DRUG ABUSE TREATMENT
(Part 2)

HEARINGS
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tion and distribution. As we are increasingly successful in impacting the heroin traffic, we anticipate mounting pressure aimed at diverting methadone and other licit narcotics. Since take-home methadone is the "weak link" in the licit chain, it behooves all responsible agencies to examine ways and means of lessening vulnerability. This, as was outlined earlier by Mr. Dogoloff, is the course which has been undertaken by NIDA, FDA, and DEA under Dr. Bourne's leadership. We support this approach to the problem. However, we feel that present problems must be dealt with before there is any further relaxation of take-home. Mr. Bensinger, in his comments to the Food and Drug Administration concerning the proposed narcotic treatment program standards, concluded:

"The DAWN data indicates an abuse problem associated with take-home medication under current rules and regulations. It is reasonable to conclude that further harm would result from a lessening of the criteria for take-home medication. It is our 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. We strongly urge NIDA and FDA to reconsider the proposed take-home regulations with the view towards maintaining tight federal control of take-home supplies."

While we do not endorse any relaxation of take-home at this time, it is our conclusion that the steps which are being undertaken in the Methadone Diversion Study Group effort to lessen diversion should be provided every opportunity for success. Simultaneously, research with LAAM (L-Alpha Acetyl Methadol) should be carried forward as rapidly as possible since its long-lasting effect could conceivably negate much of the present need for take-home and, hence, the resultant diversion.

Mr. Chairman, this concludes my testimony. I will be happy to answer any questions.

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PREPARED STATEMENT OF BERNARD BIHARI, M.D., DEPUTY COMMISSIONER, NEW YORK CITY, HEALTH DEPARTMENT OFFICE OF SUBSTANCE ABUSE SERVICES

The following is an overview from the New York City experience of some of the issues which I feel need to be considered in the national and local planning of efforts to control methadone diversion.

I believe that the planning of such efforts must consider the nature and magnitude of the problem, the role of illicit methadone use in narcotic addicts, the sources of illicit methadone, and a careful weighing of the pros and cons of suggested measures. The latter should include some assessment of methadone treatment when considering the use of measures that might threaten its efficacy (see attached Overview).

I. THE ROLE OF ILLICIT METHADONE USE IN NARCOTIC ADDICTS

A number of studies have demonstrated that the primary role of illicit methadone in the ecology of street drug use by heroin addicts, is to reduce the size and cost of their narcotic habits and prevent withdrawal sickness. Most addicts interviewed in these studies report that they rarely if ever use illicit methadone for euphoria, but rather to prevent the narcotic abstinence syndrome. In some cases, heroin addicts temporarily maintain themselves on methadone (at a street cost of $8 to $10 per day) to avoid the need to continue the intense criminal activity required to obtain $40 to $80 per day for the usual street heroin habit. Many then resume heroin use after some period of time.

In other cases the switch from heroin to illicit methadone for a few days or a few weeks serves as a transition to legitimate treatment. Some addicts, finding that they can function better and feel more comfortable on methadone enter methadone maintenance treatment programs where genuine rehabilitation then becomes possible.

Although the above comments are not meant to condone the availability and use of illicit methadone by narcotic addicts, it is important to understand that it is not as destructive nor as dangerous as those unfamilar with these factors might assume.

The group in which its use is most dangerous is those poly drug abusers whose illicit methadone and heroin use is occasional and casual. These people because of absence of physical tolerance to narcotics are in more danger of serious narcotic overdose reactions just as they are in constant danger of overdosing with other

drugs of abuse, such as barbiturates, placydil, valium, etc. These are people who abuse and may overdose from any drug available.

II. SOURCES OF ILLICIT METHADONE

There are three possible sources of illicit methadone. These include sale of dispensed methadone by patients in programs, diversion from manufacturing, distributing and storage sites by robberies, and illicit manufacture and distribution by organized crime.

Although the latter cannot be ruled out, there is presently no evidence available indicating illicit manufacture of methadone.

The other two sources appear to be the major ones. These are:

A. Diversion by patients—there is evidence that a significant percentage of patients in treatment programs sell some of their take home methadone. The only exact figures available regarding the number are New York City arrest figures (457 individuals in 1974), though these presumably represent only a portion of the number of patients involved. The staff and patients in NYC–MMTP estimate that 15–20% of patients sometimes sell their methadone and that 5–10% do so regularly.

B. Diversion as a result of thefts—this appears to be a substantial source of illicit methadone, more than had been previously suspected. The Comptroller General's office of the U.S. General Accounting Office released a report in 1975 prepared in response to a request by Congressman Charles B. Rangel providing details regarding those sources of illicit methadone.

The report itself states:

"Our analysis of DEA records showed that the reported thefts and losses of methadone occurring during fiscal year 1973 consisted of the following:

Type	Number	Dosage units
Night break-in	1,073	961,851
Armed robbery	317	693,590
Employee theft	16	12,441
Customer pilferage	11	6,163
Other	71	67,211
Total	1,488	1,741,256

As indicated by the above tabulation, night break-ins and armed robberies accounted for most of the reported methadone diversions."

Since the report indicates that a majority of the night break-ins and armed robberies were in the N.Y.C. area, I would assume that most of the stolen methadone is sold in the illicit methadone market in N.Y.C. If all of this stolen methadone were sold in N.Y.C., it would provide 4,770 doses of illicit methadone for sale every day of the year.

The report goes on to make specific recommendations for action by the appropriate federal regulatory agencies, recommendations which I strongly support.

It should be mentioned that although no comparable figures are available of the number of doses per day sold by patients in treatment programs, the fact that nearly 5,000 doses per day of illicit methadone are available from break-ins and armed robberies suggest that these may be a major source of illicit methadone in N.Y.C.

III. MEASURES TAKEN BY NYC-MMTP TO CONTROL DIVERSION

A. To prevent robberies, break-ins and thefts, we have a number of carefully designed procedures and policies. In summary they are:

1. The individual clinic keeps an exact accounting of the methadone received each day from the hospital pharmacy. All unused methadone is returned to the pharmacy at the end of the day. The pharmacist and clinic nurse together count the number returned, enter it on to the "Weekly Methadone Accounting Record" and both initial the entry. The difference between the number of methadone diskets received by the clinic in the morning and the number returned in the evening must correspond exactly to the total number recorded in the "Daily Medication Record," with any discrepancies accounted for.

2. The methadone is transported between clinic and pharmacy by a nurse and a security guard, and if the clinic is in a separate building a police car accompanies the Program vehicle.

3. All methadone is administered and dispensed in dissolved form, and all methadone ingested in the clinic is swallowed under the direct observation of the nurses. The nurses routinely require the patients to speak after they have taken the methadone, to insure that it has been swallowed.

4. Take home medication is dispensed in child proof bottles. The empty bottles must be returned and accounted for.

5. 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 and for close monitoring of these activities in all of our 34 clinics by the NYC-MMTP Central Office. The computerized data from these forms allow us to account for every milligram of methadone administered or dispensed to each of our 11,500 patients every day.

B. To prevent diversion by patients:

1. All patients drink the medication in the clinic six days per week for the first three months of treatment (as do all patients in all MMTP programs, under FDA and state regulations).

2. After three months, patients who have discontinued criminal activity and have shown no signs of drug abuse are reduced to a five time per week schedule of clinic visits, with two take home doses allowed per week. Patients are then kept on this schedule until they have demonstrated significant evidence of probable responsibility in the handling of methadone. The following factors are considered in making this judgment:

a. Background and history of the patient.

b. General and special characteristics of the patient and the community in which the patient resides.

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

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

e. Regularity of clinic attendance.

f. Absence of serious behavioral problems in the clinic.

g. Stability of the patient's financial condition.

h. Stability of the patient's home environment.

i. Stability of the patient's family and other relationships.

j. Absence of past and/or current criminal activity.

k. Length of time in methadone maintenance treatment.

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

3. A number of clinic policies are designed to identify and deal with those patients in whom there is some possibility of methadone diversion. We receive a monthly list from the NYC-PD 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 still in active treatment (if not already aware of the arrest). These patients, if not incarcerated, are all put on daily pick up schedules until the case is resolved.

4. Where evidence of heroin abuse is demonstrated through urine testing, patients are put on a daily pick-up schedule. This eliminates the possibility of the sale of methadone. Patients with evidence of abuse of other drugs are also put on frequent pick-up schedules, both to increase the degree of clinical supervision and to reduce the possibility of sale of methadone to obtain money for other drugs.

5. Since some methadone sales occur in the immediate vicinity of clinics, NYC-MMTP has a strictly enforced "no loitering" policy. Patients are not allowed to remain in the immediate environs of their clinics. The clinics send out "counselor patrols" several times per day to spot check for loitering. Patients are put on notice if they do so and discharged from treatment if they fail to respond to the warnings.

6. Finally, in addition to all of the specific measures outlined above, we have observed a relationship 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 methadone sale

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 our Central Office management staff, or if necessary replaced, we note a reduction in methadone sales, in drug abuse, and in disruptive behavior by the patients both in the clinic and in the surrounding community.

This area, the quality of clinic management, is probably the most important with regard to control of methadone diversion by patients, as it is for almost all other aspects of treatment, rehabilitation and good community relations. When clinic administrative leadership is effective, the quality of care and morale is high. The patients in response to their experience of the clinic as a positive and for some a corrective "family" experience take more active responsibility for their own lives and actions. In such a setting, anti-social and self destructive behavior by patients becomes minimal and rehabilitation maximal.

IV. RECOMMENDATIONS

A. I strongly support the recommendations of the U.S. Comptroller General's Office regarding security measures for methadone distribution, as a means of reducing the major role that break-ins, robberies and theft of methadone supplies play as a source of illicit methadone.

B. I would urge that the agencies monitoring and regulating methadone clinics require all of them to follow the guidelines NYC-MMTP has developed, described above, to minimize methadone diversion by patients. Many programs in N.Y.C. have similar or equally effective policies and procedures, but some clearly do not.

C. I would urge that the problem of illicit methadone be understood in proper prospective. It is a problem that if viewed in a distorted or over emotional fashion, could be quite seriously exaggerated, and in consequence could result in inappropriate responses. Some recommendations have been made to deal with this issue which are seriously lacking in an understanding of the nature and sources of the problem and which would in consequence worsen the problem of narcotic abuse. A prime example of such is the recommendation that all patients be placed on "no take home" schedules, drinking their methadone in the clinic seven days a week. Such a measure would drive many patients out of treatment, back to heroin and illicit methadone use and to criminal activity. One fourth of all the patients in methadone treatment in Boston left its program on the day Boston adopted a "no take home" policy five years ago, and the voluntary rate of termination from treatment thereafer doubled. In N.Y.C., assuming the same patient response, this would result in 8,500 patients immediately leaving treatment with an additional loss of 3,000 to 4,000 more patients in the following months. Thus at least 12,000 patients would leave treatment, return to heroin and illicit methadone use and to burglaries, muggings, armed robberies and the other crimes associated with heroin addiction. It would also seriously impair the rehabilitative efficacy of methadone maintenance treatment, thereby undermining its most important social value. It would prevent growth and foster dependency in those patients who chose to remain in treatment, thereby discouraging patients from efforts to grow to a point where they may attempt to detoxify and lead drug free, treatment free lives. Finally, it would not eliminate the problem of illicit methadone, since patients are only one source of this, while it would seriously worsen the problem of heroin addiction by making treatment less attractive and less effective.

Only an informed response that intelligently addresses the issues concerned can positively effect a social problem such as this one.

Methadone Treatment in New York: An Overview

Methadone maintenance treatment, one of the major effective rehabilitative treatments for narcotic addiction, is one of the centerpieces of the national drug abuse treatment effort.

There are currently 29,000 people in methadone maintenance treatment in New York City with 12,000 in N.Y.C. Methadone Maintenance Treatment Program, 12,000 in voluntary non-profit programs and 5,000 in proprietary programs.

A. HOW IT WORKS

Methadone is provided to the patient in single daily doses dispensed in clinics staffed by physicians, nurses, counselors, and administrative staff. There are four elements central to its effectiveness.

1. Relief of the craving for heroin, without the side effects of euphoria, sedation or tranquilization which accompany heroin use.

2. Relative blockade of the euphoria producing effects of all narcotics, thereby reducing one of heroin's major appeals.

3. Provision of a focus for an intense attachment or connection, much like family love. This property is present for the addict in all drugs of abuse.

Methadone maintenance differs from drugs of abuse in the lack of sedation or euphoria and in the freedom from destructive effects on life style, and social, psychological and physical functioning.

4. Provision by the clinic staff of a context for a "corrective family experience" by the patient in his/her relationship to the clinic staff. This is a central psychotherapeutic element of methadone maintenance treatment, complementing the role of one to one counseling.

B. TREATMENT OUTCOME

1. Outcome is measured by several factors. Chief amongst these are the following: (Note—data is from the N.Y.C. Department of Health Methadone Maintenance Treatment Program, 1970–1977)

a. Heroin Use—Drops from 100 percent of patients before admission to 15 percent after six months. This group of 15 percent decreases heroin use from an average of 25 times to 2 times per week.

b. Active Criminality—Decreases from 95 percent before admission to less than 10 percent during the first year in treatment.

c. Employment—Increases from 12 percent on admission to 43 percent six months later. In addition, 12 percent of patients are homemakers with small children and 8 percent return to school.

d. Non-narcotic Drug and Alcohol Abuse—Decreases from 75 percent before admission to 25 percent after six months.

e. Retention in Treatment—68 percent remain after 12 months and 58 percent remain after 24 months.

2. Treatment "Failure"—Aside from a significant reduction in criminality and heroin use, approximately one-fourth of patients fail to show progress in other areas. These are patients who do not show significant social productivity and who continue to abuse pills and alcohol. This group is quite difficult to manage, sometimes requiring termination from treatment for serious alcohol or drug abuse or when persistent loitering is disruptive to the community. The plans for improving treatment services for this group, if additional funds become available, will include increased staffing with mental health professionals and the development of day programs within the clinics providing pre-vocational workshops, vocational training, educational services, group therapy, etc.

3. Detoxification—At the present time, approximately one-third of successfully rehabilitated patients can discontinue methadone treatment after 2 or 3 years and remain indefinitely free of drug abuse. The remainder relapse within 12 months and have to return to treatment to maintain their rehabilitative progress. Those successful patients who do not choose to leave treatment or who leave and then return because of a relapse appear to need continued treatment to preserve their rehabilitative gains. If such patients continue to be socially productive and free of heroin use, criminal activity and non-narcotic drug abuse, the programs consider them successfully rehabilitated, much as are people with other medical problems who need continued treatment in order to remain stable and healthy.

C. COST EFFECTIVENESS

The average cost per patient per year is $1,900 nationwide. The N.Y.C. Methadone Maintenance Treatment Program however, in response to city and state budget cuts, reduced the cost in the '77–78 fiscal year to $1,450 per patient per year, the irreducible minimum consistent with maintenance of the rehabilitative elements of treatment.

This cost level compares favorably with that for other treatment approaches, and is considerably cheaper than $24,000 per year per prison inmate. The social costs per addict which accompany drug related crime are of course enormous.

D. ROLE IN RELATION TO OTHER TREATMENT APPROACHES

In the past methadone treatment has often been considered to be competitive with the drug free treatment approaches. On close examination, however, this is not the case. The average age of people in methadone treatment is 30, 10 years older than the average in drug free programs. Methadone patients have all been addicted to narcotics an average of 10 years before admission. Only a small percentage of patients in drug free treatment settings are chronic narcotic addicts with similar long histories, most presenting mixed abuse of a variety of drugs and alcohol. In addition, the younger patients in drug free programs suffer from many of the more serious problems of mid and late adolescence, requiring special approaches to these problems. The methadone patient has different life-style patterns and different psychological problems accompanying his heavier more chronic drug use, and is much more in need of substitution therapy as a base on which to build his rehabilitative efforts. Thus methadone and drug free approaches are both necessary, and are complementary in the efforts to treat drug abuse.

E. COMMUNITY PROBLEMS

The patient group described above who show little rehabilitative progress are responsible for most of methadone programs' community problems since they frequently loiter near clinics, sell and take illicit drugs, sometimes sell methadone, etc. Well run programs have developed a variety of successful techniques for dealing with these problems, techniques which are currently being adopted by all clinics in New York City under the direction of a committee appointed by the Office of Drug Abuse Services and the New York City Health Department.

Adoption of these guidelines has already reduced the number of problem clinics, with a parallel decrease in the objective indications of methadone sales.

F. FUTURE

The testing of a long acting form of methadone called Levo-Alpha-Acetyl Methadol (or LAAM) is now in its final stages. This methadone substitute requires only 3 doses per week, and will therefore reduce the clinic visit frequency required by federal and state regulations. It will also decrease the amount of take-home narcotic available for illicit sale, thereby reducing this small but important public health hazard associated with methadone maintenance treatment.

In addition, the gradually reducing animosity between methadone and drug free programs is leading to efforts by the various programs to learn from each other's experience. Methadone programs in New York are showing a greater interest in the use of group treatment techniques and in the integration of knowledge from the mental health disciplines in their treatment services. Several of the agencies with a drug free orientation have begun methadone-to-abstinence programs which attempt to integrate elements of drug free and methadone related approaches for a patient group intermediate in age and presenting problems between those generally served by these modalities.

Future cross fertilization may involve comparisons of the similarities and differences in the ways in which the various treatment approaches provide the two basic elements required for rehabilitation of addicts and alcoholics; availability of a means for a strong attachment leading to connection to the agency as a surrogate family, followed by provision of a corrective family experience.

PREPARED STATEMENT OF MICHAEL BADEN, M.D., OFFICE OF CHIEF MEDICAL EXAMINER, THE CITY OF NEW YORK

The great majority of deaths due to methadone use is of persons not enrolled in maintenance treatment programs who have not developed a tolerance to the narcotic's effects and who have obtained the drug by illicit diversion. The abuser does not realize that the therapeutic amount of methadone for someone in treat-

ment, often 60 to 100 mgm in the orange juice container, is equivalent in potency to more than 20 five dollar bags of street heroin (which may contain two to five mgm heroin each) and may be fatal for the non-tolerant user.

Death from methadone poisoning is due to true pharmacologic overdosage with depression of brain functioning and breathing, as contrasted to death following street heroin use which is more obscure because more than 95% of the unsterile intravenous injection consists of unknown diluents in constantly changing amounts. In more than one-half of the fatalities in which methadone causes or contributes to death other drugs are also present but in quantities insufficient in themselves to cause death (most commonly alcohol). These deaths are predominantly of Black males in their late twenties who may or may not be heroin addicts, reflective of the City's narcotic addict population.

The illicitly obtained take-home methadone container is sometimes found with the name and program of the patient to whom it was dispensed still present. Problems of confidentiality and privacy have prevented full utilization of this information to prevent diversion. We have found no evidence that clandestinely manufactured methadone has caused deaths in New York City.

Persons enrolled in methadone programs who have developed and who maintain tolerance to the therapeutic dosage do not die of methadone overdose. However there is an excessively high incidence of violent death, especially homicide, in this group, and death from multiple drug abuse (particularly alcohol and heroin). Another group of particular concern are babies and children born to mothers on methadone maintenance. We have investigated a small number of deaths in greater than expected incidence classified as Sudden Infant Death Syndrome, and also of battered children in this group.

The most effective measure that can be quickly taken to decrease deaths due to methadone use is to better control diversion.

PREPARED STATEMENT OF VERNON D. PATCH, M.D., ASSOCIATE PROFESSOR OF PSYCHIATRY, HARVARD MEDICAL SCHOOL

Methadone Maintenance as demonstrated by Dole and Nyswander in 1965 was a highly effective treatment for narcotics addiction in a highly selected population of addicts. The original thinking in the field of drug treatment was that narcotic addiction for most patients was a chronic relapsing illness; that detoxification of narcotic addicts by methadone substitution and slow withdrawal was generally unsuccessful; and that methadone maintenance was going to be a life long treatment for many patients. Take home methadone privileges for methadone maintenance patients were considered necessary to give the addict patient freedom to live a more normal life and to be free to travel for work, school or vacations, all necessary aspects of rehabilitation. Rising addiction in the late 1960's created an atmosphere for widespread acceptance of the treatment concepts underlying methadone maintenance. The National Institute of Mental Health's Division of Addict Rehabilitation began substantial funding of drug treatment programs in 1969, balancing methadone maintenance with drug free or abstinence treatment programs. SAODAP was created in 1970 and gave substantial impetus to methadone maintenance treatment and the wars began between rivaling treatment modalities competing for federal funds. Research on treatment efficacy took a back seat to the development of a vast network of drug treatment programs across the country.

Crime continued to increase in the United States and some disillusion developed that methadone maintenance could really reduce related crimes. Other problems developed. Some doctors openly sold methadone to readily available customers. Methadone clinics were overpopulated. Addict patients flocked to treatment and became unwelcome and decidedly unpopular with residents living near methadone clinics. Clinic loitering became a well known term among drug treatment personnel. Methadone diversion reared its head as clinic patients sold part of their take home methadone supplies for profit. Clinic robberies and theft of methadone shipments added to the supplies of street methadone. Demand for methadone even permitted active street sales of "spit out" methadone carried from the clinics by patients in their mouths. News reports of methadone poisonings in children who drank the take home methadone supplies of one or both of their addict parents and news of methadone deaths of addicts took over front

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