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METHADONE DIVERSION

A REPORT

OF THE

SELECT COMMITTEE ON NARCOTICS ABUSE AND CONTROL

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I. INTRODUCTION

In order to achieve a full understanding of the scope of methadone diversion, the Select Committee on Narcotics Abuse and Control conducted its first of two hearings, on April 19, 1978. This hearing concentrated on the diversion of methadone into the illicit market, deaths and illnesses resulting from methadone overdoses, and the proposed Federal methadone regulations' possible influence on diversion and patient care. The hearing also sought to determine where in the treatment process diversion is most likely to occur, what efforts have been undertaken to minimize diversion, and what alternatives exist to avoid methadone diversion itself.

Witnesses at this first hearing, held in Washington, D.C., included: Mr. Lee I. Dogoloff, Associate Director, Domestic Policy Staff, the White House; Dr. Michael Baden, deputy chief medical examiner, New York City; Mr. Ed Menken, vice president, Project Return, New York City; Dr. Bernard Bihari, deputy commissioner, Office of Substance Abuse Services, New York City; Dr. Vernon D. Patch, Boston; Mr. Kenneth A. Durrin, Director of the Office of Compliance and Regulatory Affairs, Drug Enforcement Administration; Mr. Karst J. Besteman, Deputy Director, National Institute on Drug Abuse; and Dr. Stewart L. Baker, Jr., Associate Director for Alcohol and Drug Dependence, Veterans Administration.

The committee held its second methadone diversion hearing in New York City on May 5, 1978, principally addressing the question of why diversion is such a particular problem in New York City and what efforts and remedies have been tried at the State and municipal levels to cope with this problem. The second hearing was also directed toward assessing the effectiveness of methadone maintenance as a treatment modality, particularly, whether it is merely a "filling station" process.

The committee heard from a number of witnesses who focused on the question of methadone maintenance and its effect upon New York City. These witnesses included: William T. Bonacum, deputy commissioner, Division of Criminal Justice Services, New York City; Detective Sgt. Bernard Gillespie, New York City Police Department; Blake Fleetwood, writer, New York Magazine; Daniel Klepak, director, medical services, Division of Substance Abuse Services, New York State; Dr. Kim Keeley, deputy director for medical services, Division of Substance Abuse Services, New York State; and Dr. Robert B. Millman, Cornell University Medical Center, New York City. The committee also heard from a woman—Anita—who has been a methadone patient for some time. She described some of the experiences she encountered during her years as an addict and patient on methadone. She readily admitted that but for continuous methadone maintenance for about 10 years, she might have become heroin addicted again. However, she added, that it is "no fun to be on methadone," and she would much rather be drug free. Despite the inconvenience methadone treatment involves, the alternative is far worse.

II. HISTORICAL BACKGROUND

Methadone (hydrochloride) is a synthetic opiate developed in Germany during World War II as a substitute for morphine. It is considered to be slightly more potent than morphine on a milligram basis when administered subcutaneously, and is relatively more effective orally.

Methadone was released in the United States in 1947 and it quickly came into use at the U.S. Public Health Service Hospital at Lexington, Ky., and at other hospitals.

Although methadone has been used in the United States as an analgesic, its primary use here has been in the prevention of withdrawal symptoms for heroin addicts undergoing detoxification. Used in this fashion, methadone has been valuable in reducing the dose and cost of heroin to addicts but has been ineffective in helping the addict in his/her social rehabilitation and has rarely led to abstinence. In 1964, Drs. Vincent Dole and Marie Nyswander, while working at Rockefeller University in New York City, recognized that methadone was effective when administered orally and its effects were of considerably longer duration than heroin. Using these attributes, Drs. Dole and Nyswander conceived the notion that methadone, given orally in gradually increasing dosages once a day over a period of several weeks, might produce a "blockade" against substantial amounts of heroin. This blockade with methadone might also change the lifestyle of the addict, releasing him/her from the need to hunt for a "fix" every 4 to 6 hours. The addict might then have an opportunity to become involved in his/her own social rehabilitation. Drs. Dole and Nyswander conducted an experiment with six volunteers who were given methadone under carefully controlled circumstances, over a period of about 1 year. The results were promising. This experiment has since expanded substantially and currently there are approximately 40,000 patients receiving methadone treatment in the Greater New York City area alone. In 1972, FDA approved methadone for use in narcotic addiction treatment. To date, there are about 680 methadone facilities in the country, and approximately 100,000 persons undergoing maintenance.

III. SUMMARY OF COMMITTEE'S INQUIRIES

A. Methadone Diversion

1. STAFF INVESTIGATION

In the fall of 1977, the Select Committee on Narcotics Abuse and Control began an investigation into the effectiveness of the New York City methadone treatment programs. The committee's findings revealed a high and most disturbing rate of methadone diversion into the black market. By interviewing local law enforcement officials, representatives of the business community, prisoners, addicts, ex-addicts, and administrators of methadone as well as drug-free programs, the staff was able to document numerous cases of illicit sales by addicts enrolled in methadone maintenance programs. Some addicts were enrolled in multiple programs simultaneously. Further staff investigations revealed the deficiencies in the New York City methadone treatment programs made it relatively easy for methadone to be diverted. Though the patterns of methadone diversion were not precisely the same in all situations, they did fit into several general categories. These categories include: (1) loose or careless procedures in evaluating, admitting, and treating patients; (2) overly generous dispensing of the drug including unusually heavy dosage units; (3) inadequate recordkeeping and physical security of drug supplies; (4) unqualified staff or inadequate facilities; and (5) operations beyond the capacity of the staff or facility in workload and number of patients handled.

As a result of these deficiencies, four major complications were documented: (1) reduced effectiveness of methadone treatment programs in achieving their objectives of freeing the patient from drug-dependence and stabilizing him/her on a minimal dosage; (2) development of a viable and effective black market in methadone including some persons whose primary drug of addiction is methadone; (3) addiction to methadone by persons, especially young people, because of its easy availability without ever having been exposed to heroin; and (4) deaths, illnesses, and hospital emergencies from self-administered methadone overdoses.

2. OUTSIDE STUDIES AND INVESTIGATIONS

(a) The Fordham Study

In examining the many facets of methadone diversion, the committee reviewed other studies and investigations in order to gain information relevant to our line of inquiry.

A study was conducted in 1974 and 1975 by Fordham University's Institute for Social Research, funded by the National Institute on Drug Abuse. Known as "The Fordham Study," it was undertaken in order to determine the source and method of methadone diversion and to gain an understanding of the street use of illegally obtained metha-

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done. The study was administered in five major cities throughout the United States which included: New York, Philadelphia, Detroit, Washington, and San Francisco. Three separate lines of inquiry were pursued: street addicts were questioned, patients in methadone maintenance programs were interviewed, and police seizures of methadone were monitored.

Among the information sought from the addict/patient was a Drug Use Profile that included first drug used, type of drugs used, and drugs most recently used. Also sought was information on an Illicit Drugs Profile and an Illicit Methadone Profile. Within these categories the addict/patient was questioned about drug and methadone availability, sources, prices, purposes for use, and forms of use (oral, intravenous).

A committee witness, Dr. Vernon Patch, criticized the National Institute on Drug Abuse for not publicizing the Fordham Study in its entirety. Dr. Patch argued that the Fordham Study showed that (1) methadone diversion existed, (2) diversion increased in the period 1973–1975, and (3) the sources of the diversion were (primarily) methadone maintenance patients and take-home supplies. Since these findings would be harmful to methadone maintenance programs and could lead to more stringent program controls, Dr. Patch testified that the results of the Fordham Study remained unpublished, although a 1977 NIDA publication by Dr. James A. Inciardi entitled, "Methadone Diversion: Experience and Issues," did contain a summary of the study. This volume, however, was criticized by Dr. Patch for its claim that diverted methadone is primarily used for therapeutic purposes by addicts and for its use of Project DAWN as a measure of methadone diversion. Mr. Karst J. Besteman, Acting Director of NIDA, responded to the criticism by saying the Inciardi report had been sent to all drug abuse treatment programs and to Single-State Agencies. He further stated that the Fordham Study was approximately 500 pages and therefore too voluminous to be of value to the treatment planning community.

(*b*) *Report of the Methadone diversion study group*

The Office of Drug Abuse Policy (ODAP) began an investigation into methadone diversion in 1977. Before an assessment of the problem could be made, accurate and reliable information had to be obtained, particularly in New York where the problem was so widespread. In the summer of 1977, the staff of ODAP and the National Institute on Drug Abuse (NIDA) went to New York to begin negotiations with the Medical Examiner in an effort to bring the city back into the DAWN reporting system. This effort was successful and reporting resumed in September 1977. With the necessary information available, the Methadone Diversion Study Group was formed under the Strategy Council, chaired by ODAP. The group consisted of representatives from the Food and Drug Administration (FDA), NIDA, and the Drug Enforcement Administration (DEA).

The group selected four cities—New York, Miami, Boston, and Washington—for intensive analysis, utilizing the DAWN reporting systems, as well as agency contacts in each city. New York and Miami, which currently prescribe take-home medication, were chosen because they were known to have a significant number of methadone related emergencies and deaths. Boston and Washington, with no take-home, were selected for comparison. The group did not investigate all avail-

able research on methadone diversion, but rather looked to information concerning life-threatening methadone-related situations, principally overdoses and deaths.

(c) *General Accounting Office study*

The U.S. General Accounting Office (GAO) also examined methadone in a study entitled, "Methadone Deaths in New York City," which was completed in March 1977 and released in November 1977. Concerned about the high number of methadone deaths in New York, Congressman Charles Rangel (D–N.Y.), a member of the Select Committee, requested the Government analysis. The study was not only interested in the circumstances of methadone-related deaths but also in the Drug Enforcement Administration's (DEA) use of its increased authority under the Narcotic Addict Treatment Act of 1974 to regulate methadone programs.

When the Narcotic Addict Treatment Act of 1974 was signed into law (Public Law 93–281), DEA assumed authority to register methadone treatment programs and to suspend and revoke a program's registration if it did not comply with standards. DEA also was given the authority to establish and enforce strict security measures and recordkeeping standards for treatment programs. These standards are enforced through preregistration and regulatory investigations.

3. SOURCES OF DIVERTED METHADONE

According to the testimony of Dr. Bernard Bihari, Deputy Commissioner, New York City Health Department, Office of Substance Abuse Services, there are three possible means by which methadone can be diverted. These include: the sale of dispensed methadone by patients in programs; the thefts from legitimate methadone outlets, such as manufacturers, hospitals, and treatment programs; and the illicit manufacture and distribution by organized crime. Although the latter cannot be ruled out, at this time no evidence exists which supports this premise. Evidence does exist which indicates that methadone is not imported illegally. While Customs officials have discovered other smuggled drugs, they have never seized any methadone. Accordingly, it has been concluded that methadone is either synthesized in this country or legitimately imported by reputable pharmaceutical houses. It is not marketed on the street by the large illicit importer.

(a) *Thefts of supplies between manufacture and consumption*

The GAO Study indicated that methadone has been diverted by robberies of patients and programs, night break-ins at clinics, and the interception of supplies during shipment. In fiscal year 1975, methadone outlets in the New York City area reported that about 52,000 dosage units were stolen. (Two thefts accounted for 25,000 stolen dosage units.) This represents about 1 percent of the dosages dispensed annually for take-home in New York City.

Mr. Kenneth A. Durrin, Director, Office of Compliance and Regulatory Affairs, Drug Enforcement Administration, testified that there are no indications that significant diversion of methadone exists at the program level or from manufacturers or wholesalers. An analysis of drug theft reports, which are required to be submitted to DEA, revealed that in-transit losses, or actual thefts of methadone, provide a relatively insignificant source of illegal methadone.

According to DEA, when contrasted with an estimated 85,000 patients enrolled in methadone programs, each receiving an average of 40 milligrams per day, the 18,000 dosage units reported stolen in 1977 calculate out to less than 6/100's of 1 percent of the 31 million dosage units of methadone administered or dispensed in treatment programs in 1977. DEA feels that these figures amply illustrate their success in limiting diversion from program stocks and supplies, and that nonpatient diversion of methadone exists on a very small scale.

(b) Weak program administration

Dr. Bernard Bihari observed that a relationship exists between the overall quality of clinic management and the likelihood of a variety of patient abuses, including methadone sales. Those clinics with disproportionate numbers of patients arrested for selling their methadone frequently, on closer examination, show evidence of inadequate and inconsistent administrative leadership. In such clinics, as a result of lack of clarity about policies and procedures and a lack of consistency in implementing these due to poor leadership, some patients may respond to their anxiety about this with inappropriate behavior. When the administrative leadership of such a clinic is more closely supervised by the Office of Substance Abuse's Central Office there is a reduction in methadone sales, in drug abuse, and in disruptive behavior by the patients both in the clinic and in the surrounding community.

The quality of clinic management is probably most important with regard to control of methadone diversion by patients. Superior clinic management is also instrumental in treatment, rehabilitation, and good community relations. When clinic administrative leadership is effective, the quality of care and morale is high. Patients respond very positively and take a more active responsibility for their own lives and actions. In a positive setting, antisocial and self-destructive behavior by patients become minimal and rehabilitation maximal.

Staff diversion

The GAO Study found that in poorly operated treatment programs, lack of control due to negligence or ignorance could result in methadone finding its way into illegal traffic. Diversion could be caused by a program's failure to adequately safeguard and account for its supply of methadone; this in turn could permit employee or patient theft of the drug.

Mr. William T. Bonacum, Deputy Commissioner, Division of Criminal Justice Services, New York City, testified that there were some staff personnel, security personnel, and nurses who could establish a relationship with a patient in the clinic. Methadone could then be diverted to the patient for sale with some portion of the proceeds coming back to the clinic person. Mr. Bonacum said this was not found to occur very often.

Patient abuse

Commissioner Bonacum cited statistics from the Fordham Study which indicated the intensity of patient abuse. A total of 1,324 persons were interviewed; 599 being street addicts and 725 drug program patients.

Of the street addicts interviewed:

Over 90 percent indicated that patients in methadone maintenance were the source of illegal methadone on the street;

Only 3 percent said that illegal methadone was "impossible" to obtain;

Forty-eight percent asserted that more than half of the patients in programs sold some or all of their methadone;

Thirty-five percent commented that less than half of the patients in maintenance sell some or all of their medication.

Of the patients in programs interviewed:

62.3 percent identified patients in programs as the usual source of illegal methadone;

Additionally, patients were identified by 18.9 percent of those questioned, as an occasional source of illegal methadone;

When program patients were asked in New York about how widespread the patient sales of their take-home medication, 41.4 percent said either that "everybody does it" or that "more than half (of the patients) do it."

Seventy-three percent of those questioned admitted to selling their own methadone.

4. GENERAL CHARACTERISTICS OF ABUSING PATIENT

Dr. Bihari gave testimony concerning patients selling their take-home medication. He believes that diversion would not occur if all the patients who are inclined to sell their methadone were on a daily pick-up schedule. He also stated that if these patients were identified and their take-home limited, the amount of methadone diverted from clinics could be decreased. According to Dr. Bihari's experiences, patients who sell their methadone possess certain general characteristics which are:

(1) They generally are people who are unemployed and are otherwise not socially productive;

(2) Almost all people selling their medication have a history, while in treatment, of significant abuse of alcohol or heroin or non-narcotic drugs;

(3) Many of these people loiter around the clinic. This occurs in part for social reasons but also because of the availability of buyers;

(4) Those who are involved in serious behavioral management problems in the clinic, people who menace staff members, get in fights with other patients, try to bend the rules or break them, are much more likely to be the people who sell their methadone; and

(5) People who are arrested for crimes other than selling methadone are much more likely to be involved in sales than are the general clinic population.

(*a*) *Abuse of take-home*

The studies which were reviewed indicate that the patient's abuse of his/her take-home medication is the major contributor to the problem of methadone diversion. Currently a controversy exists over a take-home or a no take-home policy.

Those who believe a take-home policy is beneficial and important to the rehabilitation of the patient include, Mr. Lee I. Dogoloff, Mr. Karst J. Besteman, and Dr. J. Richard Crout. They testified that:

1. available data does not support a correlation between take-home methadone and diversion, at least not as reflected by methadone related morbidity and mortality;

2. the existence of a take-home policy does not appear to be a predictor of methadone abuse problems in a given community;

3. the proposed methadone regulations should be promulgated for the entire country. Other areas should not be punished because New York City has widespread diversion. If there is a particular problem in a city it can be dealt with at the city and State level;

4. since one of the objectives is to change lifestyle, and to encourage people to seek employment, it may be counterproductive to have patients come into the clinic every day.

Others, who testified against a relaxation of take-home standards, were, Dr. Stewart L. Baker, Jr., Commissioner Bonacum, and Mr. Kenneth A. Durrin. They maintained:

1. take-home methadone is the "weak link" in the illicit chain and all responsible agencies should examine ways and means of lessening its vulnerability;

2. the present problems surrounding methadone must be dealt with before any relaxation of take-home is approved;

3. it is reasonable to conclude that further harm would result from a lessening of the criteria for take-home medication. Allowing an increased degree of latitude on take-home will create even greater problems with abuse of take-home medication than presently exist;

4. there is a direct relationship between methadone carried away from the clinic and its increased potential for diversion. The opportunity for "skimming" or selling part of the take-home methadone finds the frequently unemployed, peer-pressured client quite vulnerable for engagement in this lucrative, illegal practice.

(*b*) *Multiple enrollments*

Some laxity in the control of patient enrollment was cited by Commissioner Bonacum. He testified that there were some reports, in New York, of dual enrollments, meaning that a patient was signed up in more than one clinic at the same time. This could, of course, give the patient more opportunity to sell his/her methadone.

Commissioner Bonacum spoke of a central registry which might eliminate, or at least inhibit, the incidence of multiple enrollments. No one could agree on the kind of identification that should be used. Suggestions were offered including fingerprinting or footprinting the patients or using their social security numbers. There were difficulties with each proposal. Fingerprinting the patient causes problems because there might be a substantial number who are out on warrants and these persons would be liable for arrest. This would discourage people from coming into the clinics. If social security numbers were to be employed for identification, there would be a chance that patients would obtain several numbers in a fraudulent manner, thus allowing them entry into more than one clinic.

In an effort to help resolve the problem, New York instituted a central registry where all addicts in treatment, in the five boroughs and Westchester, are registered at the Community Treatment Foundation. This foundation is a private, nonprofit organization, connected with Rockefeller University. It derives some of its support from fees and some from the State.

5. METHADONE-RELATED DEATHS AS A MEASURE OF DIVERSION

One significant measure of methadone diversion is deaths involving or related to methadone. The use of narcotic related fatalities has been used as a measure of narcotic abuse for years. Such a measure must, however, be viewed cautiously. The thoroughness of autopsy reports, police records, patient records, reports of next of kin, etc., will all determine whether or not a particular death is attributable to narcotics in general and to methadone specifically. Nevertheless, having introduced methadone into the general community through treatment centers, the cost of this introduction must be tallied. The ultimate social cost of methadone diversion is death and, as such, it must be considered a major indicator of illicit use of methadone. Were methadone not being diverted and introduced into illicit channels, there would of course be almost no methadone deaths.

(a) Source of Statistics

All methadone involved death reports ultimately result from reports furnished by medical examiners and coroners. The data on methadone death will therefore be no better than the reports furnished by these sources. Currently, methadone involved deaths are reported to the Drug Abuse Warning Network (Project DAWN) by medical examiners and coroners from 24 Standard Metropolitan Statistical Areas throughout the United States. These data serve as the major basis for reporting methadone deaths. Regrettably, there is no uniform reporting methodology. Autopsies are performed differently by different coroners having different available facilities.

(b) Extent of Methadone-Related Deaths

In the period May 1976 through April 1977, Project DAWN reported 310 methadone involved deaths. For the same period 1,680 morphine/heroin involved deaths were reported; thus methadone, a drug of choice in the treatment of many addicts, was involved in approximately 20 percent as many deaths as heroin/morphine, a rather discouraging commentary on methadone's benefit/risk ratio. The New York City area has the highest number of methadone deaths, a dubious distinction which has not been challenged since the inception of Project DAWN. In the first 9 months of 1977, the New York City medical examiner reported 159 methadone involved deaths to Project DAWN.

(c) Manner of Methadone-Related Deaths

The overwhelming majority of methadone-related deaths occur as a result of combination with other drugs such as alcohol and sedatives. This suggests that polydrug abuse is causing many deaths and that methadone alone may not be the cause of death in a majority of cases. Evidence further indicates that many of the methadone deaths do not involve methadone patients, thus demonstrating that diversion of methadone to the nontreatment population is happening. In addition to alcohol, drugs commonly involved in methadone deaths include amitriptyline (Elavil) heroin, diazepam (Valium) and barbiturates. It should be noted that, with the exception of heroin, all of these drugs are easily obtainable through physicians' prescriptions.

6. EMERGENCY ROOM DATA

Another measure of methadone diversion is emergency room mentions involving methadone. Such data are available from Project DAWN. Mentions need not correspond to persons since a person may show up more than once in a hospital emergency room. Among the top 26 drug mentions in hospital emergency rooms, methadone ranked 19th. New York City has the highest rate of methadone mentions in hospital emergency rooms but a significant portion of these mentions involved legally prescribed methadone and may be the result of side effects of the drug rather than overdose. The witnesses contended that it is legitimate to use methadone mentions in hospital emergency rooms as an indicator of diversion but the caveats accompanying such use must be borne in mind in drawing conclusions from the DAWN data.

7. PRIMARY ADDICTION TO METHADONE

Data on the number of persons with a primary addiction to methadone would, of course, be useful as an indicator of methadone diversion. Committee staff found some indications of primary methadone addiction in New York City, but valid and reliable data are difficult to come by. Despite the lack of good data, reports of primary addiction to methadone must be considered as one measure of methadone diversion.

8. USE OF DIVERTED METHADONE

Diverted methadone is most frequently used by adults with histories of active heroin use. A NIDA-sponsored study found 84 percent of active addicts on heroin, 8 percent on other drugs, and only 4 percent on methadone. In this sense the major purpose of diverted methadone use is to help active heroin addicts reduce the size and cost of their narcotic habits and prevent withdrawal sickness. Very few street addicts appear to be using methadone to permanently detoxify.

The group in which diverted methadone is most dangerous is in those polydrug abusers whose methadone and heroin use is occasional and casual, and where the purpose of using the drug is to evoke euphoria. This group, because of the absence of physical tolerance to opiates, is in danger of overdosing on methadone or heroin just as it is in danger of overdosing from other abused drugs, such as barbiturates or tranquilizers.

B. Methadone Regulation

Dr. J. Richard Crout, Director, Bureau of Drugs, Food and Drug Administration, testified that the regulation of methadone and methadone treatment programs is the joint responsibility of the Department of Health, Education, and Welfare, through the FDA and NIDA, and the Department of Justice, through the Drug Enforcement Administration (DEA). DEA's responsibilities address the security of methadone stocks, while FDA and NIDA jointly address the safety and effectiveness of methadone as a treatment modality, and the concomitant issues of appropriate medical treatment standards.

The Narcotic Addict Treatment Act of 1974 (NATA) provides the framework for DEA investigation and registration of methadone treatment programs. This act was passed in May 1974 and the implementing regulations became effective in November 1974.

With the effective date of the NATA, DEA for the first time was given authority to mandate specific security and recordkeeping requirements for treatment programs and to revoke registration for security and recordkeeping violations. Since November 1974, a preregistrant investigation of every narcotic treatment program has been conducted prior to actual registration. Once registered with DEA, each program is scheduled for an indepth accountability investigation every third year as a part of DEA's cyclic regulatory investigations program. These investigations, according to testimony by Kenneth A. Durrin, director of the Office of Compliance and Regulatory Affairs at DEA, have resulted in 172 violation actions against clinics.

Mr. Durrin testified that DEA's regulatory program has been highly effective in curbing methadone diversion at the program level. Nationwide, the number of dosage units of methadone (calculated at an average dosage unit of 40 mg.) reported to DEA as lost or stolen were approximately 20,500 units in calendar year 1976 with a silght drop to approximately 18,000 units in calendar year 1977. When contrasted with an estimated 85,000 patients in methadone programs each receiving an average of 40 milligrams per day, the 18,000 units reported lost or stolen in 1977 calculate out to less than .06 of 1 percent of the 31 million units of methadone administered or dispensed in treatment programs in 1977. However, DEA Administrator Peter B. Bensinger, in a letter to the Select Committee, stated that even DEA's regulatory enforcement successes cannot solely solve the problem of methadone diversion. He stated that in an analysis of drug theft, STRIDE (System to Retrieve Information from Drug Evidence), and DAWN data point to methadone take-home supplies as the major source of methadone diversion. Administrator Bensinger said that methadone thefts are low, and purchases and seizures of methadone are also low but pointed out that DEA efforts are directed at large-scale diverters and dealers, and methadone is not appearing at these levels.

NATIONWIDE REPORTED METHADONE THEFTS

Based on information supplied by Mr. Bensinger the number of dosage units of methadone (based on a standard dosage unit of 40 mg.) reported lost/stolen to DEA is as follows:

Facilities	1st half, calendar year 1976	2d half, calendar year 1976	1st half, calendar year 1977
Pharmacies	1,328	3,388	2,343
Practitioners	53	132	298
Other firms [1]	3,130	2,512	797
Manufacturer/distributors	3,229	6,722	5,173
Total	7,740	12,754	8,611

[1] Includes analytical laboratories, teaching institutes, hospital/clinics, and narcotics treatment programs.

Utilizing an estimate of 100,000 individuals in methadone programs and a standard dosage unit of 40 mg. dispensed per day per individual, an estimate of 18 million dosage units would have been dispensed for a half year.

The total dosage units reported lost/stolen would represent the following percentages of the estimated 18 million dosage units dispensed for a given time period:

.04 percent for first half calendar year 1976.
.07 percent for second half calendar year 1976.
.05 percent for first half calendar year 1977.

Administrator Bensinger, in his letter to the Select Committee, stated that STRIDE data indicates there were 11 DEA cases in which methadone was seized in New York City from January 1975 to November 1977. A review of nine cases revealed that the primary purchases were of heroin and cocaine; the methadone was seized incidental to searches of residences, individuals, or vehicles. Containers seized in three cases were labeled with the name of a clinic or methadone treatment program.

There were, stated Mr. Bensinger, 32 individuals arrested in 8 methadone seizure cases. Of the 32 individuals, 16 indicated that they used drugs and of the 16, 7 indicated that they used methadone. He also stated that in four cases where methadone was seized, none of the personal history sheets indicated the individuals arrested used methadone.

The use of methadone for treating narcotic addiction is subject to regulation and control by the Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301) and Title I of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (42 U.S.C. 257(a)). Dr. Crout stated that the FDA may not approve a methadone treatment program until the necessary State authority approval is granted and the program is registered under NATA.

Dr. Crout testified that in approving methadone for narcotic addiction treatment, FDA weighed the drug's therapeutic benefit to the individual patient against the risks of use to the public at large. Methadone's addictive potential, stated Dr. Crout, poses a risk to public health through diversion from approved medical settings. The initial methadone treatment regulations of 1972 established a restricted distribution system which addressed both individual and public health concerns. Methadone's availability for narcotic addiction treatment was restricted to approved narcotic addiction treatment programs, and, for analgesia and in-patient detoxification, to hospital pharmacies, and in remote geographical areas to approved local pharmacies. Methadone's antitussive indication was withdrawn because other drugs with less abuse potential provided comparable or better relief for that indication. This system assured methadone's availability for its approved medical indications and minimized potential abuse through diversion by restricting its availability to approved treatment progams and hospital settings.

Those portions of the 1972 regulations which restricted the distribution of methadone for analgesia were successfully challenged in court by the American Pharmaceutical Association (APhA). APhA successfully argued that the only restriction FDA can impose on a drug, once approved, is a prescription only requirement. Accordingly, since July 1976, methadone has been generally available at the retail pharmacy level for analgesia. A senior member of the Select Committee, Mr. Paul G. Rogers, sponsored legislation (the Drug Regulation Reform Act of 1978) which would, among other things, provide FDA

with the authority to impose those restrictions on distribution and use necessary to assure a drug's safe and effective use.

Dr. Crout testified that the FDA does not use seizure as a mechanism for compliance. The bulk of FDA's compliance activity is done by "regulatory letters" which cite the list of deficiencies after an inspection, with the threat to take legal action, unless the deficiencies are corrected. He said that 99 percent of FDA's enforcement activity is the result of "voluntary" compliance to letters, rather than formal legal actions.

Representatives of DEA, FDA, NIDA, and the Veterans Administration serve on the interagency Methadone Treatment Policy Review Board, which reviews and recommends policy in connection with the treatment of narcotic addiction with methadone.

Dr. Stewart L. Baker, Jr., Associate Director of Alcohol and Drug Dependence, Veterans Administration, testified that during the last several years the VA has actively participated in the activities of the Methadone Policy Review Board. The VA has derived considerable benefits from this participation, particularly through learning early of planned FDA, NIDA, and DEA initiatives in this program area and in considering the impact on treatment services for veterans, and has had the opportunity in a free and open discussion for responding with their own proposals and thoughts.

The VA, according to Dr. Baker's statement has implemented the physical security requirements for controlled substances specified in 21 CFR 1301.72, 1301.73, and 1301.74 for nonpractitioners in lieu of the lower security requirements of 21 CFR 1301.75 for practitioners. Double locked storage room enclosures containing GSA class 5 safes or vaults for substance storage are further protected by infra-red or ultrasonic motion detector systems monitored by police. Dispensing areas of pharmacies and clinics are restricted to authorized personnel and include bullet resistive transaction windows to deter armed hold-up attempts. Daily transaction records for schedule II and schedule III narcotics are maintained and a monthly inventory inspection by a disinterested official is required. The VA believes the integrity of the storage and dispensing system is sound.

Individual States may go beyond Federal regulations and make dispensing controls tighter in an effort to lessen the likelihood of methadone diversion to the illicit market.

Section 108(e) of H.R. 11611, the administration's proposal to revise the current drug provisions of the Food, Drug, and Cosmetic Act, would provide sufficient authority to the FDA to adequately regulate certain drugs, such as methadone.

In October 1977, NIDA and FDA proposed revisions to the FDA regulations on the subject "conditions for use of methadone in maintenance and detoxification programs." The stated purpose of these revisions was twofold: (1) to allow greater flexibility in clinical standards and (2) to provide more specificity in areas in which the proposed clinical standards mandate level of performance. However, a side effect of the proposed revisions could exacerbate the methadone diversion problem.

There are two proposed changes to the minimum standard for admission to methadone programs:

a. reducing the requirement of a 2-year history of addiction for entry into a maintenance program to a 1-year history; and

b. permitting the admittance of persons under 16 years of age to maintenance treatment in certain rare cases if approval is obtained from both FDA and the State authority.

According to FDA and NIDA, the 2-year history requirement was predicated on (a) the belief that methadone maintenance should be a treatment of last resort reserved for the hardcore chronic narcotic addict and (b) the fear that the nonaddicted or those minimally addicted would apply for treatment. The 1-year requirement is the result of findings that the aforementioned feared situation only occurs infrequently and the belief that the decision whether to admit someone should be within the clinical judgment of the program physician.

As to the second change, it is predicated on the finding that detoxification of many of these younger patients has been insufficient and morbidity with heroin is greater than morbidity with methadone.

While the proposed rule would retain the substance of the current regulatory requirements regarding take-home medication, it includes a provision that would permit a patient to take home a 6-day supply under certain circumstances, if the medical director has entered into the patient's record an evaluation that such patient has satisfactorily adhered to each of the criteria for measuring responsibility in handling methadone.

The proposed rules would eliminate all mandatory urine testing with the exception of an initial screening urinalysis for new patients.

FDA and NIDA were aware of the opposing points of view on this change and they have set them out as follows.

a. The belief that mandated weekly drug urinalysis on all patients is a waste of time and money. Furthermore, some clinics make minimal use of urine test results because of the questionable results and/or the lengthy periods between urine testing and reports of the urinalysis.

b. The belief that weekly drug urinalysis is a valuable psychological aid and deterrent in helping reduce illicit drug use by patients.

Dr. Baker testified that the Veterans Administration supports the proposed FDA Methadone Regulations as they respond to the need for more individualized treatment planning and for more effective attention to due process review, particularly in regard to involuntary discharges from treatment programs. This support is with the understanding that the exemption of Federal programs from State authority and requirements of State law is applicable throughout.

Mr. Lee I. Dogoloff, Associate Director, Domestic Policy Staff, the White House, testified that regulations alone cannot deal with the diversion problem. Tightening up the procedures, getting to know the clients better, and having better clinical decisions made as to who should and should not receive take-home medication are the means that have proved most effective in lessening the problem of diversion.

The issue of diversion, Mr. Dogoloff stated, is primarily an issue relating to New York. The White House does not feel that it is appropriate to penalize all patients across the country by tightening up the Federal regulations. The White House wants Federal regulations to provide guidance and to give the kind of flexibility that is necessary so that each State may institute its own regulations.

The methods of methadone treatment for narcotic addiction, Dr. Crout stated, must be weighed against the risks which diversion may present to the public at large. An overly great emphasis on diversion, however, could discourage or even prevent patient rehabilitation. This could precipitate longer treatment stays or encourage dropouts. Premature treatment termination poses a serious risk to the dropout patient for medical complications associated with narcotic addiction and to the public at large from increased crime and loss of individual increased productivity. Dr. Crout sees relatively few viable options available to limit diversion of methadone and thus supports the proposed FDA–NIDA regulations.

Kenneth H. Durrin, Director of the Office of Compliance and Regulatory Affairs, DEA, testified he does not support the new proposed regulations, particularly the 6-day take-home provision, because it would adversely affect DEA's ability to prevent diversion.

Dr. Stewart L. Baker, Jr., Associate Director of Alcohol and Drug Dependence, Veterans Administration, in his statement supported most of the proposed regulations, but opposed the change in minimum urine testing. Urine tests, said Dr. Baker, provide a system of external controls which are needed by many patients. They still provide the only practical way to measure drug use. The finding of illicit drugs in the patient's urine is an objective measure of the client's behavior. Such information has considerable relevance to counseling activities and is fed back to the staff counselor for direct discussion with the patient. Eliminating such an important diagnostic and therapeutic tool would adversely affect the structure and process of counseling and rehabilitation activities.

The problem of false positives and false negatives has been eliminated during the past several years through improved laboratory efficiency, according to Dr. Baker. The accuracy of such tests has been improved, so that they are in the acceptable range of credibility and utility for counseling and program monitoring by both VA and non-VA programs. As such urine testing should be continued.

The VA believes random monitoring of drug use through weekly urine tests is required for effective long-term treatment of drug abuse. Should the proposed liberalization be adopted as a general standard, the VA would plan to continue with the current standard of testing, as an important external control and an objective measure of deviant behavior.

Dr. Robert L. DuPont, Director of NIDA, in a letter to the Select Committee, stated that NIDA's position on the relaxation of the urine-testing requirements is not one solely based on the validity and reliability of laboratory results. A majority of clinicians (i.e., medical directors of methadone programs) who were questioned when the regulations were being drafted wanted urine-testing frequency (and the qualitative spectrum of drugs to be tested for) to be left to the clinical judgment of the program/medical director. The rationale offered by these clinicians for justifying this position was:

a. Controlled blind proficiency testing has shown that a significant percentage of reported results are inaccurate, raising questions about the validity of urine testing.

b. Some clinics make only minimum use of urine test results because of the questionable validity factor; however, NIDA is currently working toward establishing a more reliable and quicker turnaround test to be utilized by clinics and laboratories for testing urinalysis.

c. Delays between urine collection and the receipt of urinalysis reports are sometimes excessive. Often results are not returned for a week which questions the usefulness of the testing. Further, the daily or weekly drug testing on well-motivated patients who are for months or years consistently "clean" while in treatment is thought to be of questionable utility. The money spent on testing these consistently "clean" patients could more effectively be used for additional counseling staff or other program needs. The cost for drug screening is also rising and these limited funds could be more effectively used.

The proposed changes, stated Dr. DuPont, are merely intended to provide clinicians with greater flexibility and minimal regulations regarding urinalysis testing. These proposals are what the Secretary believes to be the minimal standards for the appropriate methods of professional practice in the medical treatment of narcotic addiction with methadone, and if a State chooses to have more stringent requirements on urine testing, then they may do so at their own discretion.

Dr. DuPont also agrees that with the proposed changes in the maximum number of days of take-home medication allowed to each patient. He said that take-home methadone dosages have often been related to methadone diversion. Although a great deal of data are available, there are still large, important gaps in our knowledge relating to the methadone diversion issue. If take-home dosage were eliminated in an attempt to decrease methadone diversion, it would impose hardships on the methadone client. This would result in clients becoming less able to maintain employment and/or other productive activity. Additionally, it could produce large-scale dropouts leading to some relapses into drug abuse and addiction. Some data are available which indicate that methadone program dropouts have a much higher death rate than those who remain in the program. If this is true, then it is conceivable that by reducing take-home privileges, one type of death is decreased and another increased. It can also be argued that decreasing the census in methadone programs could increase the demand for, and therefore the supply of illegal heroin. Additionally, eliminating take-home may impose a hardship on those employed in regular jobs or pursuing educational opportunities. The new regulations would allow the program physician to exercise his/her clinical judgment in granting take-home privileges without State or Federal approval thus making methadone treatment more responsive to the needs and time constraints of the patients.

C. The New York Experience

1. Methadone abuse—a New York experience

According to Mr. Dogoloff, methadone abuse is concentrated in several of the major metropolitan areas in the eastern third of the United States. In general population rates, as well as absolute numbers, New York City emerges as the leader in methadone abuse.

Dr. Dominick J. DiMaio, Chief Medical Examiner of New York, supported this position stating that New York on a per capita basis, has a much worse drug problem than other cities. He also stated that when death rates from drug overdoses were examined, New York has the largest number, which indicates there is a problem.

Why is this diversion problem unique to New York? Dr. Michael Baden, Deputy Medical Examiner of New York, testified that part of the reason is that the city has more heroin users and more methadone users (32,000 of the 85,000 methadone patients in the United States are located in New York City) than any other one city. As a result, the city also accounts for more than half of all methadone deaths in the United States. The problem is further aggravated because most of the patients are permitted to take home some methadone which leads not only to diversion but to increased number of deaths.

Chairman Wolff cites as reasons for New York's prominence, a larger number of low-income people, the area of the city itself, and the unique character of the city.

According to Mr. Daniel Klepak, Director, New York State Office of Substance Abuse Services, both the Health Department and the Division of Substance Abuse Services have roles in the licensure and approval procedures for methadone maintenance treatment programs. However, the day-to-day oversight of the programs, and all matters related to funding are the province of the Division of Substance Abuse Services. Further, no methadone maintenance program can operate without the approval of the division pursuant to State law and Federal regulation.

Mr. Klepak stated that approximately 580,000 substance abusers are located in New York State, 290,000 of which are narcotic addicts. Of the total number of addicts 77 percent live in New York City; 95 percent of the State's total reside in the greater metropolitan area, comprised of New York City, Nassau, Suffolk, Rockland, and Westchester Counties. Only 11 percent of those individuals identified as serious drug abusers in the State are under any treatment. Of those persons under treatment, 65 percent or two-thirds are in methadone maintenance programs.

There are about 33,000 people being maintained on methadone in New York State, 29,000 of them are in methadone maintenance programs in New York City.

At the present time there are four modalities which are being utilized in New York State, as cited by Mr. Klepak. The numbers of individuals under treatment by modality follows:

Methadone maintenance	32,700
Residential drug free	2,760
Day care drug free	2,433
Ambulatory drug free	11,739
Total	49,632

Mr. Klepak noted that there are a variety of methadone maintenance providers, most of which are nonprofit. The largest provider is the New York City Department of Health and the second largest is Beth Israel Medical Center. Other providers include: Albert Einstein Medical Center, St. Luke's, Columbia Presbyterian, and Mount Sinai. There are also 4,000 to 5,000 individuals who are treated by private doctors in methadone maintenance clinics.

Mr. Klepak indicated that if a heroin addict were left on the street it would cost society about $25,000 a year in terms of his/her criminal activity. If he/she were in a State prison, the cost to society would be $15,000 annually. An average drug treatment program costs about $2,700 a year. The average methadone maintenance treatment program slot cost in New York State is $1,800 annually.

Dr. Robert L. DuPont, Director of the National Institute on Drug Abuse provided the Select Committee with information regarding the Federal allocation of moneys and treatment slots to New York State and New York City as follows:

	NIDA allocation to New York City for—	
	Treatment	Methadone maintenance treatment programs
Fiscal year 1976	$13, 210, 000	$3, 104, 588
Fiscal year 1977 (estimated)	14, 958, 453	3, 720, 116
Fiscal year 1978 (projections)	16, 408, 564	3, 426, 584

	NIDA treatment slots allocated to New York City	NIDA treatment slots allocated to New York City for methadone maintenance programs
Fiscal year 1976	7, 306	2, 107
Fiscal year 1977 (estimated)	8, 624	2, 855
Fiscal year 1978 (projections)	9, 891	2, 820

NIDA contract funds in the fiscal years indicated above were used to fund "methadone to abstinence" (MTA) slots and not methadone maintenance in the traditional sense. NIDA grant funds, on the other hand, were used to fund traditional methadone maintenance treatment slots.

New York State provided New York City with approximately a total of $16,800,000 for 24,500 methadone maintenance treatment slots in fiscal year 1976, 1977, and 1978. Figures indicate that 32,000 patients in New York State receive methadone maintenance treatment; 28,845 of these patients live in New York City. The Division of Substance Abuse funds 21,961 treatment slots including 11,240 administered by the New York City Health Department. Of the total 160 methadone maintenance clinics the division funds 110. Nonprofit programs care for 2,457 patients and proprietary programs provide service for an additional 4,431.

Those patients in methadone programs represent the largest population in any drug treatment modality, making methadone maintenance the most widely relied on method of treatment.

The New York Division of Substance Abuse Services has launched a number of steps that will help to eliminate or reduce diversion. They are:

Efforts to involve the community groups in hopes of developing solutions to problems has culminated in the establishment of the Methadone Maintenance Community Relations Task Force.

This includes clinic operators, representatives of local community planning boards, borough presidents, and the New York City Council and private citizens.

The division will be enforcing regulations that make program operating approval contingent on the clinic's responsiveness to the needs and concerns of the community. Each program must submit a plan on steps it will take to avoid disruption of the community and to assure responsiveness to community needs.

In order to alleviate the problem the following actions were suggested: clinic staff patrols of clinic neighborhood; reorientation and intensive counseling of patients on the need to avoid disruption of the community; and the establishment of hotlines between the clinics and the community.

A model clinic will be started in cooperation with a community planning board and a nonprofit hospital. Requirements include assurance that the program will be carefully run with full attention to the needs of the community as well as the patients.

Qualified medical supervision and counseling is vital. Doctors' attendance and attention is necessary in order that proper doses of medication be determined. The division will insure that physicians prescribe only the minimum dosages of medication consistent with patient needs. Programs will be checked to see that they take steps to assure that the clients are ingesting the methadone rather than holding it in their mouth to be spat out later for sale.

Patients who are on programs for less than 3 months are required to pick up their medication 6 days a week, Monday through Saturday. After 3 months of satisfactory participation in the program the patient can pick up three times a week provided: (1) there has been no evidence of substance abuse, (2) attendance has been regular, (3) participation in all components of the program has been good, and (4) the patient's behavior has been appropriate.

After 2 years of satisfactory participation in the program the patient is allowed to pick up two times per week. If there are two or more consecutive positive urines all take-home privileges are withdrawn.

The division has instituted severe disciplinary action against programs not conforming to the Drug Enforcement Administration or Food and Drug Administration's standards. Failure to comply with required improvements may result in termination of the Division of Substance Abuse Service's approval to operate these clinics.

Dr. Bernard Bihari, Deputy Commissioner of the Office of Substance Abuse Services, New York City, presented measures which are being undertaken in order to prevent robberies, break-ins, and thefts. In summary, they are:

Each clinic will keep an exact accounting of the methadone received each day from the hospital pharmacy. All unused methadone must be returned to the pharmacy at the end of each day. The difference between the number of diskets (tablets) received by the clinic in the morning and the number returned must correspond precisely to the total recorded amount.

The methadone will be transported between the clinic and pharmacy by a nurse and a security guard. If the clinic is off hospital grounds, a police car will be provided to accompany the program vehicle.

Methadone will be administered and dispensed in dissolved form and ingested under the direct observation of the nurses.

Take-home medication will be in child-proof bottles. All empty bottles must be returned to the clinic.

All methadone administered or dispensed is entered on the "Methadone Dosage and Pick-up Schedule" form and on the daily medication record. These serve as instruments for maintaining exact accounting of the medication received, dispensed and administered and serve as the basis for exacting control at the clinic level. The computerized data from these forms allow accounting for every milligram of methadone administered and dispensed to each of 11,500 patients every day.

The Office of Substance Abuse Services also recommended means by which patients diverting methadone would be eliminated.

All patients will be required to attend the clinic 6 days a week for the first 3 months.

After 3 months, patients who have discontinued criminal activity and have shown no signs of drug abuse are reduced to a five times a week pick-up, with two take-home doses allowed. Patients will remain on this schedule until they have shown evidence of responsibility in handling methadone. The following factors are considered in making this judgment:

Background and history of patient.

General and specific characteristics of the patient and the community in which the patient resides.

Absence of past abuse of non-narcotic drugs, including alcohol.

Absence of current abuse of non-narcotic drugs and alcohol and narcotic drugs, including methadone.

Regularity of clinic attendance.

Absence of serious behavior problems in the clinic.

Stability of the patient's financial condition.

Stability of the patient's home environment.

Stability of the patient's family and other relationships.

Absence of past and/or current criminal activity.

Length of time in methadone maintenance treatment.

Assurance that take-home medication can be safely stored within the patient's home.

A number of clinics are designed to identify and deal with those patients in whom there is some possibility of methadone diversion. The office receives a monthly list from the New York City Police Department of the names of all individuals arrested for alleged methadone sale. The list is matched with our patient roster and the clinics are notified about those who are in active treatment. If these patients are not incarcerated, they are placed on daily pick-up schedules until the case is resolved. When urines show up positive for heroin, the patient is placed on a daily pick-up.

There is a strictly enforced "no loitering" policy. Patients cannot remain in the immediate vicinity of their clinics. Counselor

patrols are sent out to check for loitering. Patients are warned and discharged if they fail to comply with clinic policy.

A direct relationship exists between the quality of clinic management and the likelihood of patient abuses, including methadone sales. Clinics that have a disproportionate number of patients arrested for methadone sales show evidence of inadequate and inconsistent administrative leadership. When the division's central office management staff supervises such clinics there is a reduction in methadone sales, in drug abuse, and in disruptive behavior.

2. NEW YORK CITY LAW ENFORCEMENT

Methadone diversion is not high on the priority list of law enforcement in New York City, stated William T. Bonacum, Deputy Commissioner, Division of Criminal Justice Services, New York City. The 663 methadone arrests in 1974 represented less than 4 percent of all drug arrests. Sgt. Gillespie cited 1977 statistics as similar. There were 678 methadone arrests which represented 3 percent of the total narcotic arrests in the city.

Specialist enforcement agencies, such as Police Narcotics Divisions, DEA, and Narcotics Task Forces do not give methadone a high priority. The police view methadone as a controllable problem but local precinct commanders are attentive to the problem only when community pressure is exerted. Methadone arrests are made only to identify the fact that methadone is flowing freely out of clinics. When the community pressure abates, the attention of the commanders usually diverts too, from methadone diversion to other more serious crimes.

District attorneys and judges also give methadone diversion a low priority. There is little or no penalty attached to possession of illegal methadone or to actually selling illegal methadone.

Sgt. Gillespie commented on the policy concerning methadone traffickers to the effect that priorities are set based upon limited resources. Top priority is given to heroin abuse with methadone a much lower priority. One-third of the total manpower is devoted to street-level operations in methadone, marihuana, PCP and nickel or dime bags of heroin.

According to Mr. Bonacum, the local police precinct commanders and the narcotics division of the police department, respond to community complaints. Small-scale operations are launched in order to determine whether the complaints are founded. If they are, clinics are put out of business. The community can be a strong catalyst for law enforcement action.

Commissioner Bonacum expressed concern over methadone diversion being ignored by police or law enforcement personnel. Methadone diversion diffused among many thousands of patients around the city leaves the police without a precise system or organization to attack. He stated that there is little prospect that the police could be any more effective in dealing with the diversion problem by arresting individuals than they were or have been in dealing with the heroin problem by that means. The Commissioner believes the solution will not be found in law enforcement.

D. The Boston Experience

The city of Boston began operating a methadone maintenance and detoxification clinic in June 1970 at Boston City Hospital. Initially the treatment philosophy of the clinic was high dose methadone maintenance and earned take-home privileges. During the fall of 1971, it became clear to clinic staff that take-home privileges created problems in the clinic. Patients with take-home privileges found their take-home was an extremely valuable commodity on the street. Methadone diversion through sale or theft and a collection of individuals around the clinic seeking methadone "supplies" led the clinic to request funding for 7 days a week, 12 hours a day operation (4 hours a day Saturdays and Sundays). On April 10, 1972, the Boston City Hospital Drug Clinic formally shifted to a no take-home policy, an action not taken capriciously. The Boston City Council had threatened a cutoff of funds unless this policy was instituted. Cases of street sales of methadone to children, primary methadone addiction and overdoses also made a no take-home policy likely since the alternative clearly was no methadone. For the Boston area it was clear that no take-home was the only way methadone was to survive.

Several effects were noted by the shift to a no take-home policy. Many of the patients discharged during April 1972 were badly inconvenienced by the new policy. Despite expanded clinic hours, patients complained of a lack of sufficient flexibility to allow daily clinic visits. Approximately 1 year after initiation of the no take-home policy, employment of the clinic patients had dropped from 73.4 percent to 38.8 percent. Increased patient dropout rates were also noted after the policy was underway.

Even with the negatives of the no take-home methadone policy several pluses emerged. Patients who dropped out of treatment when no take-home was initiated returned to treatment. Treatment capacity was operating at 100 percent with a waiting list and many addicts in treatment reported being employed.

Staff of the Select Committee made a field trip to Boston in the fall of 1977. Despite the obvious limitations of cost and inconvenience associated with the Boston program, several virtues were noted. Overdose deaths and emergency room episodes in Boston are substantially below what they were. Interviews with the Boston police and even some of the addicts in treatment indicated little diversion and what diversion does exist in Boston may come from two clinics (one private and one Federal) which allow take-home doses of methadone. Patients go to the New York City area and purchase street methadone. The benefits (even given the associated problems) of a no take-home methadone maintenance policy appear obvious.

IV. FINDINGS

1. The Select Committee finds that the New York City take-home methadone policy is a source of leakage and diversion to street sales and usage. This illicit methadone flow extends outside the New York City area, the committee having evidence that persons as far away as Boston are being supplied with illicit methadone purchased in New York City.

2. The Select Committee finds that methadone maintenance clinics have a very high dropout and recidivism rate among their clients. Such high rates in dropout and recidivism should not necessarily be regarded as program failure since clinics do offer clients an alternative to street trafficking.

3. The Select Committee finds that almost all diversion of methadone is the result of methadone clinics with take-home policies. Theft from clinics, drugstores, or pharmaceutical houses, account for only a minute amount of diversion.

4. The Select Committee finds that there is far from unanimous agreement that the proposed new methadone regulations should be implemented. Of particular concern is the advisability of 6-day take-home privileges and the cancellation of mandatory urinalysis requirements.

5. The Select Committee finds that methadone clinics offer few, if any, substantial rehabilitation aids and many clinics thus serve merely as "filling stations."

6. The Select Committee finds that of federally funded drug abuse treatment slots, approximately 30 percent are methadone treatment. An inordinately high percentage of these treatment slots, when compared to other modalities, are filled by young black males.

7. The Select Committee finds that dosage units of take-home methadone in New York City are excessive, often in the range of 80 milligrams or more per day. This high dosage unit represents a diversion threat and undoubtedly accounts for a fair proportion of the street methadone sales.

V. RECOMMENDATIONS

1. The Select Committee believes that treatment of addiction via methadone represents a skilled sub-speciality of medicine and not merely a branch of community medicine or psychiatry. It is recommended that physicians working in methadone clinics be required to receive training in drug abuse and its psychosocial ramifications, and that such training be continuously updated. Training should also be made available to drug abuse counselors. It is recommended that these requirements be made a part of the proposed new methadone regulations.

2. The Select Committee recommends that the proposed methadone regulations require urinalysis of all clients at random though regular intervals. The Committee cannot endorse the existing language of voluntary urinalysis at the discretion of each clinic. If, as claimed, reliability and validity of urine tests is not high, then these should be increased by recourse to "double blind," or "marked" studies. In this instance, the methodology and technique for high validity and reliability exist; they have only to be adhered to.

3. The Select Committee appreciates fully the many and diverse difficulties associated with a no take-home policy such as administered by the City of Boston. Nevertheless, the leakage occurring in the New York City take-home system is unacceptably high. The committee therefore believes that the proposed change to 6-day take-home in some circumstances as found in the proposed methadone regulations represents a clear and present danger to the public health and should be stricken from the proposed regulations. It is further recommended that take-home methadone privileges should be limited to 1-day supplies and that a dose of 60 milligrams be set as the maximum take-home dose. Such regulations should become a part of the new regulations.

4. The Select Committee recommends that auxiliary services become a fact in every methadone clinic and not be more a theoretical than actual entity. Client-counselor ratios should not exceed 30:1, employment and vocational services should be in place and functioning. Services to pregnant and addicted mothers should be mandatory at all clinics. In this program the special needs of women on methadone treatment should be fully understood by all treatment staff and the treatment plan adjusted to terminate male-oriented counseling.

5. The Select Committee recommends that a special initiative be instituted to ensure that ethnic and other minorities are assigned to treatment modalities that best meets their needs, and not to methadone as a matter of course. Methadone, the committee believes, is a treatment of last resort and not "a matter of course."

VI. CONCLUSION

The hearings on methadone diversion have convinced this committee that, properly utilized, methadone is a legitimate treatment modality for opiate addiction. It must, however, be seen as one treatment modality, not the sole one. Methadone treatment does indeed involve the substitution of one addictive drug for another, and this constitutes a moral, medical, and legal dilemma.

From a public health perspective, methadone diversion and illicit sales represent a significant threat. This committee documented numerous cases of primary methadone addiction, of drug death due to illicit methadone and of emergency room episodes involving methadone. Illicit methadone must be minimized; that is why the committee has concluded that take-home dosage units represent a major threat. The benefits of methadone treatment are great but the social and public healtl costs, of its widespread use are also great.

The committee believes that the appropriate Federal agencies must intensify their search for alternatives to methadone. The social, and public health benefits, and costs of alternative drugs such as LAAM and narcotic antagonists must be scientifically considered.

A. Staff Findings

1. Committee staff investigations revealed deficiencies in the New York City methadone treatment system which contributed to the diversion of methadone.

2. As a result of the deficiencies, which were evidenced, major complications were documented: (1) reduced effectiveness of treatment programs in achieving their objectives of freeing the patient from drug dependence and stabilizing him/her on a minimal dose; (2) development of a viable and effective black market in methadone; (3) addiction to methadone by persons, especially young people, because of its easy availability; and (4) deaths, illnesses, and hospital emergencies from self-administered methadone overdoses.

3. There are three possible avenues whereby methadone can be diverted. These include: (1) the sale of dispensed methadone by patients in programs; (2) the thefts from legitimate methadone outlets, such as manufacturers, hospitals, and treatment programs; and (3) the illicit manufacture and distribution by organized crime.

4. The quality of clinic management is probably most important with regard to control of methadone diversion by patients.

5. Superior clinic management is also instrumental in treatment, rehabilitation, and good community relations. When the administrative leadership is effective the quality of care and morale is high and patients respond very positively.

6. Patients in methadone maintenance programs were the largest source of illegal methadone on the street.

7. The major contributor to the problem of methadone diversion is the patient's abuse of his/her take-home medication.

8. Diverted methadone is most frequently used by adults with histories of active heroin use. A NIDA-sponsored study found 84 percent of active addicts on heroin, 8 percent on other drugs, and only 4 percent on diverted methadone.

B. Staff Conclusions

1. It is reasonable to conclude that further harm would result from a lessening of the criteria for take-home medication. It is of concern that allowing an increased degree of latitude on take-home will create even greater problems with abuse of take-home medication than presently exist.

2. A relationship exists between the overall quality of clinic management and the likelihood of a variety of patient abuses, including methadone sales.

3. In poorly operated treatment programs, lack of control due to negligence or ignorance could result in methadone finding its way into illegal traffic. Diversion could be caused by a program's failure to adequately safeguard and account for its supply of methadone; this in turn could permit employee or patient theft of the drug.

4. Eliminating urine screening for various drugs could hamper the counselor's ability to treat the patient. The counselor would not be able to determine other drug use, which is utilized as an indication that the patient is unable to cope or is experiencing problems

C. Staff Recommendations

1. The Committee supports the U.S. General Accounting Office regarding security measures for methadone distribution, as a means of reducing the major role that break-ins, robberies, and thefts of methadone supplies play as a source of illicit methadone.

2. An indepth case-by-case analysis of medical examiner reports regarding methadone-related deaths, in New York City, should be undertaken. This would determine in detail the nature and extent to which methadone abuse is involved in morbidity and mortality, as well as methadone—other drug interactions and synergistic effects when methadone is used in combination.

3. Specific information and warnings should be required on all methadone bottles, including the dangers of improperly used methadone.

4. The return of all used methadone bottles to the program is a necessary step toward the elimination of widespread diversion. The program should then dispose of these bottles in a manner that precludes their reuse.

5. The physician should not be the only one to make the decision regarding take-home medication or increased privileges. A joint decision should be entered into by all staff who are relating to the patient including the physician, the counselor, and the nurse.

6. Selection of staff is one of the most important aspects of the treatment setting. It is recommended that programs hire a more professionalized staff, who have specific skills in counseling. A psychiatric social worker can be very effective in providing a counseling

provision to other staff and in helping them develop the skills of determining the needs and responsibilities of their patients.

7. Accelerated research should be encouraged to develop LAAM and test its feasibility as a replacement to take-home methadone for appropriate patients.

8. There needs to be close supervision by the Single-State Agency concerning the quality of clinic management, since this impacts on diversion. Ways of examining management are difficult but there are means to objectively look at the quality of administration of programs that NIDA and the SSA's have been working on.

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