DIVERSION OF LICIT DRUGS TO ILLEGAL MARKETS

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HEARING

BEFORE THE

SELECT COMMITTEE ON NARCOTICS ABUSE AND CONTROL HOUSE OF REPRESENTATIVES

NINETY-SIXTH CONGRESS

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WEDNESDAY, OCTOBER 31, 1979

HOUSE OF REPRESENTATIVES,
SELECT COMMITTEE ON NARCOTICS ABUSE AND CONTROL,
Washington, D.C.

The Select Committee met, pursuant to notice, at 2:25 p.m., in room 2255, Rayburn House Office Building, Hon. Lester L. Wolff (chairman of the Select Committee) presiding.

Present: Representatives Tom Railsback, Stephen L. Neal, Benjamin A. Gilman, Lawrence Coughlin, and Robert Livingston.

Staff present: Patrick L. Carpentier, chief counsel; Roscoe B. Starek III, minority counsel; Daniel F. Leonard and Frederick R. Colgan, staff investigators; George R. Gilbert, staff counsel; and Michael S. Backenheimer, Elliott A. Brown and Gerald H. Dubin, professional staff members.

Mr. WOLFF. My apologies to all concerned for being late. There are so many things that are happening that it makes it difficult for me to be not in two places, but at least three places at one time.

At the moment, I am searching out my passport because I have to attend the funeral of the President of Korea tomorrow morning. I can't find my passport. That is part of my problem.

I hope you will all forgive me.

Today's hearing by the Select Committee deals with the nature and extent of legitimate psychoactive drug diversion.

Properly prescribed and taken, psychoactive drugs have a most legitimate place in the practice of medicine. When, however, these same substances are overprescribed or find their way to the streets and into the hands of dealers and abusers they extort a terrible price on society.

With the recent reduction in the number of active heroin addicts we have seen a corresponding increase in the number of persons using legitimate psychoactive drugs for nonmedical purposes. These persons represent all spheres of our society and no social or demographic group is immune.

The money to be made by the unscrupulous who traffic in these drugs is enormous. A 4 milligram dose of one kind sells on the street for $35 to $45. Another one brings $15 and a nonnarcotic drug like one of the tranquilizers commands $2 on the street. When you consider the retail prices per tablet at 7 cents to 17 cents, you can readily see the high profits on the illicit market.

These few illustrations serve to make plain the committee's concern and awareness of legitimate drug diversion. We shall, today, attempt to gain a Federal and local perspective of the problem so that we may achieve a set of findings from which rational and useful recommendations may be made.

To help us understand the many complex facets of legitimate drug diversion I am most pleased to welcome Mr. Lee I. Dogoloff, Associate Director for Drug Policy, Domestic Policy Staff, the White House. Mr. Dogoloff, if you can please proceed and tell us what the administration has in mind to reach this particular area of the problem.

Mr. RAILSBACK. Mr. Chairman, before you do, can I have unanimous consent to put in a very, very brief statement?

Mr. WOLFF. I'm sorry. Of course you can.

Mr. RAILSBACK. I think rather than make it, I would just as soon get to the witnesses. But I would like to have it follow your statement in the record.

Mr. WOLFF. Thank you, Mr. Railsback. In my haste here——

Mr. RAILSBACK. No, no. That's all right.

Mr. WOLFF [continuing]. I neglected that.

Without objection, the complete statement will be read into the record. And I might compliment the gentleman from Illinois for the outstanding work that he has done in the hearings in Chicago which were actually the precursor, if you want to call it that, of this hearing.

Mr. RAILSBACK. I may just add that Congressman Morgan F. Murphy was co-chairman along with Henry J. Hyde and Cardiss Collins. And the four of us attended those hearings.

[Mr. Railsback's opening statement follows:]

OPENING STATEMENT OF THE HONORABLE TOM RAILSBACK

Thank you, Mr. Chairman. I concur in your remarks and would like to compliment you for recognizing the importance of the matters that we will consider today and the urgency of convening this hearing to examine the enormous increase in the abuse of licit drugs.

On July 30, 1979, Morgan Murphy and I, joined by two of our distinguished colleagues from Illinois, Henry Hyde and Cardiss Collins, held one day of hearings in Chicago on the diversion of legal drugs for illegal uses. Our actions were prompted by a most revealing investigation conducted by a special task force of the Chicago Tribune which disclosed the widespread abuse of both prescription and dispensed drugs in the Chicago area.

The investigation culminated in a five-day series in the Chicago Tribune which concentrated on a number of unscrupulous physicians who dispensed controlled substances to patients after a cursory or no physical examination. We learned that the use of narcotics and amphetamines in the Chicago area was reaching epidemic proportions, and the abuse of these licit drugs was directly attributed to the prescribing practices of physicians.

As a result of the Tribune's series and our hearing in Chicago, Governor Jim Thompson signed into law a bill which was passed overwhelmingly by the General Assembly which closed some of the loopholes in the Illinois Controlled Substances Act. The new law requires physicians to fill out a prescription form in triplicate whenever a controlled substance with a high abuse potential is dispensed directly from their office. Moreover, the law prohibits the use of preprinted prescription forms for any controlled substance. Finally, the law has recognized the enormous abuse in Illinois of Preludin and has re-classified this drug into Schedule II.

Today, we will review and update the information we gleaned from the hearing in Chicago, and I know that today's hearing will enlighten us further about this serious and ever-increasing problem.

We learned in Chicago that the abuse of licit drugs now causes more deaths than the abuse of illicit drugs. In particular, there are more deaths from overdoses of licit drugs than from heroin.

Mr. Chairman, today's hearing is crucial to the efforts of this Committee to combat the abuse of drugs in our society. I am anxious to hear the thoughts and recommendations of the distinguished panel you have assembled this afternoon.

Mr. WOLFF. Mr. Dogoloff, you have taken an oath before, you will not have to be resworn before this committee. Maybe some of the others who haven't been here before will have to swear to their testimony, but you will be testifying under your prior oath. Am I correct in that?

TESTIMONY OF LEE I. DOGOLOFF, ASSOCIATE DIRECTOR FOR DRUG POLICY, DOMESTIC POLICY STAFF, THE WHITE HOUSE

Mr. DOGOLOFF. You are correct.

Mr. WOLFF. Please proceed.

Mr. DOGOLOFF. Thank you, Mr. Chairman. It is a pleasure to be here today and talk about an issue that is a serious one, as you have said. We have now reached a point where the abuse of prescription drugs has health consequences, negative health consequences, that outweigh those from illegal drugs such as heroin and cocaine.

The real problem, it seems to me, rests with the growing acceptance of drug use by all segments of our society. The concept that a pill will solve problems is just too all pervasive.

This is certainly reflected in the adolescent use of marihuana and adults' reliance upon prescription drugs. These drugs are of particular concern to us since they affect a disproportionate number of elderly and women. We must try to change these attitudes. And I think that the hearings that you have held in the past and today's hearings will certainly help in that regard.

Although law enforcement efforts can have some impact, much more must be done through medical education, patient education, peer pressure, and so forth. Over the past 2 years, our office has chaired an interagency working group of concerned Federal agencies, professional and trade associations, and some State representatives.

We have determined that there are systems which will allow us to identify possible points of diversion.

Under the Controlled Substances Act, basically, the States have responsibility for what we have found is the major source of diversion occurring at retail and practitioner levels and not at a wholesale diversion level.

In order to get at that problem very early on in the administration, we asked the Drug Enforcement Administration to do a complete review of all manufacturers of licit drugs to ascertain the potential for diversion and found that it just wasn't coming at that level. Most pharmacists and physicians do not have criminal intent when they overprescribe or dispense controlled substances.

Therefore, in the majority of instances, we believe it is inappropriate and ineffective to rely solely on law enforcement. In those States which have effective control systems, we found that the key element was communication. The use of educational activities and peer pressure combined with Federal and State regulatory activities were very effective.

Just the hearing highlighting of the issue, calling attention to it, asking practitioners to stop and think about what it is they were doing, that in itself has a major impact.

We were honored, Mr. Chairman, to have you open a meeting which we organized on September 12 which brought together the concerned Federal agencies, officials from seven States, and several professional, educational, and trade associations. The participants at that meeting agreed on the following points:

One: The health hazards of prescription drug abuse exceed that of heroin. That is also clearly borne out in the DAWN data.

Two: Inappropriate prescribing practices by some physicians and diversion from pharmacies have been the primary sources of these drugs reaching the illicit market.

Three: Only a small percentage is derived from unscrupulous or impaired physicians or from the diversion at the wholesaler and manufacturing level.

Next, no one agency, either Federal or State, could effectively deal with the problem. Common elements of successful State programs include professional education, professional peer pressure, regulatory and licensing activities, with law enforcement as a final resort.

States should consider establishing a prescription drug task force, bringing together the concerned medical and pharmacy associations, State regulatory officials, and enforcement authorities.

And lastly, information is available from the Federal information systems such as the ARCO system to help identify points of diversion.

I have submitted for the record the minutes of that meeting as well as the six specific actions that are being undertaken to follow up that meeting. In general, we will continue our research efforts on the use of prescription drugs. We will foster education of physicians and other health care professionals on the appropriate prescribing of these substances.

We will inform the State Governors of the seriousness of prescription drug diversion and urge that task forces be set up at a State level.

I have requested that the Surgeon General convene a national prescription drug conference in order to share existing State initiatives.

And finally, I have established an ad hoc group to advise the Strategy Council on Drug Abuse in this area. This administration is committed to addressing the problem of prescription drug abuse as one of our highest priorities. And we look forward to working together on this important issue.

Thank you.

Mr. WOLFF. Thank you, Mr. Dogoloff.

I am going to pass the questioning to Mr. Railsback.

Mr. RAILSBACK. Thank you, Mr. Dogoloff. And I am wondering, can you give us a little more background about the FDA's proposal to withdraw approval for the use of amphetamines in treating obesity? I was not, I guess, familiar with that.

Mr. DOGOLOFF. Some States have done that and found that it has been successful in reducing the problem with the amphetamines. I do not want to sort of overlay a personal opinion on top of what is a considered judgment and process that FDA has gone through to come up with a position.

Although it seems to me that that does make sense, that given the limited, as I understand it, medical usefulness of that drug for things, you know, outside of that, and the other options that are available, too, for obesity, to preclude that might be very useful.

Mr. RAILSBACK. Do you know, have they actually made this in the form of any kind of a formal proposal?

Mr. DOGOLOFF. I believe they have, but I am not sure. And I can find out that and supply that information for the record, or if there is someone here from FDA.

Mr. RAILSBACK. I might just mention that when we were in Chicago, many of the so-called pill-pushing clinics, actually without any kind of a meaningful physical exam, were dispensing tremendously large quantities of pills. And they were doing it under the guise of trying to cure obesity.

And so I certainly think that is a step in the right direction. I would like to know more about it if you can get me some more information about it.

Mr. DOGOLOFF. I followed with interest not only the hearing, but the series of articles in the Chicago Tribune on the issue. And I think that was very, very useful in drafing attention to the problem. Illinois was represented at our meeting on September 12, and they are doing some very fine things in that regard.

Mr. RAILSBACK. They have a new law that I think was just signed into law by the Governor.

On page 5, you mentioned that only a small percentage is derived from unscrupulous or impaired physicians. And yet, in the previous sentence, you indicate that the inappropriate prescribing by some physicians and the diversion from pharmacies have been the primary source of these drugs reaching the illicit market.

Are you saying that although the doctors aren't unscrupulous, they are not very smart, or what?

Mr. DOGOLOFF. No; I think there are a lot of things that go into how that occurs. And for the most part, physicians are responsible, acting in a responsible way. And there is not a malice in their motives in terms of their prescribing practices.

Mr. RAILSBACK. Even those that prescribe these tremendously large quantities?

Mr. DOGOLOFF. No; I feel differently about those doctors. And the problem is one or two physicians in a community can literally cause an epidemic of licit drug abuse.

We are also talking about the misuse of drugs that may be legitimately prescribed because of a lack of patient education, taking the time to help a patient understand drugs or understand drug interactions, which oftentimes happens in the case of the elderly.

Mr. RAILSBACK. Is it your belief that generally speaking, the medical societies have been cooperative? Have they been working with the Government? And are they taking what you believe to be the necessary steps to maybe remedy or rectify some of the problems that we have seen?

Mr. DOGOLOFF. I think on a national level, that is true, yes, they have been cooperating. They participate, for example, on a regular basis and attend meetings of our interagency coordinating group on licit drug problems, including the AMA and the Pharmaceutical Manufacturers Association, come to the meetings and are very responsive and very helpful.

I think on a State-by-State level, some medical societies and boards of pharmacies are more vigorous in enforcement than others. What

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we are hoping to do is by highlighting this issue, by sharing techniques, that will foster increased activity on their part. I will discuss this issue in a letter that I am going to send to each of the Governors in an attempt to highlight it. This will help to encourage those who aren't vigorous, and cause them to think about varying degrees of response.

It is very difficult, as you know, to take away a doctor's license to practice. And that is a very serious step. We want more and more to be thinking about intermediate steps for physicians as a way of getting a message across so that, for example, in some cases it may be appropriate to deny the physician the right for a while to prescribe the class II drugs and let him prescribe other drugs at the same time.

So we are not, in effect, taking that very drastic step and have a differential response and begin to think in those terms about the problem.

Mr. RAILSBACK. I would like to just add that in Chicago when we had the hearings, I really got the feeling that the doctors that testified that I thought were trying to be helpful, they really did not approve of the whole sale prescription of some of these drugs for, say obesity. And yet, I still got the feeling that they really didn't want to take the steps of necessarily outlawing them.

And yet, given their druthers, that's what they would want to do inasmuch as I don't think any of them used that kind of prescription practice.

So I guess I hope that maybe the FDA will be successful in its efforts, particularly because there really isn't in my opinion—at least I haven't seen it—much evidence that these drugs are that helpful in combatting obesity or that there are other things that are equally as good.

Mr. DOGOLOFF. I would agree.

Mr. RAILSBACK. Thank you very much.

Mr. NEAL. Thank you, Mr. Dogoloff.

I am just wondering, are you in favor of moving drugs of high abuse into higher classifications?

Mr. DOGOLOFF. Yes, I think we have to be flexible with that. And we have to use our indicator systems to help us understand which drugs have a high abuse potential and as they do, to be flexible and change that, if for no other reason, not only to increase controls, but it also gives a different signal to the physician, to the pharmacist, as to how they need to think about that drug before they prescribe it and also to the patient who treats a drug differently when there are controls on how many times you can have it renewed and so forth. So that it gives, I think, more respect for the drug as you move it up into the schedule.

Mr. NEAL. Do you have any understanding of why different age groups seem to prefer different drugs of abuse? Someone mentioned to me the other day, and I had just never thought of it before, it is very rare that young people abuse Valium, for example. Yet Valium seems to be a drug of considerable abuse among the adult population.

Mr. DOGOLOFF. I think it is more likely to be prescribed for adults. And adults probably have more knowledge of it, more awareness of it, being around. It is more available to them through legitimate prescription.

They then, unfortunately, sometimes become dependent on it. And children are not likely to have that available to them in the same way.

So I think it has to do with prescribing practices and use.

Mr. NEAL. So it is your feeling that the abuse of Valium and other such drugs begins through a legitimate process?

Mr. DOGOLOFF. For the most part, that is so. And its diversion out of that licit process is not coming at the manufacturing level. Quaaludes, I guess, is maybe the only drug where we have some real evidence it is being provided illicitly and comes into the country where we have had some major seizures of Quaaludes coming in from Colombia. But other than that, most of it is produced licitly in the country and diverted at the retail practitioner level and not at the wholesale levels.

Mr. NEAL. I am just curious. I had also heard there had been a good deal of interdiction of amphetamines manufactured abroad and coming in. Is that not true?

Mr. DOGOLOFF. Some of that, yes. But recently, it has really been Quaaludes for the most part.

Mr. NEAL. Thank you, Mr. Dogoloff.

Are there further questions?

Mr. RAILSBACK. No. That is all.

[Mr. Dogoloff's prepared statement appears on p. 67.]

Mr. NEAL. Our next witness is Mr. Bensinger, Administrator of the Drug Enforcement Administration.

Mr. Bensinger, it is good to see you again. It is always nice to welcome you to the committee.

Please feel free to put your entire statement in the record and summarize if you like, or proceed as you wish.

TESTIMONY OF PETER B. BENSINGER, ADMINISTRATOR, DRUG ENFORCEMENT ADMINISTRATION, U.S. DEPARTMENT OF JUSTICE; ACCOMPANIED BY KENNETH A. DURRIN, DIRECTOR, OFFICE OF COMPLIANCE AND REGULATORY AFFAIRS, DEA

Mr. BENSINGER. Thank you very much, Mr. Chairman.

Mr. NEAL. Would you like to put your entire statement in the record?

Mr. BENSINGER. I would, if I could. And I would like to provide a summary.

I would also like at this time to invite Kenneth Durrin who is the Director of our Office of Compliance and Regulatory Affairs to make himself available in case you would like to ask any specific questions of Mr. Durrin.

Mr. Chairman, the problem of retail diversion is serious and growing. And it is, in my opinion, a problem that generally has not been fully addressed, except perhaps for this committee which has already held a hearing in Chicago, as Congressman Railsback has pointed out, and done considerable research on the subject.

It has been covered like a lizard under a rock without the headlines of cocaine and heroin and large mother ship marihuana arrests, but it is a $1 billion business, and a business which is striking, from a health standpoint, more injuries and more overdose deaths in the population of the United States than heroin and all other drugs combined.

It is a business that is perpetrated because of the tendencies and

criminal activities, of a number of physicians and pharmacists, not a large percentage, not a large number, but individually that have a tremendous impact on literally hundreds of thousands of Americans.

The total amount of controlled substances that is prescribed and controlled is over 20 billion dosage units. The amount that is illicitly diverted would approximate 250 to 300 million of those 20 billion dosage units.

There are some 600,000 registrants that the Drug Enforcement Administration registers under the Controlled Substances Act of which 96 percent are at the retail practitioner level. Our agent workforce includes some 220 compliance investigators and 20 special agents. Our registrant to investigator ratio is 2,500 to 1.

And candidly, I think we need some significant changes in the resources that are available to combat this problem and perhaps some changes in the law, as well.

I say we need changes in the resources because, principally, the Controlled Substances Act, the congressional mandate we have as an agency is to focus on the manufacturer and wholesale distributor of these licit, legal manufactured drugs. And the State and local jurisdiction have the responsibility to police, to investigate, prepare for prosecution, and to prosecute the physicians and doctors at the local level.

Candidly, the resources at that level are not adequate to meet this challenge. I think they need to be beefed up at the State and local level. I think our resources which have been used generally to provide seed and initial funding assistance to the States through the investigating units, the DIU's, should be expanded.

I feel, in addition, we should consider changing the law in a number of areas:

One, for example, in the amphetamine and barbiturate area, we find penalties are 5 years for Quaaludes, amphetamines, and barbiturates because they are nonnarcotic. And I would suggest that this committee and its membership may want to consider whether section 401 of the Controlled Substances Act ought to be amended to provide that illegal sale and distribution of nonnarcotics as well as narcotic drugs receive the same penalty.

The power that the Drug Enforcement Administration has over registrants is also limited in that we can only remove registration if a registrant falsifies an application or is convicted of a drug-related felony. In some States, the violation of the Controlled Substances Act in their States is a misdemeanor offense. And there are and have been indicated reluctances of State medical societies and registering boards to remove entirely the doctor's right to practice.

Once that is removed, then we have the right to rescind the doctor's right to store narcotics. It seems to me an examination of the present procedure is in order.

In addition. Mr. Chairman, we have seen instances—this is a sample of a doctor's clinic in California——

[Holding up a picture.]

Now, the photograph shows drug abusers and dealers lined up before the doctor's office opened in the morning. What the photo doesn't show is that the line extended completely around the block and then

around another block. Our undercover agent reported at 8 a.m., an hour before the office opened, there were 20 people already in line. The physician had to hire a special security guard to keep the line orderly.

This particular doctor was arrested and charged with 35 counts of drug related offenses. The type of drugs this doctor was distributing included Quaaludes, Dilaudid, Preludin, Ritalin.

We have recommended that the Food and Drug Administration remove the indicator for obesity for amphetamines and for Preludin. This is a major drug substance that has been widely diverted. It has been a subject in Washington of major examinations.

We feel if FDA concurs with our recommendation, that the total production of amphetamines that would be legally authorized under the Controlled Substances Act would be cut by 80 percent.

We feel, in addition, that there is a strong need at the local level for stronger support in prosecution and in sentencing.

And I might add, there have even been some Federal cases where we have seen individuals given 5- to 10-year sentences with sentences suspended. An individual in New Hampshire, in particular, was responsible for 60 percent, I believe—Ken, you correct me—of the amphetamines that were available in that State in the entire year, 2 percent of the national production at one point in time, who received a suspended sentence upon conviction.

We feel generally the level of awareness in the minds of the public is not sufficient to really address the problem.

On the left is a cost and street price chart showing amphetamines, Dilaudid, methaqualone, Preludin, Talwin, and Tuinal. If you looked at the value of the retail cost, the amphetamine for 17 cents is sold on the street for $12. Dilaudid at 17 cents is up to $56. Preludin, selling for slightly less than 25 cents, has been sold for as high as $15.

[See exhibit A on p. 44.]

The total value of these drugs alone is close to $1 billion in the diversion field. And that is only six out of the total legitimate controlled substances that numbers in the tens of thousands—in fact 20,000.

This market is so large, Mr. Chairman, that we are presently reviewing a CENTAC operation for one of the major organized criminal activities specializing in retail diversion.

We have seen individuals recruited who are overweight to go around to doctors' clinics and just to buy pills. And then go into a van and day after day buy pills and then go out on the street and sell them for 20 or 30 times the amount they paid for them.

Mr. WOLFF. Almost as good as oil today.

Mr. BENSINGER. It could well be. It has certainly reached a percentage of the population that has not been subject to some of the embargoes that the petroleum industry in the past has.

I think we need, obviously, more information to the public about the dangers of diversion. I think your hearing, Mr. Chairman, is excellent to call to the Congress and to the American people the problems about licit diversion.

I think that you will find our agency feels frustrated in the sense that we don't have a mandate at the retail level that we feel is adequate to impact on the problem, either legally or in terms of resources. And

we see at the State and local level a lack of resources as well. There is a clear gap. There is a clear need.

We are at your disposal to answer any questions that you may have on this very serious and important problem.

Mr. WOLFF. Thank you, Mr. Bensinger. As always, your testimony is one that is not only provocative, but it gives us a good overall picture of the existing situation.

One of the elements that we have found in our investigations of the Veterans Administration for example, is a redundancy of prescriptions. We found that some veterans getting prescription drugs from the VA hospital were then going out and obtaining a number of additional prescriptions from other doctors to treat a specific illness. Then especially in Pureto Rico, these prescription drugs would be diverted into the illicit market.

Second, we found people who had a specific health problem using this health problem as a device to pick up whatever amount they sought by going from doctor to doctor. The cost of the visit to the doctor—and this might be a very legitimate doctor—is regarded as a cost of doing business. With those profits in mind, you know, a pile of pills is almost better than food stamps. They can go in and "cash" these pills almost anyplace they want to.

What are your thoughts on the idea of some sort of a central registry where the prescriptions would have to be filled on a centralized basis so there would not be this redundancy? Do you think this would——

Mr. BENSINGER. I think that is an excellent idea, Mr. Chairman. I think a central registry, not only of the practitioners, but conceivably of the prescription itself. And I would ask Ken Durrin—I think it is in five States, Ken, where this exists.

Mr. DURRIN. That's correct. California, Idaho, Illinois, New York, and Rhode Island, all have some kind of triplicate or duplicate prescription system. I have talked with officials from all of those States, and they have found that these have been useful in terms of tracking promiscuous script-writing doctors, as well as tracking patients who are doctor shoppers that go from one doctor to another as you describe.

One of the problems that New York State has been faced with in particular, California as well, is the tremendous volume of prescriptions and digesting and regurgitating leads from this kind of system. The State of Idaho doesn't have that kind of a problem. They can pretty neatly keep track. They have a machine card system.

Mr. WOLFF. Is it only the practitioner that has to report, or do the pharmacists also have to report on an individual prescription basis?

Mr. DURRIN. The pharmacists are the ones that report under the normal triplicate script system. The practitioner fills out the prescription for the patient in triplicate. Two copies go to the patient and the physician keeps one. The prescription the patient received is then cashed in a pharmacy where one copy is maintained as a record in the pharmacy and one copy goes to the government.

Mr. WOLFF. I don't think that California has a very good record of this because we have found most of the diversion in that area. So that doesn't speak very well for that system.

Mr. DURRIN. This is true. And as I say, one of the problems is with a mass of paper involved here, using the system effectively to seek

out and learn who are shopping from doctor to doctor. And of course, these people are very clever and use different names and the like. It is very difficult to track some of them down.

Mr. WOLFF. Can it be tied into a social security card, something like that? We have registrations for everything today.

Mr. DURRIN. There are a lot of third-party payment systems that do use social security numbers on insurance-paid prescriptions around the country.

Mr. WOLFF. On this score, something that was highlighted in the media recently was Elvis Presley's death and the redundancy of prescriptions he had. Is DEA looking into this situation at all?

Mr. DURRIN. That is being handled at the State level. Basically, the kind of problem here is a State monitoring problem. DEA primarily concerns itself with the wholesale type of distribution. And we get into the retail level on a——

Mr. WOLFF. Don't you get into the practitioner level?

Mr. BENSINGER. We can and do on a selected basis. I think the two problems that are characterized by Elvis Presley's death and the drug use that is attributed and talked about and referred to in news articles related to it, one, is the doctor-patient relationship. And here is one of the reasons——

Mr. WOLFF. I don't think that should be disturbed. I think that is more important to protect.

Mr. BENSINGER. That is important, and that is one of the issues where sometimes doctors who may be making available just tremendously large numbers of drug capsules to patients say that is their best medical judgment.

On the other hand, I understand physicians and professionals looking at the total dosage numbers that have been ordered for any one person say clearly this is excessive. And what you have in a prosecutorial situation, and we have seen this many times, and we have taken some individual practitioners to court, is the argument we are the doctor.

We don't want to propose that we act in that role, but the doctor would say, "That is my judgment that that person needed those pills."

Sometimes that happens without an examination. Sometimes, that happens though the doctor may not even know who that patient may be. The situation is, in fact, characterized to the extent that we have started a crackdown, Mr. Chairman, in 22 States, of 109 major practitioners, doctors, and pharmacists.

Mr. WOLFF. May I interrupt you for just a moment, Mr. Bensinger?

Mr. BENSINGER. Sure.

Mr. WOLFF. As I understand it, there was a medical doctor who was convicted here. Was it in the District or was it in Maryland?

Mr. CARPENTIER. In the District.

Mr. WOLFF. In the District. He was convicted in this District, and his license was revoked. He moved into New York and is still practicing medicine.

Now, don't you have any control over a situation such as that?

Mr. DURRIN. Mr. Chairman, we are very familiar with that case. As a matter of fact, jointly with the Metropolitan Police Department here, we made the criminal case on that doctor here in the District of Columbia where he did lose his license.

Mr. WOLFF. When was that?

Mr. DURRIN. If my memory serves me correctly, I believe it was approximately 1975.

Mr. WOLFF. 1975? This is the end of 1979, and this fellow is still practicing in New York.

Mr. DURRIN. That doctor lost his DEA registration which he does not have today, I might add. And he lost his license here in the District of Columbia.

Now, we have a problem with regard to this particular case because an application for registration with DEA is a currently pending matter before DEA. And Mr. Bensinger will be the deciding officer under the Administrative Procedures Act. And he is not in a position to speak to this particular case at this time because he will be the adjudicating officer.

Mr. WOLFF. Let me go a step further. Some of these things that are nonnarcotics are controlled substances. Can that doctor prescribe these even if he doesn't have his license for narcotic substances?

Mr. DURRIN. The doctor cannot prescribe controlled substances without a DEA registration, regardless of whether he has a license in a State. He has to have the registration for controlled substances. If he prescribes them without a DEA registration, he is in violation of the law.

Mr. WOLFF. What contact do you have with the local medical societies.

Mr. DURRIN. When we make a case and when a conviction is brought on a physician, this information is turned over to the State licensing authorities for the appropriate action. Appropriate action may or may not be forthcoming.

Mr. BENSINGER. That is the problem, Mr. Chairman. It is characterized by, in the case of our ARCOS reporting system which, out of 600,000 practitioners, maybe 1 percent of that number were engaged in unusual ordering practices.

When that is broken down to 20 large States with maybe only 6 to 8 investigators per State looking at 500 different potential leads, the investigations don't get done.

Mr. WOLFF. I think one aspect of this particular hearing and subsequent hearings we will hold on this subject is the fact that this should not be a broad-brush denunciation of the medical practitioner. I think it should be clearly understood.

Mr. BENSINGER. We concur.

Mr. WOLFF. And it is either the unscrupulous or unknowing physician who is involved in this type of procedure. I think by castigating an entire profession, we would be in grave, not only difficulty, but it would be a grave injustice to the medical profession and the pharmaceutical profession.

But I think that where we have specific cases like this, it is a gross miscarriage of justice that someone is able to practice medicine in one area after having been convicted in another.

Was a conviction obtained?

Mr. DURRIN. He was convicted. He was sentenced to 45 years and fined $100,000. That case went all the way to the Supreme Court, incidentally, where his conviction was affirmed.

Mr. WOLFF. He is not in jail, so obviously it was overturned.

Mr. DURRIN. No. It was not overturned. He received a reduction in sentence and received early parole for good behavior, and so he served his term, and he is out.

Mr. WOLFF. That is beyond me.

Mr. DURRIN. It is beyond me, Mr. Chairman, but that is the case.

Mr. WOLFF. Mr. Railsback.

Mr. RAILSBACK. May I ask what triggers the revocation procedures for their DEA registration? In other words, say you have widespread allegations about pill pushing, which we have had in the city of Chicago, as disclosed by the Chicago Tribune series.

It is necessary for there to be a conviction before the DEA takes a look at that guy's DEA registration?

Mr. DURRIN. Yes. As far as the practitioner goes, the doctor goes, or a pharmacy, that is correct, Mr. Railsback. The registrant must have been convicted of a drug felony or he must have materially falsified his application for registration with DEA, provided that he has a State license.

Mr. RAILSBACK. That is required by statute?

Mr. DURRIN. By statute. We are locked into the State license of the individual doctors.

Mr. BENSINGER. And that is something, Mr. Railsback, if I might say, that we in the Department of Justice are looking at. Because in some cases it may be the clear, flagrant misuse of the right to inventory and store controlled substances, lack of adherence to administrative records, lack of adherence to the procedures under which that person first obtained the registration that could, in fact, in the public's interest, justify nonrenewal or revocation of that license.

Mr. RAILSBACK. How often are they renewed, by the way?

Mr. BENSINGER. Annually. They are renewed annually. But the basis by which a doctor loses his license has to be a conviction, a felony conviction, or a misrepresentation in the application.

Mr. RAILSBACK. OK. Then who has the initiative once, say, a physician or pharmacist is convicted, in initiating the procedure to revoke?

Mr. DURRIN. We take the initiative on that.

Mr. RAILSBACK. You have the right to take the initiative there?

Mr. DURRIN. Yes.

Mr. RAILSBACK. Let me ask you this. I guess, Peter, I would ask you, I kind of get the feeling—and this we got in Chicago as well—that your primary enforcement activity with respect to diversion is the use of so-called diversion investigation units. Would you say that is correct?

Mr. BENSINGER. Yes; that is certainly one of the major areas of retail diversion emphasis. The principal resources of the agency are put at the wholesale and manufacturing level.

Mr. RAILSBACK. Right. Now, as I understand your testimony, there are not very many Federal personnel that can be diverted to the diversion investigation units. In other words, the DEA does not have very many personnel that can be—I don't want to use the word "divert"—assigned to that particular job.

So then the primary reliance in the diversion investigation units is with the State people as well?

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Mr. BENSINGER. That's correct.

Mr. RAILSBACK. What, if any, kind of a training program do we have for those State people, or is there any at all?

Mr. BENSINGER. Yes; there is. And Ken could describe it.

Mr. DURRIN. Yes. Of course, each of these diversion investigative units—and we have 19 of them now, 18 States and here in the District of Columbia—receive initial training from DEA.

Mr. RAILSBACK. How long is that?

Mr. DURRIN. That is a 1-week training course. And we also assign a DEA agent as a full-time working member of the unit which provides additional on-the-job training.

We also hold periodic training sessions from 3 to 5 days for State pharmacy board inspectors, medical investigators in regional locations throughout the country. Our most recent one was in the New Orleans area.

We have in the past year hold them also in Atlanta and in Albany, N.Y., for the New England area.

Mr. RAILSBACK. Is the Diversion Investigation Unit a relatively new thing?

Mr. DURRIN. That has been in existence since 1972. We started with our first three pilot States, Michigan, Alabama, and Texas. As I say, we are now up to 18 States and the District of Columbia. It has been a very effective thing.

We have, incidentally, about 200 State investigators committed to this endeavor throughout the country in addition to 20 DEA agents.

Mr. RAILSBACK. Is that a large increase? In other words, does the 200 now committed represent a relatively large increase, say, in the last year or two?

Mr. DURRIN. It has been gradually going up since the program started in 1972. But there have been, I would say, probably 60 to 70 in the last 2 years, roughly in the last 2 years.

Mr. RAILSBACK. In your opinion, based on what we know in the recent revelations, in all of the persons is there any more personnel?

Mr. DURRIN. Yes.

Mr. BENSINGER. Clearly.

Mr. RAILSBACK. Substantially more?

Mr. BENSINGER. Clearly, we think so.

Mr. RAILSBACK. Both State and Federal?

Mr. BENSINGER. Yes. We have doubled the number of personnel, both at the State and Federal level, in the last 3½ years. But that is still far from what is needed to combat this problem effectively.

Mr. RAILSBACK. Thank you.

Mr. WOLFF. Mr. Coughlin.

Mr. COUGHLIN. I have no questions at this time, Mr. Chairman.

Mr. WOLFF. Mr. Livingston.

Mr. LIVINGSTON. I have no questions, Mr. Chairman.

Mr. WOLFF. Mr. Bensinger, before you leave, may I divert for a moment. This has nothing to do with this particular hearing, but it has been said recently that a number of old moonshiners that existed up in the mountain areas, are now going into the marihuana business. Did you hear anything about that?

Mr. BENSINGER. There are certainly some people in some hills of northern California and other States, most other States.

Mr. WOLFF. How about around this area?

Mr. BENSINGER. In this area, I would not consider myself an expert on the Virginia and Maryland hill marihuana growers. Most of the traffic coming into this area generally would be imported, but there have been reports in Virginia and to the west of some selected areas of domestic marihuana growth.

I can give you a more substantive response in writing and would be happy to do so.

Mr. WOLFF. I would appreciate it if you would, because the question has been posed to us, and I would like to respond.

Mr. BENSINGER. Very good, Mr. Chairman.

The only other comment I would make would be in conclusion, if I could, to just a follow-up on this one specific retail diversion initially we have taken. And that is to select 109 targets who have clearly, we feel, demonstrated they have not only been in clear violation of the law, but represent some of the largest retail diversion networks on an organized basis in some 22 States.

We do not think those investigations which are now underway will solve this problem. We think they will, as they become a matter of public record and are prosecuted in the jurisdictions in the States in which the principal businesses are located, raise the attention not only of the public, but the size and the scope of the problem. And we hope that the State and local jurisdictions in which these operations take place will provide additional resources as Congressman Railsback's line of questioning would indicate are needed.

Mr. WOLFF. Are you working with someone now? We have the Inspector General of HEW coming here. Are you working with HEW on this type of situation?

Mr. BENSINGER. We have been in a number of bureaus, not only with NIDA and FDA, but we have had contact, I believe, Ken, with the Inspector General.

Mr. DURRIN. That is correct. On medicare, medical fraud cases we furnish them with leads from our computer file as well as with data on violative doctors from our DIU's.

Mr. WOLFF. Is there a widespread problem in medicare today?

Mr. DURRIN. I think the Inspector General could speak better to that than I could. In the terms of the overlap between controlled substance diverting registrants and medicare-medicaid, we have not seen to date a large overlap there. Apparently, the different types of violators are sticking pretty much to their own ballgame.

We have had a couple of significant investigations jointly with the FBI in Kansas City and in Philadelphia involving both controlled substance diversion and medicare-medicaid fraud.

Mr. WOLFF. One area that has interested the committee, and I believe a task force has already been set up on this, is the problems of the aging.

Mr. BENSINGER. Yes.

Mr. WOLFF. The problem is the overprescription by practitioners and unscrupulous nursing home operators who use this as a device for attaining tranquillity in their particular facility. The fact is that they are able to use less supervisory personnel by keeping these people tranquilized and in bed.

I just wondered whether or not there is anything that you are doing in that area?

Mr. DURRIN. When that type of information comes to our attention, we turn it over to the appropriate State authorities. It is more of a medical and association problem than it is a controlled substances diversion problem.

It is a very real problem, I couldn't agree with you more, but we do turn that over to the State medical authorities who really have the responsibility to make sure that patients are getting what they need and not being bombed out every day.

Mr. WOLFF. We will pass that on to Mr. Lowe who I am sure can respond to some parts of that.

Any further questions?

If not, we thank you very much, Mr. Bensinger and Mr. Durrin.

Mr. BENSINGER. Thank you, Mr. Chairman. I share your comment about not indicting the entire medical profession. Having the benefit of a doctor as a wife, I wouldn't want her to hear my point of view in this fashion.

Mr. WOLFF. I wouldn't want to have any further trouble with my neck in this fashion.

[Mr. Bensinger's prepared statement appears on p. 78.]

Mr. WOLFF. Mr. Lowe, I am going to ask if you and your colleagues would mind taking the oath.

[Mr. Lowe, Mr. Cogan, and Dr. Nelson were sworn by the chairman.]

TESTIMONY OF RICHARD B. LOWE III, ACTING INSPECTOR GENERAL, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, ACCOMPANIED BY PHILIP H. COGAN, DIRECTOR, DIVISION OF LAW ENFORCEMENT COORDINATION AND DATA COLLECTION; AND DR. MICHAEL NELSON, CHIEF MEDICAL OFFICER, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, OFFICE OF INSPECTOR GENERAL.

Mr. WOLFF. Would you identify the gentleman accompanying you?

Mr. LOWE. I would be happy to, Mr. Chairman.

On my left is Dr. Michael Nelson who is the Chief Medical Officer for the Office of Inspector General.

And on my right is Mr. Philip Cogan who is the Director of our Division of Law Enforcement Coordination and Data Collection of the Office of Inspector General.

Mr. Chairman and members of the committee, I am very happy to be here this afternoon, and I am pleased to outline for you the remarks which I have submitted for the record.

Mr. WOLFF. Without objection, your full statement will be included in the record.

Mr. LOWE. Thank you, Mr. Chairman.

We are particularly concerned with drug diversion in the medicaid program because the real dollar cost to medicaid caused by drug abuse goes far beyond the actual cost of the medication. The true figure must include the cost of office visits, laboratory tests, X-ray and other services to "legitimize" the prescriptions. This is to say nothing of the larger human loss and suffering due to the physically and mentally debilitating effects of drug abuse.

The Drug Enforcement Administration has informed us that 80 to 90 percent of the drug diversion from legitimate channels is at the practitioner level. Because of their legislative authority restricting them from implementing major controls at the retail level, DEA concentrates its control efforts at the highest level of the normal drug distribution chain. However, these persons account for less than 2 percent of the total universe of individuals who are legally registered to handle controlled substances.

We found that DEA does not presently have the resources to assist HEW in an initiative to investigate diversion through the medicaid program. In the event that new directions are undertaken in the future, I hope that drug diversion from the medicaid program will be included.

We believe the majority of medicaid recipients and providers are honest, but controls are necessary for the few abusers. Since medicaid is a State-administered program, there are 53 different programs, one for each participating State and jurisdiction. Consequently, controls vary from State to State.

Controls that have been effective in several States are:

First: Implementation of a formulary to limit the type of drugs available.

Second: Limitation on the quantities of prescription drugs per recipient in any given period of time.

Third: Restriction of known abusers to a single physician or pharmacy for routine services. This is otherwise known as "lock-in" producers.

Fourth: For known abusers, establishment of "prior authorization" requirement before routine services will be reimbursed.

Since its inception, the Office of Inspector General has launched several initiatives to identify aberrant practices by way of computer, and we stand ready and willing to help any State interested in using computer screens to identify aberrances.

The benefit of our computer techniques is that it surfaces the targets for which we then proceed with the investigations to determine if these aberrant practices indeed are either criminal in nature or abusive in nature.

Last year "Project Crackdown," utilizing computer screens in the drug abuse area, was assigned to the Health Care Financing Administration under the direct management of their Office of Program Validation. The objectives of Project Crackdown are twofold:

First: We wish to identify and to take action against medicaid drug pushers at all levels, including those who operate under the guise of medical practice, as well as those who actually operate on the streets.

Second: Working with the States involved in the project, we are seeking regulatory and administrative improvements to prevent Federal and State financing of drug abuse.

Indeed, the irony of it all is that the Federal Government is financing this licit drug diversion.

To date, the results of Project Crackdown can best be described as spotty, and frankly, overall, somewhat disappointing. But I will get to

that at the conclusion of this statement. We have seen only a handful of convictions, but there are some 60 to 100 cases under active investigation at the present time.

In addition, the four controls I mentioned a moment ago have been shown to be successful in the States that implemented them. In Detroit, for example, visits and prescription acquisition by high risk recipients decreased 80 percent and 93 percent respectively.

Wisconsin experienced a 90–percent decrease in the utilization of certain drugs after the medical examining board banned the prescribing of specific drugs except for a few limited purposes.

Other States such as Illinois and California registered successes after instituting a more restricted formulary. The approach in Louisiana and Texas has been a bit different. There, the quantities of drugs covered under medicaid have been limited.

At this point, let me share with you some ideas that the Office of Inspector General is considering:

First: To require termination from participation or a very long suspension from Federal health programs after being convicted of violating any provision of the Controlled Substances Act.

The difference here is that the present law enables us to restrict or indeed to terminate providers if they are convicted of violating any of the terms of the medicaid or medicare laws. But in the case of investigating a provider in a drug area, very often it is easier, even though it is difficult, it is much easier to convict or to prove an abuse of the narcotics laws than it is of the medicaid laws. This is contrasted to the requirement to prove violations where medical judgments and the validity of prescriptions are involved.

But there is no corresponding ability to terminate him or her if the violation is of the Controlled Substances Act.

Second: To seek amendment to the Social Security Act to make it illegal for a practitioner to pay a pharmacist to fill his prescription for controlled substances.

Again, presently, we have a law that makes it illegal for the pharmacist to pay the physician, but the corresponding payment is not. And that poses a problem.

Third: To upgrade from misdemeanor to felony the punishment for use of medicaid cards to aid in the procurement of controlled substances to be sold on the street by drug pushers.

Fourth: To suspend payments for prescriptions, supplies, and services ordered by physicians suspended from medicaid.

In conclusion, we feel that we can have a significant impact on the diversion problem. Regulatory and administrative modifications to the program are preventive and will decrease the burden on law enforcement agencies.

It is obvious that law enforcement alone cannot solve the problem. We, therefore, have to combine varied resources of Federal, State, and local agencies to maintain a mix of regulatory and law enforcement initiatives.

Now, I mentioned Project Crackdown. And I indicated the fact that it proved disappointing. It proved disappointing, frankly, because Project Crackdown was essentially a law enforcement effort. We attempted to crack down. And what we did is we got 10 States as participants, and we attempted to really crack down on this diversion problem with the traditional law enforcement approach.

Well, maybe in fact, Project Crackdown wasn't a disappointment after all, because what it did do was point out the fact that the traditional law enforcement approach is not the answer.

Indeed, it showed us that those States which were using some of the examples that I mentioned like lock-ins, formularies, medicaid management information system improvements, prior authorization, the red cards, that is when a recipient is determined to have been an abuser of drugs, he is then furnished a separate and distinct type of medicaid card, which limits the services available.

In California, it happens to be a red card. That identifies that person as an abuser of prescription drugs. And therefore he is placed in a particular prior authorization category.

And, indeed, we have better enforcement or stronger efforts at termination of providers who abuse the system.

And you mentioned earlier in prior testimony the triplicate prescription method. We have found through Project Crackdown that this is the approach that we must take in conjunction with law enforcement support on the tail end.

But I can tell you, Mr. Chairman, that my prior discipline was that of prosecution, indeed, in the city and State of New York. I was in Robert Morgenthau's office as chief of the trials division for 12 years.

And I can tell you that this area is very difficult for law enforcement on the traditional approach.

Indeed, you take DEA, the problem with the diversion, this drug diversion, as opposed to the traditional narcotic drugs like heroin and cocaine, et cetera, these are individual, single transactions in terms of the prescription and the filling of that prescription. Individual, that is, "small potatoes," or peanuts for them in terms of their efforts and what their responsibilities are. Yet, overall it is a massive problem.

Indeed, I cannot even tell this committee the extent of the medicaid dollars that are going out on the drug diversion end and how much this government is actually paying. We don't know yet. We are making every effort to try to itemize and determine how large the problem is.

We do know it is large. We cannot tell at this time exactly how much of the medicaid dollar is indeed spent to support this illegal effort.

So I thank you for the opportunity to summarize my remarks for you, Mr. Chairman. I am very happy to answer any questions that you may have.

[Mr. Lowe's prepared statement appears on p. 82.]

Mr. WOLFF. Thank you, Mr. Lowe.

First, just let me say that we are very happy to see the amount of dedication and interest that you have put into this area. Knowing your background, we know that you will continue to do that.

Mr. LOWE. Thank you, sir.

Mr. WOLFF. I am interested in attempting to elicit from you information as to the overprescription by medical practitioners in medicare more than medicaid in the maintenance of people in nursing homes and similar facilities.

Is there any ongoing investigation? Are you looking at this situation at all?

Mr. LOWE. Mr. Chairman, I do know that we are constantly receiving this kind of information. And if I could just take one moment to show you how, as you know, the Inspector General's Office, for example, has the oversight responsibility of the State medicaid fraud control unit, what we commonly refer to as the section 17 units of Public Law 95–142.

Joseph Hines, as you know, the special prosecutor for New York, is the deputy attorney general in charge of the medicaid fraud control unit in New York. We receive a communications network from 26 of these medicaid fraud control units who have the responsibility for investigating nursing homes, hospitals, along with the overall medicaid provider program.

The information that we have received so far is that there is indeed, an apparent pattern of overdrugging, or overprescribing, for the elderly.

The efforts which we are coordinating are between section 17 units and ours to determine how we can make inroads into this area. You could probably appreciate the difficulty in determining when you have a populace of elderly people who are in the more infirm condition than younger, "healthier" individuals.

And so, therefore, a pattern of prescription usage is normal.

Mr. WOLFF. One of the points that I really am very much interested in in this particular area is that the pattern of senility is being actually accentuated and fostered through this overmedication thus making people much more the public charge than they ordinarily would be without institutionalizing them.

Mr. LOWE. I guess, Mr. Chairman, what I would really like to say is this: it is, indeed, a problem. It is something that we are looking at. And I, unfortunately, am not in a position to tell you that we have a handle on that problem.

I will tell you this, that it will be an effort that I will leave here today and beef up. And I will be happy to report to you at any time at your request as to the results of our efforts.

Mr. WOLFF. We would appreciate that.

And my time has expired. So Mr. Coughlin.

Mr. COUGHLIN. On the Federal medicaid payments, what proportion of that goes to prescription drugs, do you know?

Mr. LOWE. Yes, sir, I have that figure. The part that goes for prescription drugs is $1.127 billion.

Mr. COUGHLIN. Of a total of?

Mr. LOWE. Of a total payment of $19.401 billion.

Mr. COUGHLIN. Of the $1.127 billion that goes for prescription drugs, what proportion of that do you estimate is diverted?

Mr. LOWE. We do not know. That is what I mentioned earlier. And we are making every effort to try to learn that. We feel that obviously this committee should know that. We should know it. But we do not know it at this point.

Mr. COUGHLIN. What thoughts have you had, and albeit limited, what thoughts do you have of steps that can be taken to prevent diversion of prescription drugs?

Mr. LOWE. Well, first of all, I have to emphasize the fact that it is primarily a State problem. When I say "primarily" I don't mean

that we in the Federal Government do not bear any responsibility. But what I means is that it is 53 jurisdictions which administer a medicaid program. And the administering of that program varies with each State.

One of the primary ways that we could make inroads into this area is to develop better medicaid management. And the development of more efficient management of the medicaid program involved development of medicaid management information systems.

It is the collecting and analysis of information that is the key, because the collecting of the information shows the aberrant billing practices, shows the aberrant prescription uses, shows the aberrant uses by the individuals.

Mr. COUGHLIN. How would you collect that information?

Mr. LOWE. You collect the information through implementation of what we call the MMIS system, the medicaid management information system. It is the use of computers which collects billing data which is constantly monitored and looked at.

That is the second problem. There are many States who do not have the system in place. There are those States that have it in place, but don't have either the resources or the personnel to monitor it.

If you have the system and you don't use it, you are not going to get the benefit out of it. And this is where we feel our greatest input to the States is—either through monetary support or technical support to implement these management information systems. When you have that, then you can put into place the controls which I previously mentioned—formularies, lock-ins, prior authorizations. So, that you can monitor the people who are abusing the system.

Mr. COUGHLIN. Just so I am clear as to what we are talking about, what you are saying is that a medicaid prescription, once it is filled, in order to obtain reimbursement, would go back to the State to be entered into a computer. If there were an undue number of prescriptions for a particular patient, you would be able to have a computer drop that out and call attention to that aberration. Is that correct?

Mr. LOWE. That's correct. For example, the triplicate prescription form is almost unnecessary in medicaid because the medicaid information system has all that information. And it is all there.

Mr. COUGHLIN. It has to be there in order to have payment for medicaid prescription drugs.

Mr. LOWE. That's correct. And it is the monitoring of that information that gives rise to the supervision.

Mr. COUGHLIN. I wouldn't think that monitoring would be very hard if it is all in the computer already.

Mr. LOWE. Well, it still takes personnel. And if the States are not committed or if they don't have the resources—I don't mean to point fingers at the States. I just mean that they need assistance. And that is where we feel our greatest role can be.

Mr. COUGHLIN. But the computer can drop out or flag any aberration of the prescription form, can't it? They don't need to monitor it. The computer does the work.

Mr. LOWE. Yes, sir, the computer does the work. But you are talking about mounds and mounds of paper. And you have got to have the commitment to look at that paper.

Mr. WOLFF. If the gentleman would yield, it reminds me of the fact we have vehicles out in space which send back messages in a few minutes. However, it takes us about 4 to 5 years to analyze that information transmitted in a matter of minutes. That seems to be a part of the problem.

Mr. LOWE. It is the followup, sir. Once you get the information, then you have got to have the resources that go out and validate it. If you have a kickout of aberrant billings, then you have to have people to compare the billings with the services that were provided in the case of physicians. You have to validate to determine if what is on the computer screens is justified or not.

You cannot just use the information as kicked out of the computer as evidence that the physician or the pharmacist has billed them improperly. It requires followup investigation. All the computer does is surface your targets. Then, you must use the targets that have been surfaced for you to go forward and do the investigative legwork. That is the problem.

Mr. COUGHLIN. And who would that investigative legwork be done by?

Mr. LOWE. The States.

Mr. COUGHLIN. State personnel?

Mr. LOWE. Yes.

Mr. COUGHLIN. Can any investigation be done by Federal personnel in that?

What I am getting at is if you have got the computer to kick out the three most egregious cases in any particular State and you went after those. I expect you could significantly affect diversion just by example.

Mr. LOWE. There is no question that publicity, that kind of deterrence, is very useful. For example, that occurred in Philadelphia where we started Project Crackdown. Crackdown emanated by the enterprising resourcefulness of a reporter in Philadelphia. And then with the attenuating publicity that occurred, they found that half of the investigations were worthless because the street markets dried up because the physicians were aware of the efforts that were being made.

But I agree with that.

Actually, the computers with the medicaid data are in the hands of the States, not the Federal Government.

Mr. COUGHLIN. Thank you, Mr. Chairman.

Mr. WOLFF. Thank you.

Mr. Livingston?

Mr. LIVINGSTON. No, Mr. Chairman. I had a couple of questions, but they were fairly well answered by this gentleman.

Mr. WOLFF. Thank you very much.

One final question. Could you furnish for the record what percentage of the prescriptions under medicaid are filed by mail or filled by mail?

Mr. LOWE. I don't know, Mr. Chairman. I would be happy to furnish that information.

[The information referred to follows:]

We have contacted a variety of people including the Health Care Financing Administration's Pharmaceutical Reimbursement Board, State medicaid agencies, private pharmaceutical organizations and others. The consensus is that there are very few prescriptions filled by mail under medicaid. The feeling is that since the recipients do not have to pay for services, there is no incentive to send away for prescriptions; it is much more convenient and timely just to have prescriptions filled at a community pharmacy.

Mr. WOLFF. Yes. I say, if you could furnish it for the record.

Mr. LOWE. Absolutely.

Mr. WOLFF. We have found in the case of the VA hospital in Puerto Rico, for example, that there is a serious problem there as a result of the prescriptions by mail because they are continued for a period of 6 months without reexamination of the individual. The individual may not need that particular type of substance any longer.

Mr. LOWE. Yes; but I will be happy to furnish that.

Mr. WOLFF. Thank you. And thank you very much, Mr. Lowe.

Mr. LOWE. Thank you very much, sir.

Mr. WOLFF. I am going to have to declare a short recess to vote. Then we will come back for the concluding panel of Mr. Niport, Mr. Parker, and Dr. Adams.

We will recess until the vote is over.

[Brief recess.]

Mr. WOLFF. The committee will come to order.

Our final panel for the day is Mr. Jerome Niport, director of the Medical Assistance Compliance Administration, State of Maryland; Mr. Richard D. Parker, Sr., independent pharmacist, Kensington, Md., and Dr. John E. Adams, chairman of the Commission on Medical Discipline, State of Maryland, and Mr. Payne.

Mr. PAYNE. Thank you, Mr. Chairman.

Mr. WOLFF. I am going to ask you if you will take the oath, if you don't mind, please.

[Mr. Niport, Mr. Parker, Dr. Adams, and Mr. Payne were sworn by the chairman.]

Mr. WOLFF. Mr. Niport, would you please proceed? You can do one of two things—either read your statement, or you can put it into the record at this point. Without objection, it will be formally put into the record, and if you can summarize, we would appreciate that.

TESTIMONY OF JEROME NIPORT, DIRECTOR, MEDICAL ASSISTANCE COMPLIANCE ADMINISTRATION, STATE OF MARYLAND, ACCOMPANIED BY LAWRENCE PAYNE.

Mr. NIPORT. Fine. The statement is rather brief, Mr. Chairman.

Mr. Chairman, members of the committee: My name is Jerome Niport. I am the director of the Medical Assistance Compliance Administration within the Maryland Department of Health and Mental Hygiene. This is the department in Maryland that is the single-State agency charged with administering the Maryland medicaid program.

Perhaps as such, I represent the portion of the health care delivery system that is financed totally by public funds. And when we speak today of abuse in the medicaid program, we are speaking of abuse for which you and I pay out of our pockets.

I hope I will be able to represent to some extent the other States' medicaid programs.

First, I would like to introduce Mr. Lawrence Payne who is a member of my administration and was the one who spearheaded the drug utilization review.

The administration which I direct is responsible for, among other things, review and control of the utilization of medical services reimbursed by Maryland medicaid. Within our program, we include prescription drugs which, in the last fiscal year, numbered approximately 2.5 million prescriptions for which we paid approximately $16 million.

The drug utilization review effort is an integrated process involving three distinct elements:

The drug prescriber or physician;

The drug dispenser or pharmacist; and

The drug recipient or patient.

The results of our reviews leave absolutely no doubt that all three elements quite often contribute to and even more so encourage diversion of legitimate drugs into the illicit market.

First of all, physicians are manipulated by patients, by threats, persuasion, misrepresentation, and sometimes, unfortunately, higher office fees, into prescribing precisely the drugs desired by the patients in quantities far exceeding medically acceptable consumption rates. And in succumbing to this manipulation or often as a result of poor record-keeping, physicians often exceed maximum duration of drug use as recommended by the manufacturers or other authorities.

I have examples from our information system that are quite vivid. I have before me an example of a physician in the Maryland medicaid program whose prescribing in the medicaid program resulted in 69.3 percent of his prescriptions being central nervous system drugs and cough preparations, antihistamines, that tend to enhance the effect of these drugs.

I have many examples of this.

Mr. WOLFF. What has happened with that particular example?

Mr. NIPORT. I will get to that in a few moments if you will bear with me, sir.

Second, the pharmacists. The pharmacists often in our program dispense drugs in quantities or combinations which are patently inappropriate without verifying the legitimacy of the prescription or the intent of the prescriber. I must say, however, that many of them are frustrated by inaction on the part of local law enforcement agencies and courts. And they are not motivated to report forged prescriptions.

The individuals or the recipients or the patients who have medical assistance cards for eligibility who, by Federal regulation, must be guaranteed freedom of choice shop a variety of physicians to secure prescriptions to their own order.

Also, with a medicaid card and a stack of prescription blanks that they can get fairly easily, there is virtually no limit to the number of forged prescriptions that they can pass.

The motivation to divert prescription drugs into illicit channels is enormous. I won't go into detail. The markup is outrageous. I would like to point out one thing, though, that the markup is even more favorable in the medicaid program because the medicaid recipient pays zero. In Maryland, he pays a 50 cent coinsurance on every prescription, but this makes it virtually free.

The office visit to the physician's office to get the prescription costs him zero. So there is even more incentive. I would like to point out one thing, though. Our major problem in Maryland is not the narcotics.

I am talking about in the medicaid program now. We have had an active drug utilization review effort in Maryland for a good while. We have had what is commonly referred to as the triplicate prescription in our Maryland program for a good while so we actually see the prescription that was written by the physician that was filled by the pharmacy.

Our major problem, as I said, is not the narcotics, but the virtual flood of the minor tranquilizers, the minor drug abuse drugs, the benzodiazepams, tranquilizers, Valium, as being virtually pumped into the market. It is in Maryland the largest number of prescriptions or the drug that is prescribed the most often of any in our program.

I don't have to tell you the amount that these things bring on the street. Approximately 30 percent of the drugs prescribed in our program are those that are classified therapeutically as central nervous system drugs. They ease pain; they elevate moods; they sedate; they hypnotize; they stimulate.

Our attempts to control the inappropriate prescribing of these drugs has met with at best mixed results. How do we control all this? Well, we don't control it very well. And the most aggravating part is that we are fully aware of a lot of the abuse, although we can't quantify it into the actual dollar because it is virtually impossible to look at computer listings and determine what is abuse and what is not.

But we have the wherewithal in Maryland to conduct prescribing studies which we have done recently, and we have found that out of over 4,800 physicians in Maryland who prescribe under our program, 16 percent of them wrote 75 percent of all prescriptions.

Now, this is not in and of itself abuse, but it does point out vividly, I think, over-prescribing of all kinds of drugs. We focused in at the time on the stimulants, and we found that 45 physicians, less than 1 percent of the physicians, prescribing in our program, wrote for half of the stimulants, one-fifth of the psychotherapeutic drugs and one-tenth of the sedatives and hypnotics that were given in the office setting in Maryland medicaid.

A number of physicians clearly prescribing excessive amounts of stimulants purportedly for weight control were referred to our statewide medical society. There was an appreciable change in the prescribing habits of these physicians.

However, we arrived at the ultimate solution to this problem. We simply cut out paying for these drugs under our program, and nobody is suffering one iota.

I say cut out, I mean virtually cut out. We do allow these drugs to be dispensed only where the physician in his own handwriting on the prescription puts down one of a few diagnoses for which we allow the prescription of these drugs. And the net result has been that we have virtually dried up the abuse in these drugs.

However, as I said earlier, the minor tranquilizers are our major problem. And I think it is the view that the medical profession has of these drugs. I can't help but relate to you a conversation that was held at a meeting with members of the medical profession not too long ago by members of our program addressing this very point where we wanted to remove these tranquilizers as covered services in our program.

One physician, when he heard we were talking about removing Valium as a covered service in the medical assistance programs, almost fell off the chair and readily admitted, "My God, without Valium, I couldn't practice medicine."

How do we cope with the recipient abuse, the patient? This is probably the most frustrating of all. Recipients with a history of acquiring abuse-prone drugs from many different physicians are first "counseled," warned, and then finally asked to select a primary physician and primary pharmacy to service them.

Now, such a provision is difficult to administer at best when you have many abusers of the programs. And often, the individual either continues what he is doing by acquiring someone else's medicaid card or just ignores this completely. And I have some vivid examples of recipient abuse. I have before me some cases where one recipient—and this is in a 1-year period—saw 30 different physicians, paid visits to 15 different hospital outpatient departments—and these are different than the 30 physicians—and had his 235 prescriptions filled at 28 different pharmacies. He was shopping around, bouncing around, thinking nobody would ever know.

I could go on and on. We have one who saw 42 different doctors and had his prescriptions filled at 44 different pharmacies.

As Mr. Lowe indicated, you have to have the information first, but once you have the information, where do you go? What do you do? How do you stop it? We have been successful to some degree in some areas, but I think we are, under our current procedures, trying to empty the ocean with a thimble.

We have had a situation where we called in a physician who was blatantly overprescribing abuse-prone drugs, and counseled him. About 1 month later, we received a call from a medicaid recipient who was rather disturbed.

"What is the matter?"

"Well, I was to Dr. So and So to get my regular Valium prescription, and the doctor told me he would give it to me, but he couldn't write it on medicaid prescription. I would have to pay for it," which was fine as far as we were concerned, which indicated we had some impact.

However, what we accomplished was chasing this abuse from the publicly funded market to the privately funded market. So it really didn't solve the problem.

I think it is apparent from what was said today that steps have to be taken to stem the flow of these drugs into the illicit channels. Maryland, and I am sure all the other States, will continue to do all that is in their power to reduce the flow, but our power is severely limited.

On the national level, I would recommend strongly educational programs to enhance physicians' awareness of the limited benefit over time of many of these abuse-prone drugs; to the accumulative effect of certain drugs even when they are taken as prescribed; and the dangerous interaction of certain drugs, especially with alcohol.

Further, I endorse the programs of Federal assistance to States to attack the problem of prescription forgery—and I am sorry to say my own State has not taken advantage of it.

Finally, I recommend most strongly something that would be of benefit to every medicaid program in the country, and that is, that we

be allowed by Federal regulation to incorporate provisions in our State programs to suspend benefits to those individuals who abuse them.

Right now, our hands are tied. All of the gimmicks that you have heard of locking into one provider, special cards, they work to some degree, but they do not solve the problem. The only way that we can deny benefits to an individual is where he has been convicted of a fraud against the medicaid program. And, quite frankly, very little attention or priority is placed on this by prosecutors.

Fraud convictions against our program by recipients are virtually impossible to get. Convictions of providers based on overprescribing is virtually unknown. And we have no vehicle right now with which to stop the known abuser from continuing to abuse the program.

I do thank you for the opportunity to bring to light our problems. I think you could probably guess by my presentation I also brought to light indications of our frustrations. I hope that somehow, we can be given the resources with which to attack the problems that we know exist, we identify, and in many cases, are helpless to solve.

[Mr. Niport's prepared statement appears on p. 86.]

Mr. WOLFF. Mr. Niport, I thank you for a very comprehensive statement. I must say that we share frustrations because we hear this constantly from various people. And it is an extremely frustrating situation for those of us who are legislators. Members of this committee are very dedicated members serving above and beyond because of the fact we are a Select Committee. So we have additional committee responsibilities.

But we must not throw up our hands with this situation. We must continue to provide whatever we possibly can in the interim until we find the ultimate solution.

I am going to pass on now to our next witness, Mr. Richard Parker. Mr. Parker, would you proceed, please?

TESTIMONY OF RICHARD D. PARKER, SR., INDEPENDENT PHARMACIST, KENSINGTON, MD.

Mr. PARKER. Mr. Chairman, I would like to enter into the record my prepared testimony.

Mr. WOLFF. Without objection, your full testimony will be included.

Mr. PARKER. I will try to excerpt from my testimony certain facts.

In the area of drug abuse, I have seen a variety of problems which need to have corrective action taken to control either by regulation or legislation. Among the most serious forms of abuse are the prescriptions presented to pharmacists which have been forged or altered or which have been issued by licensed practitioners not in the usual course of practice.

It is the latter of these abuses which poses the more serious problem to pharmacy. Physicians in the District of Columbia may prescribe controlled substances and the prescriptions may be filled in the nearby Maryland or Virginia pharmacies in the proper course of business.

The problem arises when a practitioner orders a medication other than in the proper practice of his profession. In this case, it is difficult to obtain evidence substantial enough to stop him from this activity.

Recently, my pharmacy became a member of a voluntary cooperative chain of independent pharmacies in the Washington-Maryland-Virginia area operating under the name of Care Drug Centers of Washington. While associating with my colleagues, I have found the abuse of the right to prescribe a prevalent concern and have discovered an unwillingness on the part of some to take action.

This reluctance on the part of pharmacists is usually based on the perceived requirement to appear in court as a witness with resultant loss in pay. This perception is compounded by the feeling of wasting time since most convictions result in release with reprimand or short-term confinement in revolving door fashion.

Other pharmacists feel they are not in a position to refuse prescriptions which should be suspect since they are written by licensed practitioners and difficulty could arise if they failed to supply the substance. For whatever reason, the availability of drugs in this manner is a major source of illicit drugs on the streets and in the schools.

Forged and altered prescriptions are more easily controlled because pharmacists are more willing to take time in the apprehension of criminals or those under the control of drug habit. Most of these prescriptions have some flaw or other feature which calls them to the attention of the alert pharmacist. He then contacts the alleged prescriber and upon determining the illegitimacy of the prescription calls a local law enforcement team.

In this latter instance, some pharmacists are reluctant to "get involved" because of the fear of retaliation in the form of personal harm or possible property damage. Many stories are told across the Nation of pharmacists being murdered or beaten by persons attempting to obtain drugs.

While the major source of licit drugs being diverted to the street market is the improper prescribing of some practitioners, there is another source which needs attention. Persons with a drug habit and those seeking to sell controlled drugs often find it more lucrative to burglarize pharmacies known to stock these wanted substances.

In recent months, armed robberies have occurred with the criminals bringing a shopping list for the most desired drugs.

There is another side of the problem to which we must address ourselves. And that is the commission of crime by those seeking to obtain drugs. Many muggings, burglaries, shopliftings, and purse-snatchings are performed by desperate addicts in efforts to obtain funds to support the habit. These persons are sometimes less rational, and so more violent than similar persons performing the same type of crime.

To prevent the commission of crimes for the purpose of drug abuse, I propose the following:

First: A continued attempt to stop the spread of drug abuse by education of the general public and followup monitoring of rehabilitated addicts. This is the obvious best method to decrease the demand for drugs.

Second: Strengthen the forces presently in use to stop the distribution and sale of controlled substances. The vice-narcotics unit in Montgomery County and the similar forces in other jurisdictions do a tremendous job in enforcement when they have the opportunity.

Third: Strengthen the regulatory processes whereby practitioners may have their right to prescribe suspended or revoked and assess criminal penalties in a more rapid application of due process.

Fourth: Adopt legislation making it a Federal crime to rob a pharmacy in search of controlled drugs. Local enforcement agents are unable to prevent the interstate traffic in drugs.

Fifth, impose longer sentences on second offenders who sell or distribute drugs. I have been told the need exists for more correctional facilities to eliminate the release of criminals to make room for others. Judges now have to determine which is the worst criminal when deciding the punishment to be handed down.

Sixth, design other methods of control which would make it more difficult to use prescriptions to obtain drugs for illegal use. Forms in triplicate similar to these in use to obtain drugs from suppliers—form 222 DEA—could be used to order the most abused drugs in the normal course of practice.

In summation, I do not wish to indict the practitioners who oversee the health needs of the Nation. The very small minority involved in this unethical practice is such that internal controls would be effective if the regulatory remedies were available to them. The medical-chirurgical faculty of Maryland does a commendable job in this area.

I thank you for the opportunity to appear before this committee and am willing to answer any questions pertaining to this matter.

Mr. WOLFF. Mr. Parker, thank you very much. I am impressed with one point. Just prior to the time you mentioned some of your recommendations, I spoke to chief counsel and said to him, "Why is it that we don't have a law which says that it is a Federal crime for anyone to either holdup or to burglarize a pharmacy which has controlled substances therein?"

And you came along with the same suggestion right after that. I don't know whether that was ESP upon my part or what have you, but I think it is an important factor. I think it would certainly be something to give consideration to. I have asked counsel to investigate this.

Mr. PARKER. I think legislation has been introduced on this subject in the past and probably is still sitting somewhere around the House or Senate.

Mr. WOLFF. It is our job to motivate people in that direction.

[Mr. Parker's prepared statement appears on p. 87.]

Mr. WOLFF. Dr. Adams?

TESTIMONY OF DR. JOHN E. ADAMS, CHAIRMAN, STATE OF MARYLAND COMMISSION ON MEDICAL DISCIPLINE

Dr. ADAMS. Thank you, Mr. Chairman. With your permission, I will not read my statement. I would ask it be entered into the record.

Mr. WOLFF. Without objection, the entire statement will be included in the record.

Dr. ADAMS. Thank you, sir.

The statement gives some indication of the structure and function of the commission on medical discipline in Maryland which is the State agency empowered to remove physicians' licenses, practice licenses.

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It also, I think, gives some indication of our success in interfacing with other State agencies and very importantly interfacing with the medical profession.

The basis of the system in Maryland is the profession itself. And without counting them, I would guess that perhaps 500 different physicians in Maryland through 30 or more peer review groups are the keystone of this system in terms of case finding and preliminary investigation and recommendation to the commission.

In lieu of that, what I would like to do is tell you very briefly a few current cases that I think illustrate the breadth of the problem and some of the reasons for the problem. I am reminded of one physician we saw recently, a youngster about 35 years of age, who is 2 years out of residency programs, an orthopedic surgeon. And the complaint against him was that he had made an attempt to sell samples. As it turned out, this attempt to sell samples was probably the responsibility of his office help who were, as far as we could tell, skimming. But as a result of that complaint, his practice was looked at, and it was found that he was heavily involved in sports medicine. And he was informally and without any record dispensing muscle relaxants to athletes he was working with.

We had this physician in and talked to him at considerable length in a session. And he said that he had never been told that, he didn't realize that what he was doing was improper.

This physician was informally reprimanded by the commission, and he will be watched in the future.

The second case that comes to mind is a physician who, because of or with at least serious alcohol and narcotic addiction, in a 9-month period was singularly responsible for the distribution of some 1,500 prescriptions for Dilaudid which over the 9 months' period then represented a street value of in excess of $2 million.

This physician, the license of this physician, was lifted just yesterday.

Mr. WOLFF. May I ask how long do these proceedings take?

Dr. ADAMS. It is quite variable. The investigations can be quite brief in terms of a few weeks. They can stretch on for a number of months. It depends upon the complexity of the problem.

Mr. WOLFF. We heard, just a few moments ago, of a situation wherein a conviction of an individual practitioner was obtained here in the District in 1975. The man is still practicing in 1979 in New York.

We wrote to the State and found out that proceedings were taking place, but got no further information. Does that same situation apply as well in Maryland?

Dr. ADAMS. It may. The commission has its own problems, largely budgetary. And we are presently attacking the State with greater vigor, attempting to solve those budgetary problems. But basically, the mechanism to prevent what I call doctor chasing, which you brought up, is this: Whenever a State takes formal action against a man's license, that action is forwarded to the Federation of State Licensing Boards which is a national agency which, in turn, assembles all of those reports into a single piece of paper and redistributes it to all of the State licensing and disciplinary boards. Then, the individual State boards are supposed to review those reports and pick out their own practitioners from that list and review the actions taken against them and then take their own action.

And a case of that sort, I do not think would escape very long in Maryland. It might take a few months for us to get to him because of problems with backlog and lack of investigatory help, but the likelihood is that that physician would not open up in Maryland.

Mr. WOLFF. Those cases that you cited Mr. Niport, what happened with those? You told me you were going to tell me at the end.

Mr. NIPORT. These cases were referred to the drug committee of the medical society.

Mr. WOLFF. What has happened?

Mr. NIPORT. Nothing happened there. They had the same problems Dr. Admas mentioned. We have since referred many of them directly to the commission. And the commission is now investigating some of these.

But they are still writing tremendous quantities of these drugs.

Mr. WOLFF. To my mind, this is an extremely serious situation that requires action. Not only by this committee as an oversight committee, but it requires action by the local authorities as well. It is hard to understand the great hue and cry that some of our politicos raise concerning drugs. Then, when it comes down to doing something about it, there is very little in the way of money to fund the operations that are necessary. That applies to our law enforcement agencies, and with our treatment programs. Everybody is willing to talk about the war on drugs, but we furnish people with a bunch of cap pistols and water pistols to do the job.

Mr. NIPORT. We are probably inundated. Dr. Adams' commission, whether he wishes to say so or not, it is my understanding they are not paid, that they are voluntary.

Is that right, Dr. Adams?

Dr. ADAMS. Yes.

Mr. NIPORT. And the resources are so limited that they can only attack so many of the problems in a given time.

Mr. WOLFF. Do you have any opportunity to get any funding through LEAA for this type of operation?

Mr. NIPORT. We don't.

Dr. ADAMS. We have not investigated that. I could not really answer whether there is an opportunity or not. We are presently asking the legislature for proper funds. I think in fact that until the last couple of years, the level of activity was less than desirable. It is my belief, and I think the record would show, that the level of activity presently is much increased and will continue to increase if it were properly funded.

Mr. WOLFF. The committee is concerned that the problem of legal or licit drug abuse in this country may be larger than the problem of illegal narcotics traffic perhaps not in dollars and cents, but certainly in the number of abusers that are involved. We keep concentrating our efforts; perhaps we were stimulants for that in heroin users. Then we beat that problem or reduce it a little bit, move onto something else. Now the big cry is PCP.

It is obvious that there are more people today who are abusing these drugs and these substances of abuse on a licit basis than there are on

an illegal basis. And it is contradictory. It is illegal as well as legal.

It seems to me that this is an area that goes almost totally unnoticed because it is not very dramatic. You don't make a big drug bust and have the old cops and robbers chase that you normally associate with the drug bust.

Yet, it makes the problems of the law enforcement officers that much more difficult. It undercuts and undermines their very basic ability to do their job.

Dr. ADAMS. I was interested in the frustration experienced by the DEA people over their inability to act except when a man's license was lifted. And I submit that in the system that we have, that is not a problem, given a system with enough resources. The reason being that when we investigate apparent overprescribing, the medical reports of the patients involved are examined. And there must be in those records strong medical justification for the prescribing.

If there is not, then we are empowered to take action against that man's license so we do not need to wait for a major event. And that is in our law. It is part of our legislation.

Mr. WOLFF. I must commend you, Dr. Adams, and I understand your service is voluntary. And you are certainly heeding the admonition of physician heal thyself.

Dr. ADAMS. Could I complete my statement?

Mr. WOLFF. Oh, I'm sorry. I didn't mean to interrupt you.

Dr. ADAMS. The third position I wanted to tell you about—and this is the most important one, I think—is the physician who is in his late fifties, early sixties, practicing in a suburban area that is failing. And because the area is failing, his practice is failing. And in order to buck up his practice, if you will, he developed the tendency to please people. So that he fairly rapidly gets into the habit of giving people whatever they want.

This is a very common situation in abused-drug prescribing. In the particular situation that I am reminded of, a pusher was apprehended by the police in one of our counties. And that pusher was substituted by a female undercover agent who then called on the doctor and established a rapport with the doctor, and then wired for sound, made several buys from the doctor, with him stating on tape that he knew that this agent was going to turn around and resell these drugs on the street.

The later part of this story is unusual in that the vast majority of physicians who do write improperly are unaware that the drugs may be sold on the street. So that this physician undoubtedly will suffer substantial sanctions on his license.

And this case is about to come before us.

The final case I wanted to tell you about, which I think also illustrates the point I wanted to make is that of a professor of pediatric surgery, full-time academic surgeon, in one of our medical schools who was approached by the mother of one of his patients who was a nurse, and told the doctor that she was running a home for cancer patients, terminal cancer patients, and she was having difficulty in getting a physician to see these patients, and she needed drugs to keep these patients comfortable. Would he prescribe for them.

And he said, "Fine. I know you; you are my patient's mother; I will do this."

About 6 months later, another nurse, a friend of the first lady, came along, and she also had a home for terminal cancer patients. And he also prescribed for her, accepting no money from either one of them at any time. And after this went on for about 2 years, there was a knock on his door one day, and it was the police.

In order to defend himself, and even though it is not admissible, he took a polygraph, and the polygraph showed that what he was claiming was true, at least insofar as the polygraph was concerned, that he was not aware, as he stated, that there was a problem with diversion. He was a full-time academic physician who got no money from what he had done. And he did not know, no one had ever told him, he had never read it in the newspaper, there was any problem with diversion.

And tragically, that physician will also suffer sanctions on his license.

The point that I am trying to make is that I think that—and it has been said many times here today so I won't dwell on it—education at many different levels is necessary. Medical students, for example, are taught what drugs do to nerve ends, but they are never taught what happens or what could happen to a prescription when it leaves the desk of the physician.

Older physicians forget that there are alternatives to drug prescription. And when someone comes in who is anxious because of family problems, this anxiousness makes the physician in turn anxious, and particularly if he has got a waiting room full of patients.

The easiest way to get rid of this patient or make this patient happy is to write him a prescription for Valium or for whatever, one of the many psychotropics. So that the older physician needs not only to be reminded that there is a major diversion problem, but he also needs to be reminded that there are alternatives to prescribing drugs.

And I would also like to second the motion relative to computer control systems. I believe that the MMIS system in Maryland which Mr. Niport told you about has been helpful to us because it detects cases. And once we know where the problems are, we can look at them and take action, and we have taken action.

The problem is that that is only the tip of the iceberg because that only covers medicaid recipients. And that is a very small, very minority percentage.

What I think needs to be done is a major computer program in which all controlled substances, including the prescriber, the recipient, and the prescription itself need to be listed in a computer system. And then, there would be limits set beyond which there would be fallouts either—not on drug interactions, that is too complicated, but simply on amounts of drugs to individual patients.

This would find the cases for us. And having found the cases, we would be able to take action.

There are a lot of other things I could comment on, but I don't want to prolong your afternoon. And I do appreciate the opportunity to come here and talk with you.

[Dr. Adams' prepared statement appears on p. 89.]

Mr. WOLFF. We certainly appreciate your coming here.

I am going to ask Mr. Gilman who has his questions to take over. As I indicated to you a little while ago, I have to take off for overseas very shortly.

I do want to say, however, that we are very grateful for the dedicated work of you gentlemen who are attempting to solve this problem. This organization is a very interesting one. I would like to know more about it.

I feel that there is always an attempt to put people into categories and in some broad-brush fashion attach a stigma, whether it be to the pharmacists, the medical practitioner, or people who are administering medicaid, and challenge or charge you for all the frauds and abuses that exist. Yet, when it comes down to it, we really are not backing up those agencies that are necessary to produce the result.

This committee is determined that it will not follow the patterns of previous committees and indicate that the only place for everybody is in jail. We feel however, that the law enforcement part of it, is a very necessary ingredient. There are those who will charge that we are oriented too much toward law enforcement.

The fact is you just couldn't do without policemen. It would be a great idea if we didn't have to have police in this country, if we didn't have to have military machines. But we have to have it in order to maintain that order so there is freedom within our society.

Similarly, it cannot be just education, and it cannot be just enforcement. There has to be a broad mix, and it is a multifaceted problem. And it requires a multifaceted series of answers. You can be sure this committee is going to continue to pursue this and other avenues until we are able to provide all of you with the proper and necessary implements.

I thank you, and I am going to ask Mr. Gilman to assume the chair.

Mr. GILMAN. Thank you, Mr. Chairman.

Gentlemen, could you tell us roughly how many people are involved in investigations in the professional organizations in the State of Maryland?

Dr. ADAMS. I am sorry, sir, I didn't hear you.

Mr. GILMAN. How many people do you have involved in the investigatory field in the professions with regard to drug abuse?

Mr. NIPORT. I could speak to the medicaid program. We have about 4 or 5 people in drug.

Mr. GILMAN. For the whole State?

Mr. NIPORT. Yes.

Mr. GILMAN. And how many are in the pharmaceutical field?

Mr. PARKER. We only have a peer review committee of our own. And as Dr. Adams has pointed out, we can only act with people who have been brought up on charges. We have no authority——

Mr. GILMAN. Do you have any investigators?

Mr. PARKER. We have a board of pharmacy which has a staff, but it is underfunded. And this is the major problem we find, I think, in all areas—the underfunding of the staff that has to do the work.

Mr. GILMAN. As part of that staff, do you have any investigators, Mr. Parker?

Mr. PARKER. They are not mine, see; they are board of pharmacy's, and there are probably 7 or 8 on this particular staff who are borrowed from the State board of health, the Health Department of the State of Maryland.

Mr. GILMAN. And, Dr. Adams?

Dr. ADAMS. We share the same staff that the pharmacists do. There are two investigators used by all 18 health regulatory boards that the State of Maryland has of which the Commission is one. The same problem is true with the legal help and secretarial help, whatever.

Most of the work in our system presently is done by voluntary physicians.

Mr. GILMAN. Volunteer physicians?

Dr. ADAMS. Yes, sir.

Mr. GILMAN. Then, there are only two investigators that are doing all of the investigation work in pharmaceutical problems in the medical profession and in the medicaid abuse? Or there are a few more, I guess.

Mr. NIPORT. We have about four or five.

Mr. GILMAN. But you don't extend over to the pharmacy and medical professions outside of medicaid?

Mr. NIPORT. No, sir.

Mr. GILMAN. There are about 5,000 physicians in Maryland?

Dr. ADAMS. 20,000 registered.

Mr. GILMAN. 20,000 physicians. How many pharmacists?

Mr. PARKER. There are about 3,000 pharmacists in Maryland.

Mr. GILMAN. I guess you are understaffed. Has any request been made to the State legislature to have an investigatory unit that would look into these areas?

Dr. ADAMS. I am not completely familiar with it. I do know that a medicaid fraud unit has been recently set up in Maryland. I am sure Mr. Niport knows more about it. But for my own part, we are launching a major campaign for proper funding for the Commission on Medical Discipline in Maryland. And a bill has been drafted to provide for adequate funding and will be introduced into the sessions of the legislature.

Mr. GILMAN. There must be a drug enforcement unit in the State of Maryland, is there not?

Mr. PARKER. It is under the department of health.

Mr. GILMAN. How many investigators do they have?

Mr. PARKER. There are the ones I referred to.

Mr. GILMAN. There are about two?

Mr. PARKER. We have about seven that tour the State. They take different areas from time to time, investigating pharmacies for other things besides the diversion of drugs. They come in on a routine check-up. And while they are there, they will have a tendency to investigate any reports we give them.

Mr. GILMAN. Mr. Parker, you are a pharmacist, are you not?

Mr. PARKER. Right.

Mr. GILMAN. How often have they been in your drugstore?

Mr. PARKER. They come in my store about once a year. We get more response from the local law enforcement units. When we have a problem, we call them.

Mr. GILMAN. They come at your request, that is, once a year?

Mr. PARKER. No; I am talking about the local police department. They have a narcotics unit in Montgomery County. When we have a suspect, we call them.

Mr. GILMAN. Would these two people be able to call on every pharmacy in the State once a year?

Mr. PARKER. They do call on every pharmacy. Sometimes, they call more frequently if there is a suspect pharmacist. Other than drug abuse, they may be doing something improperly in recording, whatever. The inspectors routinely check them more frequently.

Mr. GILMAN. How much time do they spend in your pharmacy when they come in?

Mr. PARKER. A couple of hours as a rule.

Mr. GILMAN. How do they spread 3,000 around with three guys?

Mr. PARKER. There are not that many pharmacies; that is pharmacists.

Mr. GILMAN. How many pharmacies?

Mr. PARKER. I think somewhere in the neighborhood of 1,700; I am not privy to the full information of those. There is a lot of change.

Mr. NIPORT. Somewhere between 800 and a thousand.

Mr. GILMAN. I would hope that you would make a request for sufficient investigatory people. It would seem to me that it would be very difficult to examine the abuse without proper investigation.

Mr. NIPORT. Mr. Gilman, if I may, every time we seek additional resources, we have to prioritize, if you will. And what to the medicaid program is a flagrant drug abuser, someone who gets 200 prescriptions a year, four a week, is not an overly extensive abuser to our program. Two hundred prescriptions a year could be $1,000, $1,200, $1,300. And that is not really that much more than the average medicaid recipient costs the State of Maryland. So just looking at numbers, there is not that much incentive on the part of the administration to allocate additional investigators to solve a problem that is costing $1,200 a year more than the average medicaid recipient costs us.

They give more precedent to those abuses of the system that are much more dramatic as far as cost.

Now, the cost, as I said, it costs our program $1,200, $1,300 a year. That $1,200 or $1,300 a year on the street could be worth 20, 30, 40, 100 times that.

Mr. GILMAN. You are aware of that, I would hope, that someone else on the other end of that budget is aware of that and those of us who work in this area certainly are highly aware of it. And I don't think you can put the dollar value at just what the retail value of the drug is.

What we are trying to do is close every loophole possible. And it is true that the sale of pills and some of the amphetamines and barbiturates are probably a smaller part of the overall picture. Yet, it is a substantial amount as indicated by some of the testimony today, getting into the millions and billions of dollars.

And when we talk about Valium and when we talk about some of the other abusers, we find that they are substantial abuse. And the only way we are going to get at it is to follow some of the objectives of the Federal strategy.

As you know, in the 1979 Federal strategy, there is a portion that says the professional and business associations of organizations and professions related to drugs will be encouraged to intensify the monitoring of their profession as an industry and impose swift and adequate sentences among those independents who violate their codes of ethics. And if they don't have adequate investigation, we don't have any monitoring to speak of, unless you wait for a complainant to walk in the door. And there are not too many volunteers out there these days.

I would hope that you do give some attention to following the objectives of the Federal strategy. We have been long enough in trying to develop a Federal strategy. We were pleased to see finally some Federal approach to the problem of an organized manner. And I would hope that those State organizations and people at the local level will recognize that every facet of drug abuse is extremely important. And the only way they are going to do the job is proper manpower and proper tools. And if you need it, you should be shooting for it. And if they are not responding, let our committee know, and we will help you shoot for it.

It is certainly an important part of this overall war on drug abuse. I would welcome any suggestions you might have for any areas you see where there is some need at the Federal level to help you in your efforts.

Certainly, I think your intent is to be commended. While you don't have the overall ability, you certainly intend to try to do the job. I think the big problem is to make sure you have the adequate wherewithal.

How extensive is the drug diversion market in your State?

Dr. Adams?

Dr. ADAMS. I don't know exactly. All I have are impressions. And my impressions are it is quite extensive.

Mr. GILMAN. Mr. Parker?

Mr. PARKER. I would have to agree, it is extensive. One of the problems I addressed earlier was the interjurisdictional problem where prescriptions are written in the District of Columbia, and we are not fortunate enough to have the same commission in the District of Columbia, we have with Dr. Adams. So a doctor in the District of Columbia can see a patient and write a prescription without doing the routine examination and specifying the cause or diagnosis for prescribing.

And these District of Columbia prescriptions find ways across the State lines in stacks. And we have assisted police by checking the patient that comes in with a prescription, or we will follow them outside and get the tag number, the identification of the car, the person driving it, the person receiving the medicine. And we will sometimes find you have a driver and two or three people in the car, they will go from store to store with these prescription blanks, obtaining drugs which obviously is a conspiracy to purchase drugs illegally and sell either here or in some other State where the greatest demand is.

Mr. GILMAN. Mr. Niport, any idea of how extensive it is?

Mr. NIPORT. I don't think anybody can quantify it. The only thing we can say is that the largest amount that we pay out is in drugs that are central nervous system drugs which are the abuse-prone drugs.

Mr. GILMAN. How much do you pay out in a year for those kind of drugs?

Mr. NIPORT. There are so many different drugs, I can tell you what we paid for Valium. We paid over $600,000 in 1 year just for Valium. And that is the cost level. You can multiply that by a factor of 10 or 20 as to the street value.

So we are talking about $6 million in Valium.

I don't mean to imply that every prescription for Valium is for an abuse purpose. But we find that any time there are the flagrant abusers in our program, Valium is almost without exception one of the drugs that they have taken.

Mr. GILMAN. Has any agency or legislative commission in the State attempted to undertake a research project to determine how extensive the drug abuse is in the State of Maryland?

Mr. NIPORT. Not that I know.

Dr. ADAMS. Not to my knowledge.

Mr. PAYNE. We did, I might point out, at the request of our State legislature, a comprehensive prescribing practices study of all of the physicians in Maryland who prescribed under the medical assistance program. We did in fact use computer technology to prepare prescribing profiles of almost 5,000 physicians.

Mr. GILMAN. Is that being utilized?

Mr. PAYNE. It has been submitted to our legislature. It is in their hands. And we, of course, as Mr. Niport pointed out, have already used the information that was developed through that study to make recommendations to our Medical-Chirurgical Faculty and Board of Medical Discipline.

Mr. GILMAN. How many physicians and pharmacists have been disciplined for the abuse of their right to prescribe and dispense drugs, Dr. Adams?

Dr. ADAMS. Disciplined for the abuse of their right?

Mr. GILMAN. Yes.

Dr. ADAMS. Last year, we took formal action against the licenses of about 15 physicians.

Mr. GILMAN. For drug abuse?

Dr. ADAMS. No; total. And probably half of those would have elements of bad prescribing in them.

The point here is that someone who tends to write improperly also has other problems. And so that the action taken against him is based upon professional incompetence which encompasses a number of problems, including bad prescription practices.

Mr. GILMAN. Are those permanent revocations?

Dr. ADAMS. They may or may not be; it depends on the situation.

Mr. GILMAN. Were there any reprimands in addition to the revocations of certification for drugs?

Dr. ADAMS. Yes.

Mr. GILMAN. How many reprimands?

Dr. ADAMS. I don't know offhand. This year, we will handle 300 or 400 complaints. And probably 50 of those will be specifically bad prescribing. And of those 50, there may be 6 or 10 licenses lifted, and the rest will be reprimanded.

Mr. GILMAN. Do you turn over any of your results of your cases to the criminal authorities?

Dr. ADAMS. If there is criminal activity, yes, sir. Very often, the activity we find is not covered in the criminal code. There is no—it is my understanding in Maryland there is no—criminal violation of someone who writes a prescription without, for example, doing a physical examination or without proper indications that that is not a criminal violation. It is a violation of our statute, but not of the criminal statute.

Mr. GILMAN. Mr. Parker, how many pharmacists have been censured or revoked or reprimanded?

Mr. PARKER. This really comes under the purview of the Board of Pharmacy. And I am not a member of that board. I have only heard about two in the last year.

Mr. GILMAN. Two in the entire year?

Mr. PARKER. Right.

Mr. GILMAN. Mr. Niport, how many have been disciplined as a result of fraudulent or abrasive practices in the Medicaid?

Mr. NIPORT. We don't have the authority to discipline them. We can only refer to the licensing boards or functions. We do, though, on a continuous basis contact prescribers, counsel them. Those that we find are sometimes more flagrant, we will call in and issue warnings. And these are the ones we usually refer to the Commission.

And we are in a position where we can take no action until they have either been convicted of something or their license has been suspended or revoked.

Mr. GILMAN. Where you do find forgeries, some abusive practice, do you refer it to any criminal authorities or who do you refer them to?

Mr. NIPORT. There is very little exhibited interest in forged prescriptions in Maryland.

Mr. GILMAN. I don't understand that.

Mr. NIPORT. I don't either.

Mr. GILMAN. You mean by the authorities?

Mr. NIPORT. I must say that Montgomery County does a fine job. The Baltimore City Police Department had the equivalent of 1½ persons on this problem. And virtually nothing is being done in these areas. Anne Arundel County also has a rather significant effort underway. But it is the type of thing that the prosecuting officials do not consider very much of a priority because every incident is involving $5, $6.

As I indicated in my testimony, the pharmacists are frustrated, they call the police, and nobody wants to follow up on it. Or if they do, it is constantly postponed and postponed and postponed. They have gotten to the point where they will send the forged prescriptions to us, and we have been frustrated in trying to get anyone in law enforcement to pay any attention to it.

Mr. GILMAN. Let me understand that correctly. Your medicaid people, your investigators, would find some forged prescriptions?

Mr. NIPORT. Most of the forged prescriptions we get are sent to us by pharmacists.

Mr. GILMAN. The pharmacists send them to you, and you investigate them?

Mr. NIPORT. Most of them are quite obviously forged. We will check with the doctor.

Mr. GILMAN. And you report them to the local police?
Mr. NIPORT. And that is where it dies.
Mr. GILMAN. Nothing further happens?
Mr. NIPORT. Yes, sir.
Dr. ADAMS. The same thing is true, sir, relative to the practice of medicine without a license. One would think that is a fairly serious offense because it connotes a lot of hazard to the public.
Mr. GILMAN. I would hope so.
Dr. ADAMS. But in terms of the action that one can stimulate by reporting such a matter to the authorities, it is difficult to get them to take action. It is a low priority item in my experience.
Mr. GILMAN. Doesn't the State have some unit that does this sort of investigation and prosecution?
Dr. ADAMS. In my tenure in this involvement which goes back about 8 years, I remember one case in which we were able to get the State's attorney to indict a physician for practicing without a valid license. And the only reason that happened was because he had inconvenienced a large number of the public. And the public en mass marched down to the State's attorney's office demanding action.
We had previously requested the same action which had not occurred. It is a low priority item. It has no pizzazz to it.
Mr. GILMAN. Has the medical profession made a request to the State administration to beef up its enforcement procedures?
Dr. ADAMS. Not specifically, except through the commission which regularly requests action. In other words, all we can do is take away a license. And having disenfranchised a man, that is as far as we can go.
If he continues to practice, all we can do is refer him to the law enforcement authorities. And even in that situation, to get action is difficult.
Mr. GILMAN. Well, you have all apparently pointed to the failings of some of the law enforcement people, which is something that we certainly should be looking at.
Tell me, do you feel that the professional societies can be doing more to beef up its enforcement both the medical profession and pharmaceutical society?
Mr. PARKER. The pharmaceutical association has no right really, no legal status, to do anything except to deny them membership in the association. We can refer them if we find some violation that hasn't already been caught by the authorities. We can refer it to criminal investigation or to the board of pharmacy for their action.
The board of pharmacy can take action, but then they have the same kind of administrative procedures act. They have to call them in for hearing, show cause orders, all these things which do take time. And we don't have that many pharmacists we find are really in violation in our area that I know about.
The ones I hear about are after the action has been taken by outside agencies. And there are limited numbers of them. I know of a couple instances some years ago that fell through the cracks. For what reason, I don't know.
But these are people who were selling back when you could sell cough syrups, and so forth.

Mr. GILMAN. Do you feel that the agency that is in charge of licensing at the State level—and I would assume that is a State education department—who is in charge of your licensing?
Dr. ADAMS. Health department.
Mr. GILMAN. The State health department. Are they doing a responsible job in policing the professions with the exceptions of the fact they have a limited number of investigators? Do you feel that they could be doing a lot more?
Dr. ADAMS. In terms of medicine, except for Mr. Niport's input, there is very little that is being done by the health department. It is all being furnished directly from the public. Our complaints come in directly from the public and from physicians, from the medical societies.
And you asked previously whether the medical society is doing all it can. In our State, I don't see how it could do much more. What we need is the ability to pursue and prosecute cases as they are found.
Mr. GILMAN. Well, we want to thank you for your appearance. It apparently sounds to me like we need a lot more attention at both the professional level and the law enforcement level.
Again, I ask, do you have any recommendations to our committee where we may be of help to you in the work that you are trying to do?
Dr. ADAMS. I think if your committee were to underline your concerns to the State government that this would help us in getting our points across for proper funding, more support, and so forth——
Mr. GILMAN. Certainly, we will try to be helpful in that endeavor.
Any other suggestions, gentlemen?
Mr. NIPORT. I can only suggest inasfar as the medicaid laws and regulations to authorize the States to take action when there is a finding of abuse. We do not have the ability to deny benefits where there is flagrant abuse. We have to cut them off at the pass, so to speak, and try to prevent the abuse even though it is there, and it is constant, and it is ongoing, too. And the ability to prevent it is very limited.
Mr. GILMAN. Good suggestion.
Yes, sir.
Mr. PARKER. The only thing I could add, with Mr. Niport's suggestion on MMIS, which is a very effective information-gathering system for medicaid, if we were to go to a triplicate form for the heaviest abused narcotic and other control drugs where this information could then be funneled into a computer system, and at that point monitored for the heaviest abuse, obviously, this would be a mountain of work, and you would only be able to get to the heaviest abuser.
I think this would help effectively cut down on the major amount of illicit distribution of legitimate drugs.
Mr. NIPORT. We have found, if I may, that where physician/prescribers in the past wrote indiscriminately for certain drugs, when it was known they were under surveillance or when it was known they had to put down on the prescription a specific diagnosis, and when they knew it was controlled and someone was watching the incidence of prescribing, it went way down.
I hesitate to say it, but sometimes the knowledge that "big brother" is watching is very effective.
Mr. GILMAN. Any other suggestions?

Mr. PAYNE. I might for my part add just the one that any national program to enhance physician awareness of the long-term effects of certain drugs, any interaction of certain drugs, drugs with alcohol. I don't believe there is sufficient continuing education in pharmacology. And I believe there should be.

Mr. GILMAN. I am inclined to agree with you from the prior testimony we have heard, Mr. Payne. And we certainly will be trying to emphasize some of that.

What are the local societies trying to do with regard to raising the consciousness of their people with regard to the dangers of drug abuse and of the illicit narcotic trafficking? Is there any program in the medical society?

Dr. ADAMS. The State medical society has ongoing programs in this area, but its resources, I think, are relatively limited.

The State medical society a few years ago did, for example, sponsor amphetamine regulations in Maryland. And there exists now in Maryland specific prohibitions against amphetamines, specific prohibitions against the use of amphetamines except in very selected situations which does not include obesity, except for a single, one-time trial.

In other words, you can use legally amphetamines for a total period of 8 weeks, once in any given patient. So anyone who violates that is violating State law.

Mr. GILMAN. Mr. Parker, is the pharmaceutical society doing anything?

Mr. PARKER. We have several publications that we mail out to our membership. We have similar regional meetings. We have had in the past a telephone chain set up where when something happens that it looks like it is going to spread through the area like a pattern of drug distribution, we call the other stores to alert them.

We have been trying now for 2 years to get a mandatory continuing education bill through the State legislature, and they tell us it will get through this year. We found some resistance from some organizations because they feel it is going to add to the cost of pharmaceutical services. But I don't think it will add beyond the value that they receive from the continuing education program.

Mr. PAYNE. One device, if I might bring it up, because I think it is interesting and shows cooperation in this instance between the pharmacy wholesalers, the drug houses in the State of Maryland with the medical assistance program, when we became alerted to the fact through our own investigations that a series of blank medicaid prescriptions had been stolen or lost, disappeared, the doctor can't account for them any more, we immediately send out a pharmacy alert.

And the drug wholesalers who visit or have occasion to touch every store in the State sometimes, generally within 24 or 48 hours, cooperate with us and actually distribute these fliers. So actually within 24 hours, we have put in the hands of the pharmacists in virtually every pharmacy in the State the latest information we have about any scripts that might be stolen or lost.

And they know from that point if they appear, they are not to be filled. We get good cooperation on this.

Mr. GILMAN. It is encouraging to hear that.

Well, I want to thank you, the panelists, for appearing. I want to thank the officers and other members of the Montgomery County Narcotics Unit, Dusty Rhodes—Officer Dusty Rhodes—and those who prepared the exhibit we have in the front of the room for their help in bringing this exhibit before us and pointing out how extensive the forged script problem is.

[See exhibit B on p. 45.]

Mr. GILMAN. Your suggestions certainly have been noted. And we will, I am sure our committee will, explore what we can do to be of help in trying to bring some of those to bear.

Are there any further questions, Mr. Carpentier?

Mr. CARPENTIER. No.

Mr. GILMAN. Mr. Starek?

Mr. STAREK. No. Thank you, Mr. Chairman.

Mr. GILMAN. There being no further questions, the hearing stands adjourned.

[Whereupon, at 5:15 p.m., the hearing was adjourned.]

EXHIBIT A

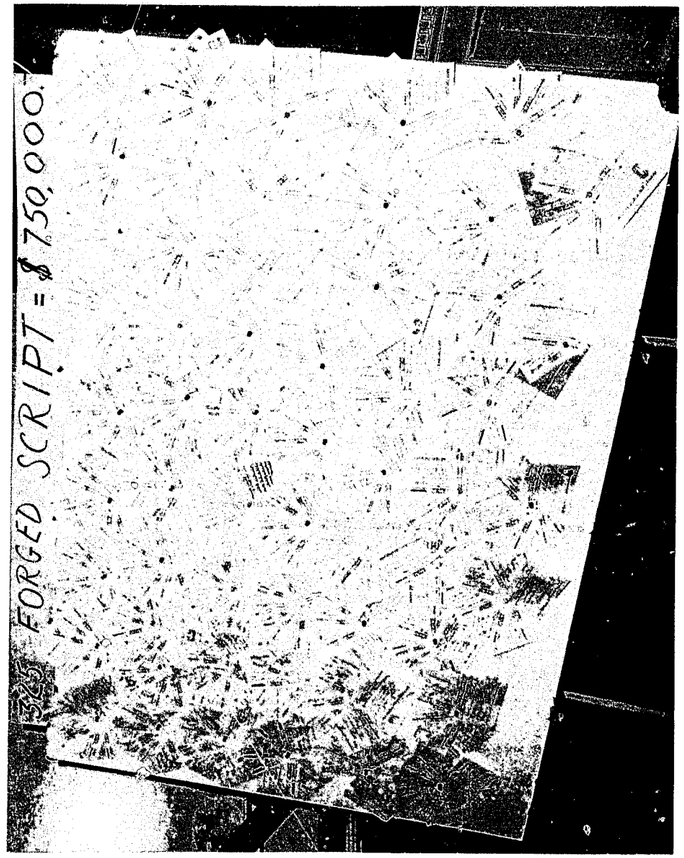
ESTIMATED STREET VALUE OF DIVERTED DRUGS

IN MILLIONS

	Retail Cost/d.u.	Street Price/d.u.	
Amphetamines	$0.06-0.17	$4-12	$240
Dilaudid	$0.17	$40-60	$50
Methaqualone	$0.10-0.13	$5-12	$34
Preludin	$0.24	$5-15	$48
Talwin	$0.13	$4-12	$40
Tuinal	$0.05	$4-12	$14

$426 MILLION

EXHIBIT B



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SUBMISSIONS FOR THE RECORD

THE WHITE HOUSE

WASHINGTON

November 26, 1979

Dear Mr. Chairman:

During the recent hearing held before the House Select Committee on Narcotics Abuse and Control on the Diversion of Licit Drugs Congressman Railsback asked that I furnish a status report on the FDA proposal to withdraw approval for the use of amphetamines in the treatment of obesity.

Enclosed please find a copy of the Federal Register which gives the background of the proposal by the Food and Drug Administration to ban the use of amphetamines for treatment of obesity. The proposed ban would not include the prescribing of amphetamines for the treatment of narcolepsy and minimal brain dysfunction. The FDA has received numerous requests for further hearings on the proposal and is currently considering whether there is sufficient justification on the basis of new data to warrant further hearings.

I hope this information will clarify the issue. Please let me know if I can be of further assistance.

Sincerely,

Lee I. Dogoloff
Associate Director
Drug Policy Staff
Domestic Policy Staff

The Honorable Lester L. Wolff
Chairman
Committee on Narcotic Abuse and Control
U.S. House of Representatives
Washington, D.C. 20515

[Docket No. 79N-0190; DESI 5378]

Amphetamines: Drugs for Human use; Drug Efficacy Study Implementation; Amendment or Previous Notice and Opportunity for Hearing

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces its decision that the indication for the management of exogenous obesity should be removed from the labeling of drug products containing an amphetamine. An opportunity for hearing is offered in the notice.

DATE: Hearing requests due on or before August 16, 1979.

ADDRESSES: Communications forwarded in response to this notice should be identified with the reference number DESI 5378, directed to the attention of the appropriate office named below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

Supplements (identify with NDA number): Division of Neuropharmacological Drug Products (HFD-120), Rm. 10B-04, Bureau of Drugs.

Original abbreviated new drug applications and supplements thereto and notices of claimed investigational exemption for a new drug (identify as such): Division of Generic Drug Monographs (HFD-530), Bureau of Drugs.

Request for Hearing (identify with Docket number appearing in the heading of this notice): Administrative Proceedings Staff—Hearing Clerk Office (HFA-305), Rm. 4-65.

Requests for the report of the National Academy of Sciences-National Research Council: Public Records and Document Center (HFI-35), Rm. 12A-12.

Requests for opinion of the applicability of this notice to a specific product: Division of Drug Labeling Compliance (HFD-310), Bureau of Drugs.

Other communications regarding this notice: Drug Efficacy Study Implementation Project Manager (HFD-501), Bureau of Drugs.

FOR FURTHER INFORMATION CONTACT: Ronald L. Wilson, Bureau of Drugs (HFD-32), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3650.

SUPPLEMENTARY INFORMATION:

Definition

For the purpose of this notice, the term "amphetamine," the name ordinarily used to designate the racemic form of the drug, is used to cover several drugs or isomers within a class, and the term "dl-amphetamine" is used when reference to the racemate is intended. Unless otherwise stated in the text, the term "amphetamine" includes dextroamphetamine, dl-amphetamine, methamphetamine (which is used in this notice to cover both the dextro-isomer and the racemate), a mixture of dextroamphetamine and dl-amphetamine, and salts of the drugs. The drug products described below, which are the subject of this notice, contain an amphetamine in either the single-entity or combination form.

1. NDA 5-378; Desoxyn Tablets containing 2.5 milligrams or 5 milligrams methamphetamine hydrochloride per tablet, Desoxyn Gradumet Tablets containing 5, 10, or 15 milligrams methamphetamine hydrochloride per tablet, and Desoxyn Elixir containing 20 milligrams methamphetamine hydrochloride per 30 milliliters; Abbott Laboratories, 14th and Sheridan Rd., North Chicago, IL 60064.

2. NDA 5-540; Methedrine Tablets containing 2 milligrams or 5 milligrams methamphetamine hydrochloride per tablet; formerly marketed by Burroughs Wellcome & Co., 3030 Cornwallis Rd., Research Triangle Park, NC 27709.

3. NDA 5-756; Drinalfa Tablets containing 5 milligrams methamphetamine hydrochloride per tablet; E. R. Squibb & Sons, Inc., P.O. Box 400, Princeton, NJ 08544.

4. NDA 5-969; Racemic Desoxyephedrine Hydrochloride Tablets containing 5 milligrams dl-methamphetamine hydrochloride per tablet; High Chemical Co., 1760 N. Howard St., Philadelphia, PA 19122.

5. NDA 6-003; Miller-Drine Tablets containing 10 milligrams dl-methamphetamine hydrochloride per tablet; Smith, Miller & Patch, Inc., 401 Joyce Kilmer Ave., New Brunswick, NJ 08902.

6. NDA 10-093; Biphetamine "7½" Capsules, Biphetamine "12½" Capsules, and Biphetamine "20" Capsules, containing 3.75 milligrams, 6.25 milligrams, and 10 milligrams each of dextroamphetamine and amphetamine per capsule, respectively, all as cation exchange resin complexes of sulfonated

polystyrene; Pennwalt Prescription Products, 755 Jefferson Rd., Rochester, NY 14623.

7. NDA 11–522; Obetrol Tablets containing 2.5 milligrams or 5 milligrams of amphetamine asparate, amphetamine sulfate, dextroamphetamine saccharate, and dextroamphetamine sulfate, per tablet; Obetrol Pharmaceuticals, Division of Rexar Pharmaceutical Corp., 398 Rockaway Ave., Valley Stream, NY 11581.

8. NDA 12–042; Eskatrol Spansules containing 15 milligrams dextroamphetamine sulfate and 7.5 milligrams prochlorperazine maleate per sustained-release capsule; Smith, Kline & French Laboratories, 1500 Spring Garden St., Philadelphia, PA 19101.

9. NDA 17–071; Benzedrine Sulfate Spansule containing 15 milligrams of amphetamine sulfate per capsule; Smith, Kline & French Laboratories.

10. NDA 17–076; Dexedrine Spansules containing 5, 10, and 15 milligrams of dextroamphetamine sulfate per sustained release capsule; Smith, Kline & French Laboratories.

11. ANDA 83–563; Amphetamine Sulfate Tablets containing 5, 10, 15, or 20 milligrams of amphetamine sulfate per tablet; Delco Chemical Co., 7 MacQuesten Pkwy., North, Mt. Vernon, NY 10550.

12. ANDA 83–564; Delcobese Spansules containing 1.25, 2.5, 3.75, or 5 milligrams of amphetamine adipate, amphetamine sulfate, dexroamphetamine adipate, or dextroamphetamine sulfate per sustained release capsule; Delco Chemical Company.

13. ANDA 83–735; Dexampex Tablets containing 5 milligrams or 10 milligrams of dextroamphetamine sulfate; Lemmon Pharmacal Co., Sellersville, PA 18960.

14. ANDA 83–889; Methamphetamine Hydrochloride Tablets containing 10 milligrams of methamphetamine hydrochloride per tablet; Lemmon Pharmacal Co., P.O. Box 30, Sellersville, PA 18960.

15. ANDA 83–900; Benzedrine Tablets, containing 5 milligrams or 10 milligrams amphetamine sulfate; Smith, Kline & French Laboratories.

16. ANDA 83–902; Dexedrine Elixir containing 5 milligrams per 5 milliliters of dextroamphetamine sulfate; Smith, Kline & French Laboratories.

17. ANDA 83–903; Dextroamphetamine Sulfate Tablets containing 5 milligrams or 10 milligrams of dextroamphetamine sulfate per tablet; Lannett Co., 9000 State Rd., Philadelphia, PA 19136.

18. ANDA 83–930; Dextroamphetamine Sulfate Tablets containing 10 milligrams of dextroamphetamine sulfate per tablet; Halsey Drug Co., Inc., 1627 Pacific St., Brooklyn, NY 11233.

19. ANDA 84–001; Ferndex Tablets containing 5 milligrams dextroamphetamine sulfate, Ferndale Laboratories, Inc., 780 W. Eight Mile Rd., Ferndale, MI 48220.

20. ANDA 84–051; Dextroamphetamine Sulfate Tablets containing 5 milligrams or 10 milligrams of dextroamphetamine sulfate per tablet; Rexar Pharmacal Corp., 396 Rockaway Ave., Valley Stream, NY 11582.

21. ANDA 84–125; Dextroamphetamine Sulfate Tablets containing 5 milligrams dextroamphetamine Sulfate; Purepac Pharmaceutical Co., 200 Elmora Ave., Elizabeth, NJ 07207.

22. ANDA 84–931; Methamphetamine Hydrochloride Tablets containing 5 milligrams or 10 milligrams of methamphetamine hydrochloride per table; Rexar Pharmacal Corp.

23. ANDA 84–935; Dexedrine Tablets containing 5 milligrams of dextroamphetamine sulfate per tablet; Smith Kline & French Laboratories.

24. ANDA 84–966; Daro Tablets containing 5 milligrams of dextroamphetamine sulfate per tablet; Vitarine Co., Inc., 227–15 N. Conduit Ave., Springfield Gardens, NY 11413.

25. ANDA 85–212; Dextroamphetamine Sulfate Tablets containing 5 milligrams of dextroamphetamine sulfate per tablet; Stanrabs, Inc., Box 3108, Portland, OR 97208.

26. ANDA 85–370; Dextroamphetamine Sulfate Tablets containing 5 milligrams of dextroamphetamine sulfate per tablet; Cord Laboratories, 2555 W. Midway Blvd., Broomfield, CO 80020.

27. ANDA 85–371; Dextroamphetamine Sulfate Tablets containing 10 milligrams of dextroamphetamine sulfate per tablet; Cord Laboratories.

28. ANDA 85–892; Dextroamphetamine Sulfate Tablets containing 10 milligrams of dextroamphetamine sulfate per tablet; Vitarine Co.

29. ANDA 86–521; Dextroamphetamine Sulfate Tablets containing 5 milligrams of dextroamphetamine sulfate per tablet; M. M. Mast & Co., 4152 Ruple Rd., Cleveland, OH 44121.

30. Dexamyl Spansule Capsules and Tablets containing dextroamphetamine sulfate and amobarbital; Smith Kline & French Laboratories; products are not the subject of an approved NDA.

It is the responsibility of every drug manufacturer or distributor to review this notice to determine whether it covers any drug product that the person manufactures or distributes. Such person may request an opinion of the applicability of this notice to a specific drug product by writing to the Division of Drug Labeling Compliance (address given above).

Background

In a Federal Register notice of February 12, 1973 (38 FR 4249), the Food and Drug Administration revised 21 CFR 130.46 (subsequently recodified as 21 CFR 310.504) to announce its findings that single-entity oral anorectic drug products containing amphetamine or dextroamphetamine are effective as short-term adjuncts in the management of obesity. Amphetamine, dextroamphetamine, methamphetamine hydrochloride, and dl-methamphetamine hydrochloride were the subject of a Drug Efficacy Study (DESI) notice published in the Federal Register on July 19, 1974 (39 FR 26459). In that notice amphetamine and dextroamphetamine were evaluated as effective for the treatment of narcolepsy and minimal brain dysfunction in children, and all the drugs were determined to be effective as short-term adjuncts in the management of obesity.

In Federal Register notices of March 30, 1973 (38 FR 8290), September 35, 1973 (38 FR 26748), and May 23, 1975 (40 FR 22570), FDA withdrew approval of all combination products containing an amphetamine, except for Eskatrol Spansules (NDA 12–042), on the basis of a lack of substantial evidence of effectiveness and a lack of proof of safety. Hearing requests were submitted by Smith Kline & French in response to the Federal Register notice of February 12, 1973 (38 FR 4279) for Eskatrol Spansules and their Dexamyl products (related products which are not the subject of an approved NDA0. The hearing request for Eskatrol Spansules is still under review by FDA, while the hearing request for the Dexamyl products is the subject of a court ruling. *Smithkline Corp.* v. *FDA*, 587 F.2d 1107 (D.C. Cir. 1978). With respect to Eskatrol and Dexamyl, the action announced in this notice is in addition to the proceedings presently pending before the agency concerning those drugs.

In another notice of February 12, 1973 (38 FR 4249), the Commissioner of Food and Drugs recognized that the use of amphetamines for long periods of time may lead to drug dependence and abuse. Their potential for abuse is related to their action as a central

nervous system stimulant; they can produce intense psychological dependence and severe social dysfunction. When the drugs were approved for use as an adjunct in the management of obesity, they were approved on a benefit/risk basis which took into consideration their potential for abuse. By limiting the use of these drugs to a short period of time and reducing the opportunity for misuse through regulatory action, the Commissioner concluded that they met the safety requirements of the Federal Food, Drug, and Cosmetic Act and were appropriate, on a benefit/risk basis, for the treatment of obesity for a few weeks as an adjunct to a regimen of weight reduction based on caloric restriction. He stated, however, that persistent abuse of these drugs would necessitate taking further steps to restrict their availability and use.

The policy of the Food and Drug Administration regarding the use of amphetamines in the treatment of obesity, as stated in the February 12, 1973 notice (38 FR 4249), was promulgated as a regulation (21 CFR 310.504; formerly codified as 21 CFR 130.46). The regulation provides the marketing conditions for amphetamines and refers to their efficacy review which found limited effectiveness for the drugs in the treatment of obesity. In light of the conclusions in this notice concerning the marketing conditions for amphetamines, a future Federal Register notice will propose revocation of this regulation.

In a Federal Register notice of October 14, 1977 (42 FR 55374), the Commissioner stated that legally manufactured and marketed amphetamines are continuing to be abused at a level that constitutes an apparently significant public health problem. He further stated that recent information made available to FDA has revealed that, in spite of the restrictions imposed over the last 5 years, there is evidence for the following conclusions:

1. Among prescription drugs, the anorectic agents are commonly used for nonmedical purposes.

2. Among the anorectic drugs, amphetamines account for more abuse episodes than other drugs in the class and also have the highest rate of abuse of all drugs in the class.

3. There has been no significant decrease in the rate of abuse of amphetamines over the past 3 years. The major reduction in their abuse appears to have occurred between 1970 and 1973 as a result of regulatory actions taken during that time, and little additional change has occurred since then.

4. A significant amount of the amphetamines used for abuse purposes comes from supplies that are legally manufactured, shipped, or prescribed.

5. There is no new evidence to challenge the previous FDA conclusion that amphetamines have no advantage over the nonamphetamine anorectic drugs as an adjunct in the treatment of obesity.

The October 14, 1977 notice also stated that because of this continuing level of abuse of amphetamines, the Commissioner believes that, consistent with his stated intent in the February 12, 1973 notice, further action under the act may be necessary to protect the public health. To provide an open forum for comments on information provided in the notice on the abuse of legally manufactured amphetamines, the Commissioner announced that a public hearing would be held on December 2, 1977. He specifically requested well-documented comment on the merits of the following possible course of action:

1. Remove the anorectic indication from the labeling of amphetamine drug products.

2. Retain the indication of narcolepsy for dextroamphetamine and dl-amphetamine products, and retain the indication of minimal brain dysfunction for dextroamphetamine, dl-amphetamine and methamphetamine products. (A notice published in the Federal Register of October 24, 1978 (43 FR 49573) eliminated the term "minimal brain dysfunction" from physician labeling in order to more accurately describe the behavioral syndromes of this indication.)

3. Require patient labeling which would provide certain information on use and warnings concerning the potential for abuse of these drugs.

On November 22, 1977 (42 FR 59917), the agency announced that the administrative record of the public hearing would remain open for 30 days after the December 2, 1977 hearing to permit sufficient time for all interested persons to submit written data, information, or views on the current patterns of medical use and abuse of amphetamines.

Review of Testimony and Written Submissions

Since the public hearing was held, FDA has carefully reviewed the testimony and written submissions (written submissions will hereafter be referred to in the text as comments). Among those who participated in the public hearing or submitted comments were representatives from the Drug Enforcement Administration, National Institute of Drug Abuse, Canadian Ministry of Health, the academic and scientific community, industry groups, health organizations, and consumer groups. A total of 38 persons gave testimony and 31 persons submitted comments. Of the 55 persons who testified or commented on the removal of the anorectic indication from the labeling of amphetamine products, 30 persons supported the action, while 25 persons opposed it. The 14 persons who testified or commented on retaining the indication of narcolepsy and minimal brain dysfunction presented unanimous support for this action. Of the 14 persons who testified or commented on patient labeling for amphetamine products, 12 supported the action, while 2 opposed it. The most substantial testimony and comments have been identified and are briefly discussed below in alphabetical order according to the last name of the person:

1. *Mr. Peter Bensinger, Administrator of the Drug Enforcement Administration (DEA).*—Mr. Bensinger reported that substantial evidence has been presented for many years to FDA and Congressional committees which shows that amphetamines are frequently used for nonmedical purposes by a sizable segment of the population, that such use can result in severe physical and psychological impairment, and that legally manufactured products provide for and sustain such usage. On the diversion of legally manufactured products, he stated that DEA estimates that reported thefts account for roughly one-tenth of the amphetamines actually diverted, the remaining nine-tenths being diverted primarily through promiscuous script writing physicians, forged prescriptions, illegal sales, and dispensing fat clinics. According to Mr. Bensinger, a principal factor in the higher rate of diversion for amphetamines is their ready availability through dispensing physicians. He reported that one physician in New England was responsible for dispensing 2 percent of the annual methamphetamine quota of the United States, or roughly one million dosage units. He added that despite the expenditure of substantial resources to bring action against this physician, the approved indication for short-term obesity treatment provides this physician and many others with considerable latitude to skirt the law.

2. *Dr. David Brillinger, Professor of Statistics, University of California at Berkeley.*—Dr. Brillinger stated that

neither the October 14, 1977 notice nor the IMS America report presents a complete statistical analysis of the time series data since they did not spell out the assumptions of the fitted statistical models on which their conclusions are based. He stated that the conclusions of the report and the notice appear essentially subjective. He concluded that the assumptions and validity of statistical models, confidence intervals, error analysis, and possible component series should be explored in the prediction of DAWN mentions data.

3. *Dr. James Cooper, Director of the Office of Medical and Professional Affairs at the National Institute on Drug Abuse (NIDA).*—Dr. Cooper stated that NIDA believes that the benefits of amphetamines to the individual and the public in the treatment of obesity are outweighed by the public health risks associated with the use of these substances. The data sources available to NIDA show that incidence and prevalence of non medical use of amphetamines remain high. He reported that, despite the prescribing of alternative non amphetamine anorectics, the strict scheduling of amphetamines, and the exercising of restraint by physicians in prescribing amphetamines, data suggest that the incidence and prevalence of non medical use of amphetamines is actually increasing, particularly among the young. Based on an analysis of these data which was summarized in his testimony, Dr. Cooper stated that NIDA supports removing the indication for obesity from amphetamines, and requiring that package labeling warn consumers of the potential harmful effects of amphetamines from continuous long-term use.

4. *Dr. John S. de Cani, Professor and Chairman, Department of Statistics, University of Pennsylvania.*—Dr. de Cani disagreed with FDA's decision to exclude the DAWN data from consistently reporting crisis centers. He also suggested using the amphetamine quota data instead of prescription data to calculate the denominator for the problem index (abuse rate).

Dr. de Cani stated that for all Schedule II anorectic drugs, the average number of monthly DAWN mentions decreased from 1974 through 1976 for each of the four consistently reporting facility groups (crisis centers, emergency rooms, medical examiners, and all facilities). For example, in Table 1 of his testimony, Dr. de Cani observed that the average number of monthly DAWN mentions decreased 20.7 percent from 1974 to 1975 and 5 percent from 1975 to 1976 for emergency rooms; for medical examiners the decreases were 27.6 percent from 1974 to 1975 and 27.3 percent from 1975 to 1976. Dr. de Cani also stated that for all Schedule II anorectic drugs, the number of average monthly DAWN mentions per 1,000 kilograms of amphetamine quota decreased from 1974 through 1976 for each of the four facility groups.

5. *Dr. John D. Griffith, Chief of the Stimulant Unit of the Addiction Research Center (NIDA).*—Dr. Griffith testified that amphetamine abuse is not a harmless practice, but can produce severe adverse effects and dependency on the drug. He stated that dependency often begins with a therapeutic use of the drug, but the use escalates into a chronic, repetitive pattern. This dependency, according to Dr. Griffith, becomes very serious when the chronic use of amphetamines produces insomnia and anxiety, among other symptoms, which gives the person the predisposition to use or abuse barbiturates, alcohol, and minor tranquilizers. He further stated that dependency on amphetamines is as difficult to treat as narcotic addiction. Dr. Griffith also testified that amphetamines are now known to produce a psychosis of a paranoid type which may result from either chronic or acute exposure to amphetamines. A month's prescription for an amphetamine will, according to Dr. Griffith, produce a psychosis in perhaps 80 percent of the patients if the drug is taken improperly. Furthermore, he stated that there is no valid method for identifying or excluding patients who are sensitive to amphetamines as to dependency or psychosis or both. In conclusion, he stated that patients are not only placed at risk when they use amphetamines, but are given a drug that is not much better than placebo for weight loss.

6. *Dr. Lester Grinspoon, Associate Professor of Psychiatry at Harvard University.*—Dr. Grinspoon supports the removal of the anorectic indication from the labeling of amphetamines. He reported that there appear to be few conditions that justify prescribing amphetamines. He questioned the use of amphetamines for weight reduction under any circumstances. He commented that after the 3–4 week euphoric high, which may cause diminished food intake and consequent weight loss, amphetamines are no longer effective as anorectics unless the user increases the dose, thus initiating a pattern of abuse. He commented that amphetamines are useful to a very select group suffering from certain varieties of narcolepsy and a number of truly hyperkinetic children, but should be prescribed only after their potential dangers are carefully weighed against their possible value.

7. *Dr. John Henderson, Director of the Bureau of Drugs and Health Protection Branch of the Canadian Ministry of Health.*—Dr. Henderson stated that legislation passed in Canada on November 1, 1971, essentially restricted the use of amphetamines to the treatment of narcolepsy, hyperkinetic disorders in children, mental retardation, epilepsy, and Parkinsonism. Any physician who needs to prescribe amphetamines for individual patients for conditions outside the approved list must obtain the authorization of the Bureau of Drugs of the Health Protection Branch. Dr. Henderson pointed out that only 36 such requests have been received for the 12-month period preceding November 1977. As there are 36,000 physicians in Canada, he observed that "Canadian physicians are practicing a high standard of medical care with a very low use of the more hazardous members of the amphetamine class of drugs." After Canada passed the legislation in 1971 that virtually ended the use of amphetamines for treating obesity, the importation of amphetamine drugs (amphetamines are not manufactured in Canada) had dropped from 757 kilograms in 1971 to 0.710 kilograms in 1977.

8. *Mr. David Joranson, Drug Abuse Policy Specialist with the Wisconsin Bureau of Alcohol and Other Drug Abuse and Dr. Karl Marquardt, Executive Secretary of the Pharmacy Examining Board of Wisconsin.*—Dr. Marquardt and Mr. Joranson conducted a study in Wisconsin on the abuse problem of a name brand amphetamine which involved a high volume of sales in some pharmacies. At the request of the Controlled Substances Board and Pharmacy Examining Board, they reviewed data that had been compiled and tabulated through the Automation of Reports of Consummated Orders System (ARCOS) of DEA and identified 465 pharmacies that had purchased 800,000 dosage units of this name brand amphetamine in 1975. Among these 465 pharmacies, 10 were identified as the purchasers of the largest quantity of this amphetamine product during 1975. The study then identified 73 physicians who had issued prescriptions for this amphetamine product which were subsequently dispensed by one or more of the 10 pharmacies during 1975. Of the total prescriptions written for this drug product by the 73 physicians, 62.7 percent were written by 8 physicians. One physician had issued 25 percent of the total prescriptions written by the 73 physicians. Another physician among the 73 had issued 92 percent of his total prescriptions for this amphetamine product. As this name brand amphetamine is only one amphetamine product in Schedule II, Dr. Marquardt and Mr. Joranson pointed out that the problem could be much larger if other amphetamine abuse by overprescribing physicians is considered. They concluded that the problem probably extends to other States, as Wisconsin is ranked 27th in per capita consumption of amphetamines. Mr. Joranson also reported that the Controlled Substances Board supports the three actions outlined in the October 14, 1977 notice.

9. *Dr. Albert Madansky, Professor of Business Administration, University of Chicago.*—For IMS America's data (Figure 8 of the October 14, 1977 notice), Dr. Madansky proposed two different models to predict trends in DAWN mentions. From his first fitted quadratic model, Dr. Madansky predicted that the estimated minimum of the abuse trend occurred in October 1976. From his second logarithmic transformed model, Dr. Madansky predicted that in each year the number of mentions will decrease by 11 percent. He predicted that by the end of 1979, the level of deseasonalized Schedule II mentions from all consistently reporting facilities will drop to 313 per month.

For FDA's data (Figure 9 of the October 14, 1977 notice), Dr. Madansky stated that the statistically significant decreasing trend was found from January 1974 through December 1976 for the observed data (amphetamines mentions with other drugs). He also saw no significant correlation between the prescription sales and Schedule II DAWN mentions for all consistently reporting facilities. He then concluded that the FDA's abuse rate (DAWN mentions/prescriptions) does not provide reliable information about drug abuse.

10. *Dr. John W. Rupel, member of the Wisconsin Medical Examining Board.*—Dr. Rupel explained that the Wisconsin Medical Examining Board is the State governmental agency that licenses and disciplines physicians and defines acceptable standards of professional practice. After an investigation into the dispensing and prescribing of scheduled stimulant drugs by Wisconsin physicians, the Board found that approximately 2 percent of the State's physicians are responsible for prescribing and dispensing the total amount of scheduled anorectic drugs that reached the public through legal channels in 1975. The Board could find no credible scientific evidence that is statistically valid and reliable to show that any of the scheduled anorectic drugs had more than a trivial advantage, at best, over placebo therapy in either the short- or long-term management of obesity. Dr. Rupel reported the investigation revealed that, of all the scheduled anorectic drugs, amphetamines have the most serious and widespread abuse. The findings of the investigation were summarized by Dr. Rupel as follows:

> A tiny fraction of physicians in our State are prescribing and dispensing large amounts of abusable drugs for a condition for which these drugs offer very little, if any, prospect of benefit. The distribution of an abusable substance with no likelihood of significant gain to the patient is a danger to the health, safety, and welfare of the public, and as such constitutes unprofessional conduct.

After reviewing these findings, the Board promulgated an administrative rule that defines as unprofessional conduct the prescribing of an amphetamine for any purpose other than the treatment of narcolepsy, hyperkinesis, drug-induced brain dysfunction, certain refractory forms of depression, or clinical research under appropriate safeguards. Any Wisconsin physician who violates the rule does so at the risk of having his or her license to practice medicine suspended or revoked. In concluding his presentation, Dr. Rupel stated that the Wisconsin experience with amphetamines and the Board's findings clearly support the evidence set out in the October 14, 1977 notice. He urged the removal of the anorectic indication as it would directly assist the efforts to deal with the amphetamine problem at the State level.

11. *Dr. Philip Tannenbaum, Medical Director and Vice-President for Medical Affairs of Smith, Kline and French Laboratories.*—Dr. Tannenbaum said that FDA's use of the problem index of abuse rate (amphetamine DAWN mentions/amphetamine prescription sales) is debatable. He stated that the data bases used to derive this index would overestimate the numerator and underestimate the denominator. For this reason, the relative contribution of DAWN mentions from legitimately produced amphetamines would be overestimated. He suggested that a revised problem index for legitimately produced amphetamines should be used, i.e., DAWN mentions associated with legitimately produced amphetamines/prescription sales + direct physician dispensing + thefts.

Dr. Tannenbaum also disagreed with FDA's decision to exclude from the analysis the following consistently reporting DAWN mentions: all data from crisis centers, all mentions involving jargon terminology, and all mentions for phenmetrazine. He contended that without the above DAWN mentions, the DAWN data (DAWN amphetamine mentions together with other drugs) used in FDA's Figure 9 of the October 14, 1977 notice only accounted for one-fifth of the data included in Figure 8. He also stated that a 27-percent reduction in total DAWN mentions (amphetamine DAWN mentions with other drugs) was still observed between 1974 (1,655 mentions) and 1976 (1,209 mentions) if the data are used from Figure 9 of the October 14, 1977 notice.

12. *Dr. Kennard Yaffe, Chairman of the Committee on Drugs of the Maryland State Medical Society.*—Dr. Yaffe spoke about the promulgation of amphetamine regulations in the State of Maryland when it became apparent to physicians of Maryland that amphetamines were severely abused and that the benefits from their use were very limited. "The benefits," according to Dr. Yaffe, "were thought to be of value in narcolepsy and the hyperkinetic syndrome of childhood, and the greatest abuse was thought to derive from prescribing by physicians of amphetamines for obesity." He briefly described the regulations as allowing amphetamines, except for methamphetamine, to be prescribed for narcolepsy and hyperkinetic syndrome of children, and requiring the conditions to be well documented in the physician's record. For other used, "the physician must ask permission from the Division of Drug Control, setting forth the problem in such detail as to permit a reasoned judgment to be made." Dr. Yaffe stated that this program has produced a sharp decline in the prescribing of amphetamines in Maryland without any problems in the treatment of obesity. He added that the removal of the anorectic indication would assist in reducing the abuse of amphetamines on the State level.

The transcript of the public hearing and a copy of all comments submitted is on file in the office of the Hearing Clerk at the address given above.

Findings of FDA

The testimonies of Drs. de Cani, Madansky, and Tannenbaum, and the comment of Dr. Brillinger were statistical criticisms of FDA's analysis of data provided to FDA from the DAWN system. After a review of their criticisms, the Director of the Bureau of Drugs finds no new information which refutes the conclusions of the October

14, 1977 notice (p. 55375) as revealed by the DAWN data. His response to these statistical criticisms of FDA's analysis of the DAWN and IMS America prescription data is as follows.

1. Dr. Brillinger's comments are valid regarding the assumptions and validity of statistical models, confidence intervals, error analysis, and possible component analysis. However, because of the limited number of data points available for our analysis (36 points), Dr. Brillinger's comments are somewhat more theoretical than practical. In response to Dr. Brillinger's comments, FDA has calculated the estimated slopes, the 95 percent confidence limits of the slopes, and the squared multiple correlation coefficient for several DAWN trend lines, to verify its statistical model. A statistically significant decreasing trend was found between January 1974 and December 1976 for amphetamine DAWN mentions with other drugs. For amphetamine mentions alone, however, no significant decreasing trend was found from January 1974 through December 1976.

2. The results of FDA's analysis of the DAWN data were quite different from Dr. de Cani's findings. For example, DAWN mentions in conjunction with other drugs for all Schedule II anorectics (including phenmetrazine), demonstrated only a 5-percent decrease from 1975 (90 mentions) to 1976 (85 mentions) for the medical examiners, compared to a 27.3-percent decrease cited by Dr. de Cani. The decrease was 1 percent from 1975 (1,334) to 1976 (1,314) for emergency room mentions, compared to a 5-percent decrease cited by Dr. de Cani. As for DAWN mentions alone for all Schedule II anorectic drugs, only a 0.9-percent decrease from 1975 (683 mentions) to 1976 (677 mentions) was found.

The figures cited in Table 2 of Dr. de Cani's testimony paper are also questionable. Because he also did not calculate the correlations between the DAWN mentions and the annual production quota data, his figures of average monthly DAWN mentions per 1,000 kilograms of amphetamine quota are not likely to be reliable.

3. Dr. Madansky failed to explain how satisfactorily his statistical models fit the observed data. He did not demonstrate that his proposed models were better than the linear models used by IMS and FDA for prediction purposes. His long-term extrapolation of the DAWN data to the end of 1979 by the fitted logarithmic model without explaining the appropriate validation procedures of the fitted model is not convincing.

Dr. Madansky evaluated only part of the data presented in the October 14, 1977 notice, namely the DAWN amphetamine mentions in conjunction with other drugs only; the amphetamine DAWN mentions alone were not analyzed. With regard to the correlation of prescription sales and DAWN mentions, his statement is true that there is no significant correlation between 1974 and 1976 for quarterly data. However FDA's reanalysis of the updated data base on monthly prescription sales and DAWN data from January 1974 through June 1978 does show statistically significant correlations.

4. As to Dr. Tannenbaum's comments on FDA's use of the abuse rate, the numerator of the abuse rate used by FDA does not appear to be overestimated. FDA excluded the jargon and crisis center data when calculating this numerator in order to avoid some of the previous criticisms of the DAWN data. Data were excluded from the DAWN crisis centers because of the invalidity of crisis center contacts, the influence of variable case-finding operations, and double counts. Data reported to DAWN in jargon terminology were also excluded because the reliability of the identification was more uncertain than when the report was made in standard medical terminology. In addition, FDA used the DAWN consistently reporting panel of emergency rooms and medical examiners to eliminate much of the instability of the DAWN system. These panels are composed of the facilities that have reported consistently during the time period studied. Thus, FDA's estimated level of abuse used in calculating the abuse rate is not necessarily overestimated as Dr. Tannenbaum indicated.

Dr. Tannenbaum commented that Figure 9 of the October 14, 1977 notice (FDA's data) shows a 27 percent decline in mentions with other drugs between 1974 and 1976. His calculation was based only on DAWN amphetamine mentions with other drugs. When the DAWN amphetamine mentions were examined alone, there was no apparent change between 1974 (604 mentions) and 1976 (621 mentions).

The Director thus finds no new information in the testimony and comments to refute the evidence of the October 14, 1977 notice on the current abuse of amphetamines. He does, however, find additional information which correlates the abuse of amphetamines with legitimate prescribing of the drugs for the treatment of obesity. He finds the testimony of Drs. Marquardt, Rupel, and Yaffe, and Messrs. Bensinger and Joranson especially revealing as to the substantial abuse of amphetamines by high volume prescribers and dispensers of the drug for the treatment of obesity. In addition, the testimonies of Drs. Henderson, Marquardt, and Yaffe demonstrate that when controls are instituted on prescribing amphetamines for this condition, the prescribing of the drugs decreases very sharply without any deprivation or harm to persons who have problems with obesity. Dr. Henderson's testimony further revealed that after legislation was passed in 1971, the overwhelming majority of the physicians in Canada did not request permission to use amphetamines in the treatment of obesity, which undoubtedly indicates that amphetamines are not an essential drug for this condition. Moreover, this information further corroborates the testimony of Drs. Griffith and Grinspoon, who find amphetamines to have limited effectiveness in weight loss.

As to retaining the indication of dl-amphetamine and dextroamphetamine for narcolepsy, and retaining the indication of dl-amphetamine, dextroamphetamine, and methamphetamine for the treatment of children with a behavioral syndrome, the testimony and comments presented on this issue unanimously supported the retention of these indications because of their medical benefit. With regard to their potential for abuse, the Director believes that with the removal of the anorectic indication from the labeling of amphetamine products, these remaining indications will not provide a source of the drugs for abuse. Because at least 80 percent of the legal medical use of these drugs has been for weight reduction, the recommended production quotas for amphetamines will be sharply decreased after the anorectic indication is removed. As this action will substantially reduce the major supply of legally manufactured and dispensed amphetamines, the abuse rate of the drugs will also be reduced as the major source of their diversion will be eliminated. The Director therefore concludes that the continued use of these drugs for narcolepsy and the treatment of children with behavioral syndromes at this time appears to have more medical benefit than risk for abuse.

The October 14, 1977 notice also invited participants to comment on the merits of requiring patient labeling which would provide warnings against using amphetamines for weight reduction (and against using

methamphetamines to treat narcolepsy). Based upon comments received and other available information, the Director concludes that this issue should be deferred until after the action proposed in this notice is implemented. If at that time he determines that legally manufactured amphetamines continue to be abused at an unacceptable level, he will consider patient labeling for amphetamines as an additional measure to curb their abuse. Patient labeling for amphetamines may also be required when the rules have been promulgated under which patient labeling will be required for prescription products in general.

Recent Information

Since the December 2, 1977 hearing, FDA obtained additional DAWN and National Prescription Audit (NPA) data through June 1978 which permitted an updated analysis. Furthermore, FDA was able to obtain data sets from January 1974 through June 1978 on a monthly basis rather than quarterly; thus providing many more individual data points on which to base the statistical analyses. As stated previously in the document, the original analysis of the 1974 through 1976 data excluded the jargon and crisis center data when calculating the numerator of the abuse rate in order to avoid some of the previous criticisms of the DAWN data. It excluded data from the DAWN crisis centers because of the invalidity of crisis center contacts, the influence of variable case-finding operations, and double counts. It also excluded from the first analysis data reported to DAWN in jargon terminology because the reliability of the identification was more uncertain than when the report was made in standard medical terminology. In addition, FDA used the DAWN consistently reporting panel of emergency rooms and medical examiners to eliminate much of the instability of the DAWN system. These panels are composed of the facilities which have reported consistently during the time period studied.

To respond to some of the criticisms of its original analysis, FDA undertook an updated statistical analysis of monthly DAWN mentions and monthly NPA data for the period January 1974 through June 1978 to address several issues raised in these criticisms at the December 2, 1977 public hearing, namely: (1) to determine whether a correlation exists between the monthly DAWN data and the monthly NPA data, (2) to assess the trend over time for both DAWN mentions and NPA data and to fit these data with an appropriate statistical model, (3) to examine the effects of including or excluding jargon groups for amphetamine DAWN mentions alone and amphetamine DAWN mentions with other drugs, and (4) to evaluate the relationship of DAWN mentions for amphetamines versus DAWN mentions for other anorectic drugs and phenmetrazine when adjusted for their relative prescription sales.

FDA's updated statistical analyses generally show a consistent pattern whether data from the jargon group are included or excluded and whether DAWN mentions for amphetamines are used alone or with other drugs. These analyses demonstrate the following:

1. There are observed and predicted downward trends in amphetamine DAWN mentions and amphetamine prescription sales over this period. (See Figures 1 and 2.)

2. There is a significant positive correlation between reported monthly DAWN mentions and the monthly NPA data. As an example of the pattern of this observed correlation, Figure 3 displays a scatter diagram for DAWN mentions for amphetamines alone (jargon excluded) on which the estimated sample correlation is 0.83 ($P<0.01$).

3. Despite observed and predicted downward trends in both monthly DAWN mentions and NPA prescription sales for the period January 1974 through June 1978, the amphetamines have consistently demonstrated over all months statistically significant increases in DAWN mentions compared with other anorectic drugs above what would be expected when these DAWN mentions are adjusted for their relative prescription sales. The procedures for adjusting DAWN mentions by their prescription sales are reasonable because of the existing significant correlations between these two data sets. Figures 4(a) through 4(d) display these relative increases in DAWN mentions associated with amphetamines for four data sets: (a) amphetamines DAWN mentions alone, jargon group excluded, (b) amphetamines DAWN mentions alone, jargon group included, (c) amphetamines DAWN mentions with other drugs, jargon group excluded, and (d) amphetamines DAWN mentions with other drugs, jargon group included.

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Figure 1

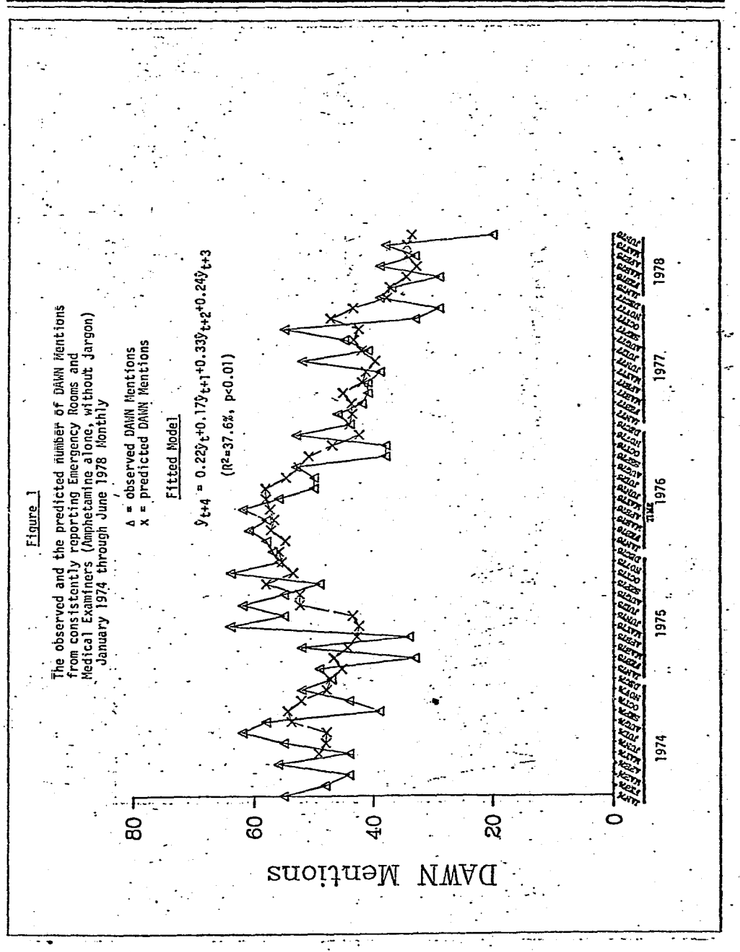
The observed and the predicted number of DAWN Mentions from consistently reporting Emergency Rooms and Medical Examiners (Amphetamine alone, without Jargon) January 1974 through June 1978 Monthly

Δ = observed DAWN Mentions
x = predicted DAWN Mentions

Fitted Model

$$y_{t+4} = 0.22y_t + 0.17y_{t-1} + 0.33y_{t-2} + 0.24y_{t-3}$$

(R^2=37.6%, p<0.01)



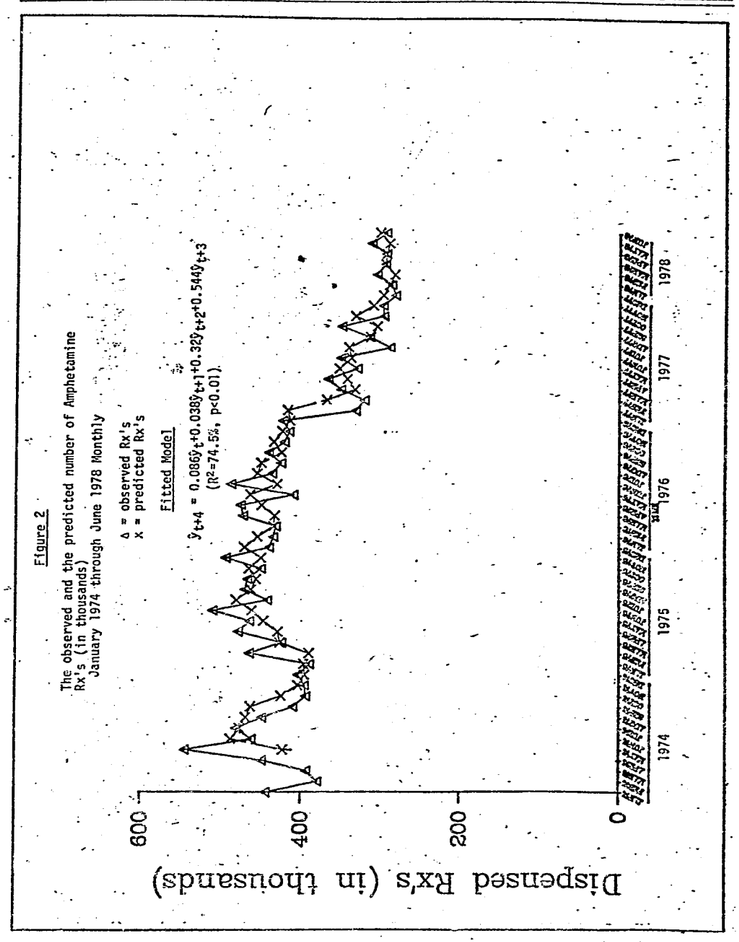


Figure 2

The observed and the predicted number of Amphetamine Rx's (in thousands) January 1974 through June 1978 Monthly

Δ = observed Rx's
x = predicted Rx's

Fitted Model

$\hat{y}_{t+4} = 0.086y_t + 0.038y_{t-1} + 0.329y_{t-2} + 0.549y_{t-3}$
$(R^2 = 74.5\%, p < 0.01)$.

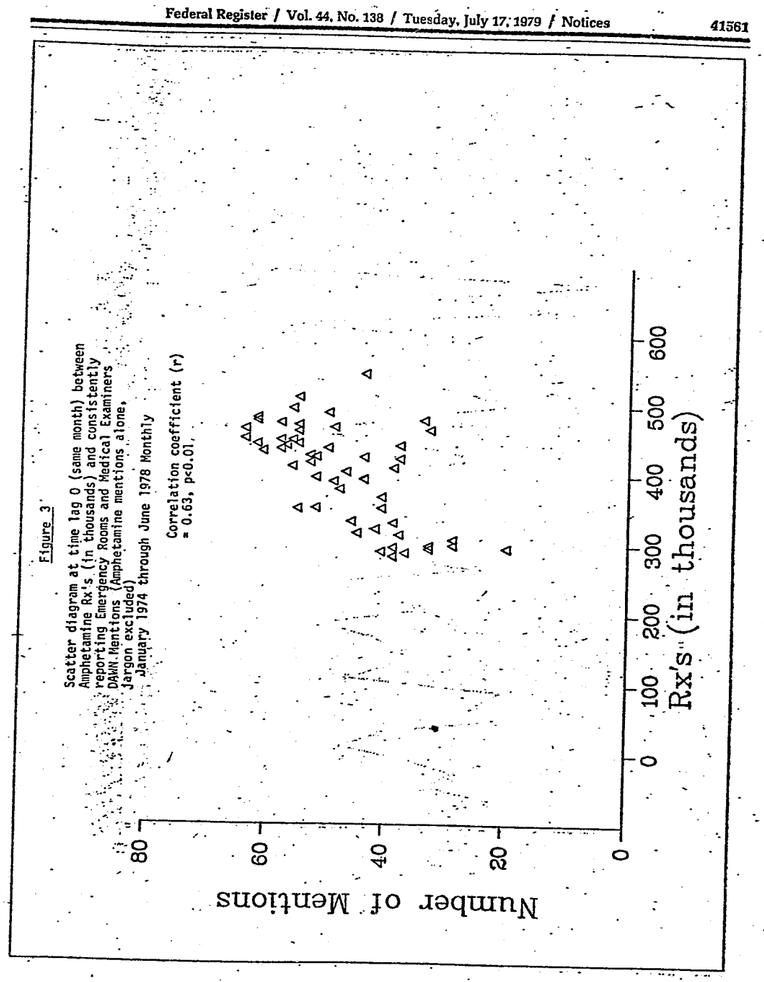


Figure 3

Scatter diagram at time lag 0 (same month) between Amphetamine Rx's (in thousands) and consistently reporting Emergency Rooms and Medical Examiners DAWN Mentions (Amphetamine mentions alone, Jargon excluded) January 1974 through June 1978 Monthly

Correlation coefficient (r) = 0.63, p<0.01

Figure 4(a)

Relative increase of reported DAWN Mentions for Amphetamines vs. other anorectic drugs and phenmetrazine adjusted for relative share of prescription sales (Amphetamines DAWN Mentions alone, without Jargon) January 1975 through June 1978 Monthly

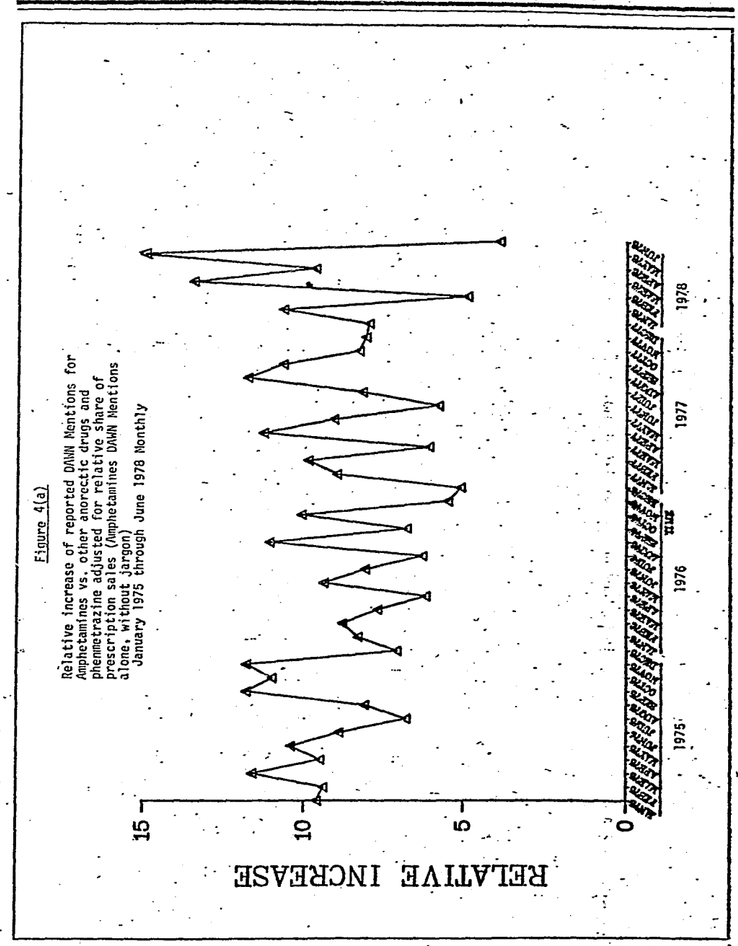


Figure 4(b)

Relative increase of reported DAWN Mentions for Amphetamines vs. other anorectic drugs and phenmetrazine adjusted for relative share of prescription sales (Amphetamines DAWN Mentions alone, with jargon)
January 1975 through June 1978 Monthly

Figure 4(c)

Relative increase of reported DAWN Mentions for Amphetamines vs. other anorectic drugs and phenmetrazine adjusted for relative share of prescription sales (Amphetamines DAWN Mentions with other drugs, without jargon)
January 1975 through June 1978 Monthly

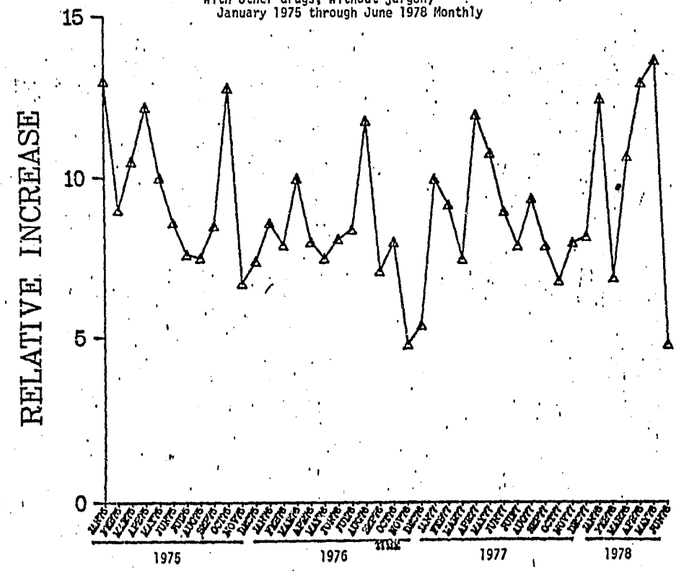
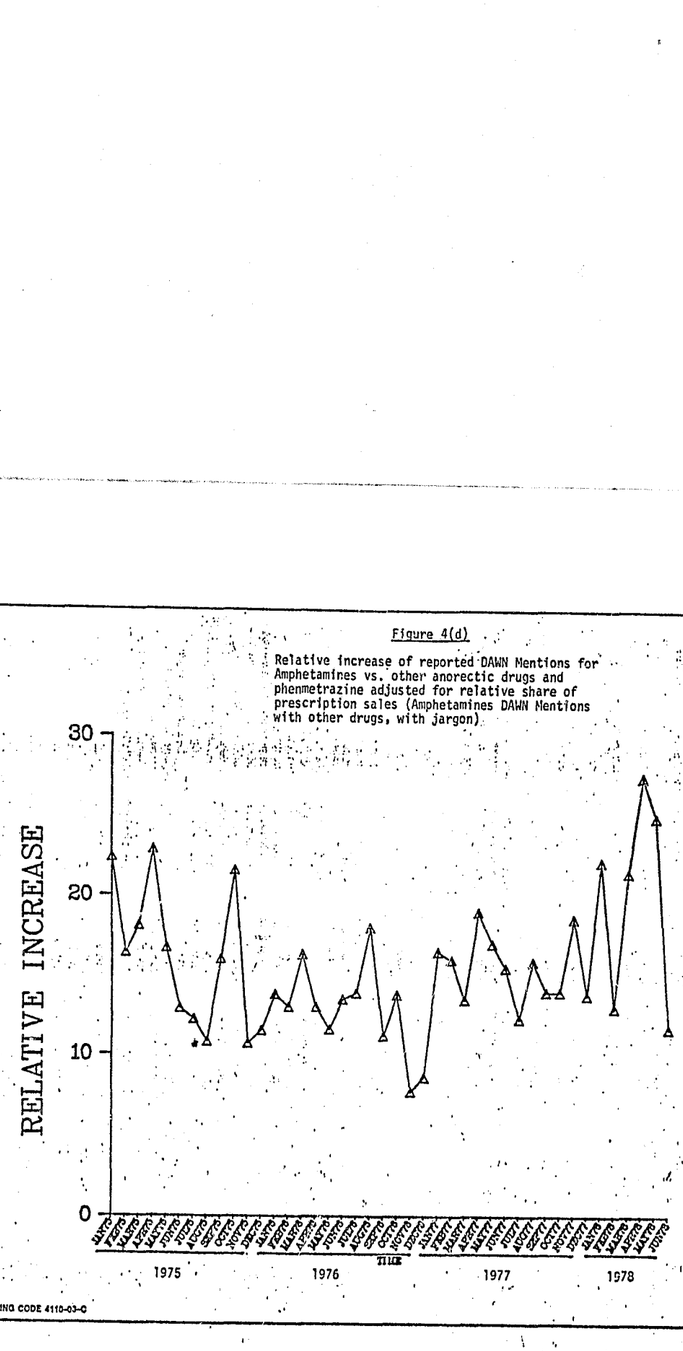


Figure 4(d)

Relative increase of reported DAWN Mentions for Amphetamines vs. other anorectic drugs and phenmetrazine adjusted for relative share of prescription sales (Amphetamines DAWN Mentions with other drugs, with jargon)



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In addition to reanalyzing the DAWN data, FDA has also reviewed information made available since the publication of the October 14, 1977 notice. This information from DEA, NIDA, and the National Clearinghouse for Poison Control Centers demonstrates that there still remains a substantial degree of amphetamine abuse. This recent information is described below as it relates to the conclusions and data described in the October 14, 1977 notice.

1. Among prescription drugs, the anorectic agents are commonly used for non medical purposes (p. 55375).

The October 14, 1977 notice referred to a household survey conducted in 1975 and 1976 on drug use among a sample population in communities throughout the United States. According to recent update from NIDA, the prescription stimulant category is still the category of prescription drugs most abused. The update also shows that there has been an increase in the number of 18–25 year olds who have engaged in the non medical use of stimulants. Data from the rural population study and veterans were not available for an update.

2. Among the anorectic drugs, amphetamines account for more abuse episodes than other drugs in the class and also have the highest rate of abuse of all drugs in the class (pp. 55375–55378).

As stated above, from January 1975 through June 1978 the reported DAWN mentions associated with amphetamines were approximately 8 to 14 times higher than reported DAWN mentions for other anorectic drugs when adjusted for their relative prescription sales. The monthly data between January 1974 and June 1978 also reveal significant positive correlations between amphetamine DAWN mentions and NPA data.

3. There has been no significant decrease in the rate of abuse of amphetamines over the past 3 years (p. 55379).

The NPA data show that the legal prescribing of amphetamines decreased 26 percent from 1976 to 1977 and 14 percent from 1977 to 1978, while the prescribing of other anorectics decreased only 9 percent from 1976 and 1977 and 8 percent from 1977 to 1978. Despite the decline in legal prescribing, information available after publication of the October 4, 1977 notice shows that there still exists a significant amount of amphetamine abuse. Data, updated through June 1978, demonstrate that DAWN mentions for amphetamines correlate to their prescription sales and still have consistently remained proportionately higher than mentions for other anorectics relative to their proportional volume of prescription sales. The conclusion that no significant reduction in the relative occurrence of amphetamine abuse has occurred since January 1974 also continues to be supported by recent data from the National Clearinghouse for Poison Control Centers. These data record the collective experience of the 580 poison centers throughout the United States. For 1977 the data still indicate that Schedule II drug products containing amphetamine continue to be reported more often each year as causing injury to users than do all anorectics in Schedules III and IV combined. In addition, DEA theft reports indicate that there was a 10 percent increase in legally manufactured dosage units of amphetamine and methamphetamine stolen in 1977 over 1976 (5.5 million dosage units in 1977 vs. 5.0 million in 1976). For other anorectics, there was a 27-percent decrease in dosage units stolen in 1977 compared with 1976 (4.0 million dosage units in 1977 vs. 5.5 million in 1976).

The substantial decrease in the legal prescribing of amphetamines as reported by the NPA is much greater than the decline in the retail prescription sales in general (26 percent vs. 3 percent in 1977 and 14 percent vs. 1 percent in 1978). This decline could be attributed to the publicity about Congressional hearings in 1976, the public hearing on amphetamines in the latter part of 1977, and actions by certain States to reduce or prohibit prescribing and dispensing amphetamines for the management of exogenous obesity.

4. A significant amount of amphetamines used for nonmedical purposes comes from supplies that are legally manufactured, shipped, or prescribed (p. 55383).

As previously stated, DEA theft reports indicate that thefts of legally manufactured dosage units of amphetamine and methamphetamine in 1977 increased 10 percent over 1976 (5.5 million dosage units in 1977 vs. 5.0 million in 1976), compared to a 27-percent decrease in thefts of other anorectics. These reports suggest that amphetamines remain the anorectic drugs most frequently desired by those who steal anorectic drugs. In addition to theft reports, reports from DEA's Diversion Investigation Units (DIU) still show that health professionals, including physicians and pharmacists, are involved in diverting a substantial amount of legal amphetamines to illicit use.

5. There is no new evidence to challenge the previous FDA conclusion that amphetamines do not have any advantage over the nonamphetamine anorectic drugs as an adjunct in the treatment of obesity (p. 55384).

No new evidence to refute this conclusion was submitted orally or as comments to the December 2, 1977 public hearing. There is a greater degree of abuse evident for amphetamines than the other anorectics. This is undoubtedly an advantage for the use of nonamphetamine anorectics rather than amphetamines as adjuncts in the treatment of obesity.

Recent Actions by State Organizations and Authorities

This notice earlier described testimony presented at the December 2, 1977 public hearing on the control of amphetamine abuse in the States of Maryland and Wisconsin by the promulgation of regulations. Besides State authorities, several health organizations submitted comments which are on file in the office of the Hearing Clerk. Among them, comments were received from the American College of Physicians, American Pharmaceutical Association, Connecticut Department of Consumer Protection, the Mississippi Medical Association, and the Wisconsin Nurses Association. All of these organizations support the removal of the anorectic indication from the labeling of amphetamine products. The Duval County Medical Society submitted information on their amphetamine abuse and control program, while the American College of Physicians submitted the following statement:

"Because long-term treatment of obesity with amphetamines has been shown to be ineffective and because amphetamines are potentially dangerous drugs, they should not be used in the treatment of obesity. The American College of Physicians supports revocation of approval of amphetamines for use in obesity control."

The Director of the Bureau of Drugs notes that there is an increasing trend among State authorities and organizations of health professionals to promulgate regulations, adopt legislation, or institute programs to combat the abuse of legally manufactured amphetamines. These actions as described below have been taken in response to several types of diversionary activities including burglaries, thefts, forged prescriptions, and high volume dispensers. Often, the type of action taken by the State is in response to recognizing a particular diversionary activity, such as high volume prescribers and dispensers.

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With this continuing level of abuse of legally manufactured amphetamines at the State level, these recent actions reflect a grave concern not only of public officials, but also of health professionals including nurses, physicians, and pharmacists. This concern is directly related to the harmful effects of amphetamines upon the individual and society. The Director therefore finds that these actions on the State level demonstrate a long-term, wide spread and growing concern about the abuse of legally manufactured amphetamine products. These actions are described below in chronological order by the date of implementation, including those which were the subject of testimony or comments.

1. The Board of Trustees of the Utah State Medical Association was one of the first organizations of health professionals to take action to combat the abuse of amphetamines. On December 9, 1970, the Board adopted the following resolution:

SINCE, the Utah Society of Internal Medicine has rendered a valuable professional and public service in announcing to the public, by formal resolution, that its member physicians will not prescribe amphetamines or similar drugs in the treatment of obesity because use of such drugs provides no lasting benefit in the treatment of that condition but, instead, frequently results in excessive and harmful use of drugs, and

SINCE, the Utah Society of Internal Medicine has advanced the cause of law enforcement and provided assistance in combating the drug-abuse problem by said resolution in which all pharmacies and law enforcement officials were informed that prescriptions bearing the names of Society members for such drugs should henceforth be considered forgeries, and

SINCE, the Utah State Medical Association concurs with the findings of the Utah Society of Internal Medicine and other medical authorities that the use of amphetamines or similar drugs by drug abusers appears to be related to heroin addiction and to contribute to the drug-connected crime epidemic, and

SINCE, the Utah State Medical Association has the responsibility to encourage its member physicians to forego prescriptions of drugs which have not been demonstrated as beneficial in patient treatment and which are likely to lead to drug abuse and potential addiction, now, therefore, be it

RESOLVED by the Board of Trustees of the Utah State Medical Association that it approves the principle pronounced by the Utah Society of Internal Medicine, and be it further

RESOLVED that Utah State Medical Association physicians be asked to refrain from prescribing amphetamines or similar drugs in the treatment of obesity, and be it further

RESOLVED that the Association send to each of its member physicians a copy of this resolution in such form that any physician may, if he desires, indicate his approval and support of the resolution by affixing his signature thereto and returning the approved resolution to the offices of the Association.

2. Maryland was the first State that acted through legislative action to control the use of amphetamines for the treatment of obesity. In July 1972 the State passed legislation and in August 1973 the State's Board of Medical Examiners promulgated regulations that essentially restricted the use of amphetamines to the treatment of narcolepsy and hyperkinesis. In rare or exceptional cases (i.e. intractable obesity), amphetamines may be used for other purposes. In all such cases, however, the prescribing physician must submit a written justification to the Board. In addition to these restrictions, all prescriptions of amphetamines must contain no more than a 34-day supply.

3. In 1974 the Arizona Board of Medical Examiners enacted a rule which states that the Board found that amphetamines and sympathomimetic drugs have a high potential for abuse. The rule allows the use of amphetamines and sympathomimetic drugs to treat obesity only after all other alternatives have been exhausted, and then for no more than 30 days. It states that any violation of this rule constitutes a danger to the public health and safety, and is considered unprofessional conduct.

4. In late 1976, the Northern Kentucky Pharmacists Association and the Boone County and Campbell-Denton Medical Societies adopted a program to reduce the abuse of legally manufactured amphetamines. Under this voluntary amphetamine control program, physicians agreed to prescribe amphetamines only for narcolepsy, hyperkinesis in children, or neurotic fatigue, and to write the diagnosis or "Phone me if necessary" on the prescription. Only original container amounts are to be specified, and patients are advised to allow the pharmacist 2 to 3 days to order the drug. The program was adopted because people were obtaining amphetamines with prescriptions, either legal or counterfeit, and selling them. Also, there was a large number of burglaries to obtain the drugs.

5. The following resolution was ratified by the Rhode Island Medical Society House of Delegates in May 1977:

WHEREAS amphetamines play no significant therapeutic role in the treatment of intractable obesity, and

WHEREAS amphetamines have a high potential for abuse, and

WHEREAS the drug abuse committee of the Rhode Island Medical Society and the Food and Drug Administration are concerned about the hazards involved in the treatment of intractable obesity by amphetamines, and

WHEREAS the Rhode Island Section of the American College of Obstetrics and Gynecology, and the Rhode Island Chapter of the American Academy of Pedistricians, and the Rhode Island Society of Internal Medicine have taken similar positions

. . . . Therefore be it resolved that the Rhode Island Medical Society be opposed to the use of amphetamines in the treatment of intractable obesity and that this use be limited to specific well recognized medical indications such as narcolepsy, minimal brain dysfunction in children (hyperkinetic behavior disorders) and certain seizure disorders.

6. On July 15, 1977, legislation was passed in New Hampshire on the dispensing of controlled substances. In essence, although a physician may *administer* controlled substances, he or she cannot *dispense* them unless there is a medical emergency. Furthermore, in such an emergency, a Schedule II drug may be dispensed only in 7-day supplies. Although the law is not specifically aimed at amphetamines, the State's experience with high-volume dispensers was an important factor in instituting this law.

7. In response to the December 2, 1977 public hearing, the Duval County Medical Society of Jacksonville, Florida, submitted information on their amphetamine abuse and control program. As described in their submission, physicians and pharmacists in Jacksonville in 1977 instituted a voluntary plan to limit the use of amphetamine, methamphetamine, phenmetrazine, and methaqualone. These substances were removed from pharmacy shelves to eliminate thefts. A 48-hour delay in filling prescriptions allows the pharmacist to verify the prescription and to order from a wholesaler. Prescription sizes are standardized prepackaged amounts so that there are no "leftovers". And finally, the local medical association formally stated to its members that stimulants should not be prescribed for obesity. The immediate result of this effort was an 81-percent reduction in the amount of amphetamines prescribed. The Florida State medical and pharmaceutical associations have endorsed this program and have asked its initiators to expand it State-wide.

8. In May 1977 the Mississippi State Medical Association adopted the following policy on prescribing amphetamines: "Prescribing of amphetamines and other stimulant drugs should be limited to specific, well-recognized indications. The use of these drugs has no rational basis in the treatment of obesity."

9. The South Carolina Commission on Alcohol and Drug Abuse has convened a task force to investigate the problem of drug abuse in women. Through this task force, which has representatives of the State medical and pharmaceutical associations, the problem of amphetamine abuse was identified. In 1978 the South Carolina Medical Association endorsed the following resolution; it was subsequently endorsed by the South Carolina Pharmaceutical Association:

WHEREAS, the prescribing of amphetamines for weight control has resulted in its abuse in some communities in South Carolina; and

WHEREAS, extended use of this drug in weight control has resulted in what appears to be a medically-sanctioned tolerance and dependency by some patients and has resulted in the added abuse of amphetamines as a street drug; and

WHEREAS, the insomnia and psychomotor agitation resulting from overuse of this drug can lead to the abuse of other drugs, such as sedative-hypnotics, and at times results in acute psychotic episodes: NOW THEREFORE

BE IT RESOLVED that the South Carolina Medical Association go on record as opposing the use of amphetamines for weight control, and, therefore,

BE IT FURTHER RESOLVED, that the South Carolina Medical Association stipulate that prescribing or dispensing these drugs for this purpose is considered unethical and poor medical practice . . . .

A bill based on the Michigan statute regulating amphetamine prescriptions is currently pending before the South Carolina legislature. Although the bill would permit the use of amphetamines to treat obesity, a thorough physical examination and a complete history of the patient would have to be taken, the therapy would be limited to 15 milligrams a day, the maximum prescription size would be 30 days, the maximum duration of therapy would be 90 days, and a diet for weight loss would have to be prescribed along with the amphetamines. In addition, the proposed bill would impose diagnostic conditions that would have to be met prior to prescribing amphetamines for the treatment of hyperactivity and narcolepsy.

10. On August 23, 1978, the Pennsylvania Medical Society adopted a position statement which encourages its members to discontinue the use of amphetamines as an anorexiant because of its deleterious effects. Part of the statement is quoted below which refers to the harm that can be caused by amphetamines even when used on a short-term basis for weight reduction.

Conditions mindful of amphetamines potential for harm assert that in weight reduction the exposure is limited to a relatively short period. Although this may be the intention, it often does not turn out that way. People who have problems controlling their need for constant gratification as indicated by compulsive eating find it hard to put aside a medication that makes them feel good. Many patients consider their attempt to lose weight doomed to failure once they lose this magic potion that protects them from themselves. When the drug is discontinued, a psychologic vacuum is created that must be filled with food. Some patients gain back even more weight then they have lost. So although short-term use of the drug causes a short-term weight loss, it also helps the patient avoid the issue of changing his eating habits. For these reasons we doubt the wisdom of using amphetamines for weight reduction under any circumstances.

11. As described in Dr. Rupel's testimony at the public hearing, the Wisconsin Board of Medical Examiners promulgated final rules on June 1, 1978, that prohibit dispensing and prescribing Schedule II drugs for the treatment of obesity. Amphetamines are permitted only for the treatment of narcolepsy, hyperkinesis, epilepsy, and drug-induced brain dysfunction.

12. The Medical Practice Board of Michigan approved a rule in 1978 which restricted the prescribing of amphetamines. Although amphetamines may still be used to treat obesity, the Michigan rule limits the therapy to a maximum of 15 milligrams a day, a maximum prescription size of 30 days, and a maximum duration of therapy of 90 days. According to the Board, a major factor in adopting the administrative rule was the prescribing of amphetamines for nonmedical purposes, generally occuring under the guise of the treatment of obesity.

13. On January 26, 1979, the Washington State Medical Disciplinary Board adopted rules prohibiting the dispensing or prescribing of any Schedule II stimulant drug for the treatment or control of exogenous obesity. The Board had "recognized that indiscriminate or non-therapeutic prescribing of these drugs was a drug abuse problem in Washington." This action was followed by the enactment of State legislation on May 2, 1979 which made the prescribing of Schedule II stimulant drugs for weight control an illegal act. Violation of this law is a crime punishable by up to two years imprisonment, and fine of up to two thousand dollars. Schedule II stimulants are allowed to be prescribed for the treatment of hyperkinesis, drug-induced brain dysfunction, and certain other indications.

14. On February 14, 1979, the New Jersey State Board of Medical Examiners in the Division of Consumer Affairs of the Department of Law and Public Safety adopted regulations concerning the prescribing, administering, and dispensing of amphetamines and sympathomimetic amines. The rules prohibit the prescribing, ordering, dispensing, administering, selling, or transferring of any amphetamines or sympathomimetic amine drug or compound designated as a Schedule II Controlled Dangerous Substance under New Jersey law, for use in weight management, dieting, or any anorectic purpose, or for the treatment of fatigue. Amphetamines and sympathomimetic amine drugs are permitted for the treatment of narcolepsy, hyperkinesis, and drug-induced brain dysfunction.

Besides the above actions, many states have adopted policies which do not permit reimbursement for prescriptions containing amphetamines for weight loss. A major reason for these policies is the reluctance of the states to use public funds to reimburse prescriptions for a drug whose limited effectiveness in the treatment of obesity is substantially outweighed by its high potential for abuse. Although many states do not allow the drug's reimbursement when prescribed for weight loss, there appears to be no restrictions when amphetamines are used in the treatment of hyperkinesis and narcolepsy.

Benefit Risk Ratio

As Dr. John D. Griffith of NIDA testified at the public hearing, there is a risk associated with the use of amphetamines, directly related to their action as a central nervous system stimulant that can produce toxic reactions, dependency, and social dysfunction. Morever, there is no new evidence that amphetamines have any offsetting advantage over the nonamphetamine anorectic drugs as an adjunct in the treatment of obesity. The anorectic review initiated by FDA in 1972 led to the conclusion that there are no significant differences among the anorectic drugs in their effectiveness in enhancing weight loss over the short term as adjunctive treatment to diet in the management of obesity. Since that time no evidence has been presented to the agency to show that this conclusion was in error. Specifically, no adequate and well-controlled trials are known to the Bureau of Drugs which demonstrate that amphetamines carry an relative

advantage over other anorectic drugs in the management of obesity.

Besides the availability of other anorectic drugs with less risk and equivalent efficacy, the efficacy of amphetamines is limited to a very short period, usually 3 to 4 weeks. Moreover, this exposure often is not limited to 4 weeks according to Dr. Lester Grinspoon of the Harvard Medical School. He testified at the public hearing that "people who have problems controlling there need for constant gratification, as indicated by compulsive eating, find it hard to put aside a medication that makes them feel good [euphoria is a side effect of amphetamines]. What is more, many patients consider their attempts to lose weight doomed to failure once they have lost this magic potion which protects them from themselves. When the drug is discontinued, a psychological vacuum is created which has to be filled with food. On occasion patients have gained back even more weight than they lost, a condition commonly known as rebound phenomenon. So, although short-term use of the drug causes a short-term weight loss, it also helps the patient to avoid the issue of changing his eating habits." In addition, Dr. Grinspoon testified that after the 4-week period amphetamines are no longer effective as anorectics unless the user increases the dose, thus creating a real potential for psychologic dependency and abuse.

From the testimony presented at the public hearing, together with information from the DEA and the NIDA, the Director of the Bureau of Drugs finds that amphetamines are being prescribed and dispensed by certain physicians for weight loss beyond the 4-week period (the physician labeling states a few weeks). Moreover, patients are not only using amphetamines for an extended time for weight loss, but they frequently increase the dosage in an attempt to deal with the diminishing anorexic effect of the drug. The Director therefore finds that the use of amphetamines in the treatment of obesity beyond the conditions of use specified in the physician labeling is exposing patients to the risk of harmful effects through the chronic use of amphetamines. In addition to patients who become involved in a pattern of amphetamine abuse through medical use for the treatment of obesity, other people abuse amphetamines solely for the euphoric and energizing effect.

Besides the damage to society in the form of neglect of family and work, financial irresponsibility, crime, and other antisocial behavior, the Director finds that chronic abuse of amphetamines also produces harmful effects on the health of the user. These harmful effects fall into three major categories: (1) central nervous system effects; (2) habituation, dependence, and addiction; and (3) amphetamine psychosis.

1. *Central Nervous System Effects.* With the development of tolerance to the peripheral adrenergic effects (such as blood pressure response), central nervous system toxic reactions have been reported. These reactions usually involve loss of hypothalmic temperature regulation, with hyperthermia, leading to cardiovascular collapse, convulsions, and death. Convulsions are most often associated with hyperthermia but can also be a complication of high-dose amphetamine use. Status epilepticus, the characteristic seizure pattern, presents a particularly serious threat to the individual. Permanent severe brain damage can result from status epilepticus. Often multiple drug ingestion will potentiate the epileptogenic effect of stimulants, for example, with phencyclidine and lysergic acid. Cerebral vascular complications can be life-threatening and include secondary intracranial hypertension leading to subarachnoid hemorrhage. Stimulant abusers with a history of congenital cerebral aneurysm and arteriovenous malformation are at an added risk of intracerebral hemorrhage. A necrotizing angiitis has been reported in amphetamine abusers. This vascular inflammatory response is especially severe in the cerebral and renal arteries.

2. *Habituation, Dependence, and Addiction.* Scientific literature has shown various degrees of dependence on amphetamines, ranging from mild habituation to strong compulsion and to using the drugs chronically. The more severe cases of dependence show all the characteristics of true addiction. According to Dr. Orina Kalant in "The Amphetamines: Toxicity and Addiction," (Ref. 24) persons who are unable to terminate the continous use of amphetamines have certain features in common. "All of them suffered periodic or chronic states of intoxication, with the usual signs of central nervous system overstimulation and sometimes sympathetic overactivity. Many had anorexia, insomnia, irritability, and erratic behavior. Abuse of other drugs was common, especially barbiturates which were taken to counteract the insomnia. Development of toleance was common, and often marked, and the problems of obtaining the large doses required led in many cases to financial hardship, neglect of family, and antisocial behaviour such as theft and forgery of prescriptions. In addition, physical dependence has been indicated recently by the discovery of certain abnormal electroencephalographic and electro-oculographic patterns during amphetamine withdrawal, which are abolished immediately by restoring the drug" (p. 120). Dr. Lester Grinspoon in "The Speed Culture" states that "the essential 'normality' and general reliability of the initial euphoric effect of amphetamine is what makes the drug so likely to produce dependence" (Ref. 25, p. 173).

3. *Amphetamine Psychosis.* Acute "amphetamine psychosis" is one of the most widely recognized phenomena of psychiatric change associated with amphetamine use. Most often the psychosis is a result of chronic abuse, but even single large doses can produce a toxic hallucinatory paranoid panic state. The amphetamine psychosis was at one time thought to be seen only in "latent" schizophrenics, but this view has been refuted by evidence from many scientific publications. A schizophrenia-like state can be induced in laboratory animals by administration of amphetamine. The most common clinical symptoms of amphetamine psychosis are paranoid delusions and vivid hallucinations of all senses. Occasionally the patient is confused and violently excited. Treatment consists essentially of drug withdrawal, though many patients have received needless shock and other therapy because of mistaken diagnosis. Unless treatment is directed to the drug abuse rather than to the psychosis, the relapse rate is high.

In most cases of amphetamine psychosis, 1 to 5 years of chronic drug abuse preceded the onset of the psychosis. There is no characteristic mental or emotional picture by which a high risk patient can be identified in advance.

After sub chronic and chronic use and during amphetamine withdrawal, symptoms of depression can be profound. Prolonged sleep and lethargy can lead to severe depression and suicide in some amphetamine users. The psychiatric manifestations of amphetamine abuse are an important cause for hospitalization among adolescents and young adults.

While the hazards from amphetamine abuse are many, little evidence is available to conclude that these risks occur in patients under treatment for narcolepsy or hyperkinesis. Children receiving daily amphetamine for learning disabilities have not shown either growth retardation or a later

tendency to drug abuse. Narcoleptics have been followed for periods of 20 to 30 years on stable daily amphetamine dose schedules. The efficacy of amphetamines in those patients has been supported by well-controlled clinical studies.

References

The following items, as well as statistical analyses of the DAWN data, are on file and available for inspection in the office of the Hearing Clerk, at the address specified at the beginning of this notice.

1. Director, National Institute on Drug Abuse, memorandum to Director, Bureau of Drugs, Food and Drug Administration, March 24, 1977, and attached reports: "Anorectics," 11 pp., and tabulation "Drug Use Among High School Seniors in 1975 and 1976," 2 pp.
2. National Institute on Drug Abuse, "An Investigation of Selected Rural Drug Abuse Programs," DHEW Publication No. [ADM] 77-451, U.S. Government Printing Office, Washington, 1977, 20 pp.
3. Robins, L., "The Relationship of Amphetamine Use to Current Adjustment," unpublished paper, 1977, 13 pp.
4. "National Prescription Audit Therapeutic Category Report," IMS America, Ambler, PA.
5. Drug Enforcement Administration, U.S. Department of Justice, "Study of Prescription and Drug Abuse Trends of CSA II, III, and IV Amphetamine and Other Anorectic Drugs, January 1, 1974-December 30, 1976," IMS America, Ambler, PA, 1977, 83 pp.
6. Food and Drug Administration data from Poison Control Center reports on anorectics for the years 1972, 1973, 1974, 1975, 4 pp.
7. Administrator, Drug Enforcement Administration, letter to Commissioner of Food and Drugs, December 30, 1976, and attached DEA report, "Amphetamine Diversion," 98 pp.
8. Drug Enforcement Administration, U.S. Department of Justice, "DEA Laboratory Analyses: Schedule II, III, and IV Anorectics," March 16, 1976, 36 pp.
9. Hearings before the Subcommittee on Monopoly of the Select Committee on Small Business, United States Senate, 94th Congress, 2d Session, on Present Status of Competition in the Pharmaceutical Industry, U.S. Government Printing Office, Washington, 1977, pp. 14433-15357.
10. Minutes of the Sixth Meeting, Neurologic Drugs Advisory Committee, Food and Drug Administration, Bureau of Drugs, February 3-4, 1977, 24 pp.
11. "National Disease and Therapeutic Index—Drug File," IMS America, Ambler, PA.
12. Drug Enforcement Administration Data on NPA drug list and Project DAWN code numbers, 9 pp.
13. Person, P. H., Jr., "The Drug Abuse Warning Network: A Statistical Perspective," Public Health Reports, 91(5):395-402, 1976.
14. Food and Drug Administration, Notice of Public Hearing, October 14, 1977, Federal Register 42[199] 55374-55388.
15. Administrator, Drug Enforcement Administration, letter to Director, Bureau of Drugs, FDA, July 13, 1978, and 37-page attachment, updating information.
16. Acting Director, National Institute on Drug Abuse, memorandum to Director, Bureau of Drugs, FDA, July 10, 1978, and 11-page attachment, "Update on Amphetamine/Stimulant Data."
17. Acting Director, Division of Poison Control, Bureau of Drugs, memorandum to Director, Bureau of Drugs, FDA, July 24, 1978, and 1-page attachment, "Update on Amphetamine Data."
18. Anthony, J. C., "The Effect of Federal Drug Law on the Incidence of Drug Abuse," *Journal of Health, Politics, Policy, and Law*, Spring 1979.
19. "Basic Neurochemistry," 2d Edition, Edited by Siegel, G. J., R. W. Albers, R. Katzman, and B. W. Agranoff, Little, Brown & Co., Boston, 1976, p. 721-722.
20. "The Pharmacological Basis of Therapeutics," 5th Edition, Edited by Goodman, S., and A. Gilman, MacMillan, New York 1975, p. 496-497.
21. Meyler, L. and A. Herxheimer, "Side Effects of Drugs," Williams and Wilkins, Baltimore, 1968, p. 3-7.
22. "Current Concepts on Amphetamine Abuse," Edited by Ellinwood, E. H., and S. Cohen, N. I. M. H. Rockville, MD, 1972, Chapter 17-19.
23. "Clinical Neurology," Edited by Baker, A. B., and L. H. Baker, Harper and Row, New York, 1978, Vol. 2, Chapter 20, p. 25.
24. "The Amphetamines: Toxicity and Addiction," 2d Edition, Kalant, O. J., University of Toronto Press, Toronto, 1973.
25. Grinspoon, L. and P. Hedblom, "The Speed Culture; Amphetamine Use and Abuse in America," Harvard University Press, Cambridge, 1975.
26. Finney, D. J., "Statistical Logic in the Monitoring of Reactions to Therapeutic Drugs," *Methods of Information in Medicine*, Vol. 10, No. 4, p. 237-245, 1971.

Conclusions

The Director of the Bureau of Drugs concludes that the evidence of continuing misuse and abuse of amphetamines, the severe risk of dependence and harmful effects that they present, and the availability of alternative drugs with less risk create an unfavorable benefit-to-risk ratio in the continued marketing of the drugs for use as an anorectic agent when compared to the limited benefit expected. Therefore the Director proposes to remove the indication for the management of exogenous obesity from the labeling of drug products containing an amphetamine. Accordingly, the July 19, 1974 Federal Register notice is amended to read as follows, insofar as it pertains to single-entity drug products containing amphetamine, dextroamphetamine, methamphetamine hydrochloride, or dl-methamphetamine hydrochloride. A mixture of amphetamine and dextroamphetamine is regarded as a single-entity drug for the purposes of this notice.

Such drugs are regarded as new drugs (21 U.S.C. 321[p]). Supplemental new drug applications are required to revise the labeling in and to update previously approved applications providing for such drugs. An approved new drug application is a requirement for marketing such drug products.

In addition to the product specifically named above, this notice applies to any drug product that is not the subject of an approved new drug application and is identical to a product named above. It may also be applicable, under 21 CFR 310.6, to a similar or related drug product that is not the subject of an approved new drug application. It is the responsibility of every drug manufacturer or distributor to review this notice to determine whether it covers any drug product that the person manufactures or distributes. Such person may request an opinion of the applicability of this notice to a specific drug product by writing to the Division of Drug Labeling Compliance (address given above).

A. *Effectiveness classification.* The Food and Drug Administration has reviewed all available evidence and concludes that single-entity drug products containing amphetamine or dextroamphetamine, or a salt thereof, or methamphetamine hydrochloride, or dl-methamphetamine hydrochloride are:

1. Effective for the indications in the labeling conditions below.

2. Effective but lack evidence of safety for use as a short-term adjunct in the management of obesity.

(For purposes of this notice a mixture of amphetamine and dextroamphetamine is regarded as a single-entity drug product):

B. *Conditions for approval and marketing.* The Food and Drug Administration is prepared to approve abbreviated new drug applications and supplements to previously approved new drug applications under the conditions described herein:

1. *Form of drug.* The drug is in capsule, tablet, or liquid form suitable for oral administration. It may be in controlled-release form.

2. *Labeling conditions.* a. The label bears the statement, "Caution: Federal law prohibits dispensing without prescription."

b. The drug is labeled to comply with all requirements of the act and regulations, and the labeling bears adequate information for safe and effective use of the drug. The indications are as follows:

dl-amphetamine, dextroamphetamine, and methamphetamine are indicated as an integral part of a total treatment program which may include other remedial measures (psychological, educational, social) for a stablizing effect in children with a behavioral syndrome characterized by the following group of developmentally inappropriate symptoms: moderate to severe distractability, short attention span, hyperactivity, emotional lability, and impulsivity. The diagnosis of the syndrome should not be made with finality when these symptoms are only of comparatively recent origin. Nonlocalizing (soft) neurological signs, learning disability, and abnormal EEG may or may not be present, and a diagnosis of central nervous system dysfunction may or may not be indicated.

dl-Amphetamine and dextroamphetamine are also effective in the treatment of narcolepsy.

3. *Marketing status.* a. Marketing of such drug products that are now the subject of an approved or effective new drug application may be continued provided that, on or before September 17, 1979 the holder of the application has submitted (i) a supplement for revised labeling as needed to be in accord with the labeling conditions described in this notice, and complete container labeling if current container labeling has not been submitted, and (ii) a supplement to provide updating information with respect to items 6 (components), 7 (composition), and 8 (methods, facilities, and controls) of new drug application form FD–356H (21 CFR 314.1(c)) to the extent required in abbreviated applications (21 CFR 314.1(f)).

b. For any person who does not hold an approved or effective new drug application, the submission of an abbreviated new drug application (21 CFR 314.1(f)) must be obtained before marketing such products. For preparations claiming controlled release, such supplements should contain studies comparing blood levels occurring with the controlled-release form with blood levels occurring with single units of the conventional form given multiple times. For example, when comparing a 30-milligram controlled-release form normally given every 12 hours with a 10-milligram conventional form normally given every 4 hours, the comparison should involve one unit of the controlled-release form given once and one unit of the 10-milligram form given every 4 hours for three doses. Protocols for these studies are required to be submitted under a Notice of Claimed Investigational Exemption for a New Drug (IND). Marketing before approval of a new drug application will subject such products, and those persons who caused the products to be marketed, to regulatory action.

OPPORTUNITY FOR HEARING

Therefore, notice is given to the holders of the new drug applications and to all other interested persons that the Director of the Bureau of Drugs proposes to issue an order under section 505(e) of Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)), withdrawing approval of all new drug applications and all amendments and supplements thereto providing for the indication as described in this announcement for the management of exogenous obesity, on the ground that new information has shown the drugs to be a risk to the patient, as well as to society, when offered for use for this indication, and that this information, evaluated together with the information available when the applications were approved, shows that such drugs are not shown to be safe for use under the conditions of use on the basis of which the applications were approved. An order withdrawing approval will not issue with respect to any application(s) supplemented in accord with this notice to delete this indication, except for those combination products which are only approved for this indication.

In addition to the specific ground for the proposed withdrawal of approval stated above, this notice of opportunity for hearing encompasses all issues relating to the legal status of the drug products subject to it, e.g., any contention that a product is not a new drug because it is generally recognized as safe and effective within the meaning of section 201(p) of the act or because it is exempt from part or all of the new drug provisions of the act pursuant to the exemption for products marketed prior to June 25, 1938, contained in section 201(p) of the act, or pursuant to section 107(c) of the Drug Amendments of 1962, or for any other reason.

In accordance with section 505 of the act (21 U.S.C. 355) and the regulations promulgated thereunder (21 CFR parts 310, 314), the applicants and all other persons who manufacture or distribute a drug product that is identical, related, or similar to a drug product named above (21 CFR 310.6) are hereby given an opportunity for a hearing to show why approval of the new drug applications providing for the claim involved should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to its legal status.

An applicant or any other person subject to this notice who decides to seek a hearing, shall file (1) on or before August 16, 1979, a written notice of appearance and request for hearing, and (2) on or before September 17, 1979, the data, information, and analyses relied upon to justify a hearing, as specified in 21 CFR 314.200. Any other interested person may also submit comments on this proposal to withdraw approval. The procedures and requirements governing this notice of opportunity for hearing, a notice of appearance and request for hearing, a submission of data, information, and analyses to justify a hearing, other comments, and a grant or denial of hearing are contained in 21 CFR 314.200.

The failure of an applicant or any other person subject to this notice pursuant to 21 CFR 310.6 to file timely written appearance and request for hearing as required by 21 CFR 314.200 constitutes and election not to make use of the opportunity for a hearing concerning the action proposed with respect to the drug product and a waiver of any contentions concerning the legal status of the drug product. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for the hearing that there is no genuine and substantial issue of fact that precludes the withdrawal of approval of the application, or when the request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, denying a hearing.

All submissions pursuant to this notice of opportunity for hearing must be filed in quintuplicate. Such submissions, except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, may be seen in the office of the Hearing Clerk between 9 a.m. and 4 p.m., Monday through Friday.

Federal Food, Drug, and Cosmetic Act sec. 502, 505, 52 Stat. 1050–1053, as amended (21 U.S.C. 352, 355) and under the authority delegated to the Director of the Bureau of Drugs (21 CFR 5.82))

Dated: July 10, 1979.

J. Richard Crout,

Director, Bureau of Drugs.

[FR Doc. 79-21553 Filed 7-16-79; 8:45 am]

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PREPARED STATEMENTS

PREPARED STATEMENT OF LEE I. DOGOLOFF, ASSOCIATE DIRECTOR FOR DRUG POLICY, DOMESTIC POLICY STAFF, THE WHITE HOUSE

Mr. Chairman and members of the Committee, thank you for the opportunity to present the Administration's position on one of the most critical problems facing us in the drug abuse field, the misuse and abuse of legally manufactured drugs.

In his Message to the Congress on Drug Abuse, President Carter noted that along with heroin, "barbiturates and other sedative-hypnotic drugs account for 90 percent of deaths from drug abuse" and stated that they should receive the Federal Government's primary attention. The President directed several departments and agencies to deal more effectively with this problem. I can report that much has been done over the past two years and attach a list of specific directives and responses to the President's Message relating to prescription drug abuse.

In looking at this issue, we have determined that there are different categories of problem prescribers and dispensers. The vast majority are doctors and pharmacists who have no criminal intent, but through a lack of knowledge or from outside pressures, are allowing controlled drugs to enter the illicit market. Another group of practitioners is the impaired physician or pharmacist who has a drug abuse problem himself. These impaired individuals are not a significant source of drugs for others. Finally, a small minority are people who have clear criminal intent and are dispensing or prescribing sheerly for profit. Each of these groups requires a different response.

The Federal response must, of course, be dictated by existing law. The powers of the Federal Government over the primary source of diversion, i.e., the retail, physician/pharmacist level, are limited under the Controlled Substances Act. We recognized early in the Administration that while Federal efforts in this area were extremely important, we could only successfully face the problem by working closely with State and local authorities and concerned professional and peer groups.

Two years ago, the White House set up an Ad Hoc Working Group to look at the abuse of prescription drugs, in particular sedative-hypnotics, minor tranquilizers, and stimulants. Since that time we have taken several steps. The Strategy Council on Drug Abuse was concerned over the diversion of legally manufactured drugs into the illicit market. This concern is reflected in the 1979 Federal Strategy for Drug Abuse and Drug Traffic Prevention which specifically addresses amphetamines, barbiturates, and tranquilizers, and devotes considerable attention to the control of these drugs.

In addition, our office, in conjunction with the NIDA, sponsored a study conducted by the National Academy of Sciences' Institute of Medicine on "Sleeping Pills, Insomnia, and Medical Practices" which showed that hypnotics appear to have a minimal benefit in severe insomnia, that the efficacy of these drugs is of relatively short duration and that other medications for sleep such as flurazepam (Dalmane) can have cumulative effects which result in daytime sedation with continued use. Among other activities, NIDA conducted a study of sedative-hypnotic drugs and is developing prescribing guidelines for controlled substances. The Food and Drug Administration has reviewed amphetamines, hypnotics, benzodiazepines, and Darvon. These reviews have resulted in FDA's proposal to withdraw approval for the use of amphetamines in treating obesity, a change in labeling of hypnotic drugs, a requirement for package inserts to indicate the duration of a hypnotic's effectiveness when used continuously, and a stronger warning statement for Darvon.

In light of our determination that this problem could only be successfully addressed in conjunction with State and local efforts, we took a policy decision that, in addition to the Federal activities directed by the President, we had a responsibility to stimulate State and local activity to identify problem areas and to take the necessary educational, regulatory or, where appropriate, criminal measures to remedy the situation. We knew that we had a great deal to learn about how States with effective control mechanisms were addressing this problem and met with many State officials having responsibilities in this area. The common element of a successful program was communication. In these States a rapport had developed between government agencies and professional societies which recognized a common problem and worked effectively together to solve it.

We also found that the most effective means of dealing with prescription drug diversion were use of peer pressure and educational initiatives to inform physicians and pharmacists who had been identified as the source of large quantities of controlled substances that medical societies and pharmacy associations were concerned over their prescribing and dispensing patterns. Regulatory actions appeared to be justified in some instances, particularly regarding the use of amphetamines for obesity and placing restrictions on a physician's right to prescribe certain drugs. State and local enforcement activity, often in cooperation with DEA's Diversion Investigation Units, was used in a small percentage of cases, most often relating to pharmacy thefts. We are attempting to inform other States of these successes and to foster similar efforts.

Our most recent effort to do this was on September 12, when we were honored, Mr. Chairman, to have you attend a meeting the Drug Policy Office arranged to discuss this question. Initially, we had expected to have a limited number of Federal and State officials in Washington to take a closer look at what we could do to improve the situation. Word of this meeting spread so rapidly that instead of the 15 individuals we expected, the final meeting was attended by over 50 people. At that time, we asked the concerned Federal agencies to explain the actions they had taken and asked representatives from seven States to describe what they had done to deal with this problem. Finally, professional and trade associations were encouraged to present their views. With your permission, Mr. Chairman, I would like to submit the minutes of that meeting for the record.

In summary, the participants agreed that the health hazards of prescription drug abuse exceeds that of heroin. The inappropriate prescribing by some physicians and the diversion from pharmacies have been the primary sources of these drugs reaching the illicit market; only a small percentage is derived from unscrupulous or impaired physicians, or from the diversion at the wholesaler/manufacturer level.

The participants concurred that no one agency, either Federal or State, could effectively deal with the problem. Common elements of successful State programs include professional education, professional peer pressure, regulatory and licensing activities, and law enforcement as a final resort. The establishment of a State prescription drug task force, bringing together these elements, has facilitated and enhanced efforts to deal with each State's unique situation. Many of the States closely cooperate with DEA and NIDA, and use data generated by Federal information systems such as ARCOS to help identify points of diversion. The need for coordinated efforts involving Federal, State, and local government agencies in cooperation with professional, education, and trade organizations was repeatedly emphasized.

Actions stemming from the recommendations made at the meeting include the following:

1. The White House Drug Policy Office will convene a meeting of representatives from the Drug Enforcement Administration, the Food and Drug Administration, and the National Institute on Drug Abuse, to develop a strategy for promoting appropriate prescribing of controlled drugs by physicians and other health care professionals. This interagency working group, in consultation with professional organizations, will review existing programs and educational resources, and will develop new resources, for increasing physician awareness and sensitivity to the problem of prescription drug diversion, and for positively modifying their prescribing practices.

2. As a follow-up to the studies on insomnia and the use of sedative-hypnotic drugs carried out by the National Institute on Drug Abuse and the National Academy of Science—Institute of Medicine, the Surgeon General is planning new initiatives that include upgrading therapeutic practices relating to insomnia and the appropriate use of hypnotic drugs. The Surgeon General will review the applicability of these educational initiatives to other problem areas such as the management of stress and anxiety.

3. The White House Drug Policy Office will write to each State Governor concerning the seriousness of prescription drug diversion. Each state will be encouraged to develop a prescription drug task force which could bring together the concerned state agencies and medical, pharmacy, and other professional societies for identifying and dealing with prescription drug diversion.

A state task force could examine the applicability of model programs that are working to control diversion in other states. HEW will compile and make available methods used by several states to deal with this problem. The Federal

Government will also make available data from its data systems that may facilitate the identification of problem areas and problem physicians. A task force could also consider the applicability to its state of regulatory actions on specific drugs; peer review of questionable prescribing practices; restrictions or limits on the prescribing of controlled drugs; and techniques being used by other states, such as triplicate prescriptions, prohibiting drug companies from distributing preprinted prescriptions for controlled drugs, serially numbering prescription blanks to enable voiding of those that are stolen or lost, etc. Some states have found that careful review of requests for payment from Medical funds may identify problem physicians and patients; guidelines can be established to limit the prescribing of certain drugs through restrictions on Medicaid payments.

4. State medical licensing boards and other relevant state agencies should review their current policies and procedures which, in some states, make it difficult to revoke a physician's license or restrict his prescribing privileges even in some cases where his peers adjudge him to be prescribing inappropriately or unethically.

5. The White House Drug Policy Office will ask the Surgeon General to convene a national prescription drug conference in order to highlight the importance of this problem and to share existing State initiatives.

6. The Strategy Council on Drug Abuse will establish an Ad Hoc group to review the existing problem of prescription drug diversion, to identify further measures that may be undertaken to decrease diversion, and to follow the progress of change in prescribing practices that these measures may bring about.

In conclusion, Mr. Chairman, the Carter Administration is committed to addressing the problem of prescription drug abuse as one of its highest priorities, particularly since the overuse and misuse of these drugs affect, disproportionately the elderly and women.

It is our duty to work towards ensuring that these valuable medications are employed properly. We must continue our efforts, both Federal and State, to prosecute those few practitioners who abuse the privileges they have and intentionally make available these drugs on the illicit market. However, we believe that the most effective way of dealing with the problem is by fostering Federal-State cooperation in identifying sources of diversion and using peer pressure and other non-criminal means of ensuring compliance with proper prescribing standards.

State governors, legislatures and concerned professional associations will have to determine the form such a program should take in light of their own circumstances. We in the Federal Government will do everything possible to encourage that adequate systems of monitoring and control are established in all jurisdictions throughout the United States and that the exemplary record of drug manufacturers and wholesalers in preventing diversion will be maintained.

We look forward to continuing to work with the Select Committee in this field and welcome any suggestions you or your staff might have on means of dealing with it. The health and welfare of a large portion of the American people depends on our doing a better job in educating patients on the proper use of these substances and preventing their reaching illicit channels.

Thank you.

Responses to President's Message to the Congress On Drug Abuse Relating to Prescription Drugs

Directive. "In recognition of the devasting effects that certain nonopiate drugs can have if abused, I am directing the Secretary of Health, Education and Welfare to expand resources devoted to care for abusers of barbiturates, amphetaamines, and multiple drug use in combination, including alcohol."

Response. The National Institute on Drug Abuse is continuing to ensure that compulsive users of any type of drug receive high priority in NIDA funded treatment programs, with priority on those individuals presenting the greatest clinical need for treatment. The Institute is currently trying to improve (1) training for health professionals in treating non-opiate drug abusers and (2) the capability of general health care facilities under HEW jurisdiction in identifying and treating problems of non-opiate drug abuse.

Directive. "I am recommending a conscious and deliberate increase in attention throughout the Federal Government to the problems related to the abuse of drugs that come originally from legitimate medical sources. Of particular concern

are barbiturates, which despite their recognized medical use, are responsible for many deaths and are frequently used in suicide attempts. I will instruct the Secretary of Health, Education and Welfare to undertake a study of barbiturates and other sedative/hypnotic drugs to determine the conditions under which they can be most safely used."

Response. The Department has completed the study on sedative/hypnotic drugs and found that:

(1) these drugs are unnecessary in many cases, often actually hinder sleep, and contribute to nearly 5,000 overdose deaths a year;

(2) benzodiazepene, with some qualification, is at least as effective as other sedative/hypnotic drugs, has a greater margin of safety and presents less risk of drug interactions;

(3) the efficacy of short-acting barbiturates is questionable when administered on a chronic basis;

(4) the existing evidence, however, does not warrant the removal of barbiturates from the market;

(5) some non-barbiturate, non-benzodiazepene sedative/hypnotics have relatively little clinical utility and carry serious risks.

Based on this study and the Institute of Medicine Study on the prescribing practices of physicians, a timetable and plans for implementation of the recommendations will be developed by May 1979.

Directive. "I will instruct the Secretary of Defense, the Secretary of Health, Education and Welfare, and the Administrator of Veterans' Affairs to review the prescribing practices of physicians under their jurisdiction, and to discourage the medical use of barbiturates and sedative/hypnotics except in cases where it is unmistakably justified."

Response. The Department of HEW is discouraging the unnecessary use of barbiturates and sedative/hypnotics in HEW facilities through surveys, internal reviews, dispensing restrictions, and physician education programs. Barbiturate purchase and non-barbiturate sedative/hypnotics (except flurazepam) purchases by the U.S. Public Health Service have significantly declined. An additional follow-up survey on the decreasing use of barbiturates and sedative/hypnotics is scheduled for January and should be completed by April 1979.

The prescribing and use of barbiturates in military hospitals continues to decrease. The Department of Defense is currently in the process of evaluating what might be done through the CHAMPUS program to control the licit use of barbiturates.

The Department will also by April 1979, determine what additional actions must be taken in the area of barbiturate use, based on the current evaluation of last year's efforts and the Institute of Medicine Study on Barbiturate Use.

The Veterans Administration has experienced a 22-percent decrease in the amount of sedative/hypnotic drugs ordered thru VA pharmacies (approximately 70 percent of the total VA prescribing).

The VA has undertaken a study of the prescribing practices in psychiatric treatment by physicians and hospitals to determine appropriate practices identifying problem cases and serve as the basis of training.

The VA has sent a Professional Services Letter on sedative/hypnotics to directors of all VA health care facilities, directed each facility to provide training on prescribing practices and conduct workshops for Chiefs of Staff and Chiefs of Veterans Administration Medical, Surgical and Psychiatric Services of VA hospitals on improving prescribing practices of medical personnel in the VA health care systems.

Directive. "I will continue the program, already begun at my direction, by which the Drug Enforcement Administration has instructed its regional offices and regulatory task forces to give priority attention to barbiturate cases."

Response. The Drug Enforcement Administration conducted 119 investigations of barbiturate manufacturers resulting in 49 adverse actions; 74 investigations of distributors resulting in 28 actions; and 72 investigations of retailers (pharmacies and practitioners) resulting in 52 actions. There was no evidence of diversion of barbiturates at either the manufacturing or wholesale level where most of the violations involved recordkeeping and security. The major diversion problem appears at the pharmacy and practitioner levels.

Directive. "I am directing the Secretary of Health, Education and Welfare to review those sedative/hypnotic drugs particularly subject to abuse to determine whether any should be removed from the market, taking into consideration not

only their safety to the individual, but also the dangers they pose to the public at large."

Response. The Department has studied the safety and effectiveness of sedative/hypnotic drugs and recommends against removing these drugs from the market. FDA, however, has recommended certain labeling revisions for the hypnotic drug package inserts which would include prescribing guides and information on the duration and effect of prolonged nightly administration. Barbiturate class labeling, which will allow physicians to easily compare and contrast the risks and benefits of various barbiturates, will be published in the Federal Register by March 1979.

Directive. "I am directing the Attorney General, in full cooperation with State officials, to begin a concerted drive to identify and prosecute those physicians who knowingly overprescribe a wide variety of drugs."

Response. The Department of Justice has worked with the States in establishing Diversion Investigation Units (DIU's) in 16 States and the District of Columbia to identify practitioners or other individuals (i.e. nurses, pharmacologists, etc.) who are involved in drug diversion. For the period extended from July 1977 to July 1978, the DIU's were responsible for approximately 484 state and local arrests and seizures totaling an estimated three-fourths million dosage units of diverted drugs. Current plans include the establishment of DIU's in three additional States each year for the next ten years, beginning with States which have the most serious diversion problems. In addition to the DIU's, Federal investigators have been able to obtain investigative leads involving diversion at the practitioner level based on an analysis of drug purchases as reported in ARCOS (the Automated Reports and Consumated Order System).

Directive. "Because of the need to improve international controls over dangerous drugs which have legitimate medical uses, like barbiturates and amphetamines, I urge the Congress to adopt legislation implementing the Convention on Psychotropic Substances, and I urge the Senate to ratify this treaty promptly."

Response. The enabling legislation for the Psychotropic Substances Treaty was enacted by the 95th Congress, and has been signed by the President.

The Treaty will be submitted to the Senate for ratification in the 96th Congress.

Minutes—Meeting To Discuss The Diversion of Prescription Drugs for Illicit Use, September 12, 1979

INTRODUCTION AND OVERVIEW

On September 12, 1979, the Office of Drug Policy convened a meeting of representatives from Federal agencies; the National Academy of Science Institute of Medicine; seven states; professional, educational, and trade organizations; and congressional staff to discuss possible courses of action to remedy the increasing problem of diversion of legal drugs to illicit use.

The meeting opened with comments by Lee Dogoloff and Congressman Lester Wolff. Mr. Dogoloff expressed the interest and concern of the White House over the problem of prescription drug diversion. He traced the origin of this meeting to an ongoing study group's recommendation. Federal law and responsibility is limited primarily to the wholesale level, where there is not much of a diversion problem. The primary problem lies with diversion from practitioners and pharmacists. The meeting provided an opportunity to share the experience of seven states that, with some Federal assistance, are coping with the problem. One aim of the meeting was to develop models to share with other states.

Congressman Wolff spoke of the immensity of the diversion problem that, until recently, has been largely ignored. He also spoke of his interest in the overuse and misuse of prescription drugs for the elderly and for women. He gave a brief history of the Select Committee's activities in this area. He expressed his conviction that we must address the social problems and seek out the root causes of substance abuse, rather than continually focus on individual drugs.

The development of a method to estimate the scope of the diversion problem was discussed by Dr. James Cooper of the National Institute on Drug Abuse. He is trying to draw inferences from data derived from DAWN, CODAP, The National Prescription Audit, and the National Household Survey. His interpretation of the data suggests that the problem lies with alcohol in combination with other drugs; sedative drugs and tranquilizers

Mr. Al Russell of the Drug Enforcement Administration spoke of the problems arising from using several data bases, which don't always agree. He spoke of a recent increase in stimulant abuse, largely derived from clandestine laboratories. He estimated that 250 to 300 million dosage units of various drugs are being diverted from legal sources. He attributed the decline in barbiturate mentions in the DAWN System to publicity and education directed to physicians and pharmacists, resulting in a decreased number of prescriptions for these drugs, rather than to any particular law enforcement efforts. He outlined DEA plans to use drug profiles of cities and states in order to target increased enforcement to specific drugs in specific areas, for example, methaqualone in Miami. He also mentioned DEA's 12-point plan to increase physician education with respect to the prescription of controlled substances. In response to Dr. David Smith's expressed concern over the ability to determine whether a street drug was diverted from a legal source or was manufactured in a clandestine laboratory. Mr. Russell agreed that DAWN data are "soft," but the DEA ballistics system can give good evidence of the source.

FEDERAL AGENCY ACTIVITIES

Several Federal agencies outlined their activities with regard to diversion. Dr. Thomas Hayes, of the Food and Drug Administration, outlined the FDA's role in recommending the scheduling of controlled substances. He detailed recent FDA reviews of amphetamines, hypnotics, benzodiazepines, and Darvon. These reviews have resulted in (1) FDA's proposal to withdraw approval for the use of amphetamines in treating obesity; (2) a change in labeling of hypnotic drugs, requiring package inserts to indicate the duration of their effectiveness when used continuously; (3) a change in the labeling of benzodiazepines which will require all of them to have a uniform statement in the "Indications" section, and a statement of warning of their ability to produce withdrawal symptoms even when used therapeutically; and (4) an increase in the warning statement for Darvon, an agreement from the manufacturer to develop a patient package insert, and increased efforts to advise physicians about the possible dangers of Darvon.

Dr. Cooper outlined NIDA's current activities: (1) A redesign of the National Household Survey, which will allow for the identification of specific drugs; (2) development of epidemiological teams which will investigate the significance of a drug being in the top 26 in the DAWN System; i.e., accuracy of the data, physician prescribing practices in the community, and the like; (3) development of prescribing guidelines for controlled substances (He cited an article in JAMA, (vol. 241, p. 1021, Mar. 9, 1979) as a useful reference for establishing the criteria for appropriate prescribing of psychoactive drugs that was developed by NIMH and the American Psychiatric Association for use by community mental health centers); and (4) development of educational programs for medical schools aimed at decreasing the diversion of prescription drugs.

Dr. Charles Krauthammer (ADAMHA) described the development of the shortly-to-be-announced Surgeon General's initiative on sedative-hypnotic drugs which will outline criteria for appropriate and inappropriate prescribing of these drugs. The research component of this initiative will focus on problems identified by the Institute of Medicine's report "Sleeping Pills, Insomnia, and Medical Practices," including the natural history of insomnia, the clinical efficacy of hypnotic drugs—especially for longterm use, and the epidemiology of hypnotic drug use. The educational component of this initiative will be directed toward upgrading therapeutic practice related to insomnia, including its differential diagnosis, choice of therapy, and appropriate prescribing practices. A syllabus on insomnia and its treatment will be prepared and sent to physicians. A similar booklet written in lay terms will also be prepared and made available for distribution to patients. The 3-year initiative will be monitored to assess its impact on prescribing practices of these drugs and may then be used as a model for similar programs in the therapy of depression and anxiety.

Dr. Peter Flynn, Department of Defense, reviewed their prescription monitoring program. Their experience with the prescribing of barbiturates from 1972 to 1976 indicated a drop in sedative-hypnotic use, including a decline in the number of dosage units prescribed and in the duration of prescribed use without any particular effort. Dr. Flynn attributed this decline to a number of factors, including a decrease in the size of our military forces, the end of the Viet Nam war, general changes in prescribing practices associated with the increasing use

of benzodiazepine drugs, the rescheduling of short-acting barbiturates to II, and increased physician awareness of problems and limitations of barbiturates. Since 1976, use of the drugs has leveled off. There was no indication of significant diversion of barbiturate drugs into illicit channels. Data from their Charleston Prescription Monitoring System indicated that military prescriptions for non-barbiturate sedatives declined by 24 percent, during the same period of time when civilian prescriptions increased by 31 percent.

Dr. Stewart Baker (VA) outlined the rather extensive program developed by the VA to upgrade the training of physicians in the prescribing of psychoactive drugs. A letter to each medical center directed its Chief of Staff to provide training on the use, safety, etc., of the drugs. Computer-based drug utilization reviews were undertaken. Video tapes were developed for medical staff training on the prescribing of psychoactive drugs. And finally, pharmacists were utilized in their educational efforts. These efforts have resulted in a substantial decrease in orders for short-acting barbiturates. Based on the VA experience, Dr. Baker concluded that with the appropriate educational efforts, prescribing practices can be modified and improved.

For the final overview, Dr. Fred Solomon reviewed the National Academy of Science's Institute of Medicine study on sedative-hypnotic drugs. He traced the declining use of Flurazepam. Dr. Solomon made the following observations: (1) Hypnotic drugs have minimal benefit in severe insomnia (10 to 20 minute decrease in the time to fall asleep; 20 to 40 minute increase in total sleeping time); (2) the efficacy of hypnotic drugs is of relatively short duration; and (3) benzodiazepines, such as Flurazepam, have active metabolites with long half-lives which result in cumulative effects and daytime sedation with continued use. Dr. Solomon highlighted the need for increased physician education; for example, more than half of the medical schools in the United States have no lectures on sleep disorders or their therapy with drugs. He predicted improved prescribing practices if the information could be gotten through to physicians.

STATE PROGRAMS

Representatives from seven states outlined how they are handling the diversion of prescription drugs to illicit channels. Mr. Thomas Kirkpatrick of the Illinois Dangerous Drugs Commission outlined the organizational structure of the Commission and its Governing Board. The Commission serves as the single state agency for drug abuse and also has the responsibility for the scheduling of controlled substances in the state and their licensing for research purposes. The Board consists of the heads of eight state agencies and public members including the past president of the state medical society. It works closely with members of the legislature who have been active in proposing and passing relevant bills, such as, prohibiting drug companies from supplying physicians with preprinted prescriptions; prohibiting companies from sending samples to physicians within the state unless specifically requested; regulating the amount of controlled substances prescribed; regulating the amount of controlled substances shipped within the state at any one time without notice; regulating advertising which presents a need to take drugs; increasing medical education about the prescription and scheduling of controlled substances. Illinois has a triplicate prescription law which covers dispensing as well as prescribing physicians. Three types of physicians pose problems: the uninformed, the impaired (addicted), and the unscrupulous. Detection is through claims made for public assistance payments. The Commission has three medical compliance officers who visit and discuss prescribing practices with physicians who are thought to be prescribing these drugs inappropriately. The majority of physicians are uninformed and are brought up to date. This usually results in a change in prescribing practices. Impaired (addicted) physicians are referred to a program for treatment.

Unscrupulous physicians may have their records inspected and, if warranted, a case can be brought against them. It is very difficult to limit the right of a physician to prescribe controlled substances or to revoke his license. Regulation is possible through the withholding of public assistance payments. The problem that remains is how to regulate and limit the availability of controlled substances without interfering with their legitimate utilization. In Illinois there has been close cooperation between the Board, the state medical society and the legislature in dealing with this problem.

Utah's program relies on practicing physicians for peer review. Dr. Alan R. Nelson reported that Medicaid claims are computer screened to develop physician and patient profiles. The drug part of the profile targets certain drugs, their frequency of prescription, and the amounts prescribed. Over-utilization of drugs by either a physician or a patient results in a sequence of events which rely primarily on educational efforts to modify prescribing practices. Initially, either a call is made to the physician or he is sent a letter that outlines the problem for a particular patient and requests him to return information to the peer review board. Both the patient and the physician are then monitored to determine if any change in prescribing follows. Failing any change, a visit to the physician is made by another physician from the professional review committee in an attempt to bring peer pressure to bear and to alter his prescribing practices. If this does not succeed, a dialogue with the licensing board begins, but it is relatively difficult and unwieldy to take action against a physician. A physician may be in danger of losing his membership in the State Medical Society. This is important since it has implications for the physician in securing malpractice insurance. This latter measure, however, is of no use in dealing with osteopaths since they do not belong to the State Medical Society. Specialty based peer committees and The Medical Letter are used in Utah to establish criteria for appropriate prescribing. Dr. Nelson felt the screening system was fairly expensive; he questioned whether it would be cost effective if it were used only for detecting the over-utilization of drugs. The State Medical Society has also established a Foundation for Continuing Medical Education. The Foundation publishes a newsletter which disseminates information regarding the diversion problem, explains the controlled substances schedules, and related matters.

Dr. Axelrod outlined New York State's triplicate prescription program covering 40,000 physicians. Physicians using inappropriate prescribing practices are referred to the county medical society which deals directly with them and suggests changes. The "clout" is the threatened loss of the right to use controlled substances. This peer contact plan is being used in only a few counties; Dr. Axelrod is not sure it would work for the entire state.

Dr. Axelrod voiced some concern over education modalities, particularly because of the large number of foreign physicians in his state. He has recommended to New York and the Federal government the rescheduling of some drugs (e.g., Valium and Dalmane), now in Schedules III and IV to Schedule II so that triplicate prescriptions would be required for them in the state, and the Federal government could exercise control over their manufacture and distribution. This rescheduling would also increase physician awareness of the problems associated with these drugs. He stated that the alternative of requiring triplicate prescriptions for all Schedule III and IV drugs would overwhelm their system. There are only a few drugs of concern in these schedules. Dr. Axelrod noted that his suggestions for rescheduling have been stoutly resisted by members of the medical community in his state. He has received good cooperation from organized medicine on other aspects of the program, however. He stated that New York is beginning to try the Utah system. The cost is not too high for obtaining the drug profiles of physicians' prescribing practices; the follow-up is probably the more expensive part of the program. Problem areas in New York include: (1) The myriad of interacting agencies, giving rise to turf problems; (2) diversion linked to organized crime that has been difficult to deal with; and (3) the great difficulty to revoke the license of a physician who has been referred to the professional conduct board followed his loss of triplicate prescribing rights.

Mr. David Joranson detailed how Wisconsin utilizes data from DEA's ARCOS system to establish drug profiles. ARCOS has been useful in determining where to look for problems. Even though the ARCOS data are not current, a physician is unlikely to change his prescribing practices from year to year without some form of intervention. Pharmacy audits pinpoint offending physicians and patients. Mr. Joranson presented statewide ARCOS profiles for amphetamines and methaqualone. In Wisconsin, the use of amphetamine drugs for obesity has been declared unprofessional and the State will no longer reimburse for such amphetamine prescriptions. Since 1976, sales of amphetamines have declined drastically. Correlated with this has been a sharp decline in amphetamine arrests in Milwaukee. Whether or not this is a cause and effect relationship was questioned by Dr. David Smith.

Dr. Noel List reported that in Maryland the Drug Abuse Administration sends registered pharmacists to inspect every pharmacy in the State at least twice per year. They inspect every Class II prescription and can inspect the prescribing of specific drugs by specific physicians. If any problem is detected it is referred to the Medical or Dental Board. Medicaid records are also reviewed. A physician may be visited and required to document his therapy. Abusers are referred to the Commission on Drugs and Prescribing Practices of the State Medical Society. Physicians will not be reimbursed for amphetamine prescriptions without special prior permission to use them. Obesity is not considered an acceptable use for amphetamine-type drugs. Education and peer pressure has been successful in modifying the prescribing practices of most physicians who have been subject to review. The physician is told he will be monitored and if he doesn't comply, a case will be made before the State Committee on Medical Discipline. An addicted physician may have his license revoked; he is referred to therapy through the impaired physicians program which involves two years of therapy and then follow-up. In 1978, about 400 physicians were reviewed (out of 9,000 active physicians in the State) and 70 were visited. Pharmacists are also involved in a peer review system through their society. Problems in the state include: (1) A large number of forged prescriptions which no one seems to be concerned about because of a lack of response by law enforcement. Physicians also appear to be lax in their control of prescription blanks. Significant loss of blanks occur in hospital emergency rooms. Medicaid prescription blanks are now serially numbered and any recorded loss is communicated to all pharmacies within 48 hours using the wholesalers as a conduit to the retail stores. (2) Patients are beginning to go from one dentist to another for narcotic analgesic prescriptions.

Mr. William McCord of South Carolina based most of his success in promoting action to his maxim, "Do it before Washington does it to you." In South Carolina, prescription drugs are the number one drug problem. A Task Force on Legal Drugs was formed with a team including physicians, legislators, the chairman of the State Medical Society, and others who could bring about change. The legislature defined the uses for which amphetamines could be prescribed; these uses did not include obesity. The Task Force succeeded in eliminating the practice of mailing large amounts of Librium and Valium to patients by physicians in the alcohol and drug abuse units of the State Veterans Hospitals. He attributed a major share of the State's drug problem to the Armed Force stationed there. The Task Force is currently looking at the applicability of triplicate prescriptions and of peer review. They are directing their educational efforts in prescribing practices to medical and pharmacy schools. Mr. McCord advocated the development of prescription drug task forces by every state to bring together the various agencies and interested groups that can effect change.

Dr. David Smith related that the strategy in California has focused on education. Educational programs are problem oriented rather than to specific drugs per se. Several courses have been developed for different types of physicians. Video tapes have been developed showing how patients may try to manipulate physicians. Discussion in these courses centers on what constitutes appropriate prescribing, excessive prescribing, and the like. California's program may include mandated education for those physicians who have become out of date and whose licenses are on probation. Other continuing medical education courses have been developed for those specializing in alcohol and drug abuse, for the general practitioner, and for physicians working primarily in a hospital setting. In addition, programs are directed at pharmacists to ensure that they are aware of their liability in filling forged prescriptions. A confidential hotline has been established for physicians with drug or alcohol problems. This hotline refers them to a confidential treatment program. The addicted physicians are not viewed as a significant source of drugs for others. Dr. Smith noted that he considered the visit by DEA representatives to the medical society to present the problem as beneficial. He expressed a concern that medical education is a declining priority of the Federal government and that that should not be if this problem is to be dealt with most effectively.

GENERAL DISCUSSION

The meeting was then opened up to general discussion as well as to some reactions from the professional organizations that were represented. Mr. Emanuel Steindler, representing the American Medical Association, announced that the new edition of the AMA Drug Evaluations book will be coming out next year and will include a special section on the prescribing of controlled substances. The

AMA is planning a continuing medical education course on the use of psychotropic drugs, and a symposium on insomnia and its management. The AMA has been working with the Career Teachers Program to increase the number of medical schools involved with Career Teachers, and the importance of their input. A new Drug Dependency Guide will also be published early next year for physicians.

Sue Boe of the Pharmaceutical Manufacturers Association noted that its member companies do not send samples of controlled substances unless requested by physicians and they also do not promote controlled substances. She called attention to PMA's role in the education of patients and consumers. In 1969, the PMA published a curriculum guide on substance abuse, and in 1978 they developed a slide show for use by community groups, especially the elderly, on the appropriate use of drugs.

Dr. William Flynn, representing the Association for Medical Education and Research in Substance Abuse (AMERSA), and a Career Teacher, outlined the Career Teachers Program and the resource they represent in the medical schools. He recommended that a major effort be made to use these Career Teachers for instructing medical students in the appropriate prescribing of drugs, since it will take a period of years to change attitudes through educational efforts. He also recommended that the student leaders of the Student Medical Association be used to work with the Career Teachers in furthering these projects.

A representative from the Veterans Administration called attention to the fact that the VA has just approved twelve (12) two-year fellowships in an alcohol and drug abuse specialty for physicians, psychiatrists, and those in family care.

Dr. Frank Standaert, representing the American Society for Pharmacology and Experimental Therapeutics (ASPET), said that that organization would like to be more involved in these educational efforts. He noted that members of ASPET have expertise on the appropriate use of drugs as well as in drug abuse. The Society is well organized for providing medical education: its members are the teachers and chairmen in departments of pharmacology in medical, dental, and pharmacy schools and are involved in undergraduate medical education as well as postgraduate continuing medical education. He noted that several years ago, ASPET had several meetings with DEA to try to develop a model curriculum but when Dr. Lewis left DEA the meetings ceased and there has been no follow-up since. Dr. Standaert also noted difficulty in trying to obtain from DEA coherent information about controlled substances and their regulation for use in teaching medical students.

Other discussion concluded that no single state agency can cope with the problem; there is a need for cooperation among many state agencies and Federal agencies as well. Since the problems in each state are unique there is probably no one model that will suffice. It will be important to collect the models of the various states and make them available to each of the other states that do not have programs.

There was considerable discussion about whether there should be another meeting of this group, but in general it was thought it would be more appropriate to call a national conference that would bring together groups in addition to those represented today to increase awareness of the problem and bring about action programs. Mr. Angarola stated that the Office of Drug Policy will follow-up on the recommendations made at this meeting.

Mr. Howard Stanley of the Office of the Assistant Secretary for Health stated that Jim Mongin had already made a commitment to follow through on some of these recommendations including the possibility of a national conference. He stated that Drs. Nightingale and Krauthammer had already had some preliminary meetings with respect to planning a national conference. It was suggested that the NIH National High Blood Pressure Program might be a useful model for educating physicians.

Further discussion centered on who was going to pay for all of these state initiatives. Wisconsin has been funding its program from existing money but that is rapidly running out. New York was characterized as running on nervous energy in four of its 62 county medical societies. It needs a commitment from somewhere in order to support a state-wide program. Dr. Nightingale suggested that some changes won't cost money: the peer review system in some states can be done at minimal cost, the development of regulations regarding payments for inappropriately prescribed drugs from public assistance funds could be done at minimal cost and might save enough money to fund the other parts of the program. Dr. Joranson expressed the belief that there is a need for an in-depth

review of the state's role, vis-a-vis what can be provided by the Federal government. A discussion followed on the need for precise information and the utility of state-wide use of the DAWN System. New Hampshire has developed a mini-DAWN at a relatively low cost. DEA has visited 18 other states and 16 have expressed interest in the mini-DAWN concept. The problem is money. It was suggested that perhaps the Office of Drug Policy could sponsor some demonstration projects utilizing mini-DAWN in other states. Mr. Russell suggested that the cost for a whole state was very high, but that sampling techniques might be equally useful and much lower in cost.

Finally, it was agreed that minutes of this meeting should be prepared and sent to all of the participants as well as to other states so that they might profit from the discussions that took place.

SUMMARY

The 1979 Federal Strategy for Drug Abuse and Drug Traffic Prevention once again drew attention to the substantial abuse of prescription drugs, in particular sedative-hypnotics, minor tranquilizers, and stimulants. In terms of health hazards, the abuse of these drugs exceeds that of heroin. The inappropriate prescribing of some physicians and the diversion from pharmacies have been the primary sources of these drugs reaching the illicit market; only a small percentage is derived from unscrupulous or impaired physicians or from diversion at the wholesaler/manufacturer level.

The President's Strategy Council on Drug Abuse and an Ad Hoc Sedative/ Hypnotic Working Group have been studying the most effective ways to deal with this problem.

On September 12, 1979, the Domestic Policy Staff's Drug Policy Office convened a meeting of representatives from Federal agencies (National Institute on Drug Abuse, Drug Enforcement Administration, Department of Defense, Veterans Administration, Office of the Assistant Secretary for Health, on the Alcohol, Drug Abuse, and Mental Health Administration); the National Acadamy of Science-Institute of Medicine; seven states (California, Illinois, Maryland, South Carolina, Utah, Wisconsin); professional, educational, and trade organizations; and Congressional staff to discuss courses of action to reduce the diversion of prescription drugs to the illicit market. The President's principal drug abuse advisor, Lee Dogoloff, and Congressman Lester Wolff, Chairman of the House Select Committee on Narcotics Abuse and Control, opened the all-day meeting. Each Federal agency outlined its role in the problem and actions it has taken. State representatives presented the different models they have developed for trying to indentify problem areas and for taking corrective measures.

All of the participants agreed that no one agency, either Federal or State, could effectively deal with the problem. Common elements of the State programs include professional education, professional peer pressure, regulatory and licensing activities, and law enforcement as a final resort. All of these elements seem essential. The establishment of a state prescription drug task force bringing together these elements has facilitated and enhanced efforts to deal with each state's unique situation. Many of these states rely on close Federal-State cooperation with DEA and NIDA, and use data generated by Federal information systems which help to identify points of diversion. The need for coordinated cooperative efforts involving Federal, State, and local government agencies in cooperation with professional, educational, and trade organizations was repeatedly emphasized.

Actions stemming from recommendations made at the meeting include the following:

1. The White House Drug Policy Office will convene a meeting of representatives from the Drug Enforcement Administration, the Food and Drug Administration, and the National Institute on Drug Abuse, to develop a strategy for promoting appropriate prescribing of controlled drugs by physicians and other health care professionals. This interagency working groups, in consultation with professional organizations, will review existing programs and educational resources, and will develop new resources, for increasing physician awareness and sensitivity to the problem of prescription drug diversion, and for positively modifying their prescribing practices.

2. As a follow-up to the studies on insomnia and the use of sedative-hypnotic drugs carried out by the National Institute on Drug Abuse and the National

Academy of Science-Institute of Medicine, the Surgeon General is planning new initiatives that include upgrading therapeutic practices related to insomnia and the appropriate use of hypnotic drugs. The Surgeon General will review the applicability of these educational initiatives to other problem areas such as the management of stress and anxiety.

3. The White House Drug Policy Office will write to each State Governor concerning the seriousness of prescription drug diversion. Each state will be encouraged to develop a prescription drug task force which could bring together the concerned state agencies and medical, pharmacy, and other professional societies for identifying and dealing with prescription drug diversion.

A state task force could examine the applicability of model programs that are working to control diversion in other states. HEW will compile and make available methods used by several states to deal with this problem. The Federal Government will also make available data from its data systems that may facilitate the identification of problem areas and problem physicians. A task force could also consider the applicability to its state of regulatory actions on specific drugs; peer review of questionable prescribing practices; restrictions or limits on the prescribing of controlled drugs; and techniques being used by other states, such as triplicate prescriptions, prohibiting drug companies from distributing preprinted prescriptions for controlled drugs, serially numbering prescription blanks to enable voiding of those that are stolen or lost, etc. Some states have found that careful review of requests for payment from Medicaid funds may identify problem physicians and patients; guidelines can be established to limit the prescribing of certain drugs through restrictions on Medicaid payments.

4. State medical licensing boards and other relevant state agencies should review their current policies and procedures which, in some states, make it difficult to revoke a physician's license or restrict his prescribing privileges even in some cases where his peers adjudge him to be prescribing inappropriately or unethically.

5. The White House Drug Policy Office will ask the Surgeon General to convene a national prescription drug conference in order to highlight the importance of this problem and to share existing State initiatives.

6. The Strategy Council on Drug Abuse will establish an Ad Hoc group to review the existing problem of prescription drug diversion, to identify further measures that may be undertaken to decrease diversion, and to follow the progress of change in prescribing practices that these measures may bring about.

PREPARED STATEMENT OF PETER B. BENSINGER, ADMINISTRATOR, DRUG ENFORCEMENT ADMINISTRATION, U.S. DEPARTMENT OF JUSTICE

Good afternoon, Chairman Wolff, Members of the House Select Committee on Narcotics Abuse and Control. I appreciate this opportunity to continue the dialogue we began this summer in Chicago regarding the very serious problem of diversion of licit drugs. As a result of a series of headline-making articles there, the citizenry of Chicago were made well aware of the practitioner-level diversion problem in their community. Today, here in Washington, D.C. we have a dual perspective: as local citizenry facing a serious retail-level diversion problem in our community, and second, as representatives of the Executive and Legislative branches of our government tasked with developing solutions to this problem that will be applicable nationwide.

At this juncture, I think that a few cold statistics will drive home the message that regulating the licit controlled substance distribution chain is a task of enormous magnitude. There are approximately 20,000 drug products controlled under the CSA and over 20 billion dosage units of these products flow through the distribution chain each year. This legitimate distribution chain consists of over 600,000 registrants, of whom 98 percent are at the practitioner level. To monitor the entire registrant population, DEA has approximately 220 Compliance Investigators and 20 Special Agents. With a registrant-to-investigator ratio of nearly 3,000:1, it is clear why we must rely on close cooperation with the state authorities.

Conservatively, 250–300 million of the 20 billion dosage units manufactured yearly are diverted. DEA estimates that 80–90 percent of diversion occurs at the retail level. The most common methods of retail diversion include: pharmacy theft, indiscriminate prescribing, forged prescriptions, and the illicit sale of legal

drugs by registrants. Individuals who obtain prescriptions and controlled substances by feigning a medical need or who obtain multiple prescriptions from different physicians are also responsible for this diversion.

We are well aware of the now all-too-familiar scenario involving the "pill-pushing" doctor, who hides behind a professional facade, while provding a steady stream of drugs into the illicit market. He is not the only health professional involved in this activity. The pharmacist who often fills prescriptions with full knowledge of the circumstances or who chooses to ignore his professional responsibility also adds to the problem. It is unfortunate that the very small number of physicians and pharmacists who are involved in diversion have cast a shadow over two noble occupations.

Others contributing to the problem are the "professional patients" whose occupation is going from doctor to doctor collecting multiple prescriptions along the way, and the professional burglar. Drug thefts in 1978 totaled over 46 million dosage units. During the first six months of 1979, the total was over 25.6 million dosage units.

The incentives for diverting legally-produced controlled substances are many and varied. Certainly, the enormous profits involved make trafficking of diverted drugs most attractive. For example, a single dosage unit of Dilaudid (hydromorphone HCl) purchased by a pharmacy or doctor for approximately 17 cents, can be sold on the streets for up to $60. The fact that heroin availability in the United States is at the lowest levels since 1971, contributes to the demand for substitutes. The demand for a wide variety of diverted drugs to supplement poor quality or non-existent heroin will continue to be an important factor affecting the diversion problem.

DEA uses the Drug Abuse Warning Network (DAWN) to monitor drug abuse trends nationwide. DAWN data is based on reports submitted from emergency rooms and medical examiners across the country in 24 Standard Metropolitan Statistical Areas (SMSA). DAWN data shows the clear relationship between deaths, injuries, and the consumption of licit controlled substances. These drugs present a much greater health hazard to the general populace than drugs wholly illegal in nature, including heroin.

According to DAWN emergency room (ER)) reporting for the period July 1978 to August 1979, a review of the 15 most abused controlled substances reveals that 11 of the 15 are primarily of legitimate origin. The type of drug abuse most frequently reported involved alcohol in combination with one or more drug substances. Then, in descending order, the most commonly abused substances were: diazepam (Valium), heroin, phencyclidine (PCP), flurazepam (Dalmane, an anorectic), marihuana, D-proxpoxyphene (Darvon) and chloridazepoxide (Librium). The number one drug in this list, diazepam, accounted for 10.6 percent of all the emergency room mentions.

The DAWN emergency room data for the same period indicates statistically significant increases in the number of mentions for methaqualone (Quaaludes), cocaine and amphetamines. The large numbers of methaqualone mentions occurred in (again, in descending order): Miami, New York, Philadelphia, and Los Angeles. Because of Miami's proximity to Colombia, a primary source nation for illicit methaqualone, a significant portion of the methaqualone available in Miami is very likely to be of clandestine origin. However, DEA shows that Florida ranked number one in per capita consumption of legally produced methaqualone.

I think it important that there is a clear understanding of exactly what DEA's authority is with respect to controlling licit substances. The Controlled Substances Act of 1970 (CSA), provides for a "closed distribution system" from manufacturer to user. That assures an adequate supply of controlled substances for legitimate medical, research and industrial needs, while at the same time reduces the widespread diversion of drugs from legitimate channels into the illicit market.

Under the CSA, DEA has been given considerable authority to monitor the commerce in controlled substances at the manufacturing and wholesaling levels. The Congressional intent to limit Federal responsibility at the retail level of the drug chain was made clearly evident at the time the CSA was enacted. Thus, DEA's statutory authority to regulate at the retail level is limited and, as such, State licensing authorities must assume the primary responsibility.

This division of responsibility is reflected in the 1979 Federal Strategy under "Control of Legally Manufactured Drugs." Here it is stated that:

Those agencies responsible for licensing and regulating the manufacture, distribution and dispensing of legally produced controlled drugs will intensify their

efforts, and focus on the upper-levels of the drug distribution chain. State and local agencies should concentrate on local retail violators. Inspections and audits will be concentrated more heavily on problem drug manufacturing and distribution facilities to uncover violations of law and regulation. More stringent application of penalties to these violators will be employed, including increased emphasis on prosecutions under the civil statutes.

The specific, comprehensive criteria that DEA can apply to wholesale level registration does not apply to the Federal registration of retail-level practitioners. Authorization by the state in which he practices entitles a practitioner to a Federal registration. DEA's sphere of control is limited to revocation and suspension, and can be exercised only when the registrant:

(1) Materially falsified a registration application;

(2) Has been convicted of a drug felony; or

(3) Had his or her state license or registration suspended, revoked, or denied.

Consequently, we depend extensively on the states' efforts. DEA's policy directed at supporting state efforts is also in keeping with our legislative mandate. Memoranda of Understanding describing Federal and state roles have been signed with 45 states and the District of Columbia.

There is no universal method employed by the states to regulate health professionals. Generally, this responsibility is assigned to a regulatory board, such as a Board of Pharmacy or Board of Medicine, and is one of a broad range of responsibilities, of which only one is the prevention of diversion. As a rule, these boards are not oriented, equipped, staffed, trained, or in some instances, even empowered to combat diversion by the health professionals they are charged with monitoring.

DEA has been successful in reducing diversion at the manufacturer/distributor level to a relatively minor portion of the total drugs diverted each year. This has been accomplished in a large part through the cyclic inspection program which minimizes the risk of diversion by insuring that manufacturers and distributors are in compliance with Federal regulations. This Federal presence and the strict enforcement of the CSA through administrative, civil and sometimes criminal actions, has had a significant impact on diversion from the upper levels of the distribution chain. The largest civil penalty against a registered distributor was levied in fiscal year 1979. Total fines and civil penalties in fiscal year 1979 for all levels of registrants exceeded $830,000. This is more than twice the total for fiscal year 1978. DEA also establishes annual production quotas which limit the production of those substances with the highest abuse potential to that amount needed for legitimate medical needs. In recent years, we have steadily reduced the quotas for such highly abused drugs as amphetamine, methamphetamine, and methaqualone. We fully intend to use this authority when it is evident that overproduced substances are being diverted into illicit channels.

Our successes at the wholesale level of the distribution chain is the result of our clearcut authority in this area. Nonetheless, we are ever mindful of the locus of the diversion problem. Our program to assist the states with the retail level diversion problem takes several basic approaches, some of which are enforcement oriented, some of which are not.

We devised the Diversion Investigation Unit (DIU) Program under which DEA serves as a catalyst to assemble funding, manpower, expertise, and various jurisdictions into a unified state effort. These units are manned and managed by state authorities, although a DEA Special Agent is assigned on a full-time basis for coordination and support. Our objective is to launch the participating state on a sound start by means of direct Federal funding and support and, ultimately, have a state-sustained, permanent DIU-type program.

DIU's were initiated on a pilot basis by Texas, Michigan and Alabama in 1972. All three pilot states have endorsed the program and are now funding their DIU's. Based on the results of these pilot programs, DIU's have been implemented in the following states: California, Illinois, Massachusetts, New Jersey, Pennsylvania, North Carolina, Georgia, New Hampshire, Nevada, Maine, Washington, Hawaii, Oklahoma, Utah, New Mexico, Florida and the District of Columbia. All but the Florida DIU are active, bringing the current total to 19. We anticipate two additional units will be added in fiscal year 1980.

In the last two years, these units have made over 1,000 arrests and seized over 1.8 million dosage units of legitimately manufactured drugs. I believe the DIU Program has demonstrated that a concerted effort by highly trained personnel can curtail the diversion of drugs on a statewide level. DIU's bring together independent state agencies having a role to play in regulatory drug enforcement into a single, cohesive unit. Each agency contributes specialized skills to the benefit of the other participants in the unit. Equally important, this program focuses public attention throughout the state on this often neglected facet of drug abuse.

There are some areas where major violators have been operating untouched by state or Federal efforts. To impact on these violators, DEA has initiated Operation Script. This project supplements existing efforts and directs DEA resources where limited activity occurred in the past. This increase in efforts focuses DEA's technical, investigative, and legal expertise to produce high impact/high visibility investigations on pre-selected violators.

Operation Script was initiated with the identification of 109 pre-selected targets in 22 states. DEA can selectively target registrants as potential sources of diversion based on DAWN data which provides indicators of drug abuse within geographical areas and ARCOS information regarding purchase of drugs by specific registrants.

The majority of these targets are at the practitioner level which, as previously mentioned, is the major source of diversion of licit drugs. DEA investigators, together with state and local law enforcement and regulatory officials throughout the United States, are actively developing cases against the most significant retail violators we have identified. Operation Script is designed to meet the current need for a high impact selective enforcement program.

I would like to emphasize that DEA still considers retail diversion to be primarily a state responsibility and, thus, we will continue all of our programs directed to increase state enforcement capabilities. I hope that our accelerated efforts will encourage the states and demonstrate to them the need for vigorous enforcement activity in the area of practitioner diversion.

The Drug Oriented Investigation (DOI) Program is another new program designed to impact on the availability of legally produced drugs in the illegal traffic. DOI's concentrate on specific drugs and involve investigations at all levels of the distribution chain. These investigations are centrally coordinated, nationwide actions aimed at collecting diversion information that may eventually be used in reducing quotas, limiting imports, rescheduling actions, and possible administrative or civil actions against the manufacturers. The initiation of three DOI's directed three highly abused controlled substances has been implemented.

The DEA Office of Enforcement is currently considering targeting, for a CENTAC Operation, an identified group of registrants operating at various levels of the licit distribution chain. The decision to implement this CENTAC will be made after the results of the ongoing evaluation are reviewed.

DEA has not limited its activity concerning the diversion problem strictly to enforcement operations. The diversion of legally produced drugs is a complex problem that mandates a combination of enforcement and non-enforcement approaches. DEA participates in four informal "working committees" which are designed to improve communication with professionals and regulated industry and to encourage establishment of self-imposed restraints and procedures that go beyond minimum standards of the law. A product of the DEA/Practitioner Working Committee is the "Guidelines for Prescribers of Controlled Substances" which has been circulated to various professional associations for approval. Five of the six major professional associations have concurred on these guidelines; the sixth association, the American Medical Association, is expected to act in December.

DEA will continue to support Federal and state actions that are aimed at curbing the misprescribing and overprescribing of controlled substances. DEA has provided statistical support for appropriate Federal and state actions involving specific drugs. Wisconsin's recent action on amphetamines and FDA's proposal along the same lines are examples of responsible government efforts to reduce the abuse of a very dangerous drug. DEA has requested that FDA also consider removing the anorectic indication from phenmetrazine (Preludin) due to its similarity to the amphetamines.

DEA will continue to provide assistance to the states for the purpose of upgrading their ability to handle retail diversion in their jurisdictions. In areas where regulatory boards cannot or will not take appropriate administrative action against a violative registrant, there is often no alternative but to initiate

a criminal case. It is preferable for a peer group or regulatory board to take remedial action to curtail illegal activity when it is first discovered. DEA has pilot programs in California and Pennsylvania to support improvement of state regulatory and enforcement capabilities in the area of retail diversion. Major factors in the overall improvement of state capabilities include increasing statutory authority, developing adequate resources, and increasing educational programs for state investigators and prosecutors.

Voluntary self-help programs, such as the Pharmacy Theft Prevention (PTP) Program, now operating in 18 locations, have proven to have positive results. In these programs, DEA acts as a catalyst to mobilize area pharmacists, police, government, and media into a joint community action approach towards suppressing pharmacy thefts. Statistics show that during a recent period while nationwide statistics on pharmacy thefts increased, thefts in PTP cities actually declined. There are several other areas which deserve additional attention at all levels of government and by the professional associations. They are:

1. Encourage health care professionals to take advantage of continuing and relevant education programs dealing in such areas as prescribing drug interactions, and the abuse of controlled substances.

2. Encourage the inclusion of courses in the proper prescribing and dispensing of psychoactive drugs in medical schools and in physician and health professional curriculums.

3. Develop a national licensing clearing house facility in order that information concerning convictions, suspensions, and revocations would be available to all states for licensing purposes.

When I last testified before the Select Committee in Chicago on the subject of retail diversion, I indicated that a review of the CSA would be initiated. This review has been conducted and DEA is currently in the process of making several recommendations concerning possible revisions.

Chairman Wolff, the work of the Select Committee on the retail diversion situation has been instrumental in calling national attention to this problem. I can assure you that DEA is committed to finding solutions to this very serious problem. I believe that the programs I have outlined for you this afternoon will enable DEA to maximize its efforts within the limits of our statutory authority. We are ready to lend whatever support we can to the states and the health care profession. Our goal is to have the same success at the retail level as we have had at the wholesale level. DEA welcomes and appreciates the continued support and interest of this Committee.

Thank you.

PREPARED STATEMENT OF RICHARD B. LOWE III, ACTING INSPECTOR GENERAL, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Mr. Chairman and members of the committee: I appreciate this opportunity to present my views on the diversion of controlled substances from the legitimate medicaid drug distribution network. I am the acting inspector general of the Department of Health, Education, and Welfare. Our authorized audit staff now totals 950. Our investigations office is authorized 229 personnel. This staff works with attorneys and program specialists to provide a multi-disciplinary approach to controlling fraud, abuse, and waste in departmental programs. My background is prosecution and management. I was the assistant prosecutor in one of the largest district attorney's offices in the United States, New York City. I have experience in the prosecution and investigation of multifaceted crime from the most violent street crimes to the mos complex white collar crimes.

We are informed by the Drug Enforcement Administration (DEA) that 80–90 percent of the drug diversion from legitimate channels is at the practitioner level. Because of insufficient legislative authority to implement controls at the retail level, the DEA concentrates its efforts at the highest level of the normal drug distribution chain (manufacturers, wholesalers, importers, etc.). However, these individuals account for less than 2 percent of the total universe of persons and entities who are legally registered to distribute and/or dispense drugs. By far, most complaints and leads regarding diversion relate to retail sources, including those participating in the medicaid program. We found that DEA just does not have the resources to assist HEW in an extensive initiative to investigate diversion through the medicaid program.

DEA, however has agreed to refer allegations to diversion investigation units (DIU) in states where DIU's exist and will initiate their own investigations of large scale diverters. DEA has provided information on the extent of schedule II purchases of individuals under investigation for medicaid violations and has stated that they will continue to provide intelligence information to HEW. If in the future there is a change in DEA's role per earlier GAO's recommendations, I would like to see a provision to include investigations of medicaid drug diversion.

We are also aware that approximately half of the reported sources involved in drug related deaths and serious drug abuse episodes were obtained through legal prescriptions. Further, a joint HEW/Justice Department information system identified the 35 leading drugs being abused. The information system revealed that legally available drugs were present in about 70 percent of the drug abuse and death situations reported by hospital emergency rooms and coroners.

We are particularly concerned with drug diversion in the medicaid program because the real dollar cost to medicaid caused by drug abuse goes far beyond the actual cost of the medication. The true figure must include the cost of office visits, laboratory tests, X-rays and other services to "legitimize" the prescriptions. This is to say nothing of the larger human loss and suffering due to the physically and mentally debilitating effects of drug abuse.

We believe the majority of medicaid recipients and providers are honest, but controls are necessary for the few abusers. Certain controls can be implemented which affect the total system. First, a formulary can be utilized to limit drugs available for reimbursement through medicaid, thereby affecting all patients and providers. This elimination of many of the more commonly abused drugs from the medicaid program should not interfere with the appropriate treatment of serious illness. Secondly, quantities of prescription drugs per recipient in any given period of time can be limited. In either instance, though, reasonable provisions for exceptions to these restrictions must be available to ensure appropriate care in unusal cases.

For known individual medicaid abusers, two additional controls have been quite effective, utilizing special medicaid cards which direct that a recipient's services should be restricted. The first would "lock-in" the recipient to a single physician, or single pharmacy, or both for all their routine services to eliminate shopping around. The second establishes a requirement for "prior authorization from the medicaid program before routine services, including dispensing of controlled substances will be reimbursed."

HEW has a special interest in the indiscriminate use of drugs and has, over the years, launched numerous initiatives to combat, control and prevent drug abuse. Many of these have been in cooperation with the Department of Justice. Within HEW the National Institute on Drug Abuse was established to prevent the problems related to drug abuse. The Institute conducts and supports research into the biomedical, epidemiological, sociological, and psychological causes of drug addiction and abuse, and develops new approaches to prevention and treatment. NIDA also finances training programs for persons entering this specialized health field, as well as supports a wide variety of community-based treatment and prevention activities. It funded drug abuse treatment services for an estimated 275,000 persons this year and currently sponsors 375 research projects funded at approximately $43 million.

The Food and Drug Administration, over two decades ago, began an effort to gather evidence against practitioners and others who dispensed legitimate pharmaceuticals outside of the patient-practitioner relationship. This function was dropped for non-controlled substances and the resources necessary to conduct the investigations were transferred to the Department of Justice in 1968. This is where the Federal responsibility for policing the illegal and legitimate traffic in controlled substances now rests.

On an experimental basis in 1976, the OIG audit agency and the social and rehabilitation service began to utilize a specialized computer program to identify medicaid vendors who had provided drugs to recipients in excess of established parameters. Print-outs listed the frequency, quantity, and types of drugs dispensed. Most of the drugs involved were controlled substances, but since we also have an interest in minimizing the diversion of non-controlled substances whose indiscriminate use are a threat to public health, other prescription drugs were also included. Both controlled substances and non-controlled substances have

an illicit street value far in excess of their legitimate costs. Thus, there can be a great profit with a medicaid financed inventory when the drugs are sold on the street.

In an attempt to attack medicaid fraud and abuse, in 1977 we launched project integrity which was a nationwide joint Federal/State initiative that used computers to identify over 2,400 physicians and pharmacists whose medicaid billing practices exceed certain criteria. Over 1,100 pharmacists were selected for the initiative because of the quantities and frequency of drugs dispensed. Most of the investigations were conducted by state investigators. To date, over 400 of the physicians and pharmacists have received administrative sanctions, and another 55 have been indicted. Thus far, 35 individuals have been convicted under project integrity, while several hundred investigations are still open. Of course, not all of the convictions and sanctions were based upon drug charges, but for the pharmacists at least, the investigations followed computer disclosure of aberrant dispensing patterns.

With respect to project integrity, in cooperation with many States and the Health Care Financing Administration we have prepared two documents for State agencies to use if they wish to institute their own computer based initiatives. The first is a lessons learned report published earlier this year, while the second is an October 1979 handbook which describes computer screens that can be used to scrutinize billing records and identify potentially liable providers and recipients. The pharmacy screens are almost entirely based upon dispensing practices. We stand ready and willing to offer technical assistance to any State desiring to implement these computerized operations, for it is indeed the State which must shoulder primary responsibility for the investigation of fraud and abuse within the medicaid program. Over half of the States have State medicaid fraud control units funded by HEW at 90 percent pursuant to Public Law 95–142. In most of the 27 jurisdictions in which there are no medicaid fraud control units, State welfare investigative agencies have this responsibility. Most of these organizations are not prepared to utilize the undercover operations that are essential to drug investigations. They are primarily specialists in white collar crime against governmental programs, and this emphasis severely limits endeavors in the undercover area. The inherently dangerous undercover investigations are difficult to prove in a court of law and are much more resource intensive than other fraud investigations. Consequently, both types of investigative agencies consider drug diversion cases a relatively low priority.

At the same time the traditional drug law enforcement agencies (bureaus of narcotics, vice squads, etc.) consider the medicaid diversion cases as too small to be worth their while. The net result is that not much investigative effort is available to the medicaid drug diversion problem. Ironically, California, the State with the most impressive record in the drug investigation of physicians (96 convictions in the past five years and 123 indictments within the last 18 months) is prohibited by State law from working undercover cases with medicaid cards. Their accomplishments for the most part have been outside the medicaid program.

In the fall of 1978, the Secretary of HEW ordered a nationwide "crackdown" on medicaid drug abuse. The project was assigned to the Health Care Financing Administration and is under the direct management of their Office of Program Validation. The objectives of project crackdown are twofold: first, we wish to identify and to take action against medicaid drug pushers at all levels, including those who operate under the guise of medical practitioners as well as those who do their dealing on the streets of our cities. Secondly, working with the states involved in the project, we are seeking the regulatory and administrative improvements which will prevent the Federal and State governments from subsidizing drug abuse.

To date, the results of operation crackdown can best be described as spotty. Typically, the problem we are faced with is medicaid recipients (or anyone with a medicaid card) visiting a physician; obtaining a prescription for controlled substances (or any other drug); taking the prescription to a pharmacy for filling; and using the drugs to support their own habit or selling them on the street. Needless to say, it doesn't take much imagination to visualize that an individual can visit a variety of physicians and pharmacists to make a real "killing." The most distressing fact is that State and Federal governments are put in the position of being the financier for this illicit drug traffic through the medicaid program.

All of this was highlighted last summer in a series of news articles printed in the Philadelphia Daily News, describing the experiences of an investigative reporter who posed as a welfare recipient. My predecessor was asked by the Secretary of HEW to immediately launch a program to attack these practices. The Secretary asked for a pilot project in each of ten major cities. Capabilities for action varied by locality, but some States such as California and New York had pre-existing programs.

We consider project crackdown an ongoing program with no end-point in sight. It should not be considered simply as a short-term remedy to a long-term problem, and we are continuing to work with those participating States whose efforts have not yet developed fully. Our expectations are that an organized assault on the problem with concomitant publicity can be a very effectivet deterrent. In Philadelphia, for instance, due to the publicity generated, law enforcement intelligence revealed that drug sources had "dried up" for a period of months.

Currently, the States are actively investigating between 60 and 100 cases under the auspices of project crackdown. To date, there have been a handful of convictions. We have seen, moreover, some very positive results in terms of identifying systemic improvements. The following are examples.

In Detroit, office visits by high-risk recipients decreased by 80 percent, and their use of prescription drugs decreased by 93 percent following Michigan's establishment of a prior authorization requirement each time these high risk individuals sought services. Michigan also instituted a lock-in procedure which prevented recipients from shopping around from one physician to another. This translates into an estimated savings of $400,000 for the 104 recipients currently on the restricted program.

Wisconsin experienced a 90 percent decrease in the utilization of certain drugs after the medical examining board banned the prescribing of specific drugs except for a few limited purposes. Other States such as Illinois and California registered similar successes after instituting a more restricted formulary or list of allowable dugs. This action was also coupled with close monitoring of the prescribing physicians and recipients. The highly visible sanctions taken by these two States surely contributed to the deterrence.

The approach in Louisiana and Texas is a bit different. They have a very restricted drug program which limits the quantities of drugs covered under the medicaid program.

Some additional innovations are on the horizon. In New York, the department of social services through its bureau of medicaid fraud and abuse is attempting to correlate medical examiners' records of overdosed medicaid recipients with their obtaining large amounts of abused drugs.

A unique prosecuting unit in the Philadelphia District Attorney's office headed by a physician/lawyer is being supported by the Pennsylvania State Medicaid Fraud Control Unit through a special funding agreement.

As you heard at a previous hearing, California has completed preliminary research regarding a computered drug review system that would monitor prescribing patterns, drug interactions and drug abuse. The system would have the capability of reviewing a patient's drug record prior to dispensing a new or refill prescription. The usefulness versus cost of such a system on a national scale is difficult to predict. These approaches teach us a valuable lesson—the solution to drug abuse is not solely a law enforcement responsibility, but rather mechanisms have to be installed to prevent drug abuse.

At this point, let me share with you some ideas the Offices of Inspector General is considering which may help to curb the diversion problem as it relates to medicaid:

1. Require termination from participation (or a very long suspension) in Federal health program after being convicted of violating any provision of the Controlled Substances Act.
2. Amend the Social Security Act to make it illegal for a practitioner to pay pharmacist to fill his prescriptions for controlled substances.
3. Upgrade from misdemeanor to felony the punishment for use of medicaid cards to aid in the procurement of controlled substances to be sold on the street by drug pushers.
4. Suspend payments for prescriptions, supplies, and services ordered by physicians suspended from medicaid.

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In conclusion, we feel that we can have a significant impact on the diversion problem. Regulatory and administrative modifications to the program are preventive and will decrease the burden on law enforcement agencies.

Law enforcement efforts in this area require resources beyond those currently available. Even the best prosecutors encounter difficulties in presenting cases where medical judgment is at issue.

It is obvious that law enforcement is not the sole answer, but it is important to muster the resources of a variety of Federal, State and local agencies and to maintain a mix of regulatory and law enforcement initiatives.

PREPARED STATEMENT OF JEROME NIPORT, DIRECTOR, MEDICAL ASSISTANCE COMPLIANCE ADMINISTRATION, MARYLAND DEPARTMENT OF HEALTH AND MENTAL HYGIENE

My name is Jerome Niport. I am the Director of the Medical Assistance Compliance Administration, Maryland Department of Health and Mental Hygiene, the single-state agency charged with administering the Maryland Medicaid Program.

The Administration which I direct is responsible for the review and control of utilization of medical services reimbursed by Maryland Medicaid. This includes prescription drugs, which in the last fiscal year numbered over 2.5 million prescriptions and for which we paid about $16 million.

Drug utilization review is an integrated process comprising three distinct elements:

1. The drug prescriber.
2. The drug dispenser.
3. The drug recipient.

The results of our reviews leave no doubt that all three elements of a prescription transaction permit, and quite often even encourage, diversion of legitimate drugs into illicit channels.

Physicians are manipulated by patients, by threats, persuasion, misrepresentation or higher office fees, into prescribing precisely the drugs desired by the patient, in quantities far exceeding medically acceptable consumption rates. In succumbing to this manipulation, or as a result of poor record keeping, physicians exceed maximum duration of drug use recommended by manufacturers and recognized pharmacologic authorities.

Pharmacists dispense drugs in quantities or combinations which are patently inappropriate without verifying the legitimacy of the prescription or the intent of the prescriber. Frustrated by inaction on the part of local law enforcement agencies and the courts, pharmacists are not motivated to report forged prescriptions.

Individuals with Medical Assistance identification "shop" a variety of physicians to secure prescriptions to their order. With a stock of bought or stolen Medical Assistance cards, a credit card imprinter and prescription blanks readily available in most physicians' offices and clinics, there is virtually no limit to the number of forged prescriptions an enterprising individual can pass.

The motivation to divert prescription drugs into illicit channels is enormous. A prescription for 100 Valium 10 mg. has an actual ingredient cost of $18.78 and a "street" value of $200 to $400 in Baltimore. It is no surprise, therefore, that Valium is the most frequently sought and prescribed drug in the Maryland Medical Assistance Program. Other drugs which, like Valium, affect the central nervous system, command comparable prices. Analgesics such as Demerol Dilaudid, Percodan and Morphine sell for as much as $20 to $40 a tablet.

Approximately 30 percent of the drugs reimbursed by Maryland Medicaid are classified therapeutically as central nervous system drugs, viz. they ease pain, elevate moods, sedate, hypnotize or stimulate. Our attempts to control the inappropriate prescribing and misutilization of such drugs have met with mixed success.

A recent study of the prescribing practices of 4,886 Maryland physicians participating in Medicaid revealed that 16 percent (770) wrote 75 percent of all prescriptions. More specifically, 45 physicians, less than 1 percent of those participating, ordered half of the stimulants, one-fifth of the psychotherapeutic agents and analgesics, and one-tenth of the sedatives and hypnotics given in the

office setting. A number of physicians clearly prescribing excessive amounts of stimulants for weight control were referred to the Committee on Drugs of the Medical and Chirurgical Faculty, the statewide Medical Society in Maryland. There was an appreciable change in the prescribing habits of these physicians. As the ultimate solution, such drugs are no longer covered by the Maryland Program,

Recipients with a history of acquiring abuse-prone drugs from several different physicians are first "counselled", then warned and finally asked to select a primary physician and pharmacy; however, such a restriction is difficult to administer and often the individual simply acquires someone else's Medicaid card.

It is apparent that steps must be taken to stem the flow of prescription drugs into illicit channels. Maryland, and I am sure other states as well, will continue to do all in our power to reduce that flow; however, that power is limited.

On the national level, I recommend educational programs to enhance physicians' awareness to the limited benefit, over time, of many central nervous system drugs; to the accumulative effect of certain drugs even taken as prescribed; and to the dangerous interaction of certain drugs, including alcohol.

Further, I endorse the programs of Federal assistance to states to attack the problem of prescription forgery.

Finally, I recommend most strongly that Federal Medicaid regulations allow states to incorporate provisions to suspend certain benefits to those individuals who abuse them. As of now, we can only deny benefits to an individual who has been convicted of a fraud against our Program. The problems we have been discussing have not, up to now, been given much attention or priority by prosecutors or police.

I thank you for this opportunity to bring our problems and frustrations to light. I sincerely hope that somehow we will be given the resources to combat this ever-growing problem in our society.

PREPARED STATEMENT OF RICHARD D. PARKER, SR., INDEPENDENT PHARMACIST, KENSINGTON, MD.

Mr. Chairman and members of the committee, my name is Richard D. Parker, Sr. and I live in Glenwood, Maryland. My profession is that of Registered Pharmacist and I am employed at Kensington Pharmacy, Inc. in Kensington, Maryland. I have been employed in Kensington since 1947 and have been Registered to practice Pharmacy since 1951.

Having served as President of the Prince Georges-Montgomery County Pharmaceutical Association (1965–66) and President of the Maryland Pharmaceutical Association (1977–78), I have been in close association with leaders in local organizations. I have also been active in national organizations, attending their conventions and working with them in attempts to make the profession better able to serve the public.

In my capacity as Chairman of the Legislative Committees of the local and state organizations, I have been involved in many hearings and have seen many attempts to adopt corrective legislation when agencies were already in existence with the power and directive to regulate. In these cases, the agency was usually short funds to do a proper job, or was hampered by opinions from the Attorney General's office which interfered with decisions to go forth in operation to correct problems. In the area of drug abuse, I have seen a variety of problems which need to have corrective action taken to control, either by regulation or legislation.

Among the most serious forms of abuse are the prescriptions presented to Pharmacists which have forged or altered, or which have been issued by licensed practitioners not in the usual course of practice. It is the latter of these abuses which poses the more serious problem to pharmacy. Physicians in the District of Columbia may prescribe controlled substances and the prescriptions may be filled in the nearby Maryland or Virginia pharmacies in the proper course of business. The problem arises when a practitioner orders a medication other than in the proper practice of his profession. In this case it is difficult to obtain evidence substantial enough to stop him from this activity.

Recently, my pharmacy became a member of a voluntary cooperative chain of independent pharmacies in the Washington-Maryland-Virginia area operating

under the name of Care Drug Centers of Washington. While associating with my colleagues I have found the abuse of the right to prescribe a prevalent concern and have discovered an unwillingness on the part of some to take action. This reluctance on the part of pharmacists is usually based on the perceived requirement to appear in court as a witness with resultant loss in pay. This perception is compounded by the feeling of wasting time since most convictions result in release with reprimand or short-term confinement in revolving door fashion. Other pharmacists feel they are not in a position to refuse prescriptions which should be suspect since they are written by licensed practitioners and difficulty could arise if they failed to supply the substance. For whatever reason, the availability of drugs in this manner is a major source of illicit drugs on the streets and in the schools.

Forged and altered prescriptions are more easily controlled because pharmacists are more willing to take time in the apprehension of criminals or those under the control of drug habit. Most of these prescriptions have some flaw or other feature which calls them to the attention of the alert pharmacist. He then contacts the alleged prescriber and upon determining the illigitimacy of the prescription, calls the local law enforcement team.

In this latter instance, some pharmacists are reluctant to "get involved" because of the fear of retaliation in the form of personal harm or possible property damage. Many stories are told across the nation of Pharmacists being murdered or beaten by persons attempting to obtain drugs.

While the major source of licit drugs being diverted to the street market is the improper prescribing of some practitioners, there is another source which needs attention. Persons with a drug habit and those seeking to sell controlled drugs, often find it more lucrative to burglarize pharmacies known to stock these wanted substances. In recent months, armed robberies have occurred with the criminals bringing a shopping list for the most daring drugs.

There is another side of the problem to which we must address ourselves and that is the commission of crime by those seeking to obtain drugs. Many muggings, burglaries, shopliftings, and purse-snatchings are performed by desperate addicts in efforts to obtain funds to support the habit. These persons are sometimes less rational and so more violent than similar persons performing the same type of crime.

To prevent the commission of crimes for the purpose of drug abuse, I propose the following:

First, a continued attempt to stop the spread of drug abuse by education of the general public and follow-up monitoring of rehabilitated addicts. This is the obvious best method to decrease the demand for drugs.

Second, strengthen the forces presently in use to stop the distribution and sale of controlled substances. The Vice-Narcotics unit in Montgomery County and the similar forces in other jurisdictions do a tremendous job in enforcement when they have the opportunity.

Third, strengthen the regulatory processes whereby practitioners may have their right to prescribe suspended or revoked and assess criminal penalties in a more rapid application of due process.

Fourth, adopt legislation making it a federal crime to rob a pharmacy in search of controlled drugs. Local enforcement agents are unable to prevent the interstate traffic in drugs.

Fifth, impose longer sentences on second offenders who sell or distribute drugs. I have been told the need exists for more correctional facilities to eliminate the release of criminals to make room for others. Judges now have to determine which is the worst criminal when deciding the punishment to be handed down.

Sixth, design other methods of control which would make it more difficult to use prescriptions to obtain drugs for illegal use. Forms in triplicate similar to these in use to obtain drugs from suppliers (Form 222 DEA) could be used to order the most abused drugs in the normal course of practice.

In summation, I do not wish to indict the practitioners who oversee the health needs of the nation. The very small minority involved in this unethical practice is such that internal controls would be effective if the regulatory remedies were available to them. The Medical-Chirurgical Faculty of Maryland does a commendable job in the area.

I thank you for the opportunity to appear before this committee and am willing to answer any questions pertaining to this matter.

PREPARED STATEMENT OF DR. JOHN E. ADAMS, CHAIRMAN, STATE OF MARYLAND COMMISSION ON MEDICAL DISCIPLINE

Mr. Chairman and members of the Committee, thank you for inviting me to appear before you this afternoon. My statement is in response to your request for information concerning the nature of the interaction between the Commission on Medical Discipline of Maryland and the problem of diversion of physician-prescribed drugs to the illicit market.

Our Commission is deeply concerned and intimately involved with this problem in a number of ways. From its experience, it is this Commission's opinion that there is a significant diversion of drugs to the street at the hands of physicians, but that the vast majority of this diversion of drugs to the street at the hands of physicians, but that the vast majority of this diversion in unintentional or inadvertent.

This Commission is empowered by law to place sanctions on the license of any Maryland-licensed physician. Sanctions can range from reprimand, to probation, to revocation. It remains, therefore, for the Commission to identify, quantify and document such problems and then to take appropriate action. For these purposes, the Commission has a number of resources upon which to draw.

For example, the Commission works closely with the Medical Assistance Compliance Administration, which at the present time has the ability to detect over-prescribing by physicians, as well as "doctor-shopping" by Medicaid recipients, utilizing computer compilation of physician and pharmacy reimbursement claims. A substantial number of cases of over-prescribing are reported to the Commission as a result of this computer surveillance, and perhaps 30 physicians presently are under active investigation by the Commission and its agents as a result of this detection mechanism. It is my understanding that this computer surveillance capability soon will be extended to Medicare claims as well, substantially increasing the scope of this surveillance.

When a case of apparent over-prescribing by a physician is reported to this Commission, the complaint is referred to a component committee or county society of the Medical and Chirugical Faculty of Maryland (the state medical society) for investigation. The component to which the complaint is referred must investigate the complaint thoroughly and must furnish the Commission with a report and recommendation concerning action to be taken by the Commission, within 90 days of referral. The Commission considers, but is not bound by, the recommendation of the investigating component, and may perform additional investigation of its own. Normally the investigating component will interview the physician involved and will examine the medical records of the patients concerned with the complaint, in order to determine medical justification for the prescriptions. If the prescriptions appear to be medically justified by the medical records, a recommendation of no action generally is forthcoming. As often as not, however, surveillance detects over-prescribing which cannot be justified medically. In such case, depending upon the degree and type of inappropriate prescribing, a recommendation for disciplinary action usually is forthcoming. Alternatively, a full review of practice review. Not infrequently, over-prescribing is the tip of an iceberg of generally substandard practice, which can be corrected by appropriate remedial action by the Commission .

Several other sources of complaints involving over-prescribing exist, but the same investigative, adjudicative and disciplinary mechanisms are used. The public, in the form of individual patients, may detect excessive prescribing because of an adverse reaction. The Division of Drug Control of the State routinely performs on-site surveys of Maryland pharmacies, and through auditing of prescription records, frequently detects instances of apparently inappropriate prescribing. After a preliminary review of the problem by the Drug Committee of the State Medical Society, whose chairman also serves as a consultant to the Division of Drug Control, the matter is referred to the Commission for further action if the prescribing is found to be not medically justified. Complaints also come from physician peers who, in either the private or institutional practice setting and by way of patient referral, mutual patient involvement or hospital peer review activity, become aware of inappropriate prescribing practice. Such complaints usually are referred initially to the local medical society, which performs an investigation and makes a judgment as to the necessity for referral to the Commission, or in the alternative, for private counselling.

In the past, inappropriate use of amphetamines by physicians in Maryland was very widespread. This problem largely has been corrected by the advent of comprehensive regulations regarding the medical indications and appropriate use to which amphetamines are restricted. Widespread publication of these regulations has cured most of the amphetamine problem in this State. The residual amphetamine problem is being detected and managed through the mechanisms already described, and by medical society and state agency surveillance, detection and counselling. Continued abuse always generates referral to the Commission for appropriate disciplinary action.

It is the Commission's distinct impression that most over-prescribing by physicians is unintentional, as a product of poor practice habits or a lack of awareness of the potential for abuse, as well as a lack of awareness of the amount of abuse that exists. A physician may not be stimulated to keep cumulative patient records, or if in keeping them, may not be stimulated to watch for excessive prescriptions for an individual patient. Over years of practice, his patient-record keeping system may have fallen into disarray or, being preoccupied with a busy practice, he may not have become aware of modern policies and practices. When a problem is brought to their attention, most physicians correct their practice and come into immediate compliance and with considerable chagrin. For example, in previous years, the practice of supplying pharmacies with pre-signed blank prescriptions for the convenience of the pharmacist and the patient was relatively prevalent. Today, in spite of close surveillance, it is difficult to find an instance of this inappropriate practice.

Cases of intentional diversion of drugs to the street by a physician are rare in this Commission's experience. One such case presently is under Commission prosecution at this time, having been brought to the Commission by police, complete with voice-recorded evidence that the physician knew that his prescriptions were medically unjustified and were being resold on the street. The police, who traditionally have been frustrated in their attempts to obtain successful prosecution in such cases, are very aware of this Commission as an additional resource and consequently are satisfied to work closely with the Commission in such intances. Knowing the past attitude of the Commission to such cases, it is difficult for me to imagine that this physician will not suffer an outright revocation of his license.

Fortunately, such cases are most uncommon in this Commission's experience. It is of interest to note that even physicians who are chemically dependent upon drugs or alcohol characteristically divert drugs to themselves but not to the public. These experiences have led this Commission to the following conclusions:

1. Diversion of physician-prescribed drugs remains a significant problem.
2. Cooperation between multiple private and public agencies in a carefully administered surveillance and disciplinary system has been extremely effective remedy to the problem in this State.
3. The continuation of this effort, combined with a major educational effort directed toward physicians would be effective in eradicating the diversion of drugs at the hands of physicians.

It remains then, for such an educational effort to be launched. In this regard, all final Commission actions are published in our State Medical Journal for their educational value. Unfortunately, however, neither the private sector nor this Commission have the resources available at the present time to engage in an educational effort of a magnitude sufficient to comprehensively and quickly close the portals of entry of drugs to the street from physicians' offices. With assistance, a solution to the problem is at hand and this Commission and the State Medical Society and all of its committees and components are willing and eager to assist.

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