing codeine. *Some* examples are:

Robitussin-AC	Cheracol (with codeine)
Elixir Terpin Hydrate with Codeine	Cosadein

For a more complete listing of Controlled Substances, contact the Regional Office of the Bureau of Narcotics and Dangerous Drugs in your area. A listing of the Regional Offices can be found at the back of this booklet.

Retail Dispensing Restrictions for Controlled Substances

Schedule V Controlled Substances and any non-prescription items in Schedules II, III, and IV, may be dispensed without a prescription at retail provided that:

(1) The dispensing is made only by a pharmacist or pharmacist intern and not by a non-pharmacist employee even if under the direct supervision of a pharmacist. However, after the pharmacist has fulfilled his professional and legal responsibilities, the actual cash, credit transaction, or delivery, may be completed by a non-pharmacist;

(2) Not more than 240 cc. (8 ounces) or not more than 48 solid dosage units of any Substance containing opium, nor more than 120 cc. (4 ounces) or not more than 24 solid dosage units of any other Controlled Substance may be dispensed at retail to the same purchaser in any given 48-hour period without a prescription.

(3) The purchaser at retail is at least 18 years of age;

(4) The pharmacist requires every purchaser at retail of a Controlled Substance not known to him to furnish suitable identification (including proof of age where appropriate);

(5) A bound record book is maintained which contains the name and address of the purchaser, name and quantity of Controlled Substance purchased, date of each sale and initials of the selling pharmacist. This record book shall be maintained for a period of two years from the date of the last transaction entered in the record book, and it must be made available for inspection and copying by officers of the United States, authorized by the Attorney General;

(6) Other Federal, State or local law does not require a prescription.

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Symbols and Labeling

Each commercial container of Controlled Substances will have on its label a symbol designating to which Schedule it belongs. The symbol for Schedule I through V Controlled Substances will be as follows: (I) or C-I; (II) or C-II; (III) or C-III; (IV) or C-IV; and (V) or C-V. The symbols will be at least twice as large as the largest letter printed on the label. Controlled Substances symbols will be located in the upper right corner of the principal panel of the label of the commercial container. Symbols may be overprinted on the label, in which case the symbol must be printed at least one-half the size of the label and in a contrasting color to all other printing on the label.

Any Controlled Substance manufactured after December 1, 1971, must bear the above-mentioned symbol.

These symbols are not required on prescription containers dispensed by a pharmacist to a patient in the course of his professional practice.

What the Prescription Label Must Contain

The pharmacist filling a prescription for a Controlled Substance must affix to the container a label showing the pharmacy name and address, the serial number and date of initial filling, the name of the patient, the name of the practitioner issuing the prescription, and directions for use and cautionary statements, if any, contained in the prescription as required by law.

The label of any drug listed as a "Controlled Substance" in Schedule II, III, or IV shall, when dispensed to or for a patient, contain the following warning: "CAUTION: Federal Law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."

Registration

Every pharmacy engaged in distributing or dispensing any Controlled Substance must register with the Bureau of Narcotics and Dangerous Drugs. The registration must be renewed annually and the Certificate of Registration must be prominently displayed in the same manner as the former Narcotic Tax Stamp or former FDA Registration. The Controlled Substances Act Registration replaces the Narcotic Tax Stamp, and the FDA Registration where necessary. If a person owns and operates more than one pharmacy he must register each place of business. A registration fee of $5.00 is charged annually for each registration. Every pharmacy will receive a re-registration application approximately 60 days before the expiration date of his registration each year. If a registered pharmacy does not receive the forms within 45 days before the expiration date of his registration, he must give notice of such fact and request the re-registration forms by writing to the Registration Branch of the Bureau of Narcotics and Dangerous Drugs, P. O. Box 28083, Central Station, Washington, D. C. 20005.

New Registrations

New pharmacies that seek to become registered for the first time after May 1, 1971, must request a Registration Application for New Registrants (BND Form 224) from the Registration Branch, Bureau of Narcotics and Dangerous Drugs, P. O. Box 28083, Central Station, Washington, D. C., or from any BNDD Regional Office.

Complete instructions and return envelopes will accompany the Registration Application for New Registrants.

Note: Any change of address, location, business activity or name by existing registrants will be handled as a new registration under the system.

Registration for Co-op Purchasing, Distribution, Repackaging and Relabeling

Any pharmacy engaged in distribution (e.g., a co-op buyer for a group of pharmacies) of Controlled Substances must register as a distributor with the Bureau of Narcotics and Dangerous Drugs. In order to be registered as a distributor, a pharmacy must meet certain security requirements and keep separate records, inventories, and stocks for that registration. If the pharmacy repacks and relabels Controlled Substances, it must be registered as a manufacturer and meet certain security, labeling, quota, and recordkeeping requirements for that activity.

Registration of Pharmacists

A pharmacist working in a registered pharmacy or in a hospital or other institution registered to dispense Controlled Substances, is NOT required to register individually.

Records

What Records Must be Kept

Every pharmacy engaged in handling any Controlled Substances must keep complete and accurate records of all receiving and dispensing transactions. All such records shall be maintained for a period of two years.

All inventories and records of Controlled Substances in Schedule II must be maintained separately from all other records of the pharmacy. All inventories and records of Controlled Substances in Schedules III, IV, and V must be maintained separately or must be in such form that they are readily retrievable from the ordinary business records of the pharmacy.

All records pertaining to Controlled Substances must be made available for inspection and copying by duly authorized officials of the Bureau of Narcotics and Dangerous Drugs.

On the effective date of this Act, Saturday, May 1, 1971, or as soon thereafter as it first engages in business, and every two years thereafter, the pharmacy must make a complete inventory of all stocks of Controlled Substances on hand. This inventory record must be kept for a period of two years. Pharmacies are *not* required to submit a copy of the inventory to the Bureau of Narcotics and Dangerous Drugs.

Central Recordkeeping Locations

Invoices and receiving records (but not order forms, inventory records, or prescription records) may be kept at a central location, rather than at the registered location (e.g., chain stores), if the registrant obtains approval

of his central recordkeeping system and a permit to keep central records. The permit to keep central records will be issued by the Bureau to a registrant upon application if the Bureau approves his central recordkeeping system and will be subject to the following conditions:

(1) The permit will specify the nature of the records to be kept centrally and the exact location where the records will be kept;

(2) The registrant agrees to deliver all or any part of the records to the registered location within 48 hours of receipt of a written request from the Bureau for such records and, if the Bureau chooses to do so in lieu of requiring delivery of the records to the registered location, to allow authorized employees of the Bureau to inspect the records at the central location upon request by such employees; and

(3) The failure of the registrant to perform his agreements under the permit shall revoke without further action by the Bureau the permit and all other such permits held by the registrant under other registrations. In the event of a revocation of other permits, the registrant must, within 30 days after the revocation, comply with the requirements of this section that all records be kept at the registered location.

Continuing Records Kept by a Pharmacy

On and after May 1, 1971, every pharmacy must maintain on a current basis a complete and accurate record of each Controlled Substance received.

Copy 3 of executed Order Forms retained by the pharmacy which have been completed as described on page 12, paragraph 1, will constitute a pharmacy's receiving records for Schedule II Controlled Substances. Invoices for Schedule III, IV, and V Controlled Substances will be considered as complete receiving records IF the actual date of receipt is clearly recorded on the invoices by the pharmacist or other responsible individual.

Inventory Requirements

On Saturday, May 1, 1971, every registrant must have taken and must, every two years thereafter take, a complete and accurate record of all stocks of Controlled Substances on hand. The biennial inventory date of May 1 may be changed by the registrant to fit his regular general physical inventory date, if any, so long as the date is not more than 6 months from the biennial date that would otherwise apply. The actual taking of the inventory should not vary more than 4 days from the biennial inventory date. The inventory record must:

(1) Indicate whether taken at opening or close of business, and the date the inventory was taken;



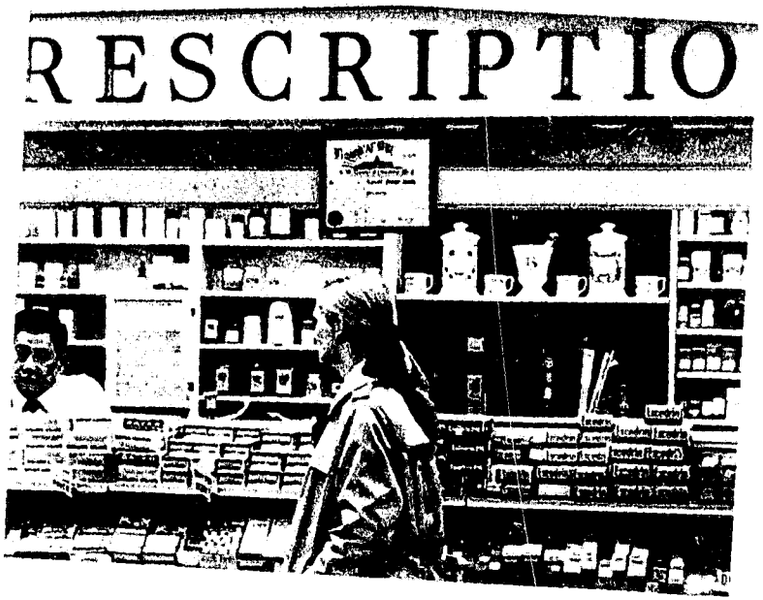
(2) Be signed by the person responsible for taking the inventory; and

(3) Be maintained at the location appearing on the registration for at least two years.

When taking the inventory of Schedule II Controlled Substances, an exact count or measure must be made. When taking the inventory of Schedule III, IV, and V Controlled Substances, an estimated count may be made unless the container holds more than 1,000 dosage units, in which case an exact count must be made if the container has been opened.

Order Forms

A triplicate order form is necessary for the transfer of controlled substances in Schedule II. In the past the Federal order forms were used for what were formerly called Class A and B Narcotics. Under the Controlled Substances Act, the use of the order forms will be for Schedule I and II drugs only.



Because the former Class B Narcotics are under Schedule III, they do not require order forms. Since April 30, 1971, the Internal Revenue Service no longer issues order forms. A registrant desiring the new BNDD order forms can obtain them by using the requisition form (BND-222D). Once a pharmacy has obtained the new BNDD order forms, they will then utilize Form BND-222B which is found in each order form book. No "charge" will be made for order forms. Do not send money for order forms.

TO ORDER FORMS, CONTACT:

BUREAU OF NARCOTICS AND DANGEROUS DRUGS
ATTENTION: REGISTRATION BRANCH
1405 EYE ST. N.W.
WASHINGTON, D.C. 20537

Power of Attorney

Any registered pharmacy may authorize one or more individuals whether or not located at the registered location of the pharmacy to obtain and execute order forms on his behalf by executing a power of attorney for each such individual. The power of attorney shall be signed by the same person who signed the most recent application for registration or reregistration and by the individual being authorized to obtain and execute order forms. The power of attorney shall be filed with the executed order forms of the purchaser, and shall be retained for the same period as any order form bearing the signature of the attorney. The power of attorney shall be available for inspection together with other order form records. Any power of attorney may be revoked at any time by executing a notice of revocation, signed by the person who signed (or was authorized to sign) the power of attorney or by a successor, whoever signed the most recent application for registration or reregistration, and filed it with the power of attorney being revoked.

Power of attorney forms should not be forwarded to the registration Branch in Washington, D.C., as in the past.

New Changes in Order Form Requirements

Several basic changes from the previous order form procedures are now effective, such as:

(1) After a registrant has issued an order form for Schedule II Controlled Substances and when he receives the items ordered, he must record, on his retained copy, the number of packages and the date such packages were received. A space on the new BNDD Order Forms has been provided for this entry.

(2) Former Class "B" Narcotics are classified as Schedule III Controlled Substances and *will not* be subject to official order form requirements.

The new BNDD order form books consist of six sets of order forms instead of the ten sets as has been the case with the former IRS order forms. A maximum of three books will be allowed each pharmacy unless its needs require more than three books at one time. In such case, the pharmacy should contact the Regional Director of BNDD in his area and explain the needs.

Lost or Stolen Order Forms

When unfilled order forms are lost, the pharmacy must execute a new form in triplicate. The pharmacy must also execute a statement containing the serial number and date of the lost form, stating that the drugs in the

lost form were never received, and attach a copy of that statement to Copy 3 of the lost form. A copy of the statement should also be attached to Copies 1 and 2 of the newly-executed order form.

When unused order forms are stolen, the pharmacy must immediately, upon discovery of such theft or loss, report this to the Registration Branch, Bureau of Narcotics and Dangerous Drugs, P. O. Box 28083, Central Station, Washington, D. C. 20005, stating the serial numbers of each form lost or stolen. If an entire book or books of order forms is lost or stolen, and the pharmacist is unable to state the serial numbers, he shall report, in lieu of the serial numbers, the date or approximate date of issuance.

If any unused order form reported stolen or lost is later recovered or found, the pharmacy shall immediately notify above-mentioned address.

Prescriptions

Who May Issue

A prescription for a Controlled Substance may be issued only by a physician, dentist, veterinarian, or other registered practitioner who is:

(1) Authorized to prescribe Controlled Substances by the jurisdiction in which he is licensed to practice his profession; and

(2) Either registered or exempted from registration pursuant to 21 C.F.R. 301.25 (military and Public Health Service physicians).

Purpose of Issue

A prescription for a Controlled Substance to be effective must be issued for a legitimate medical purpose by a practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of Controlled Substances is upon the prescribing practitioner, but a corresponding liability rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of Section 309 of the Controlled Substances Act and the person knowingly filling such a purported prescription, as well as the person issuing it, will be subject to the penalties provided for violations of the provisions of law relating to Controlled Substances.

Execution of Prescriptions by Practitioners

All prescriptions for Controlled Substances shall be dated as of, and signed

on, the day when issued and shall bear the full name and address of the patient and the name, address and registration number of the practitioner. A practitioner may sign a prescription in the same manner as he would sign a check or legal document; for instance, J. H. Smith or John H. Smith. Where an oral order is not permitted, prescriptions must be written with ink or indelible pencil or typewriter and must be manually signed by the practitioner. The prescription may be prepared by a secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations.

Refills and Renewals

No prescription for a Controlled Substance in Schedule II may be refilled and such prescriptions must be kept in a separate file.

Prescriptions for Controlled Substances in Schedule III or IV may be issued either orally or in writing by a practitioner and may be refilled *if so authorized*. The prescriptions may not be filled or refilled more than six months after the date issued, or be refilled more than five times after the date issued. After five refills or after six months, the practitioner may renew the prescription. A renewal of any such prescription shall be recorded on a new prescription blank and a new prescription number assigned to the prescription. Oral prescriptions must be committed to writing and filed by the pharmacist.

A prescription for a Controlled Substance listed in Schedule V may be refilled only as authorized by the prescribing practitioner on the prescription. If no such authorization is given, the prescription may not be refilled (the item may be sold over-the-counter, however, as explained on page 5, but the burden of determining the propriety of the dispensing is upon the pharmacist).

Transmittal of Oral Authorizations for Renewal

A practitioner's nurse or other member of his staff cannot authorize the renewal of a prescription for a Controlled Substance that has been refilled five times or is six months old. The authority for prescribing Controlled Substances is vested only with the practitioner, and he cannot delegate this function to anyone else. However, nurses or staff members receiving calls from pharmacies regarding renewals, may act as the practitioner's agent and transmit the practitioner's order.

Recording Refills

A pharmacist after refilling a prescription for any Controlled Substance in Schedules III or IV, must enter on the back of that prescription his initials, the date the prescription was refilled and the amount of drug dispensed on such refill. If the pharmacist merely initials and dates the back of the prescription, he shall be deemed to have dispensed a refill for the full face amount of the prescription.



Partial Filling of Schedule II Prescriptions

The partial filling of a Schedule II Controlled Substance prescription is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription. He may supply a portion of the quantity called for provided he makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription). The remaining portion may be filled within 72 hours of the first dispensing, however, if the remaining portion is not, or cannot be filled within the 72 hour period, the pharmacist must notify the prescribing practitioner. No further quantity may be supplied beyond the 72 hours except on a new prescription.

Partial Filling of Schedule III and IV Controlled Substance Prescriptions

Partial filling of prescriptions for Controlled Substances in Schedules III and IV is permitted if the pharmacist filling or refilling the prescription sets forth the quantity dispensed and his initials on the back of the prescription. In addition, the partial fillings may not exceed the total amount authorized in the prescription and the dispensing of all refills must be within the six month limit.

Filing of Prescriptions for Controlled Substances

Prescriptions for Controlled Substances must be filed in either one of the following three ways:

(1) A pharmacy can maintain three separate files—a file for Schedule II drugs dispensed, a file for Schedule III, IV, and V drugs dispensed, and a file for prescriptions for all other drugs dispensed.

(2) A pharmacy can maintain two files—a file for all Schedule II drugs dispensed and another file for all other drugs dispensed including those in Schedules III, IV, and V. If this method is used, the prescriptions in the file for Schedules III, IV, and V must be stamped with the letter "C" in red ink, not less than one inch high, in the lower right-hand corner. This distinctive marking makes the records "readily retrievable" for inspection.

(3) A pharmacy can maintain two files—one file for all controlled drugs in all Schedules and a second file for all prescriptions for non-controlled drugs dispensed. If this method is used, the prescriptions for drugs in Schedules III, IV, and V in the controlled drug prescription file must be stamped with the red letter "C" not less than one inch high in the lower right-hand corner, as previously mentioned.

In states where the Uniform Narcotic Act (or other state law) requires all narcotic prescription records be kept together, the Bureau is of the opinion that a positive conflict exists between Federal and state law and, under Section 708 of the Controlled Substances Act, Federal requirements prevail.

Distribution of Controlled Substances by a Pharmacy to a Physician or Another Pharmacy, Hospital or Nursing Home

A pharmacy registered to dispense a controlled substance may distribute (without being registered as a distributor) a quantity of controlled substances to a physician or to another pharmacy, hospital, or nursing home for the purpose of general dispensing: Provided, That:

1. The physician, hospital, nursing home or other pharmacy is registered to dispense the controlled substance to be distributed to him;

2. The distribution is recorded by the pharmacy delivering the substance and records are maintained by the physician, hospital, nursing home or other pharmacy showing receipt of such substances.

3. An order form is used if the substance is listed in schedule II;

4. The total number of dosage units of all controlled substances distributed by the pharmacy during the 12-month period in which the pharmacy is registered to dispense does not exceed 5 percent of the total number of dosage units of all controlled substances distributed and dispensed during the 12-month period

If, at any time during the 12-month period during which the pharmacy is registered to dispense, the pharmacy has reason to believe that the total number of dosage units which will be distributed will exceed 5 percent of the total number of dosage units of all controlled substances distributed and dispensed in the 12-month period, the pharmacy must obtain a registration to distribute controlled substances.

As an incident to a distribution as stated above, a pharmacist may manufacture (without being registered to manufacture) an aqueous or oleaginous solution or solid dosage form containing a narcotic controlled substance in a proportion not exceeding 20 percent of the complete solution, compound, or mixture.

Emergency Dispensing of Schedule II Controlled Substances

In the case of a bona fide emergency situation, as defined by the Secretary of Health, Education, and Welfare, a pharmacist may dispense a Schedule II Controlled Substance upon receiving oral authorization of a prescribing practitioner provided that:

1. The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period. Prescribing or dispensing beyond the emergency period must be pursuant to a written prescription;

2. The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information, except for the prescribing practitioner's signature;

3. If the prescribing practitioner is not known to the pharmacist, he must make a reasonable effort to determine that the oral authorization came from a practitioner, by verifying his phone number against that listed in the directory and other good faith efforts to insure his identity;

4. Within 72 hours after authorizing an emergency oral prescription, the prescribing practitioner must cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. The prescription shall have written on its face "Authorization for Emergency Dispensing." The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the 72 hour period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing. The pharmacist must notify the nearest office of the Bureau if the prescribing practitioner fails to deliver a written prescription to him; failure of the pharmacist to do so shall void the authority to dispense without a written prescription of a prescribing practitioner.

Definition of Emergency Situation for Dispensing

For the purpose of authorizing an oral prescription of a Controlled Substance listed in Schedule II of the Federal Controlled Substances Act, the term "emergency situation" as defined by the Secretary of Health, Education and Welfare means those situations in which the prescribing practitioner determines that:

1. Immediate administration of the Controlled Substance is necessary for proper treatment of the intended ultimate user;

2. No appropriate alternative treatment is available, including administration of a drug which is not a Controlled Substance under Schedule II of the Act; and

3. It is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance prior to the dispensing.

Return of Controlled Substances to Supplier

Any pharmacy lawfully in possession of a Controlled Substance listed in any Schedule may return that substance (without being registered as a distributor) to the person from whom he obtained it or to the manufacturer of the substance, provided that a written record is maintained which indicates the date of the transaction, the name, form and quantity of the substance, the name, address and registration number, if any, of the person making the return and the name, address, and registration number, if known, of the supplier or manufacturer. In the case of returning a Controlled Substance listed in Schedule II, an order form shall be issued by the supplier to the pharmacy in the transfer of such substance. This section also applies to other practitioners who wish to return Controlled Substances to the supplier.

Distribution upon Discontinuance or Transfer of Business

Any pharmacy desiring to discontinue or transfer business activities altogether or with respect to Controlled Substances must return the Certificate of Registration, and any unexecuted order forms in his possession, to the Registration Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, P. O. Box 28083, Central Station, Washington, D. C. 20005, for cancellation. Any controlled Substance in his possession may be disposed of either in accordance with disposal of Controlled Substances as listed on page 20 or by transfer to another registrant. If the pharmacy desires to transfer the substance to another registrant, it must take an inventory of all Controlled Substances which it desires to transfer and submit this inventory, together with its name, address, and registration number, and the name, address and registration number of the proposed transferee, to the Regional Director of the Bureau in the region in which it is doing business at least 14 days in advance of the date of the proposed transfer. If the Regional Director does not notify the registrant that the transfer should be postponed or cancelled, the pharmacy may transfer the substances

to the named transferee without being registered as a distributor. All Controlled Substances listed in Schedule II must be transferred pursuant to order forms. Schedule III, IV, and V substances will be transferred in accordance to the inventory prepared by the pharmacy and submitted to the Regional Director. If the Regional Director denies the pharmacy authority to make the proposed transfer, the pharmacy must either dispose of the substance in accordance with disposal instructions on page 21 or transfer the substances to another registrant in accordance with this section and/or the instructions of the Regional Director.

It should be noted that on the date of transfer of the controlled substances, all records required to be kept by the transferor with reference to the controlled substances being transferred, shall be transferred to the transferee. Responsibility for the accuracy of records prior to the date of transfer remains with the transferor, but responsibility for custody and maintenance shall be upon the transferee.

Miscellaneous Requirements

Security

Pharmacies must keep Schedule II Controlled Substances either in a locked, substantially constructed cabinet or safe. Schedule III, IV, and V Controlled Substances must be stored in a locked cabinet or dispersed throughout the non-controlled stock in such a manner to obstruct theft.

A pharmacy should not employ as an agent or employee who has access to Controlled Substances any person who has had an application for registration denied, or has had his registration revoked at any time.

Drug Theft

Any pharmacy involved in loss of Controlled Substances must notify the Regional Office of the Bureau in its region of the theft or significant loss upon discovery. In addition, the pharmacy must complete BND Form 106 regarding the loss or theft and forward the report to the Regional Office. BND Forms 106 may be obtained from any Regional Office of the Bureau. Complete instructions on how to execute BND Form 106 are set forth on the form.

Disposal of Controlled Substances

A pharmacy wishing to dispose of any excess or undesired stocks of Controlled Substances must contact the nearest BNDD Regional or District Office and request the necessary forms (BND Form 41). Three copies of Form 41 will be completed and forwarded to the Regional Office which serves the area in which the pharmacy is situated. A cover letter from the pharmacy must be attached to the reports stating that the controlled substances are not desired and the pharmacy wishes to dispose of them.

The Regional Director will authorize and instruct the pharmacy to dispose of the Controlled Substances in one of the following manners:

(1) By transfer to a person registered under the Act and authorized to possess the substance;

(2) By delivery to an Agent of the Bureau or to the nearest office of the Bureau;

(3) By destruction in the presence of an Agent of the Bureau or other authorized person; or

(4) By such other means as the Regional Director may determine to assure that the substance does not become available to unauthorized persons.

This section shall not be construed as affecting or altering in any way the disposal of Controlled Substances through procedures provided in laws and regulations adopted by any state.

Interns Residents or Foreign Physicians

Any physician who is an intern, resident, or foreign physician may issue a prescription (for an out-patient only) for a controlled substance using the BNDD registration number of the hospital or other institution by whom the physician is employed provided that:

1. The hospital or institution elects to engage in such activity.
2. The hospital or institution has determined that the physician is permitted to prescribe drugs for out patients by the jurisdiction in which he is practicing.
3. The hospital or institution authorizes the physician to prescribe under its registration and assign a specific code number for each physician so authorized. An example of code number is shown below:

Registration Number	"AB1234567-012."	Code Number

Pharmacists should contact the hospital or institution for verification if they have any doubts in filling such prescriptions.

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Below is a listing of the Bureau of Narcotics and Dangerous Drugs Regional, District, and Resident Offices, and the States in their jurisdiction. For matters concerning theft, registration, recordkeeping, security, etc., contact the nearest office in your area.

REGIONAL OFFICE	DISTRICT OFFICES	STATES COVERED
Boston Regional Office JFK Federal Building Room G-64 Boston, Mass. 02203 617-223-2170	Hartford—203-244-3230	Conn., Maine, Mass., N.H., R.I., Vermont
New York Regional Office 555 West 57th St. Suite 1900 New York, N.Y. 10019 212-971-5151	Buffalo—716-842-3218 Newark—201-645-2637 Westbury—516-997-6565 Albany—518-472-3425	N.Y., Northern N. Jersey
Philadelphia Regional Office 400 Market Street Suite 1000 Philadelphia, Pa. 19106 215-597-9530	Pittsburgh—412-644-3390 Wilmington—302-658-6551	Delaware, Southern N. Jersey, Pa.
Baltimore Regional Office 31 Hopkins Place Room 955 Baltimore, Md. 21201 301-962-4800	Charleston—304-343-1384 Greensboro—919-275-9458 Norfolk—703-441-6729 Washington, D.C.—202-755-7960	D.C., Md., N.C., W. Va.
Miami Regional Office 201 Northeast 12th Street Miami, Florida 33132 305-350-4441	Atlanta—404-526-4401 Columbia—803-765-5251 Jacksonville—904-791-3566 San Juan—809-723-5170	Fla., Ga., S.C., Puerto Rico
Detroit Regional Office 357 Federal Building & U.S. Courthouse 231 West Lafayette Detroit, Mich. 48226 313-226-7290	Cincinnati—513-684-3671 Cleveland—216-522-3705 Louisville—502-582-5900 Columbus—614-469-7482	Ky., Mich., Ohio
Chicago Regional Office Suite 1810 219 South Dearborn St. Everett M. Dirksen Federal Office Building Chicago, Illinois 60604 312-353-7875	Indianapolis—317-633-7662 Milwaukee—414-224-3395	Ill., Indiana, Wisc.

REGIONAL OFFICE	DISTRICT OFFICES	STATES COVERED
New Orleans Regional Office 1001 Howard Ave. Plaza Tower Suite 1800 New Orleans, La. 70113 504-527-6841	Birmingham—205-325-3636 Jackson—601-948-2484 Little Rock—501-378-5265 Nashville—615-749-5988 Memphis—901-534-3396	Ala., Ark., La., Miss., Tenn.
Kansas City Regional Office U.S. Courthouse 811 Grand Avenue Suite 231 Kansas City, Mo. 64106 816-374-2631	Des Moines—515-284-4700 Minneapolis—612-725-2783 Omaha—402-221-4720 St. Louis—314-622-4891	Minn., N. Dakota, S. Dakota, Iowa, Kansas, Mo., Neb.
Dallas Regional Office Room 4A5 1100 Commerce Street Dallas, Texas 75202 214-749-3631	Houston—713-226-4331 Oklahoma City—405-231-4141 San Antonio—512-225-4693 Tulsa—918-584-7611 McAllen—512-686-6556 Laredo—512-722-9976 El Paso—915-543-7475	Oklahoma, Texas
Denver Regional Office 1950 Stout Street U.S. Customs House Denver, Colorado 80202 303-837-3951	Albuquerque—505-843-3287 Phoenix—602-261-4866 Salt Lake City—801-524-4156 Nogales—602-287-4727 Tucson—602-792-6533	Ari., Col., New Mexico, Utah, Wyo.
Seattle Regional Office 221 First Avenue, West Room 200 Seattle, Wash. 98119 206-442-5443	Anchorage—907-277-7638 Portland—503-221-3371 Spokane 509-456-5342	Alaska, Idaho, Montana, Ore., Wash.
Los Angeles Regional Office 1340 West 6th Street Los Angeles, Calif. 90017 213-688-2650	Honolulu—808-546-8630 Las Vegas—702-385-6343 San Diego—714-293-5654 San Francisco—415-556-6771 Calexico—714-352-2447	Calif., Hawaii, Nevada

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APPENDIX 12

The Controlled Substances Act of 1970



a BNDD Manual for

Drug Security



FEBRUARY 1972

Prepared by
The Bureau of Narcotics and Dangerous Drugs
Washington, D.C.

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A MESSAGE FROM THE DIRECTOR

The safeguarding of Controlled Substances is a problem confronting all manufacturers, wholesalers, pharmacies and other drug handlers. Federal law limits the handling of these substances and by regulation requires that they be properly safeguarded at all times. The Bureau of Narcotics and Dangerous Drugs is charged with the responsibility for ensuring that the proper safeguards are maintained. The drug industry, of course, has the primary operational function to establish and maintain effective systems to prevent diversion. Mutual cooperation will result in fewer diversions and less accessibility for potential abusers. This pamphlet is intended to outline the steps you should take to establish proper safeguards. Further guidance can be obtained by contacting one of our Regional Offices.

Operational Safeguards

Employee Screening

Concern with personnel security must start before an employee is hired. Pre-employment screening for the purpose of identifying potential security problems is important when choosing new employees for work in or around areas where Controlled Substances are handled. The screening program should include a careful evaluation of the applicant's personal and previous employment references. Criminal background checks with local law enforcement authorities as well as with BNDD are equally important. Similar safeguards and precautionary evaluations should be made before transferring established employees to new jobs in areas where Controlled Substance manufacturing, processing, storing, shipping, and dispensing are accomplished, or any other areas where Controlled Substances are handled.

Restricted Access

The areas which must be protected against theft vary greatly depending on the type of business in which a drug handler is engaged. A manufacturer for example must be on the alert for pilferage at every level of drug handling from the receipt of raw materials through all phases of manufacturing and processing to finished product storage and shipping. He must be alert for pilferage of production rejects and of returned or damaged merchandise. He must watch for the theft of dosage form drugs, bulk raw material, and even chemical precursors. He must be certain that all Controlled Substances are secure throughout their entire chain of handling. In contrast to the security problems confronting manufacturers and other large volume drug handlers, those with which a pharmacist must contend are smaller yet no less serious. The pharmacist must make the Controlled Substance storage and prescription compounding areas secure. As in the case of larger drug handlers, a key factor in protecting against theft is limiting employee access. Access to all drug items of abuse should be restricted to the absolute minimum number of employees needed to handle daily transactions in those drugs.

General Security Requirements

The general security requirement requires all applicants and registrants to provide *effective* controls and procedures to guard against theft and diversion of controlled substances. Substantial compliance with the standards set forth in

21 CFR 301.72—301.76 may be deemed sufficient to the Bureau after an evaluation of the overall security system and the security needs of the individual registrant or applicant.

Since the overall security system is the basis for approval, the following are factors considered when evaluating whether or not the registrant must specifically meet each separate standard:

Type of activity conducted (e.g. processing bulk chemicals, preparing dosage forms, packaging, labeling, cooperative buying, etc.) The type of activity will determine a number of things such as: how many employees have access, size of the storage container and thereby how easily it can be taken, whether the controlled substance is in a usable form and therefore likely to be diverted, the length of time controlled substances are stored, etc.

Any registrant or applicant desiring to determine whether or not a *proposed* security system substantially complies with Bureau requirements as prescribed by regulations may submit plans, blueprints, sketches, etc. regarding the proposed security system to either the Regional Director in the Region where the system will be used or to the Office of Compliance, BNDD, Washington, D.C. Even though the Regional Director or Office of Compliance advises the registrant or applicant that the plans, etc. substantially comply with the security regulations, final approval will only be made at the time the system is completed and can be inspected at the location where it is to be used.

Physical security controls of locations registered and approved under the former Harrison Narcotic Act or the former Narcotic Manufacturing Act of 1960 as of April 30, 1971, are considered to be in compliance with present security regulations. However, new facilities or work or storage areas constructed or utilized for controlled substances which have not previously been approved by the Bureau (even if these new facilities are similar to those previously approved by the Bureau) will not necessarily be deemed in compliance with the security regulations.

Security Requirements For Nonpractitioners

Nonpractitioners include manufacturers, packagers, repackagers, labelers, relabelers, distributors, brokers, importers and exporters.

Minimum Security Standards for Nonpractitioner Handling—Schedule I and II Controlled Substances

Schedule I and II raw materials, bulk materials awaiting further processing, and finished products must be stored in one of the following secure storage areas:

Where small quantities permit:

a. A money safe or a GSA Class 5 rated or equivalent steel cabinet (see page 13 for specifications).

b. The safe or cabinet, if it weighs less than 750 pounds, must be bolted or cemented to the floor or wall in such a way that it cannot readily be removed.

c. The safe or cabinet must, if necessary, depending on the quantities and types of controlled substances stored, be equipped with an alarm system which when unauthorized entry is attempted, transmits a signal directly to a central protection company or a local or state police agency with legal responsibility to respond. The signal may be transmitted to a 24 hour control station operated by the registrant.

Note: all money safes must be UL approved.

A vault constructed or under construction before September 1, 1971, which is of substantial construction with a steel door, combination or key lock and an alarm system. (This facility would normally have been approved previously by the Bureau.)

A vault constructed after September 1, 1971, and meeting the following specifications or equivalent:

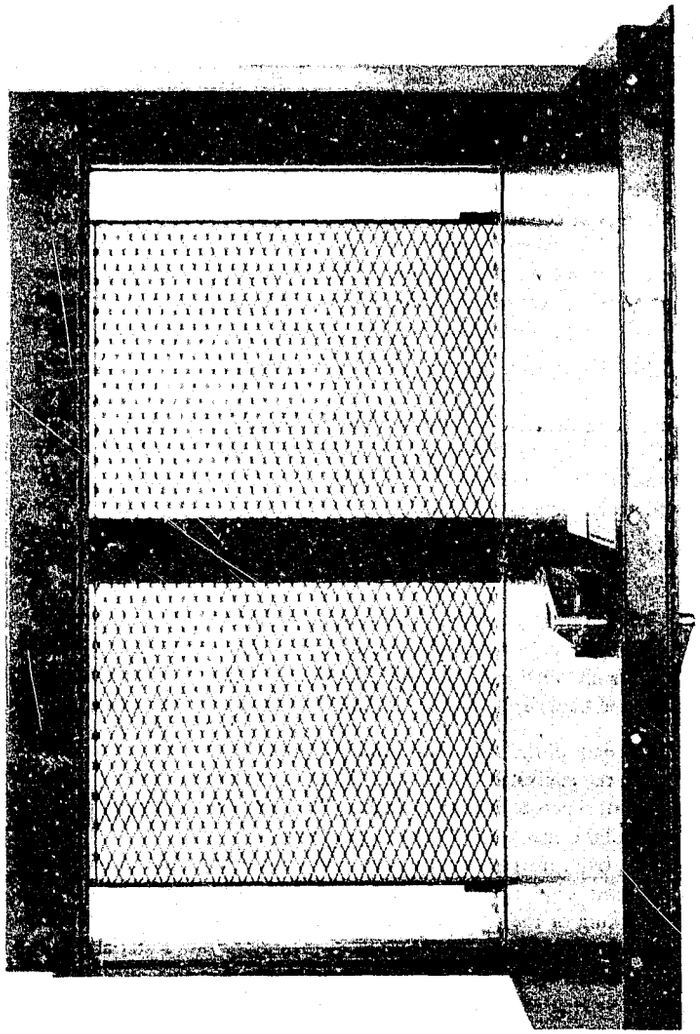
a. Walls, floors and ceilings constructed of at least 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with ½ inch steel rods tied 6 inches on center, or the structural equivalent to such reinforced walls, floors and ceilings.

b. The door of the vault must contain a multiple-position combination lock or the equivalent, a relocking device or equivalent and steel plate with a thickness of at least ½ inch. (The GSA Class 5 rated steel door meets all the qualifications for the vault door.)

c. The vault, if operations require it to remain open for frequent access, must be equipped with a "day gate" which is self-closing and self-locking or the equivalent. If the operation requires only that the vault be opened infrequently, such as to remove raw material in the morning and return raw material at night, and is always relocked immediately after use, a "day gate" is not required.

d. The walls or perimeter of the vault must be equipped with an

alarm which, when unauthorized entry is attempted, transmits a signal directly to a central station protection company, or a local or state police agency which has a legal responsibility to respond, or a 24 hour control station operated by the registrant. If necessary, due to local conditions or other problems, holdup buttons shall be placed at strategic points of entry to the perimeter area of the vault.



e. The vault door must be equipped with a contact switch.

f. The vault must have one of the following:

1. Complete electrical lacing of the walls, floor and ceiling or
2. Sensitive ultrasonic equipment within the vault or
3. A sensitive sound accumulator system or
4. Such other device designed to detect illegal entry as may be approved by the Bureau.

NOTE:

It is worthwhile to re-emphasize at this point the concept of evaluating security on an overall basis, that is, examining each element of a security system separately and then putting them all together and measuring the system against the potential theft or diversion problem the individual registrant or applicant might encounter in his special circumstances. In this way, the Bureau may approve a security system even though some of the specific standards are not met. For example: A registrant who provides 24 hour guard surveillance may not need the secure vault specifications set forth in the regulations, or a registrant who handles large quantities of inprocess liquids running through a pipe system need not vault this form of controlled substance because of the difficulties in obtaining the liquid and the probable non-restrictability of the liquid if taken. The minimum standards and general security requirements set out above are to be used by BNDD as a basis for making decisions on the specific security needs of the registrant when the overall security system is not deemed to be adequate. If the registrant does not adjust the overall security to meet what the Bureau determines to be effective security controls, then he may be subject to meeting each individual security requirement exactly as set forth in the regulations.

Minimum Security Standards for Nonpractitioner Handling Schedules III, IV, and V Controlled Substances

Minimum security standards for storage of Schedule III, IV, and V controlled substances must include two specific requirements: (1) the controlled substance must be separated from all other merchandise and during working hours the controlled substances must be kept under constant surveillance by a supervisor or a specific individual who has the responsibility for this duty. (The controlled substances may be stored with other pharmaceuticals in a separate room or storage area within a building if there is limited access to the room or storage area); and (2) the security includes an alarm system installed on the outer perimeter of the building or on the safe, cabinet, vault, or inside storage area, which must be equipped to transmit, upon unauthorized entry, a signal to a central station protection company or a local or state police agency which has a legal duty to respond, or a 24 hour control station operated by the registrant.

[illegible] requirements may be accomplished by using an automatic [illegible] the following manner: [illegible] Class A and Class C controlled substances [illegible] requirements for Class B controlled substances [illegible] which complies with the security requirements [illegible] Controlled substances may be stored in a building [illegible] building which has walls or perimeter fencing [illegible] to provide security monitoring [illegible] access is controlled by a card reader [illegible] personal identification number [illegible] key lock.

Multiple Storage Areas—Schedules I—V Controlled Substances

[illegible] necessary for registrants to maintain [illegible] controlled substances separately. Some examples [illegible] special inventory areas, [illegible] controlled substances may be stored apart from the main stock of controlled substances, provided that each storage area complies with the security requirements set forth in the previously described minimum standards.

Accessibility to Storage Areas—Schedules I—V Controlled Substances

[illegible] to minimize the possibility of internal diversion, the registrant [illegible] access to the storage areas for controlled substances to a minimum number of employees.

[illegible] that the registrant maintain a current list of each employee [illegible] and the specific controlled substances to which each employee has access. [illegible] employee maintenance personnel, janitorial staff, or other visitors [illegible] controlled substances must be escorted by an employee [illegible] and employees to provide adequate observation [illegible] that these unauthorized persons are in the storage area.

Agent or Nonpractitioners

When controlled substances are distributed by registrants [illegible] agents, or [illegible], the registrant is responsible for providing [illegible] adequate security to guard against theft or diversion while the substances are being stored or handled by the agents.

Public Warehouse and Common or Contract Carriers

[illegible] controlled substances in a public warehouse and its



possible for selecting a warehouse that will provide adequate security against theft or diversion. The registrant and not the warehouse is responsible for the security of the controlled substances. The Bureau will examine the public warehouse as part of security inspections and determine if adequate security is in place.

The registrant also is responsible for selecting a common or contract carrier that will provide adequate security for controlled substances while they are in transit. If the registrant has substantial quantities of controlled substances lost or stolen in transit when using the facilities of a particular common or contract carrier, he should take steps to choose another carrier or means of transportation for shipments of controlled substances.

Persons shall notify the Bureau, as required by [illegible]

storage or in-transit losses: securely wrapping and sealing packages containing controlled substances, utilizing unmarked or coded boxes or shipping containers, etc. when otherwise not required.

Security Controls for Nonpractitioners—Manufacturing Areas

All manufacturng activities (including processing, packaging, and labeling) involving controlled substances listed in *any* schedule must conform to the following security controls:

1. All in-process substances must be returned to the controlled substances storage area at the termination of the process. If the process is not completed at the end of a workday (except where a continuous process or other normal manufacturing operation should not be interrupted), the processing area or tanks, vessels, bins, or bulk containers containing controlled substances must be securely locked inside an area or building which affords adequate security.

2. Manufacturing activities with controlled substances must be conducted in an area or area(s) with limited access and must be kept under surveillance by an employee or employees so designated in writing by management to be responsible for the area. The designated employee(s) must be able to provide continuous surveillance of the area in order that unauthorized persons may not enter or leave the area without his knowledge. Limited access may be accomplished by use of physical dividers such as walls or partitions, by traffic control lines or restricted space designations.

3. During the production of controlled substances, the manufacturing area should be accessible only to those employees necessary for efficient operation.

If it becomes necessary for persons (maintenance personnel, visitors, etc.) to be present or pass through manufacturing areas during production, the registrant must have an employee designated in writing as being responsible for providing surveillance of the area.

Theft or Loss by Nonpractitioners

The registrant must notify the Regional Office covering his area of any theft or significant loss of any controlled substance. The registrant must also promptly complete and submit BND Form 106 regarding such loss or theft. Thefts must be reported whether or not the controlled substances are subsequently recovered and/or the responsible parties identified and action taken

against them.

Nonpractitioners—Other Security Controls

1. Good Faith Inquiry: Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant must make a good faith inquiry either with the Bureau or with the appropriate State-licensing agency, if any, to determine that the person is registered to possess the controlled substance.

2. Suspicious Orders: The registrant must design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant must inform the Regional Office of the Bureau covering his area of suspicious orders when discovered by the registrant. Suspicious order include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

Security Requirements For Practitioners

Practitioners include physicians, dentists, veterinarians, researchers, hospitals, pharmacies, or other persons registered or otherwise permitted to do research, distribute, dispense, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

Storage Area Minimum Standards for Practitioners

Minimum security standards for practitioners as set forth in the regulations are guidelines to be used in evaluating security. They may not necessarily be acceptable as providing effective controls and operating procedures to prevent diversion of controlled substances. For example, a hospital that keeps large quantities of controlled substances on hand may need a safe or vault similar to the requirements for a distributor. The same reasoning also applies to other practitioners.

The overall security controls utilized by a practitioner will be evaluated to determine if they meet the intent of the law and regulations to prevent diversion.

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Minimum Security Standards for Practitioners Handling Schedules I and II Controlled Substances

Controlled substances listed in Schedules I and II must be stored in a securely locked cabinet of substantial construction.

Even though the Federal Regulations do not specifically define the type of construction required relating to the locked cabinet, BNDD intends the regulations to mean that Schedules I and II must be given adequate protection. Therefore, depending on other security measures, a wood cabinet may or may not be considered adequate. In an area with a high crime rate, a strong metal cabinet or safe would probably be required. In other cases, a locked drawer in a desk or file cabinet might be adequate.

Some of the factors considered when evaluating a practitioner's security of controlled substances include, but are not limited to: (1) the number of employees, customers and/or patients who have access to the controlled substances; (2) the location of the registrant (high or low crime area); (3) use of an effective alarm system; (4) quantity of controlled substances to be kept on hand; etc.; (5) prior history of theft or diversion.

Methadone Storage and Handling By Practitioners

Methadone must be stored and handled under secure conditions. This is especially important in maintenance programs where large amounts of methadone will be in close proximity to addicts, and under the supervision of people whose specialty is medicine and science, and not law enforcement.

In all cases, methadone must be stored in securely locked cabinets of substantial construction. Additional security will be required for large quantities of methadone.

Handling procedures must be such as to minimize pilferage or theft.

Minimum Security Standards for Practitioners Handling Schedules III—V Controlled Substances

Controlled substances listed in Schedules III-V must be stored in a securely locked cabinet of substantial construction, except in the case of pharmacies. Pharmacies have the option of storing the controlled substances as set forth above, or concealing them by dispersal throughout the stock of non-controlled substances.

Again an overall evaluation of the practitioner's security will be made by BNDD utilizing the general and minimum security requirements as outlined in this booklet to assure that the controlled substances are afforded effective security.

Other Security Controls for Practitioners

In order to minimize the opportunities for diversion of controlled substances, practitioners have an obligation not only to provide effective physical security, but also to initiate additional procedures to reduce access by unauthorized persons as well as to provide alarm systems where necessary.

Employee or Agent of Practitioners

A practitioner must not employ an agent or employee who has had his application for registration with BNDD denied or revoked at any time, and who, as a result of his employment, will have access to controlled substances.

Loss or Theft

A practitioner shall notify the nearest BNDD Regional Office of the theft or significant loss of any controlled substances upon discovery of such loss or theft. The practitioner shall promptly complete and submit BND Form 106 regarding such theft or loss.

Specifications—Steel Cabinet and Door

Class 5 Steel Cabinet — The Class 5 steel cabinet affords the following security protection:

1. 30 man-minutes against surreptitious entry
2. 10 man-minutes against forced entry.
3. 20 man-hours against lock manipulation
4. 20 man-hours against radiological techniques

Class 5 Steel Door—The Class 5 steel door affords the following security protection:

1. 30 man-minutes against surreptitious entry
2. 10 man-minutes against forced entry
3. 20 man-hours against lock manipulation
4. 20 man-hours against radiology techniques

Application of State Law and Federal Law

Nothing in this pamphlet shall be construed as authorizing or permitting any person to do any act which he is not authorized or permitted to do under other Federal or State laws. In addition, none of the policy and information in this pamphlet may be construed as authorizing or permitting any person to do any act which he is not authorized or refuse to meet any requirements imposed under the regulations published in the most recent publication of Title 21, Chapter II, of the Federal Register.

Below is a listing of the Bureau of Narcotics and Dangerous Drugs Regional, District, and Resident Offices, and the States in their jurisdiction. For matters concerning theft, registration, recordkeeping, security, etc., contact the nearest office in your area.

Regional Office	District Offices	States Covered
Boston Regional Office JFK Federal Building Room G-64 Boston, Mass. 02203 617-223-2170	Hartford—203-244-3348	Conn., Maine, Mass., N.H., R.I., Vermont
New York Regional Office 90 Church Street Suite 605 New York, N.Y. 10007 212-264-7181	Buffalo—716-843-3218 Newark—201-645-2637	N.Y., Northern N. Jersey
Philadelphia Regional Office 400 Market Street Suite 1000 Philadelphia, Pa. 19106 215-597-9530	Pittsburgh—412-644-3390	Delaware, Southern N. Jersey, Pa.
Baltimore Regional Office 31 Hopkins Place Room 955 Baltimore, Md. 21201 301-962-4800	Charleston—304-343-1384 Greensboro—919-275-9458 Norfolk—703-627-7775 Washington D.C.— 202-755-7940	D.C., Md., N.C., Va., W.Va.
Miami Regional Office 201 Northeast 12th Street Miami, Florida 33132 305-350-4441	Atlanta—404-526-3111 Columbia—803-253-3251 Jacksonville—904-791-3566	Fla., Ga., S.C., Puerto Rico
Detroit Regional Office 357 Federal Building & U.S. Courthouse 231 West Lafayette Detroit, Mich. 48226 313-226-7290	Cincinnati—513-684-3671 Cleveland—216-522-3705 Louisville—502-582-5908	Ky., Mich., Ohio
Chicago Regional Office Suite 1800 219 South Dearborn St. Everett M. Dirksen Federal Office Building Chicago, Illinois 60604 312-353-7875	Indianapolis—317-633-7662 Milwaukee—414-272-3395	Ill., Indiana, Wisc.

New Orleans Regional Office 546 Carondelet Street New Orleans, La. 70130 504-527-6841	Birmingham—205-325-3497 Jackson—601-948-2484 Little Rock—501-375-8605 Nashville—615-242-5988 Memphis—901-534-3396	Ala., Ark., La., Miss., Tenn.
Kansas City Regional Office 811 Grand Avenue Suite 231 Kansas City, Mo. 64106 816-374-2631	Des Moines—515-284-4587 Minneapolis—612-725-2783 Omaha—402-221-4720 St. Louis—314-622-4891	Minn., N. Dakota, S. Dakota, Iowa, Kansas, Mo., Neb.
Dallas Regional Office Room 4A5 1100 Commerce Street Dallas, Texas 75202 214-749-3631	Houston—713-226-4331 Oklahoma—405-231-4141 San Antonio—512-225-4324 Tulsa—918-584-7611 McAllen—512-225-4297 Laredo—512-723-5531 El Paso—915-533-5261	Oklahoma, Texas
Denver Regional Office 1950 Stout Street New Customs House Denver, Colorado 80202 303-837-4291	Albuquerque—505-843-2056 Phoenix—602-261-4866 Salt Lake City—801-524-4156	Ari., Col., New Mexico, Utah, Wyo.
Seattle Regional Office 221 First Avenue, West Room 200 Seattle, Wash. 98104 206-442-5443	Anchorage—907-272-7638 Portland—503-226-3361	Alaska, Idaho, Montana, Ore., Wash.
Los Angeles Regional Office 1340 West 6th Street Los Angeles, Calif. 90017 213-688-2650	Honolulu—808-546-5995 Las Vegas—702-385-6343 San Diego—714-293-6654 San Francisco—415-556-6771	Calif., Hawaii, Nevada

APPENDIX 13

BNDD REGISTRATION INFORMATION

INFORMATION REGARDING BNDD REGISTRATION

Persons required to register.

Every person who (1) manufactures, imports, distributes, dispenses, prescribes or administers any controlled substance, or who proposes to engage in the manufacture, importation, distribution, dispensing, prescribing or administering of any controlled substance, or who (2) exports or proposes to engage in the exportation of controlled substances listed in Schedules I through IV, shall obtain annually a registration unless exempted by law or 21 CFR 301.23–.29, or 21 CFR 311.24–.28. Only persons actually engaged in such activities are required to obtain a registration; related or affiliated persons who are not engaged in such activities are not required to be registered. (For example, a stockholder or parent corporation of a corporation manufacturing controlled substances is not required to obtain a registration.)

Separate registration for independent activities.

(a) The following ten groups of activities are deemed to be independent of each other:

(1) Manufacturing (including repackaging and relabeling) controlled substances;

(2) Distributing controlled substances;

(3) Dispensing controlled substances listed in schedules II through V;

(4) Conducting research (other than research described in subparagraph (6) of this paragraph) with controlled substances listed in schedules II through V;

(5) Conducting instructional activities with controlled substances listed in schedules II through V;

(6) Conducting research with narcotic drugs listed in schedules II through V for the purposes of continuing the dependence on such drugs of a narcotic drug dependent person, in the course of conducting an authorized clinical investigation, in the development of a narcotic addict rehabilitation program, pursuant to a notice of claimed investigational exemption for a new drug approved by the Food and Drug Administration;

(7) Conducting research and instructional activities with controlled substances listed in schedule I;

(8) Conducting chemical analysis with controlled substances listed in any schedule;

(9) Importing controlled substances; and

(10) Exporting controlled substances listed in schedules I through IV.

(The term "exporter" includes every person who exports, or who acts as an export broker for exportation of, controlled substances listed in schedules I through IV. The term "importer" includes every person who imports, or who acts as an import broker for importation of, controlled substances listed in any schedule.)

(b) Every person who engages in more than one group of independent activities shall obtain a separate registration for each group of activities, except as provided in this paragraph. Any person, when registered to engage in the group of activities described in each subparagraph in this paragraph, shall be authorized to engage in the coincident activities described in that subparagraph without obtaining a registration to engage in such coincident activities, provided that, unless specifically exempted, he complies with all requirements and duties prescribed by law for persons registered to engage in such coincident activities.

(1) A person registered to manufacture or import any controlled substance or basic class of controlled substance shall be authorized to distribute that substance or class, but no other substance or class which he is not registered to manufacture or import;

(2) A person registered to manufacture any controlled substance listed in schedules II through V shall be authorized to conduct chemical analysis and preclinical research (including quality control analysis) with narcotic and nonnarcotic controlled substances listed in those schedules in which he is authorized to manufacture;

(3) A person registered to conduct research with a basic class of controlled substance listed in schedule I shall be authorized to manufacture such class if and to the extent that such manufacture is set forth in the research protocol filed with the application for registration, and to distribute such class to other persons registered or authorized to conduct research with such class or registered or authorized to conduct chemical analysis with controlled substances;

(4) A person registered or authorized to conduct chemical analysis with controlled substances shall be authorized to manufacture and import such substances for analytical or instructional purposes, to distribute such substances to other persons registered or authorized to conduct chemical analysis or instructional activities or research with such substances and to persons exempted from registration pursuant to § 301.26, to export such substances to persons in other countries performing chemical analysis or enforcing laws relating to controlled substances or drugs in those countries, and to conduct instructional activities with controlled substances; and

(5) A person registered or authorized to conduct research (other than research described in paragraph (a)(6) above) with controlled substances listed in schedules II through V shall be authorized to conduct chemical analysis with controlled substances listed in those schedules in which he is authorized to conduct research to manufacture such substances if and to the extent that such manufacture is set forth in a statement filed with the application for registration, and to distribute such substances to other persons registered or authorized to conduct chemical analysis, instructional activities, or research with, such substances and to persons exempted from registration pursuant to § 310.26, and to conduct instructional activities with controlled substances;

(6) A person registered to dispense controlled substances listed in schedules II through V shall be authorized to conduct research described in 21 CFR, 301.22 (a)(6) and to conduct instructional activities with those substances.

(c) A single registration to engage in any group of independent activities may include one or more controlled substances listed in the schedules authorized in that group of independent activities. A person registered to conduct research with controlled substances listed in schedule I may conduct research with any substance listed in schedule I for which he has filed and had approved a research protocol.

Separate registrations for separate locations.

(a) A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, or dispensed by a person.

(b) The following locations shall be deemed not to be places where controlled substances are manufactured, distributed, or dispensed:

(1) A warehouse where controlled substances are stored by or on behalf of a registered person, unless such substances are distributed directly from such warehouse to registered locations other than the registered location from which the substances were delivered or to persons not required to register by virtue of subsection 302(c)(2) of the CSA (21 U.S.C. 822(c)(2));

(2) An office used by agents of a registrant where sales of controlled substances are solicited, made, or supervised but which neither contains such substances (other than substances for display purposes or lawful distribution as samples only) nor serves as a distribution point for filling sales orders; and

(3) An office used by a practitioner (who is registered at another location) where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of the professional practice of the practitioner at such office, and where no supplies of controlled substances are maintained.

Exemption of agents and employees; affiliated practitioners.

The requirement of registration is waived for any agent or employee of a person who is registered to engage in any group of independent activities, if such agent or employee is acting in the usual course of his business or employment. An individual practitioner who is an agent or employee of another practitioner registered to dispense controlled substances may, when acting in the usual course of his employment, administer and dispense (other than by issuance of prescription) controlled substances if and to the extent that such individual practitioner is authorized or permitted to do so by the jurisdiction in which he practices, under the registration of the employee or principal practitioner in lieu of being registered himself. (For examples, a pharmacist employed by a pharmacy need not be registered individually to fill a prescription for controlled substances if a pharmacy is so registered, and a doctor employed by a hospital may admin-

ister and dispense, but not issue prescriptions for, controlled substances to patients in the hospital if the hospital is registered to dispense such substances.)

Time for application for registration; expiration date.

(a) Any person who is required to be registered and who is not so registered may apply for registration at any time. No person required to be registered shall engage in any activity for which registration is required until the application for registration is granted and a Certificate of Registration is issued by the Director to him.

(b) Any person who is registered may apply to be re-registered not more than 60 days before the expiration date of his registration.

(c) At the time any person is first registered, he shall be assigned to one of twelve groups, which shall correspond to the months of the year. The expiration date of the registrations of all persons within any group will be the last day of the month designated for that group. In assigning any person to a group, the Bureau may select a group the expiration date of which is less than one year from the date such person was registered. If the person is assigned to a group which has an expiration date less than 3 months from the date on which the person is registered, the registration shall not expire until one year from that expiration date; in all other cases, the registration shall expire on the expiration date first following the date on which the person is registered.

Application forms; contents; signature.

(a) If any person is required to be registered and is not so registered and is applying for registration:

(1) To manufacture or distribute controlled substances, he shall apply on BND Form 225;

(2) To dispense, or to conduct research (other than conducting research with narcotic drugs listed in schedules II through V for the purpose of continuing the dependence on such drugs of a narcotic drug dependent person) with, or to conduct instructional activities with, controlled substances listed in schedules II through V, he shall apply on BND Form 225;

(3) To conduct research with narcotic drugs listed in schedules II through V for the purpose of continuing the dependence on such drugs of a narcotic drug dependent person, he shall apply on BND Form 225;

(4) To conduct research with controlled substances listed in schedule I, he shall apply on BND Form 225, with three copies of a research protocol describing each research project involving substances listed in schedule I attached to the form;

(5) To conduct instructional activities with controlled substances listed in schedule I, he shall apply as a researcher on BND Form 225 with two copies of a statement describing the nature, extent and duration of such instructional activities attached to the Form;

(6) To conduct chemical analysis with controlled substances listed in any schedule, he shall apply on BND Form 225;

(7) To import or export controlled substances, he shall apply on BND Form 225.

(b) Each application for registration to handle any basic class of controlled substance listed in schedule I (except to conduct chemical analysis with such classes), and each application for registration to manufacture a basic class of controlled substance listed in schedule II, or to conduct research with any narcotic controlled substance listed in schedule II, shall include the Bureau Controlled Substances Code Number for each basic class or substance to be covered by such registration.

(c) Each application shall include all information called for in the form, unless the item is not applicable, in which case this fact shall be indicated.

(d) Each application, attachment, or other document filed as part of an application, shall be signed by the applicant, if an individual; by a partner of the applicant, if a partnership; or by an officer of the applicant, if a corporation, corporate division, association, trust or other entity. An applicant may authorize one or more individuals, who would not otherwise be authorized to do so, to sign applications for the applicant by filing with the Registration Branch of the Bureau a power of attorney on BND Form 231a for each such individual. The power of attorney shall be signed by a person who is authorized to sign applications under this paragraph and shall

contain the signature of the individual being authorized to sign applications. The power of attorney shall be valid until revoked by the applicant.

Acceptance for filing; defective applications; inspection.

If found to be complete, the application will be accepted for filing. A defective application will be returned to the applicant within 10 days following its receipt with a statement of the reason for not accepting the application for filing. A defective application may be corrected and resubmitted for filing at any time. Accepting an application for filing has no bearing on whether the application will be granted. An application may be amended or withdrawn after filing. The Director may inspect, or cause to be inspected, the establishment of an applicant or registrant.

Certificate of Registration; denial of registration.

The Director shall issue a Certificate of Registration (BND Form 223) to an applicant if the issuance of registration is required under the applicable provisions of section 303 of the Act (21 USC 823). In the event that the issuance of registration or re-registration is not required, the Director shall deny the application. Before denying any application, the Director shall issue an order to show cause and, if requested by the applicant, shall hold a hearing on the application.

Fee amounts.

(a) For each registration or re-registration to manufacture controlled substances, the registrant shall pay a fee of $50.

(b) For each registration or re-registration to distribute controlled substances, the registrant shall pay a fee of $25.

(c) For each registration or re-registration to dispense, or to conduct research or instructional activities with, controlled substances listed in schedules II through V, the registrant shall pay a fee of $5.

(d) For each registration or re-registration to conduct research or instructional activities with a controlled substance listed in schedule I, the registrant shall pay a fee of $5.

(e) For each registration or re-registration to conduct chemical analysis with controlled substances listed in any schedule, the registrant shall pay a fee of $5.

(f) For each registration or re-registration import controlled substances, the registrant shall pay a fee of $25.

(g) For each registration or re-registration to export controlled substances, the registrant shall pay a fee of $25.

Time and method of payment; refund.

Registration and re-registration fees shall be paid at the time when the application for registration or re-registration is submitted for filing. Payment should be made in the form of a personal, certified or cashier's check or money order made payable to "Bureau of Narcotics and Dangerous Drugs." Payments made in the form of stamps, foreign currency, or third party endorsed checks will not be accepted. In the event that the application is not accepted for filing or is denied, the payment shall be refunded to the applicant.

Persons exempt from fee.

(a) The Director shall exempt from payment of a fee for registration or re-registration the following persons:

(1) Any official or agency of the United States Army, Navy, Air Force, Coast Guard, Veterans Administration, or Public Health Service who or which is authorized to procure or purchase controlled substances for official use; and

(2) Any official, employee or other civil officer or agency of the United States, of any State, or any political subdivision or agency thereof, who or which is authorized to purchase controlled substances, to obtain such substances from official stocks, to dispense or administer such substances, to conduct research, instructional activities, or chemical analysis with such substances, or any combination thereof, in the course of his or its official duties or employment.

(b) In order to claim exemption from payment of a registration or re-registration fee, the registrant shall have completed the certification on the appropriate application form, wherein the registrant's superior (if an individual) or officer (if an agency) certifies to the status and address of the registrant and to the authority of the registrant to acquire, possess, or handle controlled substances.

(c) Important: Exemption from payment of a registration or re-registration fee does not relieve the registrant of any other requirements or duties prescribed by law.

Modification in registration.

Any registrant may apply to modify his registration to authorize the handling of additional controlled substances by submitting a letter of request to the Registration Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Post Office Box 28083, Central Station, Washington, D.C. 20005. The letter shall contain the registrant's name, address, registration number, and the substances and/or schedules to be added to his registration, and shall be signed by the same person who signed the most recent application for registration or re-registration. If the registrant is seeking to handle additional controlled substances listed in schedule I for the purpose of research or instructional activities, he shall attach three copies of a research protocol describing each research project involving the additional substances, or two copies of a statement describing the nature, extent, and duration of such instructional activities, as appropriate. No fee shall be required to be paid for the modification. The request for modification shall be handled in the same manner as an application for registration.

Termination of registration.

The registration of any person shall terminate if and when such person dies, ceases legal existence, discontinues business or professional practice, or changes his name or address as shown on the registration. Any registrant who ceases legal existence, discontinues business or professional practice, or changes his name or address as shown on the Certificate of Registration shall notify the Director promptly of such fact. In the event of a change in name or address, the person may apply for a new registration in advance of the effective date of such change.

Transfer of registration.

No registration or any authority conferred thereby shall be assigned or otherwise transferred except upon such conditions as the Director may specifically designate and then only pursuant to his written consent.

INVENTORY REQUIREMENTS

Every registrant, other than an "individual practitioner" (definition and further explanation is stated below), shall on the day he is first registered and every two years thereafter, make a complete and accurate record of all stocks of controlled substances on hand. The record must:

a. Indicate the date on which the inventory was taken and whether taken at close or opening of business.

b. Be signed by the person responsible for taking the inventory.

c. Be maintained at the location appearing on the registration for at least two years.

A registered individual practitioner is not required to keep records with respect to *narcotic* controlled substances listed in schedules II through V which he prescribes or administers in the lawful course of his professional practice; he shall keep records, however, with respect to such substances that he dispenses other than by prescribing or administering. A registered individual practitioner is not required to keep records with respect to *nonnarcotic* controlled substances listed in schedules II through V which he dispenses in any manner unless he regularly charges his patients, either separately or together with charges for other professional services, for such substances so dispensed (e.g., when he substitutes his services for those of a pharmacist).

The term "individual practitioner" means a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted by the United States or the jurisdiction in which he practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

Records required.

Every registrant required to keep records pursuant to 21 CFR 304.03 shall maintain on a current basis a complete and accurate record of every controlled substance which is manufactured, imported, received, sold, delivered, exported or otherwise disposed of by him. As a general rule these records must contain the following for each transaction:

a. Full name or "brand" name, strength and form of substance(s). (Example: *Dextroamphetamine 15mg. plus Amobarbital 60mg. capsules or "RAINBOW #2"* R.Tm. *capsules.*)

b. Actual date of distribution, dispensing, receipt, etc., (an invoice date is not sufficient if it is not the actual date of the receipt, distribution, etc.)

c. Quantity received, sold, dispensed, or otherwise disposed of. (Example: 3 x 50 capsule bottles).

d. Name and address, (registration number, if applicable) of the person to whom the substance was sold, dispensed, etc., or from whom received, etc.

For more specific details, see 21 CFR, Part 304. Records and Reports of Registrants; 21 CFR, Part 305—Order Forms; and 21 CFR 306—Prescriptions.

Copies of the "Comprehensive Drug Abuse Prevention and Control Act of 1970" (P.L. 91-513) and the regulations promulgated under this law can be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 at a nominal cost.

Important Note: When you have completed the application for registration, retain the application copy numbered 3 for your records. Submit the copies numbered 1 and 2 with appropriate fee as indicated on the application.
No application, which requires a registration fee, will be accepted for filing and processing, unless the application is ACCOMPANIED BY SUCH FEE.

PUBLIC LAW 91–513

SCHEDULES OF CONTROLLED SUBSTANCES

Establishment

Sec. 202. (a) There are established five schedules of controlled substances, to be known as schedules I, II, III, IV, and V. Such schedules shall initially consist of the substances listed in this section. The schedules established by this section shall be updated and republished on a semiannual basis during the two-year period beginning one year after the date of enactment of this title and shall be updated and republished on an annual basis thereafter.

Placement on schedules, findings required

(b) Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on the effective date of this part, and except in the case of an immediate precursor, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance. The findings required for each of the schedules are as follows:

(1) *Schedule I.*—

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has no currently accepted medical use in treatment in the United States.

(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

(2) *Schedule II.*—

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.

(C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.

(3) *Schedule III.*—

(A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

(4) *Schedule IV.*—

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substance in schedule III.

(5) *Schedule V.*—

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

(c) Schedules I, II, III, IV, and V shall, unless and until amended pursuant to section 201, consist of the following drugs or other substances, by whatever official name, common or usual name, chemical name, or brand name designated:

SCHEDULE I

Opiates

(a) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Acetylmethadol	9601
(2) Allylprodine	9602
(3) Alphacetylmethadol	9603
(4) Alphameprodine	9604
(5) Alphamethadol	9605
(6) Benzethidine	9606
(7) Betacetylmethadol	9607
(8) Betameprodine	9608
(9) Betamethadol	9609
(10) Betaprodine	9611
(11) Clonitazene	9612
(12) Dextromoramide	9613
(13) Dextrorphan	9614
(14) Diampromide	9615
(15) Diethylthiambutene	9616
(16) Dimenoxadol	9617
(17) Dimepheptanol	9618
(18) Dimethylthiambutene	9619
(19) Dioxaphetyl butyrate	9621
(20) Dipipanone	9622
(21) Ethylmethylthiambutene	9623
(22) Etonitazene	9624
(23) Etoxeridine	9625
(24) Furethidine	9626
(25) Hydroxypethidine	9627
(26) Ketobemidone	9628
(27) Levomoramide	9629
(28) Levophenacylmorphan	9631
(29) Morpheridine	9632
(30) Noracymethadol	9633
(31) Norlevorphanol	9634
(32) Normethadone	9635
(33) Norpipanone	9636
(34) Phenadoxone	9637
(35) Phenampromide	9638
(36) Phenomorphan	9647
(37) Phenoperidine	9641
(38) Piritramide	9642
(39) Proheptazine	9643
(40) Properidine	9644
(41) Racemoramide	9645
(42) Trimeperidine	9646

Opium derivatives

(b) Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Acetorphine	9319
(2) Acetyldihydrocodeine	9051
(3) Benzylmorphine	9052
(4) Codeine methylbromide	9070
(5) Codeine-N-Oxide	9053
(6) Cyprenorphine	9054
(7) Desomorphine	9055
(8) Dihydromorphine	9145
(9) Etorphine	9056
(10) Heroin	9200
(11) Hydromorphinol	9301
(12) Methyldesorphine	9302

(13) Methylhydromorphine	9304
(14) Morphine methylbromide	9305
(15) Morphine methylsulfonate	9306
(16) Morphine-N-Oxide	9307
(17) Myrophine	9308
(18) Nicocodeine	9309
(19) Nicomorphine	9312
(20) Normorphine	9313
(21) Pholcodine	9314
(22) Thebacon	9315

Hallucinogenic substances

(c) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of their salts, isomers and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) 3,4-methylenedioxy amphetamine	7400
(2) 5-methoxy-3,4-methylenedioxy amphetamine	7401
(3) 3,4,5-trimethoxy amphetamine	7390
(4) Bufotenine	7433
(5) Diethyltryptamine	7434
(6) Dimethyltryptamine	7435
(7) 4-methyl-2,5-dimethoxyamphetamine	7395
(8) Ibogaine	7260
(9) Lysergic acid diethylamide	7315
(10) Marihuana	7360
(11) Mescaline	7381
(12) Peyote	7415
(13) N-ethyl-3-piperidyl benzilate	7482
(14) N-methyl-3-piperidyl benzilate	7484
(15) Psilocybin	7437
(16) Psilocyn	7438
(17) Tetrahydrocannabinols	7370

SCHEDULE II

Substances, vegetable origin or chemical synthesis

(a) Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.

Raw opium	9600
Opium extracts	9610
Opium fluid extracts	9620
Powdered opium	9639
Granulated opium	9640
Tincture of opium	9630
Apomorphine	9030
Codeine	9050
Ethylmorphine	9190
Hydrocodone	9193
Hydromorphone	9194
Metopon	9260
Morphine	9300
Oxycodone	9143
Oxymorphone	9652
Thebaine	9333

(2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (1), except that these substances shall not include the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw	9650

(4) Coca leaves (9040) and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine (9041) or ecgonine (9180).

Opiates

(b) Unless specifically excepted or unless in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters ethers, and salts is possible within the specific chemical designation:

(1) Alphaprodine	9010
(2) Anileridine	9020
(3) Bezitramide	9800
(4) Dihydrocodeine	9120
(5) Diphenoxylate	9170
(6) Fentanyl	9801
(7) Isomethadone	9226
(8) Levomethorphan	9210
(9) Levorphanol	9220
(10) Metazocine	9240
(11) Methadone	9250
(12) Methadone-Intermediate, 4-cyano-2-dimethylamino-4,4-diphenyl butane	9254
(13) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid	9802
(14) Pethidine	9230
(15) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine	9232
(16) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate	9233
(17) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid	9234
(18) Phenazocine	9715
(19) Piminodine	9730
(20) Racemethorphan	9732
(21) Racemorphan	9733

Stimulants

(c) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers	1100
(2) Phenmetrazine and its salts	1630
(3) Any substance which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers	1105
(4) Methylphenidate	1724

SCHEDULE III

Stimulants

(a) Unless specifically excepted or unless listed in another schedule any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) Those compounds, mixtures, or preparations in dosage unit form containing any stimulant substances which are currently listed as excepted compounds under 21 CFR 308.32, and any other drug of the quantitative composition shown in that list for those drugs or which is the same except that it contains a lesser quantity of controlled substances | 1405

Depressants

(b) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect

on the central nervous system:

(1) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid 2100

(2) Chlorhexadol 2510

(3) Glutethimide 2552

(4) Lysergic acid 7300

(5) Lysergic acid amide 7310

(6) Methyprylon 2575

(7) Phencyclidine 7471

(8) Sulfondiethylmethane 2600

(9) Sulfonethylmethane 2605

(10) Sulfonmethane 2610

(11) Tilidine 9750

Narcotic drugs

Except as otherwise specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation containing any quantity of any of the following narcotic drugs, or any salts thereof:

(1) Not more than 1.8 grams of codeine per 100 milliliters and not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium 9803

(2) Not more than 1.8 grams of codeine per 100 milliliters and not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts 9804

(3) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters and not more than 15 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium 9807

(4) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters and not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts 9808

(5) Not more than 1.8 grams of dihydrocodeine per 100 milliliters and not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts 9807

(6) Not more than 300 milligrams of ethylmorphine per 100 milliliters and not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts 9808

(7) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams and not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts 9812

(8) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams and not more than 2.5 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts 9313

SCHEDULE IV

Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Barbital 2145

(2) Chloral betaine 2460

(3) Chloral hydrate 2465

(4) Ethchlorvynol 2548

(5) Ethinamate 2545

(6) Methohexital 2264

(7) Meprobamate 2820

(8) Methylphenobarbital 2250

(9) Paraldehyde 2585

(10) Petrichloral 2591

(11) Phenobarbital 2285

SCHEDULE V

Narcotic drugs containing non-narcotic active medicinal ingredients

Any compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

(1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams and not more than 10 milligrams per dosage unit.

(2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams and not more than 5 milligrams per dosage unit.

(3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams and not more than 5 milligrams per dosage unit.

(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.

(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams and not more than 5 milligrams per dosage unit.

Stimulants or depressants containing active medicinal ingredients, exception

The Attorney General may by regulation except any compound, mixture, or preparation containing any depressant or stimulant substance in paragraph (a) or (b) of schedule III or in schedule IV or V from the application of all or any part of this title if (1) the compound, mixture, or preparation contains one or more active medicinal ingredients not having a depressant or stimulant effect on the central nervous system, and (2) such ingredients are included therein in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse of the substances which do have a depressant or stimulant effect on the central nervous system.

APPENDIX 11



a study of prescription fraud vulnerability

Dr. Albert A. Glass
Special Agent Kenneth G. Goodman
Dr. Sidney W. Hinkley

Bureau of Narcotics and Dangerous Drugs U.S. Department of Justice

PROJECT SCRIPT

A Study of Prescription Fraud Vulnerability

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Special Agent Kenneth G. Goodman
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Bureau of Narcotics and Dangerous Drugs
U.S. Department of Justice

UNITED STATES DEPARTMENT OF JUSTICE
BUREAU OF NARCOTICS AND DANGEROUS DRUGS
WASHINGTON, D.C. 20537

FOREWORD

The problem of the diversion of legitimately manufactured drugs is a source of constant concern to the Bureau of Narcotics and Dangerous Drugs. Repeatedly, state and local law enforcement agencies as well as pharmaceutical industry representatives cite that prescription fraud has a substantial influence on such diversion. While sporadic studies of the problem have been conducted previously, no systematic or representative research has been accomplished. For these reasons it was incumbent upon the Bureau to definitively investigate prescription fraud vulnerability as a preliminary step to proposing remedial actions.

John E. Ingersoll
Director

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SUMMARY

The ease with which prescription frauds can be perpetrated is of serious concern to the effort to control diversion of drugs. To acquire an estimate of the vulnerability, 256 prescription frauds were attempted over a two-month period. The attempts were evenly divided among retail pharmacies and mail-order prescription firms. Among the variables involved were modes of fraud, drugs, geographic area, urban location, prescription volume and perpetrator dress mode. The results were analyzed statistically and in terms of the detailed reports made by the trained criminal investigators who acted as fraud perpetrators.

The results indicated that if a fraud perpetrator attempts common prescription fraud involving representative drugs from CSA Schedules II through V, the retail pharmacy will honor the prescription 56% of the time. By comparison, the mail-order houses filled identical requests only 25% of the time. This difference is statistically significant. It should be noted that Desoxyn (Schedule II) was honored significantly less than were the drugs in Schedule III, IV and V, but that one has a fairly even chance of obtaining Seconal and phenobarbital through a forged prescription or even by use of a bogus prescription.

The influence of the geographic and other variables were also examined and provide some interesting implications for additional study.

PROJECT SCRIPT
-- A Study of Prescription Fraud Vulnerability --

Introduction

The Bureau of Narcotics and Dangerous Drugs recognizes that attempts to obtain legitimately manufactured controlled drugs by misrepresentation, i.e., forged prescriptions and stolen prescription blanks, are significant problems confronting pharmacists and local law enforcement agencies. With the passage of the Comprehensive Drug Abuse Prevention and Control Act of 1970, more stringent controls were placed on the dispensing of controlled drugs by retail pharmacists. There is no doubt that these restrictions have served to somewhat curtail the fraudulent prescription problem. However, despite the new regulations, the problem flourishes rather than diminishes. Both retail pharmacies and mail-order prescription firms are vulnerable to this practice.

The topic of prescription fraud contains three facets:

1. How easy is it to perpetrate a prescription fraud?

2. How prevalent is prescription fraud, and

3. How can prescription fraud be remedied?

Project Script was planned and conducted to answer the first question. That is, to assess the vulnerability of pharmacies and mail-order prescription to fraudulent prescriptions.

Method

Fraud Modes and Drugs

The intent of Project Script was to examine the relative ease in perpetrating prescription fraud using common fraud techniques. For this purpose four fraud modes were adopted:

a. The forged physician's prescription.

   Through the cooperation of several physicians, legitimate prescription pads were acquired to enable the simulation of "stolen" pads that were then "forged."

b. The forged hospital prescription.

   Using names and addresses of actual hospitals in selected localities, prescription pads were printed to simulate "stolen" pads that were then "forged."

c. Physician's phone-in prescription.

   Phone calls were made by agents to imitate a physician calling in a prescription.

d. The bogus physician's prescription.

   Using completely false data, prescription pads were printed to appear relatively genuine and were then "forged."

In order to measure the relative ease of prescription fraud as a function of the specific drug ordered, four commonly abused drugs were selected, each from a different control schedule in the Controlled Substances Act.

a. Desoxyn - A methamphetamine in Schedule II, the most restrictive schedule for prescription drugs.

b. Seconal - A short-acting barbiturate in Schedule III, less restrictive than the schedule above.

c. Phenobarbital - A barbiturate that is a widely prescribed sedative in Schedule IV.

d. Robitussin A/C - A codeine-contained cough medicine in Schedule V, the least-restrictive schedule.

The essence of the study was to test the general care with which prescriptions are screened, validated or otherwise challenged. Basic to the operational procedures was the assumption that everyone dealing with the prescription function was acting in good faith. Hence, as will be seen in the directions to the agents acting as fraud perpetrators, any reasonable challenge to a fraudulent prescription was considered a failure, or a "miss."

Sampling

In a similar vein, there was no attempt to test State laws, local practices, or special conditions. Hence, the sample in which the frauds were attempted

was meant to contain some general variables that might bear on prescription fraud facility in general. For these reasons the following sampling rationale was utilized:

1. Prescription sources - both retail pharmacies and mail-order prescription houses. While hospital pharmacies also dispense prescribed drugs, the two selected sources handle the vast majority of prescriptions.

2. Retail pharmacy variables-geography (N, S, E & W); area (suburban and urban); volume (high or low prescription volumes); dress (formal or informal dress by the fraud perpetrator).

3. Mail-order prescription house variables-geography (N, S, E & W); volume (high or low prescription volumes); clientele membership (open to all clients or restricted to special membership).

Retail pharmacies were preselected by field agents in the locality designated and according to personal knowledge. The pharmacies were then compared to BNDD case files so as to exclude those that might be known to be involved in prescription fraud traffic or other criminal operations.

Mail-order houses were randomly selected from a list suggested by the Association of Boards of Pharmacy and similar lists. A previous survey conducted by BNDD offered information as to volume and membership characteristics. Again, mail-order houses were excluded if they were found to be previously under investigation for illegal practices.

See Appendix A for sampling distribution.

Directions to the Fraud Perpetrators

Fraud perpetrators were made up of experienced BNDD field agents and Headquarters agents. The field agents acted as fraud perpetrators in the retail pharmacies and as fraudulent recipients for the call-in fraud mode to mail-order houses. For simplicity, all mail-order house phone-ins were made from BNDD Headquarters.

Appendix B contains the detailed instructions to relevant agents.

To avoid recognition by a pharmacist, a given agent was responsible for only one fraudulent perpetration in any pharmacy. Before actual implementation of the research, a pilot meeting was held in the BNDD Regional Office in Chicago to review preliminary instruction to field agents and to remove any ambiguous directions or misunderstandings.

The use of experienced BNDD field agents enabled the study to acquire personnel who were trained and experienced in "acting-out" situations as well as the detailed reporting of operational events. Hence, the data obtained was both quantitative and qualitative. All agents were experienced in drug nomenclature and prescription practices.

An important fact to note was that agents acting as fraud perpetrators were strongly cautioned not to "force" a prescription fraud. Recognizing that agents possessed all the detailed knowledge and personality traits that might persuade a pharmacist, this caveat was necessary to elicit valid results. Equally important, while valid prescription pads were used in Fraud Mode A, the physician was instructed to deny the prescription if contacted by a pharmacist, so as to realistically imitate that his prescription pad had been stolen.

Agents in cities in which the selected pharmacies existed were mailed individual packets of directions and data cards. For the mail-order houses, similar packets were mailed to individual agents who acted as mail-order recipients.

Treatment of Results

Quantitative results of the 256 attempts at prescription fraud were expressed as either a "hit" (prescription is filled) or as a "miss" (prescription rejected for any reason). Statistically, this represents a binomial system. However, we cannot use the binomial distribution because we do not know the probability of hits falling in either the retail pharmacy or mail-order house populations and we are sampling without replacement. Therefore, in this case, the hypergeometric distribution applies. The hypergeometric distribution is analogous to the binomial distribution and permits the derivation of:

D- The smallest significant difference between the number of hits in the two populations (pharmacy and mail-order house) at the 95% level of significance, and

P - The probability that the outcome could have been as extreme or more extreme than the observed outcome, i.e., the difference between the largest and smallest number of hits would have been as large or larger than its observed difference, purely by chance.

An explanation of the application of the hypergeometric distribution to the two and four population cases is contained in Appendix C.

Results

1. Pharmacies vs mail-order houses

	Hits	Misses	Sum
Pharmacies	72	56	128
M-O Houses	32	96	128
	104	152	256

D=18, difference significant*

2. Suburban pharmacies vs urban pharmacies

	Hits	Misses	Sum
Suburban	38	26	64
Urban	34	30	64
	72	56	128

D=12, difference not significant

*D=18 means that if the difference in hits between pharmacies and mail-order houses equals or exceeds 18, the difference is significant at the 95% level of confidence.

3. High volume dealers and low volume dealers*

	Hits	Misses	Sum
High	61	75	136
Low	43	77	120
	104	152	256

D=25, difference not significant

4. High volume pharmacies vs low-volume pharmacies

	Hits	Misses	Sum
High	38	26	64
Low	34	30	64
	72	56	128

D=12, difference not significant

5. High volume mail-order houses vs low volume mail-order houses

	Hits	Misses	Sum
High	23	49	72
Low	9	47	56
	32	96	128

D=15, difference not significant

*Dealer means pharmacies and mail-order houses together.

6. Geographic differences among all dealers

	Hits	Misses	Sum
North	19	45	64
South	25	39	64
East	32	32	64
West	28	36	64
	104	152	256

P=0.11, differences not significant*

7. Geographic differences among pharmacies

	Hits	Misses	Sum
North	11	23	32
South	20	12	32
East	19	13	32
West	22	10	32
	72	56	128

P=0.04, difference significant in that the number of hits in the North is significantly lower than elsewhere.

*For the multiple population it was simplier to calculate probabilities rather than significant differences. Hence, a P must be 0.05 or less to be significant at the 95% level of significance.

8. Geographic differences among mail-order houses

	Hits	Misses	Sum
North	8	24	32
South	5	27	32
East	13	19	32
West	6	26	32
	32	96	128

P=0.13, difference not significant

9. Fraud mode differences among all dealers

	Hits	Misses	Sum
Mode A	28	36	64
Mode B	29	35	64
Mode C	15	49	64
Mode D	32	32	64
	104	152	256

P< 0.05, difference significant in that fraud made C (phone-ins) was significantly lower in hits than the other modes of fraud.

10. Fraud mode differences among pharmacies

	Hits	Misses	Sum
Mode A	20	12	32
Mode B	19	13	32
Mode C	11	21	32
Mode D	22	10	32
	72	56	128

P=0.04, difference significant in that fraud mode C (phone-ins) was significantly lower in hits than the other modes of fraud.

11. Fraud mode differences among mail-order houses

	Hits	Misses	Sum
Mode A	8	24	32
Mode B	10	22	32
Mode C	4	28	32
Mode D	10	22	32
	32	96	128

$P > 0.13$, difference not significant

12. Drug differences among all dealers

	Hits	Misses	Sum
Drug A	9	55	64
Drug B	32	32	64
Drug C	37	27	64
Drug D	26	38	64
	104	152	256

$P < 0.05$, difference significant in that drug A (desoxyn) was significantly lower in hits than the other drugs.

13. Drug differences among pharmacies

	Hits	Misses	Sum
Drug A	6	26	32
Drug B	24	8	32
Drug C	23	9	32
Drug D	19	13	32
	72	56	128

$P < 0.05$, difference significant in that hits for drug A were significantly lower than hits for the other three drugs.

14. Drug differences among mail-order houses

	Hits	Misses	Sum
Drug A	3	29	32
Drug B	8	24	32
Drug C	14	18	32
Drug D	7	25	32
	32	96	128

P=0.01, difference significant in that hits for drug A were significantly lower than hits for drug C.

15. Fraud perpetrator dress mode differences

	Hits	Misses	Sum
Formal	37	27	64
Informal	35	29	64
	72	56	128

D=12, difference not significant

16. Fraud perpetrator dress mode differences; urban pharmacies vs suburban pharmacies

	Hits-informal	Hits-formal	Sum
Urban	15	19	34
Suburban	20	18	38
	35	37	72

D=11, informal dress mode difference not significant

D=13, formal dress mode difference not significant

17. Fraud perpetrator dress mode differences; geographic influence

	Hits-informal	Hits-formal	Sum
North	5	6	11
South	9	11	20
East	10	9	19
West	11	11	22
	35	37	72

$P > 0.05$ for both formal and informal; differences not significant.

18. Urban and Suburban pharmacy fraud mode differences

	Hits-suburban	Hits-urban	Sum
Mode A	10	10	20
Mode B	9	10	19
Mode C	6	5	11
Mode D	13	9	22
	38	34	72

D=8, 7, 7, 8 for modes A through D; differences not significant.

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19. Geographic differences among fraud modes

	Hits				
	N	S	E	W	Sum
Mode A	5	5	9	9	28
Mode B	3	7	9	10	29
Mode C	5	4	3	3	15
Mode D	6	9	11	6	32
	19	25	32	28	104

	P
N	0.77
S	0.37
E	0.04
W	0.09

	P
Mode A	0.09+
Mode B	0.09
Mode C	0.92
Mode D	0.39

Only the East reflects a significance in that fraud mode D (bogus prescription) was significantly higher in hits than fraud mode C (phone-ins). All other differences not significant.

20. Fraud mode differences in pharmacies vs mail order houses

	Hits-pharmacies	Hits-MO Houses	Sum
Mode A	20	8	28
Mode B	19	10	29
Mode C	11	4	15
Mode D	22	10	32
	72	32	104

D=10, 9, 9, 10 for modes A through D; hence, fraud modes A, B and D are significantly more successful in pharmacies; fraud mode C is not.

21. Mail-order house membership differences

	Hits	Misses	Sum
Open	21	67	88
Membership	11	29	40
	32	96	128

D=12, difference not significant

22. Desoxyn (Drug A) - pharmacies vs mail-order houses

	Hits	Misses	Sum
Pharmacies	6	26	32
M-O houses	3	29	32
	9	55	64

D= 7, difference not significant

23. Desoxyn (Drug A) - suburban vs urban pharmacies

	Hits	Misses	Sum
Suburban	5	11	16
Urban	1	15	16
	6	26	32

D=6, difference not significant

24. Desoxyn (Drug A) - high volume dealers vs low volume dealers

	Hits	Misses	Sum
High volume	5	29	34
Low volume	4	26	30
	9	55	64

D=7, difference not significant

25. Desoxyn (Drug A) - high volume pharmacies vs low volume pharmacies

	Hits	Misses	Sum
High volume	3	13	16
Low volume	3 / 6	13 / 26	16 / 32

D=6, difference not significant

26. Desoxyn (Drug A) - high volume mail-order houses vs low volume mail-order houses

	Hits	Misses	Sum
High volume	2	16	18
Low volume	1 / 3	13 / 29	14 / 32

D=3, difference not significant

27. Desoxyn (Drug A) - geographic differences among all dealers

	Hits	Misses	Sum
North	0	16	16
South	3	13	16
East	3	13	16
West	3 / 9	13 / 55	16 / 64

P=0.45, difference not significant

28. Desoxyn (Drug A) - geographic differences among pharmacies

	Hits	Misses	Sum
North	0	8	8
South	3	5	8
East	1	7	8
West	2 / 6	6 / 26	8 / 32

P=0.45, differences not significant

29. Desoxyn (Drug A) - geographic differences among mail-order houses

	Hits	Misses	Sum
North	0	8	8
South	0	8	8
East	2	6	8
West	1 / 3	7 / 29	8 / 32

P=0.59, differences not significant

30. Desoxyn (Drug A) - fraud mode differences among all dealers

	Hits	Misses	Sum
Mode A	1	15	16
Mode B	2	14	16
Mode C	0	16	16
Mode D	6	10	16
	9	55	64

P=0.02, difference is significant in that the number of hits between fraud modes C and D are significant.*

31. Desoxyn (Drug A) - fraud mode differences among pharmacies

	Hits	Misses	Sum
Mode A	1	7	8
Mode B	1	7	8
Mode C	0	8	8
Mode D	4	4	8
	6	26	32

P=0.09, differences not significant

*The significant difference in this test is not refuted by the lack of significant difference for pharmacies and mail-order houses, separately, in tests 31 and 32. The latter tests contain smaller samples. Smaller samples require correspondingly larger differences in hits to be significant.

32. Desoxyn (Drug A) - fraud mode differences among mail-order houses

	Hits	Misses	Sum
Mode A	0	8	8
Mode B	1	7	8
Mode C	0	8	8
Mode D	2	6	8
	3	29	32

P=0.59, differences not significant

33. Desoxyn (Drug A) - fraud perpetrator dress mode differences

	Hits	Misses	Sum
Formal	1	15	16
Informal	5	11	16
	6	26	32

D=6, difference not significant

34. Desoxyn (Drug A) - mail order house membership differences

	Hits	Misses	Sum
Open	2	20	22
Membership	1	9	10
	3	29	32

D=3, difference not significant

35. Seconal (Drug B) - pharmacies vs mail-order houses

	Hits	Misses	Sum
Pharmacies	24	8	32
M-O houses	8	24	32
	32	32	64

D=10, difference significant

36. Seconal (Drug B) - suburban vs urban pharmacies

	Hits	Misses	Sum
Suburban	12	4	16
Urban	12	4	16
	24	8	32

D=6, difference not significant

37. Seconal (Drug B) - high volume dealers vs low volume dealers

	Hits	Misses	Sum
High volume	19	15	34
Low volume	13	17	30
	32	32	64

D=10. difference not significant

38. Seconal (Drug B) - high volume pharmacies vs low volume pharmacies

	Hits	Misses	Sum
High volume	13	3	16
Low volume	11	5	16
	24	8	32

D=6, difference not significant

39. Seconal (Drug B) - high volume mail-order houses vs low volume mail-order houses

	Hits	Misses	Sum
High volume	6	12	18
Low volume	2	12	14
	8	24	32

D=6, difference not significant

40. Seconal (Drug B) - geographic differences among all dealers

	Hits	Misses	Sum
North	6	10	16
South	8	8	16
East	10	6	16
West	8	8	16
	32	32	64

P=0.61, differences not significant

41. Seconal (Drug B) - geographic differences among pharmacies

	Hits	Misses	Sum
North	5	3	8
South	7	1	8
East	6	2	8
West	6	2	8
	24	8	32

P=0.94, differences not significant

42. Seconal (Drug B) - geographic differences among mail-order houses

	Hits	Misses	Sum
North	1	7	8
South	1	7	8
East	4	4	8
West	2	6	8
	8	24	32

P=0.43, differences not significant

43. Seconal (Drug B) - fraud mode differences among all dealers

	Hits	Misses	Sum
Mode A	9	7	16
Mode B	9	7	16
Mode C	4	12	16
Mode D	10	6	16
	32	32	64

P=0.21, differences not significant

44. Seconal (Drug B) - fraud mode differences among pharmacies

	Hits	Misses	Sum
Mode A	7	1	8
Mode B	6	2	8
Mode C	3	5	8
Mode D	8	0	8
	24	8	32

P=0.035, difference significant in that the number of hits between fraud modes C & D are significantly different.

45. Seconal (Drug B) - fraud mode difference among mail-order houses

	Hits	Misses	Sum
Mode A	2	6	8
Mode B	3	5	8
Mode C	1	7	8
Mode D	2	6	8
	8	24	32

P=0.94, differences not significant

46. Seconal (Drug B) - fraud perpetrator dress mode differences

	Hits	Misses	Sum
Formal	14	2	16
Informal	10	6	16
	24	8	32

D=6, difference not significant

47. Seconal (Drug B) - mail-order house membership differences

	Hits	Misses	Sum
Open	5	17	22
Membership	3	7	10
	8	24	32

D=9, difference not significant

48. Phenobarbital (Drug C) - pharmacies vs mail-order houses

	Hits	Misses	Sum
Pharmacies	23	9	32
M-O houses	14	18	32
	37	27	64

D=9, difference significant

49. Phenobarbital (Drug C) - suburban vs urban pharmacies

	Hits	Misses	Sum
Suburban	11	5	16
Urban	12	4	16
	23	9	32

D=7, difference not significant

50. Phenobarbital (Drug C) - high volume dealers vs low volume dealers

	Hits	Misses	Sum
High volume	23	11	34
Low volume	14	16	30
	37	27	64

D=10, difference not significant

51. Phenobarbital (Drug C) - high volume pharmacies vs low low volume pharmacies

	Hits	Misses	Sum
High volume	12	4	16
Low volume	11	5	16
	23	9	32

D=7, difference not significant

CONTINUED

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52. Phenobarbital (Drug C) - high volume mail-order houses vs low volume mail order houses

	Hits	Misses	Sum
High volume	11	7	18
Low volume	3	11	14
	14	18	32

D=10, difference not significant

53. Phenobarbital (Drug C) - geographic differences among all dealers

	Hits	Misses	Sum
North	10	6	16
South	8	8	16
East	10	6	16
West	9	7	16
	37	27	64

P=0.94, differences not significant

54. Phenobarbital (Drug C) - geographic differences among pharmacies

	Hits	Misses	Sum
North	5	3	8
South	6	2	8
East	5	3	8
West	7	1	8
	23	9	32

P=0.82, differences not significant

55. Phenobarbital (Drug C) - geographic differences among mail-order houses

	Hits	Misses	Sum
North	5	3	8
South	2	6	8
East	5	3	8
West	2	6	8
	14	18	32

P=0.64, differences not significant

56. Phenobarbital (Drug C) - fraud mode differences among all dealers

	Hits	Misses	Sum
Mode A	12	4	16
Mode B	10	6	16
Mode C	6	10	16
Mode D	9	7	16
	37	27	64

P=0.20, differences not significant

57. Phenobarbital (Drug C) - fraud mode differences among pharmacies

	Hits	Misses	Sum
Mode A	8	0	8
Mode B	7	1	8
Mode C	3	5	8
Mode D	5	3	8
	23	9	24

P=0.0503, differences not significant

58. Phenobarbital (Drug C) - fraud mode differences among mail-order houses

	Hits	Misses	Sum
Mode A	4	4	8
Mode B	3	5	8
Mode C	3	5	8
Mode D	4	4	8
	14	18	32

P=1.00, differences not significant

59. Phenobarbital (Drug C) - fraud perpetrator dress mode differences

	Hits	Misses	Sum
Formal	12	4	16
Informal	11	5	16
	23	9	32

D=7, difference not significant

60. Phenobarbital (Drug C) - mail-order house membership differences

	Hits	Misses	Sum
Open	9	13	22
Membership	5	5	10
	14	18	32

D=10, difference not significant

61. Robitussin A/C (Drug D) - pharmacies vs mail-order houses

	Hits	Misses	Sum
Pharmacies	19	13	32
M-O houses	7	25	32
	26	38	64

D=10, difference significant

62. Robitussin A/C (Drug D) - suburban vs urban pharmacies

	Hits	Misses	Sum
Suburban	10	6	16
Urban	9	7	16
	19	13	32

D=7, difference not significant

63. Robitussin A/C (Drug D) - high volume dealers vs low volume dealers

	Hits	Misses	Sum
High volume	14	20	34
Low volume	12	18	30
	26	38	64

D=10, difference not significant

64. Robitussin A/C (Drug D) - high volume pharmacies vs low volume pharmacies

	Hits	Misses	Sum
High volume	10	6	16
Low volume	9	7	16
	19	13	32

D=7, difference not significant

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65. Robitussin A/C (Drug D) - high volume mail-order houses vs low volume mail-order houses

	Hits	Misses	Sum
High volume	4	14	18
Low volume	3	11	14
	7	25	32

D=7, difference not significant

66. Robitussin A/C (Drug D) - geographic difference among all dealers

	Hits	Misses	Sum
North	3	13	16
South	6	10	16
East	9	7	16
West	8	8	16
	26	38	64

P=0.20, differences not significant

67. Robitussin A/C (Drug D) - geographic difference among pharmacies

	Hits	Misses	Sum
North	1	7	8
South	4	4	8
East	7	1	8
West	7	1	8
	19	13	32

P=0.02, difference significant in that the numbers of hits in the East and West were significantly higher than in the North.

68. Robitussin A/C (Drug D) - geographic differences among mail-order houses

	Hits	Misses	Sum
North	2	6	8
South	2	6	8
East	2	6	8
West	1	7	8
	7	25	32

P=1.00, differences not significant

69. Robitussin A/C (Drug D) - fraud mode differences among all dealers

	Hits	Misses	Sum
Mode A	6	10	16
Mode B	8	8	16
Mode C	5	11	16
Mode D	7	9	16
	26	38	64

P=0.83, differences not significant

70. Robitussin A/C (Drug D) - fraud mode differences among pharmacies

	Hits	Misses	Sum
Mode A	4	4	8
Mode B	5	3	8
Mode C	5	3	8
Mode D	5	3	8
	19	13	24

P=1.00, differences not significant

71. Robitussin A/C (Drug D) - fraud mode differences among mail-order houses

	Hits	Misses	Sum
Mode A	2	6	8
Mode B	3	5	8
Mode C	0	8	8
Mode D	2	6	8
	7	25	32

P=0.43, differences not significant

72. Robitussin A/C (Drug D) - fraud perpetrator dress mode differences

	Hits	Misses	Sum
Formal	10	6	16
Informal	9	7	16
	19	13	32

D=7, difference not significant

73. Robitussin A/C (Drug D) - mail-order house membership differences

	Hits	Misses	Sum
Open	5	17	22
Membership	2	8	10
	7	25	32

D=7, difference not significant

Discussion of the Results

As stated earlier, the central purpose of the study was to examine the relative ease with which the prescription frauds can be perpetrated. This was attempted in 256 tests, each of which was independent of all others, and all of which were directed by rules and guidelines. The fraud perpetrators were experienced BNDD special agents who are used to operating within stringent controls and who are familiar with how nuances of action can influence outcomes. Hence, with the sampling variables that were included in the study, the results offer a valid and reliable representation of the relative ease with which prescription fraud can be perpetrated. The qualifier "relative" ease is used because while we would prefer to see the complete preclusion of facility in prescription fraud, that goal is probably unobtainable. Hence, we do not yet know what is a practicable, acceptable level of prescription fraud perpetration.

The results provide some interesting observations:

1. Providing the fraud perpetrator attempts to use the common modes of fraud and attempts to obtain identical or similar drugs, pharmacies will fill the requests more than half of the time (56%). By comparison, the mail-order houses filled identical requests only 25% of the time. This difference is statistically significant and when broken down into the specific drugs, does not hold for Desoxyn, but does hold for Seconal, phenobarbital or Robitussin A/C. It will be recalled that Desoxyn is a Schedule II drug and as a consequence both pharmacies and mail-order houses scrutinize the prescription with care and tend to challenge its validity by phone check to the prescribing physician.

2. There is a substantive difference in the successful attempts among fraud modes in that phone-ins (Fraud Mode C) are least successful. No dealer, either pharmacy or mail-order house honored a phone-in for Desoxyn. (It should be noted that the Controlled Substances Act prohibits phone-in prescriptions for Schedule II drugs except for emergencies, and then for minimal amounts. The phone-in must then be followed by a written prescription within 72 hours).

   For the three fraud modes other than phone-in and for the other three drugs, successful prescription fraud was generally double. That is, you will be successful in passing a forged or bogus prescription twice as often as will a phone-in. More important, if one

must choose between a pharmacy and a mail-order house, the three successful fraud modes will be honored more than twice as often by the pharmacy.

The reasons for such success can only be surmised. The agents' qualitative reports tend to indicate that the pharmacist is often pressed for time and must hurry to satisfy waiting customers. He tends to accept a prescription as a valid document if it's format is familiar and no outstanding errors are noted. Therefore, where no obvious prescription fraud clues are apparent, the pharmacist may feel pressed to honor the presented script. This may explain the difference in the success of fraud mode D (the bogus prescription) in pharmacies; as compared to mode C (the phone-in), for Seconal. Pharmacists like many shopkeepers may feel intimated. The customer is present on the premises and any untoward act by the pharmacist may result in undesirable reprisal. Mail-order houses apparently do not have these pressures in that some prescriptions were received after two weeks of waiting, and, of course, the customer is not present. However, it should be noted that there were no significant differences among pharmacies or mail-order houses by volume of business or urban/suburban location. Moreover, there was no apparent influence exerted by the attire or appearance of the agent (fraud perpetrator), or whether the mail-order house was "open" or required special membership. One exception: one mail-order house operated by a labor union turned down all eight prescriptions stating that only prescriptions written by that union's staff physician could be filled.

3. A few interesting anomalies appear. Overall, considering all drugs and all fraud modes, pharmacists in the northern quarter of the country appear to be less vulnerable to prescription fraud. There is no similar difference among mail-order houses. An explanation for this result might be found in a survey of prescription fraud incidence and news coverage, perhaps tending to show that northern pharmacists have become more conscious and sensitive to the topic.

In another sense geography was found to be influential. Considering geographic differences among all fraud modes, the eastern quarter of the country tended to fill the bogus prescription (mode D) significantly more frequently than either the north, south or

west, as compared to the phone-in (mode C). Moreover, both eastern and western pharmacies honored Robitussin frauds significantly more often than did the north and sourth. This tends to support the incidence-sensitivity concept in that Robitussin A/C is an over-the-counter item up to 4 ozs. in amount. CSA requires a prescription for amounts larger than 4 ozs. Hence, the drug is held less-restrictive by CSA and yet was refused more often by the eastern and western pharmacists. Peculiarly, the condition does not hold for either Seconal or phenobarbital.

APPENDIX A

Sampling Distributions

PHARMACY TRIALS

Conditions

Trial No.	(1)	(2)	(3)	(4)	(5)	(6)	(7)
1	S	H	N	Detroit	A	1	A
2	S	H	N	Detroit	B	2	B
3	S	H	N	Detroit	C	1	C
4	S	H	N	Detroit	D	2	D
5	S	H	N	Detroit	A	2	B
6	S	H	N	Detroit	B	1	C
7	S	H	N	Detroit	C	2	D
8	S	H	N	Detroit	D	1	A
9	S	L	N	Chicago	A	1	C
10	S	L	N	Chicago	B	2	D
11	S	L	N	Chicago	C	1	A
12	S	L	N	Chicago	D	2	B
13	S	L	N	Chicago	A	2	D
14	S	L	N	Chicago	B	1	A
15	S	L	N	Chicago	C	2	B
16	S	L	N	Chicago	D	1	C
17	S	H	S	N. Orleans	A	2	A
18	S	H	S	N. Orleans	B	1	B
19	S	H	S	N. Orleans	C	2	C
20	S	H	S	N. Orleans	D	1	D
21	S	H	S	N. Orleans	A	1	B
22	S	H	S	N. Orleans	B	2	C
23	S	H	S	N. Orleans	C	1	D
24	S	H	S	N. Orleans	D	2	A
25	S	L	S	Dallas	A	1	C
26	S	L	S	Dallas	B	2	D
27	S	L	S	Dallas	C	1	A
28	S	L	S	Dallas	D	2	B
29	S	L	S	Dallas	A	2	D
30	S	L	S	Dallas	B	1	A
31	S	L	S	Dallas	C	2	B
32	S	L	S	Dallas	D	1	C
33	S	H	E	Philadelphia	A	2	A
34	S	H	E	Philadelphia	B	1	B
35	S	H	E	Philadelphia	C	2	C
36	S	H	E	Philadelphia	D	1	D
37	S	H	E	Philadelphia	A	1	B
38	S	H	E	Philadelphia	B	2	C
39	S	H	E	Philadelphia	C	1	D
40	S	H	E	Philadelphia	D	2	A
41	S	L	E	New York	A	1	C
42	S	L	E	New York	B	2	D
43	S	L	E	New York	C	1	A

Pharmacy Trials (Cont'd)

Trial No.	Conditions (1)	(2)	(3)	(4)	(5)	(6)	(7)
44	S	L	E	New York	D	2	B
45	S	L	E	New York	A	2	D
46	S	L	E	New York	B	1	A
47	S	L	E	New York	C	2	B
48	S	L	E	New York	D	1	C
49	S	H	W	Los Angeles	A	2	A
50	S	H	W	Los Angeles	B	1	B
51	S	H	W	Los Angeles	C	2	C
52	S	H	W	Los Angeles	D	1	D
53	S	H	W	Los Angeles	A	1	B
54	S	H	W	Los Angeles	B	2	C
55	S	H	W	Los Angeles	C	1	D
56	S	H	W	Los Angeles	D	2	A
57	S	L	W	San Francisco	A	1	C
58	S	L	W	San Francisco	B	2	D
59	S	L	W	San Francisco	C	1	A
60	S	L	W	San Francisco	D	2	B
61	S	L	W	San Francisco	A	2	D
62	S	L	W	San Francisco	B	1	A
63	S	L	W	San Francisco	C	2	B
64	S	L	W	San Francisco	D	1	C
65	U	L	N	Detroit	A	2	A
66	U	L	N	Detroit	B	1	B
67	U	L	N	Detroit	B	2	C
68	U	L	N	Detroit	D	1	D
69	U	L	N	Detroit	A	1	B
70	U	L	N	Detroit	B	2	C
71	U	L	N	Detroit	C	1	D
72	U	L	N	Detroit	D	2	A
73	U	H	N	Chicago	A	1	C
74	U	H	N	Chicago	B	2	D
75	U	H	N	Chicago	C	1	A
76	U	H	N	Chicago	D	2	B
77	U	H	N	Chicago	A	2	D
78	U	H	N	Chicago	B	1	A
79	U	H	N	Chicago	C	2	B
80	U	H	N	Chicago	D	1	C
81	U	L	S	New Orleans	A	2	A
82	U	L	S	New Orleans	B	1	B
83	U	L	S	New Orleans	C	2	C
84	U	L	S	New Orleans	D	1	D
85	U	L	S	New Orleans	A	1	B

Pharmacy Trials (Cont'd)

Trial No.	Conditions (1)	(2)	(3)	(4)	(5)	(6)	(7)
86	U	L	S	New Orleans	B	2	C
87	U	L	S	New Orleans	C	1	D
88	U	L	S	New Orleans	D	2	A
89	U	H	S	Dallas	A	1	C
90	U	H	S	Dallas	B	2	D
91	U	H	S	Dallas	C	1	A
92	U	H	S	Dallas	D	2	B
93	U	H	S	Dallas	A	2	D
94	U	H	S	Dallas	B	1	A
95	U	H	S	Dallas	C	2	B
96	U	H	S	Dallas	D	1	C
97	U	L	E	Philadelphia	A	2	A
98	U	L	E	Philadelphia	B	1	B
99	U	L	E	Philadelphia	C	2	C
100	U	L	E	Philadelphia	D	1	D
101	U	L	E	Philadelphia	A	1	B
102	U	L	E	Philadelphia	B	2	C
103	U	L	E	Philadelphia	C	1	D
104	U	L	E	Philadelphia	D	2	A
105	U	H	E	New York	A	1	C
106	U	H	E	New York	B	2	D
107	U	H	E	New York	C	1	A
108	U	H	E	New York	D	2	B
109	U	H	E	New York	A	2	D
110	U	H	E	New York	B	1	A
111	U	H	E	New York	C	2	B
112	U	H	E	New York	D	1	C
113	U	L	W	Los Angeles	A	2	A
114	U	L	W	Los Angeles	B	1	B
115	U	L	W	Los Angeles	C	2	C
116	U	L	W	Los Angeles	D	1	D
117	U	L	W	Los Angeles	A	1	B
118	U	L	W	Los Angeles	B	2	C
119	U	L	W	Los Angeles	C	1	D
120	U	L	W	Los Angeles	D	2	A
121	U	H	W	San Francisco	A	1	C
122	U	H	W	San Francisco	B	2	D
123	U	H	W	San Francisco	C	1	A
124	U	H	W	San Francisco	D	2	B
125	U	H	W	San Francisco	A	2	D

Pharmacy Trials (Cont'd)

Trial No.	Conditions (1)	(2)	(3)	(4)	(5)	(6)	(7)
126	U	H	W	San Francisco	B	1	A
127	U	H	W	San Francisco	C	2	B
128	U	H	W	San Francisco	D	1	C

KEY

Conditions
(1) Suburb (S) or Urban (U)
(2) Volume of prescriptions - High (H) or Low (L)
(3) Geographic Area (N, S, E or W)
(4) City
(5) Drugs - A - Desoxyn 15 mg.
B - Seconal 100 mg.
C - Phenobarbital 30 mg.
D - Robitussin A/C
(Quantities range from 30 to 100 dosage units and 8 oz of Robitussin A/C)
(6) Attire of Agent - Formal (1) Informal (2)
(7) Fraud Mode - A - Forged Prescription
B - Forged Hospital Prescription
C - Phone-In
D - Bogus Prescription

MAIL-ORDER HOUSE TRIALS

Trial No.	Conditions (1)	(2)	(3)	(4)	(5)
129	A	A	M	H	N
130	B	B	M	H	N
131	C	C	M	H	N
132	D	D	M	H	N
133	B	A	M	H	N
134	C	B	M	H	N
135	D	C	M	H	N
136	A	D	M	H	N
137	C	A	O	H	N
138	D	B	O	H	N
139	A	C	O	H	N
140	B	D	O	H	N
141	D	A	O	H	N
142	A	B	O	H	N
143	B	C	O	H	N
144	C	D	O	H	N
145	A	A	M	L	N
146	B	B	M	L	N
147	C	C	M	L	N
148	D	D	M	L	N
149	B	A	M	L	N
150	C	D	M	L	N
151	D	C	M	L	N
152	A	D	M	L	N
153	C	A	O	L	N
154	D	B	O	L	N
155	A	C	O	L	N
156	B	D	O	L	N
157	D	A	O	L	N
158	A	B	O	L	N
159	B	C	O	L	N
160	C	D	O	L	N
161	A	A	M	H	S
162	B	B	M	H	S
163	C	C	M	H	S
164	D	D	M	H	S
165	B	A	M	H	S
166	C	B	M	H	S
167	D	C	M	H	S
168	A	D	M	H	S
169	C	A	O	H	S
170	D	B	O	H	S

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M-O House Trials (Cont'd)

Trial No.	Conditions (1)	(2)	(3)	(4)	(5)
171	A	C	O	H	S
172	B	D	O	H	S
173	D	A	O	H	S
174	A	B	O	H	S
175	B	C	O	H	S
176	C	D	O	H	S
177	A	A	M	L	S
178	B	B	M	L	S
179	C	C	M	L	S
180	D	D	M	L	S
181	B	A	M	L	S
182	C	B	M	L	S
183	D	C	M	L	S
184	A	D	M	L	S
185	C	A	O	L	S
186	D	B	O	L	S
187	A	C	O	L	S
188	B	D	O	L	S
189	D	A	O	L	S
190	A	B	O	L	S
191	B	C	O	L	S
192	C	D	O	L	S
193	A	A	M	H	E
194	B	B	M	H	E
195	C	C	M	H	E
196	D	D	M	H	E
197	B	A	M	H	E
198	C	B	M	H	E
199	D	C	M	H	E
200	A	D	M	H	E
201	A	D	M	H	E
202	D	B	O	H	E
203	A	C	O	H	E
204	B	D	O	H	E
205	D	A	O	H	E
206	A	B	O	H	E
207	B	C	O	H	E
208	C	D	O	H	E

M-O House Trials (Cont'd)

Trial No.	Conditions (1)	(2)	(3)	(4)	(5)
209	A	A	M	L	E
210	B	B	M	L	E
211	C	C	M	L	E
212	D	D	M	L	E
213	B	A	M	L	E
214	C	B	M	L	E
215	D	C	M	L	E
216	A	D	M	L	E
217	C	A	O	L	E
218	D	B	O	L	E
219	A	C	O	L	E
220	B	D	O	L	E
221	D	A	O	L	E
222	A	B	O	L	E
223	B	C	O	L	E
224	C	D	O	L	E
225	A	A	M	H	W
226	B	B	M	H	W
227	C	C	M	H	W
228	D	D	M	H	W
229	B	A	M	H	W
230	C	B	M	H	W
231	D	C	M	H	W
232	A	D	M	H	W
233	C	A	O	H	W
234	D	B	O	H	W
235	A	C	O	H	W
236	B	D	O	H	W
237	D	A	O	H	W
238	A	B	O	H	W
239	B	C	O	H	W
240	C	D	O	H	W
241	A	A	M	L	W
242	B	B	M	L	W
243	C	C	M	L	W
244	D	D	M	L	W
245	B	A	M	L	W
246	C	B	M	L	W
247	D	C	M	L	W
248	A	D	M	L	W
250	C	A	O	L	W

M-O House Trials (Cont'd)

	Conditions				
Trial No.	(1)	(2)	(3)	(4)	(5)
251	A	C	O	L	W
252	B	D	O	L	W
253	D	A	O	L	W
254	A	B	O	L	W
255	B	C	O	L	W
256	C	D	O	L	W

KEY

Conditions

(1) Fraud Mode: A - Forged Prescription
B - Forged Hospital Prescription
C - Phone-In
D - Bogus Prescription

(2) Drugs: A - Desoxyn 15 mg.
B - Seconal 100 mg.
C - Phenobarbital 30 mg.
D - Robitussin A/C
(Quantities range from 30 to 100 dosage units and 8 oz. of Robitussin A/C)

(3) Clientele - Open (O) or Membership (M)

(4) Volume of prescriptions - High (H) or Low (L)

(5) Geographic area (N, S, E or W)

APPENDIX B

Instructions on Attempts to Perpetrate Prescription Frauds and Reporting Results

TEST NO. _____

PROJECT SCRIPT

Note on your operation

1. You are to execute a:

   [ ] Pharmacy script fraud

   [ ] Phone-In prescription

   [ ] Mail-Order prescription request

   [ ] "Patient" status on a phone-in mail-order prescription request

2. See the specific Guidelines covering the operation checked above.

PROJECT SCRIPT

General Orientation

1. BNDD is conducting PROJECT SCRIPT in order to independently assess the care with which pharmacies and mail-order prescription houses detect fraudulent prescriptions.

2. To accomplish the goal of the project, we require brief but careful assistance from selected agents in the Bureau. We have carefully picked a representative sample of pharmacies and mail-order houses on the basis of geography, location, volume of business and so forth. We have also selected four different drugs and four fraud modes to be used in the study. All of this, and other factors, have been included so that the final study results will stand up under scientific scrutiny and permit the Bureau to report conclusions that are valid and defensible. It is extremely important that the selected agents follow instructions carefully and execute their requirements, as directed. The results of the study will be made available to you when completed. Depending on the action assigned to you, attached are the following:

   a. A fraudulent prescription.

   b. A specific mail order house to which you are to send the prescription or, a specific pharmacy to which you are to bring the prescription or, directions for making a phone call to a pharmacy.

   c. A data card that must be completed after the required operation is executed by you.

   d. A note on the operation you are to execute.

   e. Guidelines for the specific operation you are to execute.

   f. Directions on the completion of the data card.

   g. Directions for use of relevant BNDD forms.

3. If your note calls for a pharmacy fraud, either direct script or phone-in, and if the dress is to be "formal," use coat and tie in visiting the pharmacy. If it calls for "informal" dress, visit the pharmacy using a sport shirt (of any sort) and the kind of clothing you would wear around the house on a week-end.

General Orientation (Cont'd)

4. You may be asked to act as a "patient" who will be sent a drug from a prescription mail-order house. In any event, any actions required of you are covered in the accompanying guidelines, etc.

Phone-In

PROJECT SCRIPT

Guidelines for Phoning-in a Fraudulent Prescription

1. Choose a day no later than three days from the receipt of your project assignment to make the phone call.

2. Choose a time in the day to make the call that will permit you to get to the pharmacy within an hour after the call.

3. Using the name of the pharmacy on the data card, call the prescription counter and phone in the prescription.

4. From the prescription furnished to you and pretending you are the physician, give the following information:

   a. "Your" name, address and the Region undercover phone number.

   b. The name of the "patient."

   c. The prescription order contents.

   d. The Physician's BNDD number.

   If the druggist checks back on the undercover phone, deny the prescription and consider it a miss (M). If the pharmacist questions the authenticity of the order for any reason, or implies or says that he can't go along with it, break contact politely and consider it a "miss" (M). Note this on the data card and write in the sense of his refusal under "Remarks." Of course, in this case, there is no need to then visit the pharmacy.

5. If required, follow-up by going to the pharmacy and asking for your prescription.

6. See and follow the "Guidelines for Attempting to Pass A Fraudulent Prescription to a Pharmacy or Follow-up a Phone-In Prescription."

PROJECT SCRIPT

BNDD Reporting Guidelines

1. Retail Pharmacies: Each Region will assign a case number to each of the retail pharmacies involved in the study in it's Region. All exhibits obtained from a pharmacy will be reported under the respective case number. There will be a potential maximum of eight (8) exhibits per case number. Official Advanced Fund (OAF) should be used for payment for the filled prescription.

   Exhibits should be processed as is any purchased evidence in accordance with Chapter 52 of the Agents Manual. A separate BND-6 should be prepared each time an exhibit is obtained. Negative attempts (misses) may be reported together on one BND-6. For example, of the eight attempts to fill fraudulent prescriptions in a Pharmacy, two attempts might result in the prescription being filled, whereas the other six attempts may miss. A separate BND-6 should be prepared for each of the two hits, whereas the six misses may be reported together on one BND-6. At the conclusion of the study, the respective Regions will be informed by ENA on how to close the cases. (Please note that this reporting is independent of the data card requirements.)

2. Mail-Order Houses: Only four Regions will be involved with mail-order houses. Those cities are San Francisco, Chicago, New York City, and New Orleans. Agents in these cities will send fraudulent prescriptions to 16 mail-order houses located throughout the country. The Regions that send prescriptions to mail-order houses will assign a case number of each house. Exhibits obtained by a Region from a mail-order house will then be reported and processed under the respective case number. (Again, this reporting is independent of data card entries.)

The Data Card

Test No._____ Fraud Mode ____ Drug ____ Agent Name _____

Sked____ Region Office _____

Pharmacy

Store Name: _____

Address: _____

_____

Sub ____ Vol. H____ Area____

Urb ____ Vol. L____ City____

Date Passed: _____ Results: H___ M___

Dress:_____

Remarks: _____

_____

_____

_____

_____

_____

_____

_____

Case No._____

Mail Order

M/O House: _____

_____

_____

Clientele: Open ____ Area ____ Mem.____

Vol. H____ Date Sent: _____

Vol. L____ Date of Returns _____ _____

_____ _____

Results: H____ M____

Remarks:_____

_____

_____

_____

_____

_____

_____

_____

Case No._____

(continue on reverse side, if required)

PROJECT SCRIPT

Use of the Data Card

General

1. The data card must be completed and returned to BNDD Headquarters. It is our only source for defining the results of the project.

2. Parts of the data card will already contain completed information when you receive it. You are responsible for executing the prescription fraud action assigned to you and for completing the following parts of the data card.

   a. Agent Name _____ print your last name and first name, in that order.

   b. Regional Office _____ i.e., Chicago, Miami, Seattle, etc.

   c. Complete only that half of the data card that refers to your action, i.e., either the "Pharmacy" half or the "Mail-Order" half. The half of the card referring to your action will already be partially completed.

For the "Pharmacy" Half of the Card

   a. Fill in the date the fraud was attempted.

   b. Check off either (H) for "hit" or (M) for "miss."

   c. Fill in any relevant remarks by printing out what led to the "miss" or whatever you think aided the "hit," i.e., store crowded and pharmacist pressed for time, etc.

   d. Fill in the case number.

   e. Mail in as soon as completed to BNDD-ENA
      ATTN: K. Goodman
      1405 Eye Street
      Washington, D. C. 20537

Use of Data Card (Cont'd)

For the "Mail-Order" Half of the Card

   a. Fill in the date the prescription was sent.

   b. Fill in the date that any and all responses are received, viz., this might be a return form to be filled out, a notice of relevant action, a request of some sort, or the fulfilled prescription itself. Note in the remarks section the nature of the returns so dated.

   c. Check off the (H) for "hit" or (M) for "miss" depending on whether you get the filled prescription.

   d. Fill in the case number.

   e. Mail in the completed data card as soon as completed to:

      BNDD-ENA
      ATTN: K. Goodman
      1405 Eye Street
      Washington, D. C. 20537

PROJECT SCRIPT

Guidelines for Acting as Patient in
Mail-Order Phone-In

1. The actual phone-in will be made by BNDD Headquarters.

2. You will see the date it is to be made on the data card (in this case see "DATE SENT").

3. If you receive any or no response from Mail-Order House, follow Guidelines 4-8 on the "GUIDELINES FOR MAIL ORDER PRESCRIPTION OPERATION."

PROJECT SCRIPT

Guidelines for Mail-Order Prescription Operation

1. Using the blank prescription and referring to the enclosed sample prescription:

   a. Fill in patient's name and address, as in sample.

   b. Fill in the date on which you will pass the prescription.

   c. Recopy the prescription order exactly in all details.

   d. Sign the prescription, using the doctor's name as it appears on the sample.

2. Obtain a simple, unprinted envelope and copy the name and address of the mail-order prescription house on it, as well as your real name and return address.

3. Take any piece of unprinted paper and copy your name and address on it. Insert it with the fraudulent prescription in the envelope and mail it to the mail-order house by First Class Mail (8-cent stamp).

4. If the mail-order house returns any sort of form to you and/or any sort of notice of action or delay of action, act according to its requirements.

5. For example, if a form is required to be completed, do so. If the form implies that you must be retired, fill out the form to say you are 65 or so, in age. Fill in any required information as you would imagine a fraudulent prescription perpetrator would. However, if the return requires any kind of follow-up or additional data by a physician, consider the fraud to have missed, (M on the data card). In that case attach the form or notice to the data card and so note in the remarks section of the mail order half of the data card.

6. Note the date of the receipt of the form in the "Date of Return" section.

Guidelines for Mail-Order Prescription Operation (Cont'd)

7. In the event you are successful in your order, process the required payment to the mail-order house, note all relevant dates of action and enter a check where you find the letter H (hit).

8. If you receive no drugs or notification from a mail-order house within ten (10) days of mailing your prescription, consider it a "miss," enter a check at (M) and so note in the "Remarks" on the data card.

PROJECT SCRIPT

Guidelines for Attempting to Pass a Fraudulent Prescription to a Pharmacy or Following Up a Phone-In Prescription

1. Using the blank prescription and referring to the enclosed sample prescription:

   a. Fill in a patient's bogus name and address.

   b. Fill in the date on which you will pass the prescription.

   c. Recopy the prescription order exactly in all details.

   d. Sign the prescription, using the doctor's name as it appears on the sample.

2. You are expected to imitate a prescription fraud perpetrator (P) in moderation. (We are attempting to test the Pharmacy's care in detecting a fraud, not your acting ability.)

3. Do not attempt to force a sale by intimidation or excess persuasion.

4. Observe the pharmacist's reaction to the prescription. This will help in filling out the "Remarks" section on the data card. Do not turn away and study the store or its contents. If asked by the pharmacist or a clerk to return in a short while, follow these instructions.

5. If a pharmacist becomes suspicious and refuses the prescription, politely permit this to occur. DO NOT follow-up if the pharmacist asks for additional physician's validation. Consider this a "miss" and break contact with a thank you. In short, if a simple lie is required, tell it, but if a complicated "cover" story is required, forget it. (For example, if the pharmacist asks for ID, say that you have left it at home, etc.)

6. If a pharmacist attempts to delay your request and calls the police, permit this to occur. Participate politely in the following events

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Guidelines for Attempting to Pass a Fraudulent Prescription (Cont'd)

and identify yourself only when well out of the pharmacy. Briefly explain the purpose of the fraud and request that the event be held confidential. In no case should you precipitate the need to run from the pharmacy. Only as a last resort do we expect you to have to identify yourself to a pharmacist.

APPENDIX C

Explanation on the Derivation of Significant Differences for Two and Four Population Cases

Comparison of Two Populations

Suppose that two populations, P_1 and P_2, are subjected to a number of experimental tests such that the outcome of each test is either a "success" or "failure." For a given population, the probability of a success may vary from test-to-test due to the influence of known factors (A, B, C, etc.), operant upon the population. We wish to develop a test procedure for testing the null hypothesis, H_o, that successes are equally likely for the two populations.

In order to accommodate this test procedure the sample points for the two populations should be balanced with respect to the factors (A, B, C...) as follows:

1. If a factor is relevant to a given population, the sample points from that population should be distributed evenly over the levels or categories of the factor.

2. For factors common to both populations, the sample points for both populations should contain the same proportion of points under each treatment combination (i.e., particular levels of the factors common to both populations).

Condition (1) provides for an averaging of the results over all levels of a given factor so that the results will not be biased by any particular level of the factor involved. Condition (2) insures that observed differences between responses for the two populations can be attributed to the characteristics of the populations instead of the effects of individual factors in the experiment.

In order to provide for more general comparison (e.g., comparison of the effects of various levels of a factor on a given population or comparison of the effects of a particular factor level on two populations), the populations, P_1 and P_2, may be defined so as to reflect those factors or factor levels of interest.

Notation:

Let

n_i = the number of tests conducted on population P_i, where $i=1,2$.
x_i = the number of observed successes in population P_i $(0 \le x_i \le n_i)$ $i=1,2$.
X_i = denote the random variable generating the observed x_i values, $i=1,2$.
x = total number of successes observed, x_1+x_2

Test Procedure

If successes are equally likely for the two populations and x is a fixed number, the probability distribution for X_1 is described exactly by the hypergeometric distribution. That is,

$$P\left[X_1 = x_1\right] = \frac{\binom{n_1}{x_1}\binom{n_2}{x-x_1}}{\binom{n_1+n_2}{x}}$$

In practice, we would observe x_1, x_2 and x and use the probability function above to calculate $P\left[\,|x_1 - x_2| \ge \Psi \mid x_1 + x_2 = x\,\right]$ where $\Psi = x_1 - x_2 > 0$. So, in effect our test statistic would be:

$$\sum_{|x_1 - x_2| \ge \Psi} \frac{\binom{n_1}{x_1}\binom{n_2}{x-x_1}}{\binom{n_1+n_2}{x}} \qquad (1)$$

If the probability calculated in (1) is below some predetermined value, say α, the null hypothesis would be rejected and we would conclude that successes are not equally likely for the two populations.

The test statistic (1) may alternately be written as

$$P\left[\,|x_1 - x_2| \ge \Psi \mid x_1 + x_2 = x\,\right] = \frac{\binom{n_1}{x_1}\binom{n_2}{x-x_1}}{\binom{n_1+n_2}{x}} + \cdots + \frac{\binom{n_1}{x_1}\binom{n_2}{x-x_1}}{\binom{n_1+n_2}{x}}$$

$$0 \le x_1 \le x^*, \quad \tfrac{1}{2}(\Psi+x) \le x \le x^*$$

where $x^* = \min\,(n_1, x)$ and $\Psi > 0$.

If $n_1 = n_2 = n$, the test statistic (1) simplifies to the form

$$P\left[\,|x_1 - x_2| \ge \Psi \mid x_1 + x_2 = x\,\right] = \frac{\binom{n}{x_1}\binom{n}{x-x_1}}{\binom{2n}{x}} + \cdots + \frac{\binom{n}{x_1}\binom{n}{x-x_1}}{\binom{2n}{x}}$$

$$\tfrac{1}{2}(\Psi+x) \le x_1 \le x^*$$

where $x^* = \min\,(x, n)$ and $n_1 = n_2 = n$.

Example:

One-hundred and twenty-eight (128) tests are conducted on each population. We wish to test the null hypothesis at the 95% level of significant. Sixty-four successes are observed for the first population and fifty-one successes for the second. Then the test statistic (which given the probability of an outcome this extreme or more extreme) is given by:

$$P\left[\,|X_1 - X_2| \geq 13 \;\middle|\; X_1 + X_2 = 115\right] = 2\sum_{x_1=64}^{115} \frac{\binom{128}{x_1}\binom{128}{115 - x_1}}{\binom{256}{115}} = 0.131.$$

Since the probability of an outcome at least this extreme is greater than 0.05, we would accept the null hypothesis at the 95% level of significance.

The null hypothesis would have been rejected if the number of successes in one population exceeded the number of successes in the other population by 17 or more. For example, if we had observed $x_1 = 66$ and $x_2 = 49$, the test statistic would be:

$$P\left[\,|X_1 - X_2| \geq 17 \;\middle|\; X_1 + X_2 = 115\right] = 2\sum_{x_1=66}^{115} \frac{\binom{128}{x_1}\binom{128}{115 - x_1}}{\binom{256}{115}} = 0.044 < 0.05.$$

and hence the null hypothesis would be rejected at the 95% of significance level.

Comparisons Among Several Populations

The test procedure for comparisons between two populations can be easily extended to the more general case of comparisons among k populations. The conditions regarding balancing of the sample with respect to the factor levels should be fulfilled to accommodate the test procedure. The null hypothesis, H_o, will be that successes are equally likely among the k populations.

Test Procedure:

Let

n_i = the number of tests conducted on population P_i . $i = 1,2....k.$

x_i = the number of observed success in population $P_i \cdot \{0 \leq x_i \leq n_i\}$, where $i = 1,2.....k.$

X_i = denote the random variable generating the observed x_i values. where $i = 1,2.....k.$

x = the total number of successes observed = $x_1 + x_2 + ...x_k$.

Under the null hypothesis, the probability distribution for the random variable $X_1, X_2, ...X_k$ is given by:

$$P\left[X_1 = x_1, X_2 = x_2, ...X_k = x_k\right] = \frac{\prod_{i=1}^{k}\binom{n_i}{x_i}}{\binom{\sum_{i=1}^{k} n_i}{x}} \quad \text{where } \sum x_i = x.$$

In practice we will observe $x_1, x_2, ...x_k$ and use the range of the observed values as a test criterion. Let Ψ denote the sample range defined by:

$$\Psi = \max x_i - \min x_i$$

The test statistic can be generated from the above probability distribution by calculating the probability of a range equal to or greater than the observed range. Accordingly, the test statistic J would be of the form:

$$J = \sum_{*} \frac{\prod_{i=1}^{k} \binom{n_i}{x_i}}{\binom{n_1 + n_2 + \cdots + n_k}{x}}$$

where $\sum_{*}$ extends over all values $x_1, x_2, \ldots, x_k$ such that $\max x_i - \min x_i \geq r$; and $\sum x_i = x$.

If $J \leq 0.05$, the null hypothesis is rejected at the 95% level of significance. Otherwise we accept the hypothesis of equally likely successes among the populations at this significance level.

Example:

Suppose that 16 tests are conducted on each of four populations and we observe the following number of successes in each population;

$x_1 = 10$ in P_1.
$x_2 = 12$ in P_2.
$x_3 = 8$ in P_3.
$x_4 = 8$ in P_4.

Then $x = 10+12+8+8=38$ and the sample range is given by $r = 12-8=4$. Accordingly, the test statistic J would be given by:

$$J = \sum_{*} \binom{16}{x_1}\binom{16}{x_2}\binom{16}{x_3}\binom{16}{x_4} \Big/ \binom{64}{38}$$

where $\sum_{*}$ extends over all values of x_1, x_2, x_3, x_4 satisfying the following conditions:

$$x_1 + x_2 + x_3 + x_4 = 38$$

$$\max x_i - \min x_i \geq 4$$

$$0 \leq x_i \leq 16, \quad i = 1,2,3,4.$$

Example of Prescription Phone-In to Mail-Order Prescription Firm by Fictitious Doctor

Secretary: Hello. XYZ Company

Doctor: This is Dr. A calling. I want to give you a prescription and I'd like you to mail it to B City.

Secretary: Just a minute and I'll give you the pharmacist.

Pharmacist: Pharmacist, may I help you.

Doctor: Yes, this is Dr. A. Would you take a prescription for Mr. C and mail it to him in B City?

Pharmacist: All right. What's the patient's full name and address?

Doctor: Mr. C at Ave. D in B City. I want him to have 120 phenobarbital 30 mg. One tab T. I. D. prn.

Pharmacist: What's your BNDD number, Doctor?

Doctor: My number is E.

Pharmacist: OK. We'll send it out.

(End of Conversation)

In this case, the doctor's address and phone number was not requested by the pharmacist. The prescription was nonetheless filled.

Example of Prescription Phone-In to Pharmacy
by Fictitious Doctor

Pharmacist: Hello. A Pharmacy.

Doctor: Hello. This is Doctor B calling. I want to leave you a script for a patient of mine. He'll pick it up in about an hour.

Pharmacist: Okay.

Doctor: His name is Mr. X and let's give him 60 Seconal 100 mg with the sig: one h.s. for sleep. No refill.

Pharmacist: What's Mr. X's address?

Doctor: His address is Y.

Pharmacist: And what is your first name, doctor, and address?

Doctor: I'm Doctor B and I'm located at D Avenue.

Pharmacist: What is your BNDD number, doctor?

Doctor: My number is E.

Pharmacist: Thank you and we'll have it ready for him.

(End of Conversation)

In this situation, the pharmacist did not ask the physician for his telephone number. This was typical of several of the phone-ins. In other cases, the doctor did not supply his BNDD number nor his address. Prescriptions were nonetheless filled.

APPENDIX D

Samples of Fraudulent Prescriptions

Example of Bogus Prescription
used in Fraud Mode D

WARREN H. HARTMAN, M.D.

18160 WOODWARD
DETROIT, MICH.

INTERNAL MEDICINE
869-9001

BNDD # AH 4206417

NAME John Doe DATE 11-15-72

ADDRESS 1234 Main St.

℞ Seconal 1½ gr. pulvules
#30
Sig: ī h.s. prn sleep

REFILL: 1☐ 2☒ 3☐
NON-REP ☐

Warren Hartman M.D.

Example of Hospital Prescription
used in Fraud Mode B

NAME Howard Jones DATE 12-1-72

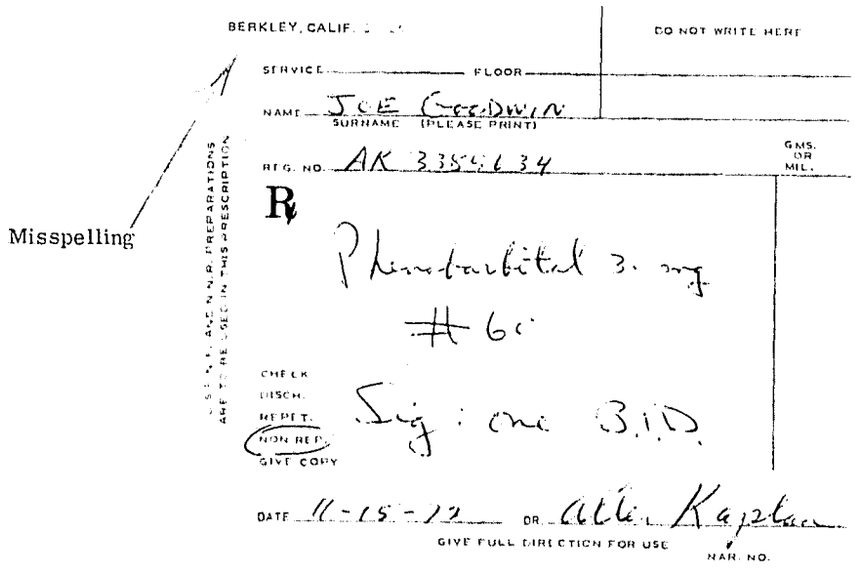
ADDRESS 412 Greenview Dr.

℞
Seconal 100 mg
#45

Sig: ī cap h.s.
prn sleep.

REFILL 0 TIMES Gerald Koncer M. D.
AK 340 2965

Example of Hospital Prescription
used in Fraud Mode B
(with printing error)



APPENDIX 15

[From The Citation, Vol. 23, No. 1, Apr. 15, 1974]

Pharmacists May Fill Out-of-State Physicians' Drug Prescriptions

Prescriptions from out-of-state physicians registered under the Federal Controlled Substances Act but not registered in the State may be filled by duly authorized Iowa pharmacists, the Iowa Supreme Court ruled. Out-of-state physicians could not be required to register in Iowa as a prerequisite to having their prescriptions filled by local pharmacists.

At the behest of the Iowa Board of Pharmacy Examiners, the State Attorney General filed a petition seeking a permanent injunction against a pharmacy to prevent them from filling prescriptions written by nonresident physicians not licensed by State authorities to prescribe controlled substances.

The pharmacy received prescriptions by mail, filled them, and returned them by mail. Some of them were written by nonresident physicians not registered to prescribe controlled substances by the Iowa Board. The Iowa Uniform Controlled Substances Act prohibited state pharmacists from filling prescriptions written by Iowa physicians who were not thus registered.

The trial court found that the Iowa Act was intended to regulate only intrastate controlled substances transactions and that nonresident physicians registered under the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970 were considered to have compiled with the Iowa Act.

The court found that the federal Act permitted Iowa pharmacists to dispense drugs on perscriptions of practitioners licensed by the jurisdiction in which they practiced. The court also held that filling prescriptions in Iowa of physicians licensed in other states constituted interstate commerce.

The trial court further concluded that requiring all out-of-state physicians to register in Iowa before they could prescribe drugs for Iowa residents to be obtained from Iowa pharmacists would place an unreasonable burden on interstate commerce. The court said that the State had the right to regulate medical licensing within its borders but not to require nonresident physicians to register in Iowa.

On appeal, the court said that it was reasonable to interpret the Iowa Act to apply only to resident physicians. The court felt that such interpretation would insure continued free movement of controlled substances between states while securing them against drug diversion from legitimate sources.

The State contended that filling of prescriptions by out-of-state physicians constituted the practice of medicine in Iowa and that the State could not be certain that such physicians were competent to prescribe such drugs. The State further argued that a nonresident physician could comply with the Iowa Act simply by registering in Iowa.

The Supreme Court said that such registration requirement would negate operation of the federal Act in the State. The court pointed out the licenses were issued by the federal authority for the purposes of federal legislation controlling drug abuse. Affirming the trial court ruling, the court found that such interest clearly outweighed any local interest in allowing only state-registered physicians to prescribe in the State.—*State of Iowa v. Rasmussen*, 213 N.W. 2d 661 (Iowa Sup. Ct., Dec. 19, 1973).

APPENDIX 16

[From Pharmacy Times, May 1973]

INDEPENDENT PHARMACIES ARE BURGLARIZED MORE OFTEN THAN CHAIN PHARMACIES

(By Leonard Reis, Research Editor, Pharmacy Times)

Wanted: *Professional person (college degree mandatory by law). Must be prepared to keep store open 7 days per week, averaging more than 10 hours per day. Chances of being burglarized are excellent.*

Not many of today's newly-graduated professional people would be attracted to a classified ad like that. Yet, according to a recent survey, these are the *very* conditions under which the typical retail pharmacy owner or manager actually works. The survey was sponsored by PHARMACY TIMES, and conducted by Marketing Evaluations, Inc. in 1972. It included representative returns from 1,044 chain and independent pharmacies throughout the nation. From the comprehensive 4-page questionnaire, a statistical "profile" of retail pharmacy owners and managers was compiled (Pharmacy Times, January 1973).

STORE HOURS

Information on store hours & customer traffic—derived from this national survey—is reported on these pages.

The typical retail pharmacy is open for business about 72 hours per week . . . slightly *less* for independent stores (71 hours), but *more* for chain pharmacies (76 hours). A full 25% of retail pharmacies are open more than 80 hours per week. However, if a pharmacy is open for this many hours, chances are 2 to 1 that it is a unit of a chain. Most retail pharmacies—almost 60%—are open on Sunday. The number of hours varies from less than 3 to more than 10, averaging out to approximately 6½ Sunday hours for the typical pharmacy. Again, units of chain stores are more likely to remain open longer, compared with independents (see summary on the opposite page).

CUSTOMER TRAFFIC

Saturday is the busiest day of a pharmacy's work-week, with an average of 285 customers per pharmacy. Ordinary weekdays are not much slower, with an average of 265 customers per day, per pharmacy. One would expect to find far fewer customers on Sundays—because of the shorter workday—but Sunday's volume seems to be only slightly less than a weekday's . . . about 252 customers. Customer traffic is correspondingly greater in units of chains for each day of the week (see summary).

SUMMARY: 9 CHARACTERISTICS OF RETAIL PHARMACIES BASED ON STORE HOURS

	All pharmacies	Independent pharmacies	Chain pharmacies
Average number of hours per week pharmacy is open for business	72	71	76
Percent of pharmacies open more than 80 hours per week	25	22	45
Percent of pharmacies with Sunday hours	58	55	75
Average number of hours pharmacy is open on Sunday[1]	6½	6	8
Average number of customers per weekday	265	247	398
Average number of customers per Saturday	285	264	441
Average number of customers per Sunday[1]	252	233	353
Percent of stores burglarized in past 5 years	52	54	38
Average number of times each store was burglarized in past 5 years	2.3	2.3	2.3

[1] Based only on pharmacies with Sunday business hours.

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There's something about a pharmacy that seems to make it a frequent target for burglary and armed robbery. Factors contributing to this include: The cash-and-carry nature of retail pharmacy and the availability of narcotic and abuse drugs.

BURGLARIES: AT LEAST ONCE IN PAST 5 YEARS

Whatever the reasons, the *majority* (52%) of pharmacy owners and managers in the PHARMACY TIMES' sample reported having been burglarizd at least once during the past 5 years. Only 38% of chain pharmacies were reportedly burglarized during the past 5 years, compared with 54% of independent pharmacies—reflecting, perhaps, differences in such factors as store location, size, and security devices.

Looking only at the sample of pharmacies which *were* burglarized, the majority of these were robbed 2 *or more times* in the past 5 years. And in this area, the independent pharmacy is on a par with the chain store pharmacy—both having *identical* averages for burglaries—2.3 per store (see last line of Summary).

APPENDIX 17

[From Drug Topics, Feb. 19, 1973]

THE RX MAIL ORDER THREAT: IS THE POSTMAN REPLACING YOU?

(By Ralph Thurlow, Senior Editor)

Giant fish eat big ones, big fish eat little ones, little fish eat tiny one—that's a law of nature and of the retail pharmacy prescription business. Chains gobble up independents, and some say discounters gobble up chains, and there are those who contend that somewhere in the great retailing depths just offshore, there's a fish that may gobble up all of them.

The threat that many see is the prescription mail-order house. Those who wax paranoid over the problem don't expect Armageddon tomorrow, but how long can it be, they ask, before consumers turn in force to pills from plain pipe racks and postman pharmacists.

That's a fair question in an era when price often outweighs service. The answer to the fear of mail order is about as elusive and complicated as the fear itself. Mail order growth, operations, opposition, controls, and relation to Federal regulations is a subject deserving of Winston Churchill's descriptive phrase, "a riddle wrapped in a mystery, inside an enigma." First unknown: How big is the Rx mail order universe, and how fast is it growing?

While there are no comprehensive figures on either dollar volume or number of prescriptions dispensed by mail order, a look at the operations of some of the big dispensers gives an idea of the industry's size. One of the big dispensers, perhaps the biggest, is NRTA-AARP Pharmacy—the program for the National Retired Teachers Association and the American Association of Retired Persons. In 1968, an HEW task force on prescription drugs reported that this organization was dispensing 4,000 prescriptions daily by mail. The latest estimate ups that figure to 6,000 a day, and the program has grown to include five pharmacies around the country, all dispensing by mail.

Another of the large-scale mail-order dispensers of drugs—the Veterans Administration—traces a similar growth pattern. In 1969, for instance, it dispensed a little over four million prescriptions by mail. That was a 14 per cent increase over 1968. By 1971, the VA program was mailing out something over five million prescriptions, and in 1972, it filled six million. Nonprofit retirement groups, unions, and Government organizations aren't the only one to exhibit a healthy growth curve when it comes to such dispensing. The proliferation of prepaid medical plans has been accomplished by an increase in mail-order prescription dispensing by pharmacies in the biggest plans. The Health Insurance Plan of Greater New York, for instance, has some 88,000 subscribers whose union contracts make them eligible for free Rx drugs under the program. A plan doctor prescribes for a subscriber-patient, the patient mails in his Rx, and HIP's mail-order center shoots back the prescription by United Parcel or regular mail. In 1968, HIP filled 50,000 prescriptions by mail; in 1972, it filled nearly 270,000 that way. Each time HIP opens a satellite pharmacy operation in an outlying part of New York City, it expects a drop in its mail order business; yet, says the plan's executive director, mail order increases.

Prescription mail order figures are harder to come by for firms that are run for profit, but the growth pattern is clear. Pastor's Pharmacy in Philadelphia, as an example, went into mail order seriously only a year and a half ago after none years in business as a discount house. With three pharmacists in a special mail division, Pastor's mail order dispensing business tripled in the past year. Another for-profit firm—Federal Prescription Service, Inc., of Iowa—started about six years ago and is now, according to some

reports, one of the state's largest businesses in terms of income from postal operations.

How many Rx mail order operations are there in the U.S.? You would expect that Federal authorities—those folks who are so intent on keeping track of poppy fields in Turkey or pharmacists' price lists locally—would have an answer to that question. They don't—or at least the FDA, BNDD, and postal authorities profess not to. Two rays of light in this corner of the great Rx mail order mystery: An educated official guess in Pennsylvania puts the number of mail order houses in that state at 10; an estimate of the number of such outfits in New York arrives at a similar figure in that state.

Put together all the union drug dispensing plans around the country, and all the regional medical plans, and all the consumer's cooperatives that are jumping on the dispensing bandwagon plus all the private entrepreneurs who shun the limelight of publicity, and you begin to understand why many pharmacists are alarmed at the mail order situation. True, nobody can name a community pharmacy that's folded specifically because of competition from the mail-order houses, but that proves little. The growing concern at this point is not economic, most pharmacists agree, but rather a concern over the professionalism of dispensing Rx drugs through the mail—isn't this a health hazard and a contributing factor to the drug abuse problem in the nation? Ammunition for the drug abuse contention recently came in the form of glaring expose-type headlines in New York City and Philadelphia.

In the New York case, Sal Rubino, then president of the state's pharmaceutical society, deliberately forged a prescription for 100 Tuinal capsules, sent it off to a Philadelphia Rx mail order house, and got the prescription back filled with no questions asked. "The prescription was filled," says Rubino, "evn though it bore no physician's identification number as required by the Bureau of Narcotics and Dangerous Drugs. And the firm didn't contact the physician to get the number for authentication." Rubino shudders to think how many more such poorly controlled mail order houses may be shipping drugs to New York addicts and pushers from out of state. "The kids we work with in the Drug Rehabilitation and Narcotics Guidance Center that I head told us how to order through the mail. They could have ordered the Tuinal as easily as I did, paid $3.17 for 100 caps, and sold it on the street for 50 cents to a dollar per cap."

Upshot of the Rubino disclosure was a request to the mail order pharmacy by the New York attorney general's office to cease its mail orders to New York residents unless it did some thorough checking first. "It is expected that upon receipt by mail of a prescription by you," said the attorney general's directive, "that you will communicate in writing with the physician given on the prescription blank to ascertain if he has written the prescription for the person. Also, if the drug called for by the prescription is a controlled drug, you should communicate with the Bureau of Narcotics and Dangerous Drugs in Washington, D.C., to ascertain if the physician is authorized to prescribe such drugs and whether the BNDD number appearing on the prescription has actually been issued to the said prescriber." The pharmacy agreed to comply and that presumably was that. But was it?

Those close to the problem point out that Key Pharmacy—the one that got its knuckles rapped—had called attention to its operation by advertising prescription drug prices, including some BNDD items, in a big daily newspaper in a big city. What about all the Rx mail order firms that are more discreet, stick to small-town newspapers and backwater journals, and advertise lower prices without transgressing the law by naming specific drugs? How do they control what they send out? Pennsylvania authorities set out to answer that question for themselves and got some more shocking answers in the great Rx mail order mystery.

Employing state police as phony mail order customers for dangerous drugs, the Commissioner of Professional and Occupational Affairs, Vincent J. Fumo, sent four prescriptions each to 16 mail order houses both in and out of his state *(Drug Topics,* Nov. 6, 1972). Nine firms, including six that were out-of-state, returned a total of 2,000 pills running the gamut of uppers and downers from Carbrital and Butisol to Desoxyn and Desbutal. None of the prescriptions were questioned, none of the phony doctors on the prescriptions were contacted, and most amazing of all, in a way, the firms were so anxious to make the sales they didn't bill the participants for several weeks. The total bill came to

$130, and in the illicit drug trade the returned prescriptions could have been marketed for $1,000.

"We tried to get our state delegation in Congress to push for Federal legislation which would specially license all mail order firms engaging in interstate drug commerce," says Fumo, "and which would require mail order houses to verify prescriptions with prescribing physicians by phone. So far the response hasn't been overwhelming." The system, according to Fumo, would be tied to a Federally dispensed list of all doctors in the country with their addresses and drug control numbers. A pharmacist filling a prescription would call the phone number on the list—not the one on the prescription—in order to thwart bogus doctors or makers of counterfeit prescription blanks. In the meantime, Fumo expects to implement a system similar to those in New York and California, where triplicate prescription blanks are filled out for Class 2 drugs by the prescribing physicians. One would go to the patient, one would be retained by the M.D., and one would go to the Pennsylvania Department of Health for scanning and inventory control. Fumo has faith that high-speed computers and technology can control the Rx mail order problem in Pennsylvania, in lieu of a meaningful Federal move for controls. Others wish him well, but point to the singular lack of success by individual states in controlling mail order Rxs coming from out-of-state. One such interested party is Robert G. Gibbs, executive director of the Iowa Pharmaceutical Association.

"We've got a problem in Iowa with Federal Prescription Service, Inc.," Gibbs says, "a firm that sends mail order Rxs all over the country as well as to Iowans. We've tried to close them up on a raft of charges for about five years, but there always seem to be technical legal limitations to what local authorities can do about interstate commerce." Because of such border hopping, Gibbs fears that no single state can solve the Rx mail order problem until the FDA gets into the act.

Gibbs cites the fact that Federal Prescription Service was pushed out of operating in Massachusetts by that state's pharmaceutical association. Then, when the class action pursued the firm into a judgment decision in Iowa, the case fell apart in a Federal court.

The California board of pharmacy has had ligation going against a Missouri mail order firm for about five years. And, two years ago, California pharmacists were unsuccessful in pushing for legislation against mail order houses. The threat then, as the pharmacists saw it, came from a prescription mail order operation that was trying to tie into the state's numerous prepaid medical plans.

While the states fight their small wars, national pharmacy organizations keep up what pressure they can to wake the FDA or some other interested organ of Government. The American Pharmaceutical Association, for instance, issued a policy statement in 1970 in opposition to profit and nonprofit organizations that offer Rx services by mail order. In 1971, the APhA issued a further statement condemning mail orders in terms of the controlled substances act. "Our opposities," says Richard Penna, head of the APhA's Academy of General Practice of Pharmacy, "rests mainly on the fact that mail order constitutes a threat to health by interfering with the patient-doctor-pharmacist relationship and also violates state pharmacy laws and regulations." Penna points out that in an era of increased concern over drug interactions, the community pharmacist who provides acute medication can't foresee possible interactions when a patient gets chronic medication from a mail order firm.

The National Association of Retail Druggists has repeatedly urged BNDD to prohibit mail order distribution of all controlled drugs. NARD's premise is that any system designed to guarantee control by checking on the authenticity of a mail order Rx would prove unworkable. Noting that NARD's members must comply with the controlled substances act, William E. Woods, the organization's Associate General Counsel, calls it "ludicrous" that an ineffective postal regulation is all that prohibits distribution of narcotic drugs through the mails—a circumstance that permits large-scale diversion of drugs for illicit use.

BNDD's and the FDA's response to such calls for action up to a short time ago: "At this time, such a ban is neither necessary nor desirable." Just recently, however, BNDD yielded to the growing clamor by way of cranking up a "study to identify the extent of occurrence of prescription forgery both in mail-order prescription firms and in community pharmacies." When the study is

completed, says BNDD, current regulations governing the prescribing and dispensing of controlled drugs will be re-evaluated. "Curious," say community pharmacists, "that they're going to study community pharmacists. That's just the group the mail order people insist need studying."

Where's mail order going, and what should be done about it? Though there are those who believe that the Rx mail-order business has plateaued—how big can the maintenance drug market for senior citizens be?—others contend that the operation is likely to get a big boost from growing agitation for open advertising of Rx drug prices and from consumer interest in lower prices. More to be feared than open advertising, according to the APhA's Penna, is the boost that mail order might get when more organized health delivery programs begin to use the mails as a mechanism for Rx drug distribution.

An even bigger threat looms, in the minds of other Washington watchers. According to some insiders, there are studies floating around the capital recommending that HEW go the route of the VA operation and dispense Medicare and Medicaid prescriptions by mail order on a large scale. The ringer in the argument is that HEW could as likely jump the other way, with inclusion of drugs under Medicare. Older folks who could have prescriptions filled for free at their local community pharmacy would hardly be interested in seeking lower prescription prices by mail order. Mail-order firms recognize that such a move would eliminate a huge slice of their pie.

Whichever way the ball bounces, it's generally agreed that the deciding bounce will come from the direction of Washington. That's according to many, is where the Rx mail order business got its biggest shot in the arm and where it continues to be nourished. When the law was liberalized for economic reasons back in the 1960s to allow the VA to mail prescriptions (including narcotics), the door was opened, in effect, to imitators all over the country. Prescription mail order operations that might once have been considered shady or questionable gained an aura of respectability.

Those who follow that line of reasoning note further that the program flourishes by reason of the tremendous difference between what the VA pays manufacturers for its bulk purchases and what manufacturers charge community pharmacists. The economics of the marketplace, so the theorists say, keeps the ball bouncing along, while political pressures from the groups of citizens who benefit most from large-scale Rx mail order operations keep the interest of Federal control agencies at a low ebb when it comes to doing something about the drug abuse problem.

That's what the theorists say.

Most pharmacists would say: "It's a riddle wrapped in a mystery, inside an enigma, to me, why community pharmacists are always the ones who have to bite the bullet."

APPENDIX 18

[From Drug Topics, Jan 15, 1973]

Drug Addicts Zero in on Pharmacies

(By Elizabeth W. Burchian, Science Editor)

Remember when a robber used to say, "Your money or your life"? Now he's more likely to snarl, "Give me all your narcotics, or I'll blow your head off." That's no idle threat. Even police force veterans shake their heads in disbelief at the viciousness accompanying today's crimes of violence. And drugstore robberies by drug addicts fall in that category.

THE SITTING-DUCK SYNDROME

Hard facts are hard to come by, but the gut feeling is strong and unanimous: This particular crime is assuredly on the increase, and pharmacists all over the country are showing more and more signs of the sitting-duck syndrome.

Many Dallas pharmacists, for example, can speak from experience. At the Marsh Lane Pharmacy, the first day of business in 1972 started with a robbery. Says manager Paul Smith: "Both men were drug users who needed a fix—real bad. They didn't want anything but heavy drugs, and they took all we had. They made me open the safe."

For the Meyers & Rossi Pharmacy in the same city, 1972 was a particularly bad year. "It's a very frightening situation," according to manager John Schmidt. "These robbers are all doped up, and they'd kill you in a split second. Now we close our doors at 5 and work out of our drive-in window."

In Boston not too long ago, police instituted special drugstore patrols which, they believe, are helping to end the recent tidal wave of drugstore robberies. But, while Boston pharmacists are breathing more easily, their colleagues in the suburbs aren't. Vincent Manduca of the North Leominster Pharmacy, located about 50 miles outside Boston, has this to say: "In the past three months we had two break-ins, and only narcotics were taken. Since we're just a half-mile from the police barracks, we're probably having fewer hits than other stores. But our branch in Leominster has had daytime holdups—the whole bit: gun-pointing at our man behind the counter and a girl clerk held with a knife at her throat. It's an awful experience. After it happens, for a while you feel suspicious about anybody who walks into the store." It seems that stepped-up risk in suburbia.

One more Bay State statistic: From May through November of 1972, 27 drug-related holdups were reported in Newton. Of 28 drugstores in that community, at least three have closed because of the continued threat of armed robberies.

Last year a Chicago pharmacist who was held at gunpoint was able, along with a female clerk, to describe the robber to the police—but to no avail. Several months later, the pharmacist was found in the trunk of his car—murdered, detectives theorized, by the same robber. And the body of a woman clerk was there too. Like the pharmacist, she had been shot to death, although she was not the employe who had helped to describe the criminal. "A case of mistaken identity," said the police. "This elderly lady hadn't even been employed at the drugstore at the time the armed robbery took place."

HOW TO MINIMIZE LOSSES

The Bureau of Narcotics and Dangerous Drugs acknowledges that the most elaborate security measures in the world are of no help in the case of armed robbery. "When a pharmacist faces a loaded gun," says a BNDD spokesman,

"there's no question about what comes first: He merely turns over the merchandise. The new crackdowns on heroin and the resulting shortages naturally mean that addicts have to find alternative sources of supply, and we've warned retail pharmacists as well as people at other levels of distribution. We also suggest that pharmacists stock a minimum quantity of the drugs we're discussing, and that they reorder more frequently. They may have to forfeit a volume discount on purchases, but we figure that's better than forfeiting a life."

The BNDD and police authorities everywhere recommend that the "addicts' drugs of choice" be kept in several safes or locked cabinets, preferably near or in the store window so that passers-by or patrolling police cars can see any action that may be taking place. Some drugstore owners oppose this, however, because they're convinced that putting a safe in the window invites a thief and makes his job that much easier.

That's not all. There are even detectives who'd like to see window displays cut down—or out—on the rationale that better visibility from the street into the drugstore will deter criminals.

Lt. Virgil Robison of the San Antonio Police Department's Robberies Division advises pharmacists not to resist in any way when confronted by armed robbers. "But," he adds, "we'll have a better chance of tracking them down if the pharmacist will take particular note of the man's hands, dress, and manner of speech. Frequently the faces are masked, so there's no help there. If the pharmacist pays attention to the three things I've mentioned, apprehending and subsequent identifying are made easier."

Lt. Robinson quotes statistics showing that 76 per cent of San Antonio's robberies last October were committed by drug addicts, though he has no breakdown indicating which victims were pharmacists.

VIEWS ON PREVENTION DIFFER

As a matter of fact, a lack of statistical breakdown is one reason why all interested parties can't come to terms on protective measures for that endangered species, the pharmacist. Police blotters, for instance, don't know what type of business was robbed; and in cases where drugstore robbers are not apprehended, what was stolen is clearly established, but whether the thief was an addict doesn't get into the statistics. Likewise, insurance companies aren't geared for the accumulation and quick retrieval of such information, their prime interest being to investigate and pay individual claims. Nor do most local pharmaceutical associations have the manpower to keep tabs on crimes that touch their members. The BNDD has security suggestions for pharmacists but relatively little data now; it's been compiling figures for just a year.

ROBBERY BY GEOGRAPHIC REGION

[In percent]

	Total	North-eastern States	North Central States	Southern States	Western States
Armed—any weapon	65.3	69.6	61.9	63.9	62.6
Strong-arm—no weapon	34.7	30.4	38.1	36.1	37.4
Total	100.0	100.0	100.0	100.0	100.0

Note.—A set of statistics drawn from the FBI's 1971 report, "Crime in the United States," indicates that, since 1966, armed robbery has increased 175 percent and strong-arm robbery 104 percent. And, in case you're interested in the distribution of that crime—

But meanwhile, having been the victim of broad daylight assault by thugs, Kurt Lange, M.D., professor of medicine and pediatrics at New York Medical College, is now a prime mover in Citizens Crusade Against Crimes, an organization that seeks to arose the community against wanton violence. In its Nov. 10, 1972 issue, *Medical World News* reported Dr. Lange's proposal that heroin should be made available to the addict at a nominal price so "drug traffic would lose its profit, its secrecy, its glamour, and the Mafia would be out of it. There would still be deaths, but only to addicts overdosing themselves."

On the other hand, quite a few pharmacists and crime investigators feel that even stricter laws and punishment would effect a downward trend in drugstore robberies. A Chicago pharmacist insists that the solution is "to make them a Federal offense, like a bank robbery. Bring in the FBI. That should halt these robberies."

In a recent editorial, *Drug Topics* noted: "Solutions are going to require more police protection. The hard-pressed cities where the pharmacist is in greatest danger haven't the cash to provide it."

And as we said then, the Federal Government should help protect the retail pharmacists. "If pharmacy's national associations give the faintest damn for the sitting-duck retail pharmacist," concluded the editorial, "they will apply all the political muscle they have to make sure that it is done."

APPENDIX 19

THE PLAIN DEALER,
Cleveland, Ohio, May 17, 1974.

Mr. JOHN M. RECTOR,
Staff Director and Chief Counsel, U.S. Senate, Subcommittee to Investigate Juvenile Delinquency, Washington, D.C.

DEAR MR. RECTOR: Enclosed is a copy of the series The Plain Dealer had on physicians. I hope that it is helpful to your Subcommittee.

Sincerely,

DAVID RIMMEL.

[From the Cleveland Plain Dealer, Jan. 27, 1974]

HOW DRUG ABUSE IS MADE EASY

The Plain Dealer, in the first of a series of articles, today points up one devilish development in the problem of drug abuse.

The expose zeroes in on the unscrupulous doctor who prescribes dangerous drugs without examination of the patient, employing a sight-unseen diagnosis for quick profit.

Investigators were members of The Plain Dealer's special team of reporters, the "I-Team." They did more than chat with officials about illegal acquisition of drugs which, if used by nonpatients, have a great potential for damage.

The team found, through the experiences of fellow reporters, the relative ease with which young persons especially can obtain dangerous drugs if they know where to go, what to ask for and if they have cash in hand.

This does not mean that the drugs, if used correctly for specific illnesses, are without merit or that doctors in general are not conscientious and highly principled.

But the series of revelations does show up loopholes in current laws and illustrates the need for better self-policing in the medical profession.

Trafficking in strong drugs for sheer profit is illegal and immoral. The I-Team's findings speak for themselves on both counts.

[From the Cleveland Plain Dealer, Jan. 27, 1974]

$15 BUYS SOPOR PRESCRIPTION—DEADLY DRUG EASY TO GET HERE

Youths and young adults seeking what they call the love drug have found a way to skirt stringent federal controls.

They are finding cooperative doctors who for a price will prescribe methaqualone.

The young drug users are under the impression that methaqualone—commonly called Sopors—frees sexual inhibitions.

It may free inhibitions. But it does something else, too.

It caused the deaths in five months last year of 41 persons, and the poisoning of 1,197 others, according to the U.S. Drug Enforcement Administration.

Last October, methaqualone was put on the federal list of most rigidly controlled drug, alongside methadone and certain barbiturates and amphetamines.

But methaqualone is still the No. 1 fad drug today.

How Greater Cleveland youngsters obtain methaqualone was discovered by The Plain Dealer's Investigative Team in a seven-week study.

The I-Team learned that at least half a dozen physicians in Greater Cleveland were freely writing prescriptions for methaqualone and other dangerous drugs, or were actually dispensing the pills.

The investigation was touched off by complaints of an East Side father who said his 16-year-old daughter took quantities of Quaalude—like Sopor, a trade name for methaqualone—at a party early in December.

The girl, a 10th grader, was brought home unconscious by friends after a party.

Later, as the girl's father talked about the incident, there was panic in his voice. "My kid's hooked pretty bad," he said. "I can't reach her."

One of the girl's friends obtained a prescription for the drug, a hypnotic sedative, from a doctor in Beachwood, he said.

The Plain Dealer Investigative Team found a doctor in Beachwood who would write a prescription for Quaalude without seeing his patient, without talking to him, without knowing a single fact about his patient's medical history.

He was Dr. Norman Fisher, whose office is in a modern building at 24300 Chagrin Blvd.

Two Plain Dealer reporters, Christine J. Jindra and George E. Condon Jr., visited Dr. Fisher's office and obtained prescriptions for Quaalude.

Neither one saw the doctor. Neither had ever been there before. Neither was sick. Neither gave the doctor or his receptionists a single fact about his or her medical history. Neither asked for a prescription for Quaalude.

But each was given a prescription for 45 tablets of Quaalude. The doctor's fee each time was $15.

Condon visited the office Dec. 21, late in the afternoon.

He found the patients, who were seated in a nine-chair waiting room, were young and subdued. They were obviously in their teens or early 20s. Long hair and faded blue jeans were plentiful.

No one asked Condon what he wanted. They seemed already to know.

Approaching a brown-haired receptionist named Joan Marinelli, who was seated behind a counter, Condon said, "Are you Sheila?"

Miss Marinelli said no.

A 1972 graduate of Euclid High School, Miss Marinelli said, "I don't want anything to do with this," and gestured to the other receptionist.

That receptionist, a pretty blonde with a ready smile, was Sheila A. Pasquale of Lyndhurst. She turned 19 on Dec. 31.

Without Condon saying anything to her, Miss Pasquale efficiently slipped a white patient information form into her typewriter and began a series of questions.

"Who referred you here?" she asked.

Condon replied, "Nick," a fictitious name.

"Nick who?"

"I don't know," Condon said. Miss Pasquale laughed and moved to the next question.

"Are you over 21?"

Condon said, "I'm 25, but I don't have any ID."

This response momentarily stymied the receptionist who looked to the other girl for advice. Condon said, "Surely, I must look 21?"

"Well, no you don't," the brown-haired receptionist said with a laugh. But Sheila went on with her questioning.

"What's your name?"

"George Edwards," the reporter said.

"Birthdate?"

"5-20-1948," he said.

"Social Security number?"

"270-46-3821."

"Address?"

Condon said he lived on Lancashire Rd. in Cleveland Heights, an address selected only that day.

"Where do you work?"

Condon said he was a waiter at two Cleveland bars. He named them.

"Oh, yes. I've been in both those places," Miss Pasquale said "I don't remember you."

"Well, you just went the wrong nights, I guess." he said.

A brief, trivial discussion about the two bars followed.

"You aren't going to use these for work, are you? These are for going to sleep," she said, laughing.

"Would I do a thing like that?" Condon answered and both laughed. Up to this point. Condon had not mentioned what he wanted or why he wanted to see Dr. Fisher. Quaalude had not been mentioned.

Condon was told, "Have a seat. It will be a minute."

Condon waited five minutes. In that time, Miss Pasquale walked into a side office, out of view of the waiting room.

While he waited, Condon saw other persons called to the counter where they received slips of paper. Each paid $15 cash.

The pattern was repeated with Condon when Miss Pasquale called him to the desk, handed him a prescription for Quaalude and charged him $15.

Dr. Fisher had written the prescription. This was confirmed by a handwriting analyst hired by The Plain Dealer, who verified that the 4-x-5½-inch prescription was written and signed by the doctor.

When Condon paid his money and turned to leave, Miss Pasquale, perhaps taking her cue from the gay Christmas decorations in the office, sent Condon away with a cheery Yule greeting.

"Have a good time at the holidays," she said. Then, her smile broadening, she pointed to his prescription, winked, and said, "You will."

The day before Condon's visit, Miss Jindra went to the office.

Addressing Sheila, Miss Jindra said, "I want a prescription."

"Who sent you?" Miss Pasquale asked.

"A fiend," Miss Jindra said.

"It's all right to tell me," the receptionist said. The reporter still refused. Miss Pasquale put the medical form into the typewriter and resumed her questions.

"Name?"

"Chris."

"Last name?"

"Do I really have to?" Miss Jindra asked.

At this, Miss Pasquale laughingly said to the other receptionist, "She really doesn't want to give us any information."

Miss Jindra gave a fictitious last name and a Mayfield Rd. address.

Although she is really 26, Miss Jindra told the receptionist she was born in 1953, making her only 20. This erased Miss Pasquale's smile, but only briefly.

"You know you have to be over 21 to buy Quaalude," she said. This was the first mention of Quaalude and it was the receptionist who referred to the dug, not the reporter.

"Are you buying for yourself or someone else?" Miss Pasquale asked.

"For myself and a friend," Miss Jindra said.

"We'll take care of that," Miss Pasquale said, indicating the age was OK.

"Social Security number?"

Miss Jindra said she could not remember. This did not bother Miss Pasquale, who typed some numbers.

"Where do you work?"

Miss Jindra answered she was unemployed. She was told to sit down and wait.

Miss Pasquale disappeared in the side office and returned five minutes later with a prescription for Quaalude and called Miss Jindra to the desk.

She charged her $15 and Miss Jindra paid and left, prescription in hand.

A handwriting analyst also verified that Miss Jindra's prescription had been written and signed by Dr. Fisher.

Two young drug users interviewed by The Plain Dealer said that Dr. Fisher was one of their sources for drugs.

A spot check of seven pharmacies in Cleveland Heights and Warrensville Heights uncovered 118 prescriptions for dangerous drugs written by Dr. Fisher in the last nine months of 1973.

More than 60% of the first 50 prescriptions checked were for persons using fictitious names or addresses, The Plain Dealer learned.

In at least one case, a 17-year-old boy was given a fictitious name and age by a receptionist in Dr. Fisher's office because he was too young to get a prescription, police said. He later purchased six prescriptions, using four different names, according to police.

Dr. Fisher's operation is so well known and so large-scale that many Cleveland Heights pharmacists refuse to fill his prescriptions for Quaalude.

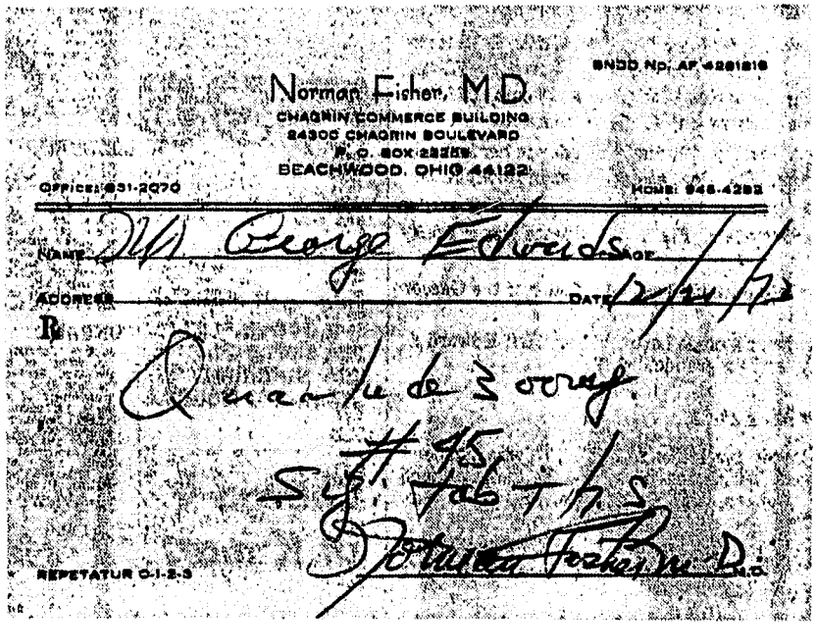
One such druggist is Ronald M. Eisenberg, owner for the past seven years of Caroll Drug, 1800 Coventry Rd., Cleveland Heights.

His drugstore is a 20-minute drive from Dr. Fisher's office.

Eisenberg said his store had been "flooded with Fisher's prescriptions" during the Christmas holidays. "On some days I had seven or eight scripts from Fisher," he said.

He refused to honor the prescriptions, he said, because, "I feel he is selling script for a drug that is being abused by the people going to him."

Dr. Fisher is best known among drug users for his Quaalude prescriptions, but he has readily supplied drug users with amphetamines ("speed"), The Plain Dealer learned.



This prescription for Quaalude was given to a Plain Dealer reporter, who used the fictitious name of George Edwards. A handwriting expert has attested that Dr. Norman Fisher's signature appears on the prescription

Dr. Fisher's prescriptions for Eskatrol and Desbutal—both amphetamines—and for Seconal, a barbiturate, were turned up by authorities.

In some cases, Dr. Fisher gave prescriptions for both amphetamines and barbiturates, commonly called "downers," to the same customers. This was in a nine-month period in 1973.

Selling prescriptions for these drugs—which are closely watched by the federal government—without even seeing the patient may be a violation of federal and state laws and medical ethics, according to legal and medical experts contacted by The Plain Dealer.

Last week, The Plain Dealer sought an interview with Dr. Fisher. He said through a receptionist that he would make no comment except in the presence of his lawyer.

The Plain Dealer contacted his lawyer who said Dr. Fisher would have no comment.

The Plain Dealer I-Team learned, however, that Dr. Fisher had stopped giving prescriptions to new patients, or to those who had been patients only once or twice before.

It learned also that all of Dr. Fisher's office records relating to prescriptions for Quaalude were ordered by him to be destroyed about three weeks ago.

Dr. Fisher was not the only doctor with questionable prescription practices who turned up in The Plain Dealer investigation. The I-Team also learned.

- A suburban Brooklyn doctor allows his patients to dictate what drug they want. He hands over a prescription and then pockets his fee.
- A Rocky River physician has been dispensing amphetamines and barbiturates. Police have had this doctor under investigation for two years and have turned over facts in the case to the Cuyahoga County prosecutor.

- Three other doctors, with little attempt at physical examination, have been prescribing amphetamines and barbiturates.

[From the Cleveland Plain Dealer, Jan. 27, 1974]

No Stranger in Court, Dr. Fisher Has Been Sued Many Times

Dr. Norman Fisher, whose wholesale selling of prescriptions for dangerous drugs was uncovered in a Plain Dealer I-Team investgation, is no stranger in local federal, county, and municipal courtrooms.

A short, balding man of 53, Dr. Fisher works from a suite of rooms in a fashionable Beachwood office building at 24300 Chagrin Blvd.

The doctor lives in a stylish neighborhood in Mentor with his fifth wife, Roberta, at 7474 King Memorial Rd.

Since 1955, he has been named a defendant in 59 cases in Shaker Heights Municipal Court and another 12 in Cuyahoga County Common Pleas Court. He also was a defendant in one U.S. District Court tax case and another in Lake County Common Pleas Court.

Court records in Shaker Heights show Dr. Fisher was sued most often for nonpayment of bills. A sample of the cases showed a default judgment was usually handed down and a financial settlement was made.

Dr. Fisher has been divorced five times—twice by a woman he married in Virginia.

One wife alleged in her petition that she and Dr. Fisher had been evicted from nine houses or motels in 12 months in 1965 and 1966.

Four of the divorces were granted in Cuyahoga County and the fifth in Lake County.

Court records indicate that each wife was forced to seek contempt of court actions when Dr. Fisher failed to pay alimony.

He was twice found in contempt of court and fined. Another three contempt citations were dropped following financial settlements.

In eight years beginning in 1956, Dr. Fisher was sued in Cuyahoga County by a department store for $1,855; a landscaping firm for $2,264; and an air-conditioning company for $870.

All of the cases were settled out of court.

One of Dr. Fisher's court actions grew out of a case brought by a lawyer who had represented the doctor in 1961 in a divorce action.

The lawyer, Morris B. Blane, asked the court to order Dr. Fisher to pay legal fees and expenses. Blane was awarded $5,500 and Dr. Fisher was ordered to sign a cognovit note for the debt.

In 1966, Dr. Fisher was indicted by the Cuyahoga County Grand Jury for writing a check to defraud an innkeeper. In 1967 he pleaded guilty to writing the check. The case of defrauding an innkeeper was dropped.

The doctor was ordered to make restitution within a year, and pay court costs.

Dr. Fisher was sued once for malpractice in Cuyahoga County, court records show. A Shaker Heights woman asked the court for $150,000, contending Dr. Fisher and another doctor incorrectly diagnosed a leg ailment. As a result, she alleged, she was forced to have the leg amputated. An out-of-court settlement was reached.

In February 1972, the Internal Revenue Service charged in U.S. District Court that Dr. Fisher had not filed income tax returns for $191,700 received in the years 1966 through 1969. The doctor pleaded guilty to one count and three other counts were dropped.

U.S. District Judge Robert B. Krupansky gave Dr. Fisher the maximum fine of $10,000 and placed him on probation for one year. The fine was paid in February 1973, according to federal court records.

IRS here told The Plain Dealer they could find no records indicating that Dr. Fisher and his wife filed a 1972 individual tax return.

Dr. Fisher was graduated from the Boston School of Medicine in 1947. He served his internship and residency in San Antonio, Tex. He was attached to the U.S. Army Medical Corps during the Korean War and was stationed in Alaska and Massachusetts.

He came to Cleveland in 1953 on completion of his Army service. He worked for three months as a surgical resident at St. Vincent Charity Hospital.

In December 1953, Dr. Fisher was granted a license to practice medicine in Ohio. The state accepted test results from the National Board of Medical Examiners instead of an Ohio test.

Dr. Fisher opened an office at 1831 Forest Hills Blvd. in Cleveland Heights and later moved to an office at 20475 Farnsleigh Rd. in Shaker Heights before moving his office to Beachwood.

[From the Cleveland Plain Dealer, Jan. 27, 1974]

DESTROY FILES, RECEPTIONIST QUOTES DOCTOR

All office records of the sale of Quaalude prescriptions were ordered destroyed by Dr. Norman Fisher, one of the doctor's receptionists told The Plain Dealer.

Receptionist Joan Marinelli of South Euclid said the doctor acted after learning that he was under scrutiny by The Plain Dealer's Investigative Team.

The doctor instructed her to gather all the records detailing the prescription sales in early January, she told the I-Team.

"I went through the files and took all those patients out that got Quaaludes and I set them aside," she said. "Then one day, he came in and I said, 'Doctor, these are all of the people that came in for the prescriptions.'

"And then he came up there and said, 'Throw them away like they never came in.' I said, OK, and I tossed them in the wastebasket."

She said she did not know how many cards were thrown away, but she said the stack was almost two inches thick. She also said the doctor instructed, "Throw everything out."

With the destruction of the patient information cards, all office traces of the prescription sales—including patients' names and fees charged—were destroyed, she said.

In an interview with Miss Marinelli, 19, and receptionist Sheila A. Pasquale, 19, of Lyndhurst, The Plain Dealer also learned that:

When it became clear that he was being investigated, Dr. Fisher in late December stopped taking new patients, but continued to service established customers.

About two weeks ago, following further indications that he was under scrutiny, the doctor told the receptionists no one would receive Quaalude prescriptions any more.

Between 30 and 40 persons a day came to the office for prescriptions.

Most of the prescription arrangements were handled by Miss Pasquale.

The strain of taking part in the sale of the prescriptions was often discussed by the two women and bothered Miss Marinelli, she said.

"It got really bad," Miss Marinelli said. "I was just fed up with all these people. I didn't want anything to do with it.

"In the back of my mind, I knew it was wrong. There were times I didn't want to go to work."

Neither woman said she felt the doctor was doing anything illegal, however.

Miss Pasquale started working for Dr. Fisher in April. A month later, she helped Miss Marinelli, her cousin, get a job in the office.

Miss Marinelli said she became unhappy with the prescription sales in December, after the volume became unbearable.

"At one time, it was maybe a couple of people came in and they got prescriptions. I'd say at the most 15 to 20," she said. "All of a sudden, around the middle of December, it got to the point where I just couldn't handle it all any more."

The two women also confirmed that some patients seeking Quaalude prescriptions did not see or talk to the doctor.

(From the Cleveland Plain Dealer, Jan. 28, 1974)

PHYSICIAN CHARGES $20 FOR 20-PILL DRUG DOSE—PATIENTS TELL DOCTOR WHAT TO PRESCRIBE

Youthful drug users take charge when they approach Dr. Peter E. Samame of suburban Brooklyn for prescriptions for dangerous drugs.

The Plain Dealer's Investigative Team found that Dr. Samame, 43, is a most cooperative physician who fulfills a patient's request for a particular drug prescription without hesitating.

Three times in one week, Plain Dealer reporters requested and received prescriptions for 20 dosage units of Quaalude. Each office call cost $20.

Quaalude is a trade name for the drug methaqualone, which, because of its potential for abuse, has been placed on the federal government's list of most rigidly controlled drugs. It is also known as Sopor, another trade name, and as the "love drug" by youths in the drug cult because of its reputation for freeing sexual inhibitions.

The U.S. Drug Enforcement Administration reported abuse of methaqualone resulted in 41 deaths and 1,197 poisonings in five months last year.

Based on statements to The Plain Dealer by federal and state lawyers and medical experts, Dr. Samame may be violating federal and state law as well as medical ethics.

In an interview Dr. Samame said he did not violate federal or state laws in writing the prescription, but that he may have violated the medical profession's code of ethics.

He denied writing prescriptions in large numbers and said he only prescribed the drugs to see if patients "were addicted or needed it to sleep."

"The only way to see if they're addicted is if they come back too often," he said.

Reporter Christine J. Jindra was able to obtain two prescriptions for Quaalude—amounting to 40 pills—in two visits to Dr. Samame only six days apart.

All Miss Jindra needed was $40. On her second visit, she told the doctor she needed more pills since her friends had used the first pills. The doctor only chuckled and joked that perhaps her "boyfriend" was using the pills.

In the cases of Miss Jindra and reporter George E. Condon Jr., who also obtained a prescription from Dr. Samame, the doctor failed to conduct a physical examination and failed to verify information given to him.

Dr. Samame's operation was uncovered during a seven-week investigation of physicians involved in the prescription selling business.

Of the half-dozen physicians investigated, Dr. Samame exacted the highest price for his service—$1 per pill prescribed.

When Condon went to his offices on Jan. 3, and when Miss Jindra obtained prescriptions there on Jan. 4 and 10, neither was challenged.

They were asked only the most perfunctory questions, and were submitted to no more thorough physical examination than being weighed by a receptionist. Neither was with the doctor more than five minutes.

Each instructed the doctor what to prescribe for them, and he obliged.

To Condon, the doctor said:

"I don't know what you need. Let me know and I'll see if I can give it to you."

After Condon described his "problem"—an inability to sleep—Dr. Samame, pen poised over a prescription blank, said, "Well, what do you want?"

Condon replied, "I'm not a doctor, but I was hoping I could get a prescription for something that would help me sleep, like Quaalude."

The doctor immediately wrote the prescription, asked for $20, then pocketed the money.

In the case of Miss Jindra, Dr. Samame asked, "What do you want?"

"My friends say Quaalude is good," she replied.

The doctor gave her a prescription for the drug and added a warning that narcotics agents were watching Quaalude closely. He then pocketed his $20 fee.

When Miss Jindra returned six days later with another request for Quaalude, the doctor appeared amused. He gave no physical examination.

"What are you here for?" he asked.

"I need another prescription. Somebody took my pills. They worked fine, but I need more," she said.

After some small talk about Miss Jindra's alleged occupation (waitress), Dr. Samame said laughingly that Miss Jindra's "boyfriend" might be using the Quaalude.

The doctor then questioned her to see if she had had any difficulties in having her prescription filled. "They keep records," he warned.

The Plain Dealer learned later why Dr. Samame was concerned about having the prescriptions filled.

The volume of Dr. Samame's prescription business has recently become so noticeable that three drugstores within a quarter mile of his office at 6779 Memphis Ave. now refuse to fill his prescriptions for dangerous drugs if written for young persons.

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Druggists reportedly have brought the matter to the attention of local and federal authorities.

Dr. Samame told The Plain Dealer he had stopped prescribing dangerous drugs several weeks ago, but when told by reporters that they knew of a prescription wrtten last Thursday, the doctor said he had just decided to stop.

He said he has only prescribed dangerous drugs for the past two months and had made only $100 to $250 by writing the drug prescriptions.

Dr. Samame denied that he had written prescriptions without giving physical examinations. "I always take blood pressure," he said

During the three visits made by reporters, Dr. Samame did not take blood pressure. He also admitted he had not obtained a medical history, taken pulse, or checked the patient's heart in many cases before writing a prescription.

Dr. Samame said he was prescribing some drugs to determine if patients were addicted to them. He said the only way to determine addiction is to see how often a patient returns for a drug.

He said he was prescribing the drugs on a "trial basis" and agreed his experiment had not worked out.

Dr. Samame said he often charged $20 for a prescription of 20 pills to discourage patients from returning.

He said he could not explain why he had not flatly rejected demands for some drugs.

Dr. Samame is married and lives at 9168 Stoney Creek Lane in Parma Heights. A native of Peru and a graduate of San Marcos University in Lima, Dr. Samame has been a U.S. citizen since May 17, 1968.

He has been licensed to practice medicine in Ohio since June 17, 1968. He came here from Pennsylvania.

[From the Cleveland Plain Dealer, Jan. 28, 1974]

VAGUE LAWS DO LITTLE TO CONTROL PHYSICIANS' PRESCRIBING OF DRUGS

Federal and state laws do little to control physicians and the methods they use to prescribe dangerous drugs.

A Plain Dealer investigation has uncovered evidence that three Greater Cleveland doctors have been openly selling prescriptions for dangerous drugs, or the actual drugs.

Another three doctors were providing pills or prescriptions with little attempt to examine their patients, The Plain Dealer Investigation Team found.

In Ohio, the State Medical Board, a group of seven physicians, polices doctors throughout the state.

The board has the power to revoke a physician's licence for "gross immorality, grossly unprofessional or dishonest conduct."

But nowhere in the law is it spelled out what a physician can or should not do before prescribing dangerous drugs.

"I wish we had something better, but we don't," said Edward M. Valentine, chief enforcement officer for the board.

David H. Beaver, an Ohio assistant attorney general and lawyer for the board, said a doctor could be prosecuted under the nebulous phrase "gross immorality."

Ohio courts have established that gross immorality is moral turpitude or an act "that would offend a reasonable man," he said.

Unlike the drug pusher or user—or the burglar—who faces specific penalties for specific acts, the physician faces no punishment under state law other than loss of his license.

Federal laws are nearly as weak.

"The medical lobby is a powerful group that will fight any attempt to limit how a doctor is to act in a specific situation," said Harold D. Murry, a lawyer with the U.S. Justice Department's Drug Enforcement Administration.

The U.S. Controlled Substances Act of 1970 supervises manufacture and distribution of drugs, but fails miserably in controlling doctors, Murry said.

Federal law sets quotas for the maufacture of some drugs and requires manufacturers to account for each dosage unit. Pharmacists, too, are required to keep records of the sale of dangerous drugs, but doctors are not required to keep records at all.

In order for a doctor to be prosecuted, federal lawyers are forced to combine two laws: the Controlled Substances Act and a law that makes it a crime to aid or abet someone in committing a crime.

Early this month a Youngstown osteopath was convicted in U.S. District Court here of one count of distributing or causing to be distributed Dilaudid, a potent synthetic narcotic. The osteopath had been writing prescriptions without giving a proper physical examination.

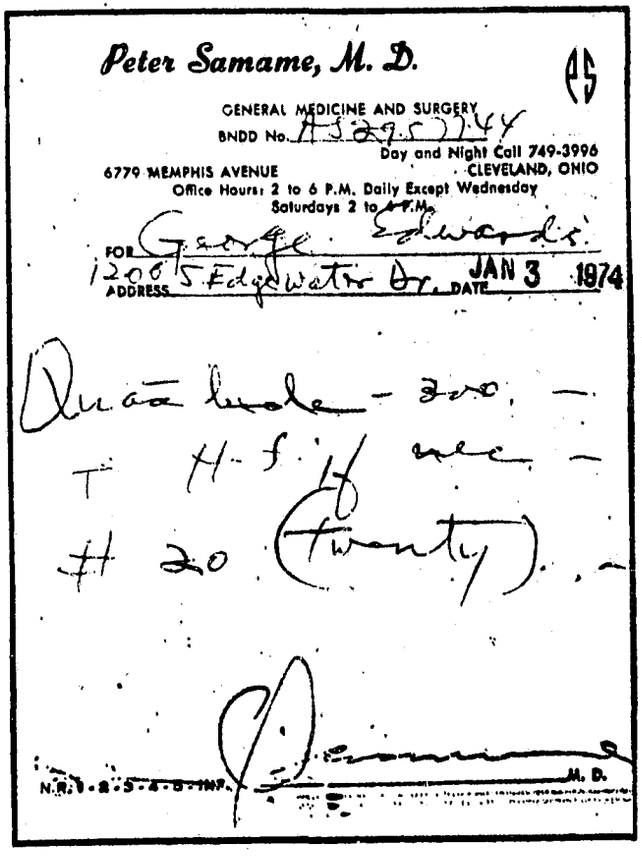
"By writing a prescription, a doctor sets in motion a chain of events that results in the pharmacist actually distributing the drug," said Asst. U.S. Atty. Clarence B. Taylor, who prosecuted the Youngstown osteopath.

In essence, the doctor was being charged with pushing drugs, Taylor said.

A key element in federal and state laws is the extent of a physical examination administered by a doctor prior to writing a prescription. If a doctor gives a physical examination and determines a drug is needed by a patient, he is acting within the law.

However, the law does not define what a physical examination includes. Under state law, the medical board determines if a doctor has given a proper physical examination.

Under federal law, expert witnesses are called into court to determine if a doctor has given a proper physical.


Peter Samame, M. D.

GENERAL MEDICINE AND SURGERY
BNDD No. AS29577-44
Day and Night Call 749-3996
6779 MEMPHIS AVENUE CLEVELAND, OHIO
Office Hours: 2 to 6 P.M. Daily Except Wednesday
Saturdays 2 to 4 P.M.

FOR George Edwards
ADDRESS 12005 Edgewater Dr. DATE JAN 3 1974

Quaalude - 300. -
T H-f if nec -
20 (twenty). -

N.R. 1-2-3-4-5-INF. M. D.

Dr. Peter E. Samame gave this prescription for Quaalude, a brand name for methaqualone, to a Plain Dealer reporter using the name George Edwards. Dr. Samame charged $20 for prescription

"WE HAVE ETHICS," SAY PHARMACISTS REFUSING SAMAME DRUG ORDERS

Citing moral and ethical reasons, pharmacists at three drugstores said they have stopped filling prescriptions for dangerous drugs written by Dr. Peter E. Samame.

The pharmacists' concern over the volume and type of prescriptions presented by Dr. Samame's patients led each one to alert local or federal authorities.

Among the drugs they were being asked to sell were: Biphetamine 20, an amphetamine compound; Tuinal, a hypnotic-sedative; Seconal, a potent barbiturate; and Quaalude, a hypnotic-sedative.

Joseph (Jay) Rezabec, a pharmacist and assistant manager at Revco Discount Drug Center, 5302 Memphis Ave. SW, said his store turns away $130 in business daily by not filling Dr. Samame's prescriptions for young people.

"There's nothing in the law that says we can't fill the prescriptions . . . but, you know, we are professionals and we have ethics," he said. "What he is doing isn't professional."

Rezabec said most of the prescriptions were for Biphetamine 20, known to drug users as "black beauties." He said the store turns away about 10 customers daily.

Two other pharmacists discussed Dr. Samame with The Plain Dealer Investigative Team but asked that their names and the names of their stores be withheld.

One druggist said he had not filled a Dr. Samame prescription for anyone younger than 35 in almost a month.

"They are legal prescriptions but morally I can't fill them because I know whose they are," he said. The pharmacist said the problem began two to three months ago.

One day he turned away about a dozen of Dr. Samame's young patients, he said. But on other days none have appeared.

The third pharmacist said he turns away about 10 customers a week whose prescriptions were written by Dr. Samame. Most of the drugs called for are Tuinal and Seconal, he said.

"I just tell them we don't carry it," this druggist said. He will sometimes call nearby druggists to warn them after he has turned away a patient who has a prescription from Dr. Samame, he added.

[From the Cleveland Plain Dealer, Jan. 28, 1974]

ACADEMY VOWS PHYSICIAN PROBE

A spokesman for the Academy of Medicine of Cleveland said the organization will investigate questions about the unethical conduct of physicians.

Dr. Theodore J. Castele, president-elect of the academy, said, "If information is available to us involving a doctor we will investigate."

He said the academy could exonerate a doctor, chastise him, suspend him or expel him from membership. The academy also could forward its findings to the State Medical Board which has the power to suspend a physician's license to practice medicine, he said.

The Plain Dealer reviewed facts concerning the conduct of several doctors with academy representatives prior to publication of its current Investigative Team report on sale by certain doctors of prescriptions for dangerous drugs.

Dr. Castele acted as spokesman for the academy in the absence of the organization's president, Dr. James R. O'Malley, who was in Chicago attending a convention.

The academy is affiliated with the American Medical Association and has 2,400 active members.

[From the Cleveland Plain Dealer, Jan. 29, 1974]

FLIMSY STORIES GET PILLS—ROCKY RIVER DOCTOR IS READY DRUG SOURCE

Dr. Leslie S. Dean, fondly called "Dr. LSD" by his young patients, has been a major supplier of drugs in Rocky River and other western suburbs for at least two years.

Dr. Dean has been investigated by agents of the Westshore Enforcement Bureau (WEB) since December 1971. On 10 occasions undercover agents purchased

dangerous drugs from Dr. Dean at his office, 1782 Wooster Rd. In only one case did the doctor perform a physical examination, WEB agents report.

Two Plain Dealer reporters, posing as patients, also were able to obtain drugs from the doctor without getting a physical examination or giving him their medical history.

They purchased amphetamines and barbiturates by giving Dr. Dean flimsy stories about needing to stay awake or having difficulty sleeping.

Dr. Dean is the third physician found by Plain Dealer Investigative Team reporters to be prescribing drugs in possible violation of state and federal laws and medical ethics.

The others were Dr. Norman Fisher with offices in Beachwood and Dr. Peter E. Samame with offices in Brooklyn. Dr. Fisher sold prescriptions for Quaalude for $15 and Dr. Samame sold prescriptions for the same drug for $20. Quaalude is considered a dangerous drug by the federal government because of its potential for abuse.

One WEB official said Dr. Dean "is causing us considerable grief and is widely known. He is the most available source of legitimate drugs in the county."

Dr. Dean denied any wrongdoing when interviewed by The Plain Dealer I-Team. He said he had violated no law and was merely practicing medicine.

The doctor said he took blood pressure and a patient's medical history before dispensing medication.

He said he has been dispensing pills since 1931 because it saves his patients money.

"When I started out in 1931, in the Depression, there were a great many people paying a lot for medicine," he said. "I could give them their medication cheaper than anyone else."

On Jan. 2 and Jan. 3 Plain Dealer reporters George E. Condon Jr. and Christine J. Jindra visited Dr. Dean's office and obtained phenobarbital, codeine, amphetamine capsules and a cold capsule.

Condon told Dr. Dean he was having trouble sleeping. "I was hoping you could help," Condon said.

"I can help you," Dr. Dean said and later asked: "You aren't taking anything else to get to sleep, are you?"

"No," Condon said.

"You aren't taking anything to stay awake, like dope, are you?" he then asked.

Condon answered "no" again and explained he was having trouble sleeping after his job as a tavern waiter.

"I work nights and, you know, you get all keyed up," he said.

Without giving a physical examination Dr. Dean gave Condon a small envelope of 50 pills. Neither the envelope nor the pills identified the medication. An analysis by the Analytical Laboratories of Ohio, 15322 St. Clair Ave. NE, showed that the pills were phenobarbital, a sedative.

Condon was in the doctor's office 17 minutes. Dr. Dean charged him $3.

Miss Jindra told Dr. Dean she was tired, had a cold and needed something to keep her awake. She explained she had a job working until 3 or 4 in the morning.

After getting her name and address, Dr. Dean went into a back room and returned with three small packets of pills. Again he gave no examination and the packets did not name the pills.

Analytical Laboratories said the pills were a Schedule II drug, one of the amphetamines, a cold capsule and codeine. Miss Jindra paid $7 for them.

Schedule II drugs are rigidly controlled by the federal government because of their potential for abuse.

Dr. Dean's method of operation appears to be in violation of the Ohio Medical Board's rules for doctors. A spokesman said the board requires a physician to give a physical examination before prescribing or providing medication.

WEB turned its cases against Dr. Dean over to the county prosecutor's office more than six months ago.

Prosecutor John T. Corrigan said his office is studying the WEB cases. "If the evidence is there, we'll take it to the grand jury," he said.

WEB agents first visited Dr. Dean's office Dec. 18, 1971. A 27-year-old agent told the doctor he was planning to drive a truck cross-country and needed pills to keep him awake and to help him sleep, WEB reports said.

For $7 the agent received 60 pills in two small brown envelopes.

An analysis of the pills by the Ohio Bureau of Criminal Investigation (BCI) showed that they were Biphetamine 20, an amphetamine compound, and Tuinal, a hypnotic-sedative. Both drugs are Schedule II drugs.

The same WEB agent returned Jan. 10, 1972, and asked Dr. Dean for "black beauties," the street name for Biphetamine 20.

According to WEB's report, Dr. Dean at first refused to give the agent the pills—saying he was being watched by police. However, Dr. Dean relented and gave the agent the pills. He charged $7.

A BCI analysis shows that Dr. Dean again gave the agent Biphetamine 20. According to the WEB report, Dr. Dean warned the agent to be careful and not to get caught or sell any of the pills.

WEB agents continued making purchases from Dr. Dean until Jan. 9, 1973. In at least one instance, police said, a drug agent was able to purchase pills from a woman who had obtained them from Dr. Dean. The woman charged 50 cents a pill.

West Side suburban police showed a great deal of sympathy for the 74-year-old doctor. They said he should retire, but at the same time they complain about his distribution of drugs.

"He is a big-hearted kind of guy," said one policeman. "He's one of the few doctors to make night calls on the sick and is available to declare a person dead when no other doctor will."

WEB's investigation of Dr. Dean is not the first time police have checked into his activities. Rocky River police say they requested in 1971 that Dr. Dean close a methadone treatment center he was operating because it was attracting too many undersirable persons. Dr. Dean complied, they said. Methadone is used to treat heroin addicts.

Dr. Dean denied he had been asked to close the clinic, and said he did so voluntarily.

Today on the door leading from the doctor's reception room to his inner office are two signs. One says: "No amphetamines or sleeping capsules will be dispensed any more."

The other reads: "No welfare patients will be accepted any more. It's impossible to collect from the state and county."

Dr. Dean said he was prescribing drugs for legitimate uses only and had no way of knowing if the drugs were later misused.

"The hippies are not using the pills correctly," he said. "But you can't tell the hippies from anyone else."

"When a patient asked me for something specific, then I know he's been somewhere else before, and I don't give it to him," Dean said.

He insisted he always took blood pressure and got a patient's medical history prior to dispensing drugs. However, in 9 of the 10 WEB visits to his office and in the two Plain Dealer visits, he made no attempt to give physical examinations.

Dr. Dean said he keeps all his records in a book and can tell which patients visited him 40 years ago, but when given a specific name and date he could only confirm the patient had been at the office. He could not say which drug had been given to that patient.

He added he had posted a sign on his office door saying he no longer dispensed amphetamines or sleeping pills in order to discourage those who might abuse the medication.

Dr. Dean said he hasn't retired because "I have responsibilities. When people are depending on you, you can't be just running off."

"I'm available," he added. "A lot of these other boys aren't. Sometimes I see 50 patients a day."

Dr. Dean, whose son also is a physician, has been practicing medicine in Ohio since 1929. He was graduated that year from Western Reserve University.

[From the Cleveland Plain Dealer, Jan. 29, 1974]

U.S. Probes Dr. Fisher on Prescription Sales

Federal agents are investigating the operations of Dr. Norman Fisher of Beachwood, whose wholesale selling prescriptions for dangerous drugs was revealed Sunday in a report by The Plain Dealer Investigative Team.

The U.S. Drug Enforcement Administration (DEA) here has been collecting evidence against Dr. Fisher following complaints by pharmacists and several police departments.

That evidence may be presented to a federal grand jury, the I-Team learned.

Donald T. Howard, special agent in charge of DEA here, said he would not deny that his agency is investigating Dr. Fisher. He also said, "We are definitely not ruling out" a grand jury investigation of Dr. Fisher and other physicians named in The Plain Dealer investigation.

South Euclid police have also been investigating Dr. Fisher's operations.

Results of that investigation were to be given today to County Prosecutor John E. Corrigan, said South Euclid Police Capt. Harold W. Kopf.

The Special Investigation Bureau of Cleveland Heights has also been investigating the activities of Dr. Fisher.

Lt. Ronald A. Salcer, head of the unit, said the investigation began in December after a former Heights woman died from an overdose of drugs.

Beachwood police also received complaints about Dr. Fisher. Police there turned over information to DEA, The Plain Dealer learned.

[From the Plain Dealer, Jan. 30, 1974]

MD Group Once Expelled Dr. Fisher.

(By George E. Condon, Jr.)

Dr. Norman Fisher, who is under local and federal investigation for selling prescriptions for dangerous drugs, was charged with unethical conduct in 1963 and later expelled from the Cleveland Academy of Medicine, The Plain Dealer learned.

Prescription policies of Dr. Fisher and five other physicians have been the object of a seven-week study by The Plain Dealer's Investigative Team.

Academy spokesmen said yesterday that Dr. Fisher was charged with "gross overcharging of fees" and an ethical conflict in 1963.

When he failed to appear at an ethics committee hearing on the charges, Fisher was suspended from the academy for five years, according to Robert Lang, executive secretary of the academy. The suspension did not hamper Dr. Fisher's right to practice medicine.

The suspension was reviewed after five years, Lang said, but the academy found no evidence he had ended his objectionable practices and Dr. Fisher did not apply for readmission. He was expelled from the academy in 1968.

The academy moved against Dr. Fisher only after several complaints, Lang said. He would not elaborate on the complaints.

There was not enough evidence then to let the board start legal action against the doctor, Lang said. But the information was passed to the state Medical Board which has the power to revoke a doctor's license.

The academy again notified the Medical Board about Dr. Fisher in October 1973—when it received complaints about the doctors' role in selling drug prescriptions—said Dr. James R. O'Malley, academy president.

Dr. O'Malley said the academy also received complaints about Dr. Leslie S. Dean of Rocky River, another doctor under investigation by police, federal agents and The Plain Dealer.

The complaints against Dr. Dean were recent and about the doctor's practice of dispensing dangerous drugs from his office, Dr. O'Malley said.

This information was also sent to the Medical Board, he said.

Dr. O'Malley reported no complaints against Dr. Peter E. Samame of suburban Brooklyn, the third doctor named in The PD investigation.

The academy will investigate the charges against the three doctors, Dr. O'Malley promised.

"Dr. Fisher is not a physician who is willing to come under the guidelines and ethics of the academy," Dr. O'Malley said. "Dr. Fisher is not completely out of our hands, however."

The board has asked Dr. Fisher to confer with academy officials and discuss the charges. Dr. Fisher indicated he would cooperate, Lang said.

Lang said Dr. Fisher first agreed to a meeting this week but canceled out after The Plain Dealer published the story about him. A new meeting has not been set.

Lang also said Drs. Samame and Dean will be asked within the next two weeks, probably by certified mail, to meet with tl[illegible]ademy.

Since Dr. Fisher has been expelled from the academy, Lang said, facts in his case will be sent directly to the Medical Board for action if he refuses to cooperate with the academy investigation.

(From the Cleveland Plain Dealer, Jan. 31, 1974)

MEDICAL BOARD SHOULD EXPLAIN

The Plain Dealer's series of revelations concerning easy access to dangerous drugs in Greater Cleveland puts the heat on the Ohio Medical Board.

Why has the board been so slow to act, or at least to make thorough investigations, in cases where specific doctors have been found selling prescriptions for dangerous drugs? The Plain Dealer's team of investigating reporters had no difficulty securing these drugs from three doctors, often sight unseen or without physical examination.

It has been disclosed that the Academy of Medicine of Cleveland at one time expelled Dr. Norman Fisher, now under investigation for selling prescriptions, and last fall passed along complaints to the medical board.

The board has the power to revoke a doctor's license.

It is the one organization which should be most zealous in policing the medical profession.

Indications are, however, that as far as the problems in Greater Cleveland are concerned, the board has not been attentive.

The academy tries to maintain a code of medical ethics and while it can recommend action, or give information to the board in Columbus, it cannot affect a doctor's right to practice. It is similar in this regard to bar associations which can censure unethical lawyers or deprive them of membership but which are not empowered to put them out of business.

When the police and federal agents are called in to investigate complaints of illegal or at least unethical drug distribution, the board should not be far behind. The board should explain why it appears derelict in performance of what should be a serious responsibility.

[From the Cleveland Plain Dealer, Feb. 1, 1974]

ETHICS FUNCTION NEGLECTED BY OHIO'S MEDICAL BOARD

(By George E. Condon, Jr.)

The president of the state Medical Board pledged yesterday to take personal control of the board investigation of Drs. Norman Fisher of Beachwood, Peter E. Samame of Brooklyn and Leslie S. Dean of Rocky River.

The promise by Dr. John D. Brumbaugh of Akron came as federal, local and state investigators continued to probe the activities of the three doctors whose practices of selling pills or prescriptions for dangerous drugs were revealed in a Plain Dealer Investigative Team report earlier this week.

His statement followed criticism of the board for allegedly being overcautious and too lenient in punishing medical professionals who stray from accepted ethical standards or break the law.

The board moves cautiously, "perhaps too cautiously," in acting against doctors charged with unethical or illegal conduct, Dr. James R. O'Malley, president of the Cleveland Acadamey of Medicine, said this week.

Dr. O'Malley urged the board to be more strict in its penalties for errant doctors.

Dr. Brumbaugh acknowledged that some criticism of the board is valid, but said most persons overestimate how much power the board wields.

The state board was set up in 1896 to police Ohio's medical professionals. It meets infrequently. Last year, it held formal hearings on only five cases among 525 complaints filed.

In a study of the board, The Plain Dealer found:

Fewer than 1% of the complaints about medical professionals ever reach the board for final action.

The board relies on only four investigators to gather evidence.

Any board penalties can be appealed to courts, where they are often overturned.

A doctor whose license has been suspended or revoked can remain in practice while his appeal is pending.

The board problems surfaced after it was learned that board investigators were notified 11 years ago about Dr. Fisher. The doctor was suspended then from the Cleveland Academy of Medicine, charged with an ethical conflict and with exacting grossly excessive fees.

The board was notified again in 1966 when Dr. Fisher was charged with passing a bad check, and again in 1968 when he was expelled from the academy. Since that time, numerous other complaints about the doctor have been filed with the board. The board has taken no action against Fisher.

In its investigation, The Plain Dealer's I-Team found that Dr. Fisher was selling prescriptions for methaqualone, often without seeing or talking to his customers.

Methaqualone is a tightly regulated, potent, hypnotic-sedative.

Lee B. Wilson of Akron, northeast Ohio's investigator for the state board, said he has been aware of complaints agianst Dr. Fisher since the late 1960s.

He added, however, that he has not had time to investigate. Wilson must handle all complaints and investigations in 18 counties in northeast Ohio. He is paid $10,254 a year.

He is one of four investigators who cover Ohio and who handled the 525 complaints received by the board in 1973. Of those 525 complaints against medical doctors, osteopaths, masseurs, therapists and others, only five cases ever made it to formal hearings before the board.

On the board are eight men appointed by the governor and approved by the Ohio Senate. Seven are medical doctors serving seven-year terms. One is an osteopath, serving a four-year term.

The doctors spent 16 days in formal hearings in 1973, hearing five new cases, deciding two cases pending since 1972, and holding the four meetings required each year by Ohio law.

In a case closely paralleling the Cleveland cases, the board heard evidence against an elderly Springfield doctor who was accused of prescribing Darvon and Seconal to customers without giving physical examinations. The doctor's penalty was a 30-day license suspension.

Dr. Brumbaugh admitted most laymen would consider a 30-day suspension a mere slap on the wrist. He insisted, however, that the board is handcuffed in its efforts to punish errant medical professionals despite the board's power to revoke licenses to practice.

"We just don't have all that power that people think we have," Dr. Brumbaugh said. "There's one reason that you try to give a reasonably not-too-severe penalty. We hope this way that the penalty won't be appealed."

Board members are paid $7.26 an hour when they work on board business. Last year, the eight members received a total of $10,600.80. Dr. Brumbaugh was paid $1,065.60.

Dr. Brumbaugh expressed concern at the board's investigative setup and said he will try to raise salaries for investigators. He announced he is ready to hire a fifth board investigator, to be assigned to the Cleveland area. "This whole area is just too much for one man," he said, "even one as good as Lee Wilson."

The board encountered difficulty hiring a good investigator because of the $10,000 salary, a staff member said. Brumbaugh said he has found a veteran Akron detective who will soon retire and join the board.

The doctor said he also plans to streamline the board's reaction to complaints about medical professionals. When informed that the board received 525 complaints last year, he said he was surprised.

"I had no idea we had that many complaints until you told me," he told The Plain Dealer.

In addition to the few formal hearings, the board last year met informally with 17 medical doctors, four osteopaths, three mechanotherapists, two masseurs, two cosmetic therapists and one podiatrist.

Brumbaugh called investigations the most important aspect of the board's work. But of the board's $454,634 budget for the current fiscal year, only a small percentage went to investigation.

The board spent $65,000 on a medical test last June and spends more than $139,000 on salaries for a Columbus office staff of an administrator, enforcement chief, administrative assistant, and 12 secretaries and clerks.

Most of the board's budget goes for testing.

[From the Cleveland Plain Dealer, Feb. 2, 1974]

Dr. Fisher Probed on Overbilling Agencies

(By George E. Condon, Jr.)

Dr. Norman Fisher of Beachwood apparently received overpayments totaling several thousand dollars in the last two years from the Ohio Bureau of Workmen's Compensation and the Cuyahoga County Welfare Department, officials of the two agencies said yesterday.

Anthony R. Stringer, administrator of the workmen's compensation bureau, said a preliminary investigation by his office indicates that Dr. Fisher apparently billed the state for medical work on patients who had stopped seeing the doctor.

Cuyahoga County Auditor George V. Voinovich also alleged that Dr. Fisher used double and triple billings to get a $113 overpayment for welfare cases he treated in 1972.

Dr. Fisher is already under federal, state and local investigation for selling prescriptions for dangerous drugs from his offices at 24300 Chagrin Blvd.

His prescription sales to people that he neither saw nor talked to were uncovered by The Plain Dealer's Investigative Team.

According to a source in the workmen's compensation bureau, Dr. Fisher treated patients who were covered by workmen's compensation and billed the state for the legitimate visits. After the patient recovered and stopped seeing the doctor, however, evidence indicates that Dr. Fisher continued to bill the state for additional visits and treatments that never occurred, a bureau investigator said.

The overpayment because of these extra billings was "considerable," reaching several thousand dollars, he said.

Stringer declined to specify the amount of the overpayment or the number of cases.

"We have found seeming discrepancies here and we are turning all our information over to the attorney general's office for action," he said. "We're interested in recovering this money for the state."

County Auditor Voinovich said yesterday that he has found evidence that Dr. Fisher was overpaid $113 in 1972 because of double and sometimes triple billing in welfare cases.

Voinovich inspected three vouchers in which Dr. Fisher billed the county for 57 visits by welfare patients. The investigation revealed, however, that there were actually only 34 visits, Voinovich said.

Voinovich sent the evidence to County Prosecutor John T. Corrigan. The auditor urged Corrigan to take legal steps to recover the money and "take any other action that you deem necessary."

Corrigan said that it appears Dr. Fisher had no right to accept the overpayments even if they resulted from clerical error.

Voinovich said he doubted the duplicate billings were clerical errors. "The pattern here gives rise to our suspicions that it may not have been clerical," he said.

"I'm not accusing or anything else," Voinovich said. "I'm saying that from the vouchers and from the checks and from looking at this, it leads one to believe there may have been some impropriety here."

Dr. Fisher has referred all questions by newsmen to his lawyer, Mark I. Perchick. Perchick said, "We must study the charges some more before we make any comment."

[From the Cleveland Plain Dealer, Feb. 2, 1974]

For an Effective Medical Board

The president of the Ohio Medical Board has been candid in admitting that the board has not been tough enough in its penalties for errant physicians and that the board's investigative setup leaves something to be desired.

Coming in the wake of The Plain Dealer's revelations about activities of doctors who sell dangerous drugs or prescribe them without proper examination of patients, the cooperation of Dr. John D. Drumbaugh of Akron, board president is as welcome as his candor.

He agrees with Dr. James R. O'Malley, president of the Academy of Medicine of Cleveland, that the board sometimes moves too cautiously against doctors charged with unethical or illegal conduct.

But he cites a practical consideration; the board is reluctant to revoke licenses to practice medicine unless there is a clearcut court decision against a physician Therefore the board often arrives at slap-on-the-wrist, brief suspensions. It has found that stiffer penalties usually are appealed and often successfully.

Because a doctor whose license has been suspended or revoked can continue in practice while his appeal is ending, we suggest two steps.

The courts should give priority to hearing serious cases involving medical persons. Time is important because a doctor literally deals with life and death; an unethical doctor, allowed to continue his medical activities indefinitely, can be a community menace.

Legislators should give thought to restructuring the board, which was set up in 1896 to police Ohio's medical beat. The 78-year-old panel is geared mainly for testing. Although investigating is a vital part of the board's work, too, a relatively small part of the annual budget is spent there. The board needs new operating procedures if it is to do an all-around effective job.

Additional legislation aimed at strengthening the board's hand appears to be without much value because of the legal difficulties involved. Certainly no one should be denied the right to go to court to protect a professional business interest. And there is danger in legislating too much power. Also, to an extent, unethical and-or illegal medical practices are in a gray area. Seldom do violations of accepted medical conduct surface so blatantly as in The Plain Dealer series.

But the fact that the Ohio Medical Board in the past has neglected the ethics aspect of its responsibility must not keep it from trying to do a better job until it is bolstered by the courts and perhaps by the legislature.

[From the Cleveland Plain Dealer, Feb. 8, 1974]

Dr. Fisher Owes $175,000 in Back U.S. Income Tax

(By George E. Condon, Jr.)

Dr. Norman Fisher of Beachwood, already under investigation for selling prescriptions for dangerous drugs, owes at least $175,000 in back federal income taxes, The Plain Dealer learned yesterday.

An official in the Internal Revenue Service said Dr. Fisher may owe a quarter of a million dollars after interest and penalties are added.

The IRS is considering seizing the doctor's Mentor home and his assets and selling them if Dr. Fisher does not pay the taxes, it was learned.

Dr. Fisher was one of three doctors whose practices of selling or prescribing dangerous drugs were uncovered recently by The Plain Dealer's Investigative Team.

The IRS issued a lien Monday against Dr. Fisher to recover back taxes for 1962 and 1971. Revenue Officer T. R. Ganger notified County Auditor George V. Voinovich and officials at the Ohio Bureau of Workmen's Compensation of the lien.

Dr. Fisher is under investigation by both agencies. He is suspected of receiving overpayments totaling several thousand dollars. The IRS lien is an effort to halt future payments to Dr. Fisher, diverting them instead to the IRS.

Voinovich ordered a halt last week to all county payments to Dr. Fisher, pending investigation of reported double and triple billing for treatment of welfare patients.

The new IRS lien joins seven on file against Dr. Fisher in the county recorder's office.

Ganger said the new lien is a step toward seizing Dr. Fisher's assets in the form of money owed him by the governmental agencies.

For the lien, Ganger said he merely picked two years out of Dr. Fisher's file, "but he owes for considerably more years."

He declined to specify the total amount owed by Dr. Fisher. He also declined to indicate how close the agency is to seizing more of Dr. Fisher's assets. He said more investigation and "a matter of paperwork" remain before Dr. Fisher's property can be sold by auction or sealed bid.

A good indication, however, of Dr. Fisher's indebtedness to the government is included in the liens on file, Ganger said.

Those liens indicate that Dr. Fisher owes $8,583.36 for 1971; $95,379.15 for 1966 to 1969; $19,549.30 for 1962 and 1964; $11,441.91 for 1963; $10,282.09 for 1965; $13,577.61 for 1961; and $16,403.95 for 1970.

The total is $175,217.37. Indications were the total could reach $250,000 when interest and penalties are added.

In February 1972, IRS charged in U.S. District Court that Dr. Fisher had not filed income tax returns for $191,700 received in the years 1966 through 1969. The doctor pleaded guilty to one count and three other counts were dropped.

U.S. District Judge Robert B. Krupansky gave Dr. Fisher the maximum fine of $10,000 and placed him on probation for one year. The fine was paid in February 1973, according to court records.

IRS yesterday confirmed that Dr. Fisher paid the fine, but revealed that he still has not paid all taxes for those years. They are included in the liens already on file.

Dr. Fisher was unavailable for comment yesterday.

[From the Cleveland Plain Dealer, Feb. 16, 1974]

FOR DRUG-AVAILABILITY PROBE—PHYSICIANS GROUP LAUDS I-TEAM

(By Oscar W. Clarke, M.D., President, Ohio State Medical Association)

Personally and on behalf of the Ohio State Medical Association, we extend heartiest congratulations for your series challenging the availability of powerful and dangerous drugs in the Cleveland area . . .

Perhaps the best description of the series was given in your editorial, "It's your move now, doctor" . . . when you used the phrase, "In a carefully documented series . . ."

The Ohio State Medical Association strongly believes that the Medical Practice Act, federal and state drug abuse laws, and federal Food and Drug Administration regulations should be stringently enforced at all times. Ohio laws are adequate but they require more vigorous implementation and enforcement . . .

It may be of interest to you to know that a physician who becomes a member of the Academy of Medicine of Cleveland and, concurrently, the Ohio State Medical Association, must formally pledge his adherence to the Principles of Medical Ethics. The American Medical Association extracts the same pledge.

Not all physicians are members of these professional medical organizations. The nonmembers, therefore, cannot be disciplined by organized medicine for unethical conduct. Their acts may be determined to be unethical, but our organizations have no authority to censure, discipline or to suspend them. If I were a Cleveland resident engaging a physician's services, I would make certain that the physician is a member of the Academy of Medicine . . .

I want to compliment The Plain Dealer and its investigative team. John Depke, Amos Kermisch, Robert McAuley, Christine Jindra and George E. Condon Jr. have carried out their assignments in a manner that reflects considerable credit on themselves, The Plain Dealer and the journalism profession.

[From the Cleveland Plain Dealer, Mar. 13, 1974]

APRIL 10 HEARING SET AT DR. FISHER'S REQUEST

COLUMBUS.—The State Medical Board has scheduled a formal hearing April 10 to look into allegations of illegal and unethical conduct against Dr. Norman Fisher of Beachwood.

Dr. Fisher requested the hearing after the board wrote last month informing him it was considering revocation or suspension of his medical license. The board in its citation letter charged Dr. Fisher with "grossly immoral" and "grossly unprofessional or dishonest" acts.

The board action was sparked by Plain Dealer I-Team disclosures that Dr. Fisher was prescribing drugs to patients without prior physical examination.

The board cited Dr. Fisher Feb. 13 for distributing drugs to two Plain Dealer reporters last December without prior physicals. In addition the board cited him for prescribing drugs without a prior physical examination to a South Euclid detective last November and December.

Feb. 13 the board also cited two others doctors who had been the subjects of Plain Dealer articles on questionable distribution of drugs. They are Dr. Leslie S. Dean of Rocky River and Dr. Peter E. Samame of Brooklyn.

Dr. Dean has not replied to the charges against him outlined in the letter from the board mailed Feb. 14. Because of a clerical mistake Dr. Samame's letter from the board was misaddressed and a new letter was prepared for him yesterday.

[From the Cleveland Plain Dealer, Mar. 15, 1974]

DR. FISHER INDICTED ON U.S. DRUG LAW

(By George E. Condon, Jr., and Christine J. Jindra)

Dr. Norman Fisher of Mentor was indicted yesterday by the federal grand jury here on one count of violating federal drug law.

Dr. Fisher is charged with the unlawful distribution of a dangerous drug. Much of the evidence presented to the grand jury had been uncovered in a seven-week investigation by The Plain Dealer's Investigative Team.

Dr. Fisher is the second physician to be indicted after disclosure by the I-Team of drug activities.

Dr. Leslie S. Dean of Rocky River was indicted last month by the Cuyahoga County Grand Jury on seven counts of violating a state drug law. His case is due before Common Pleas Judge James J. McGettrick next month.

The third doctor whose drug dispensing and prescription practices were revealed by the I-Team was Dr. Peter E. Samame, with offices in Brooklyn. Dr. Samame's case is expected to go to a federal grand jury later.

The indictment of Dr. Fisher centers on his sale of a prescription for Quaalude to a Plain Dealer investigator on Dec. 21. Quaalude is a brand name for methaqualone, a potent hypnotic-sedative blamed for deaths of 41 persons and poisoning of 1,197 others in a five-month span last year.

The prescription was given to the reporter without the reporter seeing or talking to the doctor and without the reporter ever stating he wanted a prescription. The I-Team discovered Dr. Fisher's prescription sales to be so heavy that his office staff seemed to assume patients wanted Quaalude.

Dr. Fisher has offices at 24300 Chagrin Blvd., Beachwood. Asst. U.S. Atty. William D. Beyer decided against seeking indictments against Dr. Fisher's office staff members for their roles in the prescription sales, according to a source in the investigation.

Dr. Fisher's indictment sets the date of the violation at Dec. 24, the day the reporter's prescription was filled at a drugstore.

Another prescription, bought from Dr. Fisher by a reporter on Dec. 20, is expected to be used in the trial. Dr. Fisher reportedly could not be indicted for that sale because the prescription was never filled, completing the drug transaction.

If convicted, Dr. Fisher, 52, faces a possible sentence of 15 years imprisonment or a $25,000 fine, or both.

Since 1955, Dr. Fisher has been named a defendant in 59 cases in Shaker Heights Municipal Court and another 12 in Cuyahoga County Common Pleas Court. He also was a defendant in one U.S. District Court tax case and another in Lake County Common Pleas Court.

Most of the cases centered on Dr. Fisher's alleged nonpayment of bills. Also included were divorce actions. He has been divorced five times—twice by one woman.

In 1966, Dr. Fisher was indicted by the Cuyahoga County Grand Jury for writing a check to defraud an innkeeper. In 1967 he pleaded guilty to writing the check.

In February 1972, the Internal Revenue Service charged in U.S. District Court that Dr. Fisher had not filed income tax returns for $191,700 for the years 1966 through 1970. He pleaded guilty to one count and three other counts were dropped. He paid a $10,000 fine in this case but did not pay the back taxes.

An IRS spokesman yesterday said there are 18 tax liens outstanding against Dr. Fisher. The liens total almost $200,000.

Dr. Fisher is also currently being investigated by the Cuyahoga County Welfare Department and the Ohio Bureau of Workmen's Compensation for allegedly receiving thousands of dollars through duplicate and irregular billing practices.

Drs. Fisher, Samame and Dean also face possible revocation or suspension of their licenses to practice medicine. The three have been cited by the state medical board for alleged "grossly immoral" and "grossly unprofessional or dishonest" acts.

Dr. Fisher is due before the board for a formal hearing April 10.

The three also are subject to possible disciplinary action by the Cleveland Academy of Medicine's ethics committee. Dr. Fisher has already been suspended and then expelled from the academy for unethical conduct in 1963 and 1968.

Dr. Fisher and his lawyer were unavailable for comment yesterday.

[From the Cleveland Plain Dealer, Apr. 12, 1974]

U.S. INDICTS DR. SAMAME ON DRUG CHARGE

(By Christine J. Jindra and George E. Condon, Jr.)

Dr. Peter E. Samame of Brooklyn was indicted by a federal grand jury in U.S. District Court yesterday on one count of violating federal drug laws.

Dr. Samame, 43, was charged with knowingly and willfully causing the unlawful distribution of 20 tablets of Quaalude, a trade name for methaqualone, a potent hypnotic-sedative.

Much of the evidence presented to the grand jury had been uncovered in a seven-week investigation by The Plain Dealer's Investigative Team of doctors believed to be prescribing dangerous drugs illegally.

Dr. Samame is the third physician to be indicted after the I-Team's disclosures of drug activities.

Last month a federal grand jury indicted Dr. Norman Fisher, whose offices are in Beachwood, on one count of unlawfully distributing Quaalude. He is free on $5,000 personal bond.

Dr. Leslie S. Dean of Rocky River was indicted in Common Pleas Court in February on seven counts of violating a state drug law. His case, assigned to Common Plea Judge James J. McGettrick, is expected to be heard this summer.

The Ohio Medical Board has cited all three physicians for possible illegal or unethical conduct in dispensing drugs without giving prior physical examinations.

A board hearing on Dr. Fisher is scheduled for June 27 in Columbus. Lawyers for Dr. Dean and Dr. Samame have requested time to prepare defenses.

Yesterday's indictment of Dr. Samame centers on his sale of a prescription for Quaalude to a Plain Dealer investigator on Jan. 3.

On that day a reporter was able to get a prescription for Quaalude after telling Dr. Samame that is what he wanted. The doctor did not give the reporter a physcial examination or take his medical history.

Two other prescriptions for Quaalude were purchased from Dr. Samame by another Plain Dealer reporter within the next six days.

Dr. Henry A. Crawford, a member of the state medical board, and an agent from the U.S. Drug Enforcement Administration were called before the grand jury. Two Plain dealer reporters were subpoenaed to testify.

Robert R. Disbro, Dr. Samame's lawyer, said yesterday that the doctor would plead not guilty to the indictment.

Disbro said he will investigate the methods by which evidence was uncovered for the case to see if court rules of evidence were followed.

He said there is a difference between prescribing and dispensing drugs. No one has charged Dr. Samame with dispensing drugs, he said.

Dr. Samame has offices at 6779 Memphis Ave., Brooklyn, and lives at 9168 Stoney Creek Lane, Parma Heights.

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