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Narcotic Addict Treatment Act of 1974 (P.L. 93-281).

Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended (42 U.S.C. 257(a)).

Methadone abuse and its consequences are a serious problem in New York City. The Office of the Chief Medical Examiner of New York City attributed 836 deaths from January 1974 to June 1975 to methadone, either alone or in combination with other drugs. Findings/Conclusions: Available records indicate that: the combination of methadone and other drugs was found in more deaths than methadone alone; victims were usually between the ages of 16 and 30 and not enrolled in a methadone treatment program; the methadone involved in most deaths has been acquired illegally; and the density of methadone treatment programs and patients in New York City appeared to contribute greatly to the large number of methadone deaths. Probably more than half of the patients in treatment programs sell part of their take-home supply, contributing to the illicit methadone problem. Thefts from legitimate sources also contribute to the illicit methadone supply. The Department of Justice believes that methadone take-home supplies are the true cause of illicit methadone supplies and that only the Food and Drug Administration, responsible for overseeing medical standards for methadone use in treatment programs, can decide whether to allow take-home privileges. (QM)

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UNITED STATES GENERAL ACCOUNTING OFFICE

Methadone Deaths In New York City

Departments of Justice and
Health, Education, and Welfare

Methadone abuse and deaths are a serious problem in New York City.

In the 18 months ended June 30, 1975, 836 deaths were attributed to methadone, either alone or in combination with other drugs.

This report discusses the circumstances surrounding methadone deaths in the city and observes that patients' abuse of methadone take-home privileges seems to be a major factor contributing to the problem. The take-home policy is under Federal review as is an alternative to the use of methadone in treatment programs.

The report also discusses the Drug Enforcement Administration's inspection (under a 1974 law) of methadone treatment programs. The inspections got off to a slow start but the agency says it is catching up.

MARCH 14, 1977



UNITED STATES GENERAL ACCOUNTING OFFICE
WASHINGTON, D.C. 20548

GENERAL GOVERNMENT
DIVISION

B-164031(2)

The Honorable Charles B. Rangel
House of Representatives

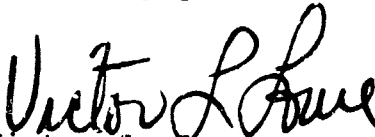
Dear Mr. Rangel:

This report discusses the circumstances surrounding methadone deaths in New York City and the Drug Enforcement Administration's inspection of methadone treatment programs under the Narcotic Addict Treatment Act of 1974. The review was made in accordance with your request.

We obtained Department of Justice comments which are discussed in chapters 2 and 3 and included as appendix I. The Department of Health, Education, and Welfare provided technical comments which we considered in preparing this report.

We plan no further distribution of this report unless you agree or publicly announce its contents.

Sincerely yours,


Victor L. Lowe
Director

D I G E S T

Methadone abuse and its consequences are a serious problem in New York City. Abuse sometimes means death for drug addicts, including patients in methadone maintenance programs and individuals who experiment with it. The large number of methadone deaths in the city apparently results from the improper or illegal use of methadone which is legally dispensed.

The Office of the Chief Medical Examiner of New York City attributed 836 deaths from January 1974 to June 1975 to methadone, either alone or in combination with other drugs. New York City--with 133 programs and 33,090 patients at June 30, 1976--has the largest methadone treatment operation in the Nation. (See pp. 2 and 6.)

The circumstances surrounding methadone deaths cannot be known with certainty; however, available records indicate that

- the combination of methadone and other drugs, such as alcohol, barbiturates, tranquilizers, and heroin was found in more deaths than methadone alone (see p. 7.);
- people who died of drug overdoses involving methadone were usually between the ages of 16 and 30 and not enrolled in a methadone treatment program (see pp. 7 and 8);
- the methadone involved in most deaths had been acquired illegally (see pp. 8 and 9); and
- the density of methadone treatment programs and patients in New York City appears to contribute greatly to the large number of methadone deaths. (See pp. 12 and 13.)

Probably more than half of the patients in treatment programs sell part of their take-home supply, contributing to the illicit methadone problem. (See p. 9.) Thefts from legitimate sources, such as manufacturers, hospitals, and treatment programs, also contribute to the illicit methadone supply in New York City. (See p. 10.) Eliminating take-home privileges could result in much less illicit use of methadone and, consequently, fewer deaths. This must be weighed against possible drawbacks in treatment--large-scale dropouts leading to relapses into drug abuse and addiction.

The Department of Justice believes that methadone take-home supplies are the true cause of illicit methadone supplies and that only the Food and Drug Administration--responsible for overseeing medical standards for methadone use in treatment programs--can decide whether to allow take-home privileges. According to Justice, a multi-agency review board is studying the take-home policy. Counterbalancing this, a recent court decision prevents the Food and Drug Administration from limiting methadone distribution only to approved treatment centers, hospitals, and selected pharmacies. This could pose a much greater problem. (See pp. 15 and 16.)

The Drug Enforcement Administration's regulatory enforcement program under the Narcotic Addict Treatment Act got off to a slow start. But, Justice said investigations of registered methadone treatment programs are now almost on schedule. Therefore, GAO is not making any recommendations. (See pp. 17 and 19.)

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ABPREVIATIONS

CME Chief Medical Examiner of New York City
DAWN Drug Abuse Warning Network
DEA Drug Enforcement Administration
DEA-NY Drug Enforcement Administration's New York
regional office
FDA Food and Drug Administration
GAO General Accounting Office
HEW Department of Health, Education, and
Welfare
NIDA National Institute on Drug Abuse
SMSA standard metropolitan statistical area

CHAPTER 1

INTRODUCTION

Methadone abuse and the deaths which result from it are a serious problem in New York City. Available Government reports indicated that the city had the greatest number of methadone-related deaths in the Nation. Concerned by this large number of methadone deaths, Congressman Charles B. Rangel asked us to obtain information on this serious problem. We examined

--the factors appearing to contribute to the large number of methadone-related deaths in New York City and

--the Drug Enforcement Administration (DEA), Department of Justice, implementation of the Narcotic Addict Treatment Act of 1974 in New York City.

METHADONE USAGE

Methadone is an addictive synthetic narcotic, with a high potential for abuse, used primarily in treating heroin addiction. It satisfies an addict's craving for heroin and other narcotics and provides less euphoria than these drugs. In treating heroin addiction, methadone is used for either maintenance or detoxification.

In maintenance treatment, a patient is stabilized by administering a fixed dosage of methadone daily for an indefinite period. The patient is maintained at a methadone level which is high enough to eliminate some of the undesirable characteristics of heroin addiction, such as narcotics "hunger," thereby enabling the patient to benefit from other nondrug therapeutic techniques.

In detoxification treatment, methadone is administered in declining dosages until the patient is no longer physically dependent on either heroin or the methadone at which time the treatment is terminated.

Generally, to be admitted into a methadone maintenance treatment program an applicant must (1) have a history of at least 2 years of narcotic addiction before applying for admittance and (2) be physically addicted at the time of application. Evidence of this history may be obtained by checking prior arrests and convictions, or through testimony of relatives or friends. In addition, applicants must be at least 16 years old; those applicants between the ages

of 16 and 18 years must, in addition to the other requirements, have a documented history of two or more attempts at detoxification. Parental or guardian consent may be required under State law.

Initially an addict enrolled in a treatment program is to report daily to receive his dosage of methadone and any necessary rehabilitative services. Federal regulations provide that a patient (an addict registered in a program) may be given a 2-day take-home supply of liquid methadone after 3 months in a program and up to a 3-day take-home supply after 2 years, if progress toward rehabilitation has been demonstrated.

As of June 30, 1975, 735 programs in the country provided methadone treatment to about 80,000 patients; New York City has the largest treatment operation. The number of treatment programs and methadone patients in the city at June 30, 1975 and 1976, follows.

Type	Number of programs		Number of patients	
	<u>6/30/75</u>	<u>6/30/76</u>	<u>6/30/75</u>	<u>6/30/76</u>
Public:				
City-operated	43	39	13,013	11,534
Other	105	77	16,651	15,228
Private	<u>21</u>	<u>17</u>	<u>6,685</u>	<u>6,328</u>
Total	<u>169</u>	<u>133</u>	<u>36,349</u>	<u>33,090</u>

RESPONSIBLE AGENCIES

DEA is responsible under the Controlled Substances Act of 1970 (21 U.S.C. 801), as amended by the Narcotic Addict Treatment Act of 1974 (Public Law 93-281, May 1974), for establishing and monitoring recordkeeping and security requirements designed to limit the probability of diversion from treatment programs. DEA registers each treatment program, prescribes drug security and drug accountability recordkeeping standards, and conducts periodic investigations to insure compliance with regulations.

The National Institute on Drug Abuse (NIDA) and the Food and Drug Administration (FDA), Department of Health, Education, and Welfare (HEW), are responsible for establishing the medical treatment standards governing the use of methadone pursuant to Section 4 of Title I of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (42 U.S.C. 257(a)). FDA monitors program compliance with treatment standards for use of methadone in treatment programs,

approves or disapproves program operations, and can take enforcement actions when programs fail to comply with regulations.

NIDA has overall responsibility for policy and coordination of Federal drug abuse prevention and treatment efforts.

Federal controls over methadone use in treating heroin addiction have increased since 1971 when the first Federal regulations governing its use as a research drug for maintenance treatment were issued. The regulations required that each maintenance program be approved for scientific merit by FDA and for drug control by DEA and included a model operating procedure covering such matters as program objectives, admission criteria and evaluation, and dosage levels.

In March 1973 when methadone was changed from a research drug to an approved new drug, FDA introduced comprehensive regulations governing its use. These regulations (1) set medical standards in the treatment of narcotic addiction, (2) established strict control standards on the amount of patients' take-home supply, maximum dosage levels, and documentation of addiction histories, and (3) required that methadone only be administered or dispensed orally, in a liquid form. The regulations also provided for a distribution system which limited the number of persons handling methadone. Manufacturers were required to ship methadone directly to approved treatment programs, hospitals, and selected community pharmacies unless FDA and DEA approved an alternate distribution method.

In May 1974 DEA's authority to regulate methadone treatment programs was increased with the enactment of the Narcotic Addict Treatment Act of 1974. 1/ Under the act, DEA has the authority to register treatment programs, establish stringent security and drug accountability recordkeeping standards, and suspend or revoke a treatment program's operation for failure to comply with Federal regulations. As a controlled substance under the Controlled Substances Act of 1970, methadone is also manufactured and distributed subject to DEA regulatory controls.

The New York State Office of Drug Abuse Services is the State agency with authority to establish regulations for operating State methadone maintenance programs consistent

1/DEA's implementing regulations were made effective in November 1974.

with federally imposed constraints. Any changes in State regulations must be introduced by this office.

We have issued several reports which dealt either wholly or partly with methadone and included review work in New York.

- An April 11, 1973, report (B-166217) provided information on narcotic addiction treatment and rehabilitation programs in New York City. The report discussed the costs, goals, and treatment methods of selected narcotic addiction treatment programs, including methadone treatment programs.
- In a January 30, 1975, report (GGD-75-50) on security controls over the distribution of methadone, we discussed the shipping, transporting, and receiving of methadone; the extent of intransit thefts and losses of controlled substances; and DEA's monitoring of such thefts and losses.
- An August 28, 1975, report (GGD-75-102) on the improvements needed in regulating and monitoring the manufacture and distribution of methadone and various opium derivatives discussed needed DEA improvements in setting and administering quotas for production of narcotics, monitoring and conducting compliance inspection activities, and training investigators who perform such inspections.
- A March 9, 1976, report (GGD-76-51) to the Congress on the need for more effective action to control abuse and diversion in methadone treatment programs discussed improvements needed in FDA's compliance investigations at treatment program locations, enforcement action against violative programs, and coordination with DEA in regulating treatment programs.

SCOPE OF REVIEW

Our review focused on (1) the circumstances of methadone-related deaths in New York City and (2) DEA's use of its increased authority under the Narcotic Addict Treatment Act of 1974 to regulate methadone treatment programs.

We examined applicable records and procedures and discussed our work with representatives of DEA's headquarters and New York regional office; the Office of the Chief Medical Examiner of New York City; the Chief Medical Examiners of Washington, D.C., and Wayne County, Michigan; the National Association of Medical Examiners; State and local

agencies involved in drug treatment and enforcement; and the City of Boston Drug Treatment Program.

We have also drawn on a study of methadone diversion prepared for NIDA by Fordham University's Institute for Social Research. The study covered the period 1972-75 in eight cities, including New York. Because of the study's depth, comprehensiveness, and recency and its use of information from sources not easily available to us--more than 100 street addicts and 200 methadone patients in New York--its findings have been considered in the preparation of this report.

CHAPTER 2

METHADONE DEATHS IN NEW YORK CITY

During an 18-month period ended June 30, 1975, the Office of Chief Medical Examiner of New York City (CME) attributed 836 deaths to methadone, either alone or in combination with other drugs. The circumstances involved in methadone deaths cannot be known with certainty because of the nature of the subject and the often imprecise or incomplete data one must deal with. Despite this, our analysis of available records indicated that

- the combination of methadone and other drugs was found in more deaths than methadone alone,
- most people who died of drug overdoses involving methadone were individuals between the ages of 16 and 30 who were not enrolled in a treatment program,
- illegal methadone (methadone which had been obtained from legitimate sources but diverted to illicit use) was involved in most of the deaths,
- patients who divert their take-home supply were the major source of illegal methadone, and
- the heavy concentration of treatment programs and patients in the city appeared to contribute to the large number of methadone-caused deaths.

HOW MANY DIE FROM METHADONE?

The CME reported that of the 1,186 narcoticism deaths during the 18-month period ended June 30, 1975, 836 (70 percent) involved the presence of methadone, either alone or in combination with other drugs. Deaths reported as being due to narcoticism are those in which the presence of a narcotic substance was chemically confirmed and judged to be a direct cause of death. The deaths, which involved the presence of methadone, were categorized as follows:

<u>Type</u>	<u>Number of deaths</u>
Methadone alone	401
Methadone and other drugs (except heroin)	312
Methadone and heroin	76
Methadone, heroin, and other drugs	47
Total	<u>836</u>

As indicated by the preceding table, methadone in combination with heroin and/or other drugs accounted for 435 of the 836 deaths, 52 percent. In addition to heroin, other drugs used with methadone included alcohol, barbiturates, and tranquilizers.

Under DEA's Drug Abuse Warning Network (project DAWN), 1/ it was reported that in 1975 selected coroners and medical examiners in 24 standard metropolitan statistical areas (SMSAs) reported 780 methadone narcoticism deaths, including 618 or 79 percent, in the New York SMSA. In 1974 selected coroners and medical examiners in 23 of the above SMSAs reported 967 methadone narcoticism deaths of which 834, 86 percent, were reported for the New York SMSA. The CME reported that in 1974 there were only 587 methadone narcoticism deaths in New York City.

The difference between the CME and project DAWN in reported number of 1974 methadone deaths resulted because DAWN statistics included four counties outside New York City and deaths in which methadone was determined to be a contributing, rather than causative, factor.

DAWN statistics included (1) deaths in which the cause was other than methadone narcoticism (for example, suicide, accident, or homicide) and (2) deaths where methadone was found in or near the body but narcoticism was not determined to be the cause of death.

Accordingly, the CME's statistics present a more accurate picture of methadone deaths in New York City; they include only narcoticism deaths in which methadone was found to be a cause of death. Project DAWN statistics, however, are useful in that they provide a relative measure of the extent of the abuse of methadone and resultant deaths.

WHO IS DYING?

The highest incidence of deaths--involving methadone alone or in combination with other drugs--in New York City is found among males and females between the ages of 16 and 30. Male fatalities outnumber female by about 3 to 1. The following table compiled from CME records shows the 1974 incidence of deaths involving methadone in New York City by age and race.

1/Project DAWN is a nationwide program to identify drug abuse trends by having selected hospitals, medical examiners and coroners, and crisis centers in 24 of the more than 250 SMSAs report drug abuse episodes or deaths.

<u>Age group</u>	<u>Number of deaths</u>			
	<u>Total in age group</u>	<u>Race</u>		
		<u>White</u>	<u>Black</u>	<u>Hispanic</u>
15 and under	2	1	0	1
16 - 20	147	55	53	39
21 - 25	206	87	79	40
26 - 30	118	43	53	22
31 - 35	51	14	31	6
36 - 40	32	9	15	8
41 - 45	20	5	12	3
46 - 50	8	3	5	0
Over 50	<u>3</u>	<u>1</u>	<u>1</u>	<u>1</u>
Total	<u>587</u>	<u>218</u>	<u>249</u>	<u>120</u>

The incidence of deaths involving methadone by age and race during the first 6 months of 1975 was essentially the same as for 1974.

The CME reported that during the 18-month period ended June 30, 1975, 111 of the 836 narcoticism deaths involving methadone were reported to be patients enrolled in maintenance programs. Of the 111 deaths, 25 were attributed to methadone alone. Of the total 836 deaths, 401, 48 percent, involved methadone alone. The remaining deaths were attributed to methadone in combination with other drugs, including heroin.

The 435 deaths reported by the CME involving methadone in combination with other drugs indicate that illicit methadone is popular in polydrug abuse. The CME said that individuals use methadone with alcohol and/or drugs, such as diazepam (tranquilizer), amitriptyline (antidepressant), propoxyphene (mild pain killer), and barbiturates. In addition, in nearly half of the methadone abuse cases reported under project DAWN for the New York SMSA in a 9-month period in 1975, methadone was used with another drug.

Illicit methadone is used for several reasons. On the basis of interviews and responses of 113 street addicts and 174 program patients, the Fordham study found that addicts used illegal methadone principally to keep from getting sick (avoid withdrawal symptoms) and to get a "high," and secondarily to temporarily detoxify themselves and limit their heroin habit. The study also suggested that methadone was most frequently used to get a high by taking it with alcohol or by using it on an irregular or spaced-out basis.

WHO SUPPLIES THE ILLICIT METHADONE?

Indications are that the major source of illicit methadone is patients in treatment programs who sell part of their take-home supply.

The Fordham study found that most of the street addicts and program patients interviewed in New York City agreed that patients in treatment programs were usually the source of illicit methadone. Further, 41 percent of the patients and 80 percent of the street addicts interviewed indicated that more than half of all patients sell part of their methadone.

In March and April 1974, DEA conducted a nationwide survey, which included New York City, to determine the availability of methadone in the street traffic. In its survey in the city, DEA found that treatment program personnel interviewed were of the opinion that the most prominent source of illicit methadone was individual patients diverting take-home dosages. DEA's attempts, however, to verify this through undercover purchases in the vicinity of 11 programs proved unsuccessful.

A physician specializing in drug abuse problems told us that some programs mistakenly set an individual's daily dosage level too high. He stated that with a little experimentation the patient can find a lower dosage level and sell the excess. The physician said that the higher dosage levels are designed not only to prevent the onset of withdrawal pains but also to block the euphoric effects of heroin. A lower dosage will preclude pain but may not block the effects of heroin taken later to achieve a high.

Patients can divert their take-home supply of methadone in several ways. For most individuals, the drug has an effective period of 24 to 36 hours. According to the CME, the patient can extend the interval between methadone doses by taking diazepam, a popular tranquilizer which, in effect, prolongs methadone action. In this case, the patient could sell part of the take-home dosage.

A program administrator, who is an ex-patient, told us it was simple for a patient to "skim off" some methadone from the take-home dosages. He said that he was able to consume his first-day 100-milligram dosage, receive two 100-milligram take-home dosages, drink 50 or 75 milligrams on the second day and 50 or 75 on the third, and sell the remaining 50 to 100 milligrams.

Nonpatient diversion

In addition to patient diversion of take-home dosages, other sources of diversion contribute to the illicit methadone problem. Thefts from legitimate methadone outlets, such as manufacturers, hospitals, and treatment programs, fall into this category. Manufacture of methadone by illicit laboratories is another possible source, but according to DEA only one such case has been identified and it was in 1968.

Federal regulations require that take-home methadone be in liquid form. Tablets, concentrate, or other formulations must be mixed with a liquid before being dispensed to patients. The presence, therefore, of nonliquid forms of methadone in the illegal market can probably be attributed to diversion of other than patient take-home dosages. DEA statistics for fiscal year 1975 show the availability of methadone in nonliquid forms: 30 percent of the 2,186 reported incidents of methadone abuse treated in hospital emergency rooms, inpatient units, and crisis centers in the New York SMSA involved methadone in these or unknown forms. According to DEA officials, about 6 percent of the methadone deaths in fiscal year 1975 involved nonliquid forms of methadone.

In poorly operated treatment programs, lack of control resulting from 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 nonliquid methadone. Another possibility is that the program might, in violation of regulations, dispense take-home dosages in other than liquid form.

Theft of liquid methadone also accounts for some diversion. In fiscal year 1975, methadone outlets in the New York City area reported that about 52,000 dosage units were stolen. ^{1/} This represents about 1 percent of the dosages dispensed annually for take home in New York City.

The take-home dosage dilemma

Take-home privileges have been eliminated in at least two major cities, and results to date indicate an alleviation of diversion problems. However, eliminating take-home privileges may bring about results which harm treatment.

^{1/}Two thefts accounted for 25,000 stolen dosage units.

The Narcotic Treatment Administration, Washington, D.C., terminated take-home privileges in July 1974. The Chief Medical Examiner of Washington told us that methadone deaths decreased after take-home privileges were eliminated. Deaths related to methadone in Washington decreased from a high of 33 in 1972 to none in 1975. According to the Fordham study, Washington police believe that eliminating take-home dosages substantially reduced diversion. Also, according to the study,

--patients in Washington programs were significantly less likely to be the source of illegal methadone and

--any illegal methadone supplied by patients was likely to have been stolen or obtained from program staff.

The City of Boston Drug Treatment Program--one of several programs in the Boston area--terminated take-home privileges in April 1972. A report provided by the program director indicated that the positive results of this action included the elimination of methadone deaths and poisonings in children and a marked unavailability of street methadone. Additionally, the report contended that loiterers were eliminated from clinic areas and the clinics became safer for everyone.

Although the experience of Washington and Boston showed positive results, other factors must be considered in a no-take-home policy. Many connected with methadone maintenance view the take-home privilege as an important part of an addict's treatment. They believe that it helps engender trust between patient and program. By using take-home privileges to reward a patient's progress, the program motivates the patient toward further progress. Curtailing or threatening to curtail the privilege can be used as a disciplinary measure to control misconduct. According to those who hold these views, elimination of take-home privileges could

--produce a large dropout rate followed by relapse into addiction;

--bind the patient to his treatment program, thereby interfering with jobs, causing loss of employment, and placing burdens on ill patients; and

--increase program costs, make adequate staffing difficult, overburden the physical facilities of programs, and prevent the expansion of services.

The Boston experience seems to support some of the objections of the pro-take-home side, while refuting others. Following elimination of take-home privileges in Boston, the daily lives of some patients were disrupted, forcing them out of jobs or school. During the next 10 months, the employment rate of patients dropped nearly 35 percent. ^{1/} Costs increased because clinic hours were expanded and the staff increased.

After the adoption of the no-take-home policy, 20 percent of the patients left the program. According to HEW, the Washington, D.C., program also had a large dropout rate.

One possible solution to the take-home dilemma would be the development of a substance which provides the addict with relief from withdrawal pains, is noneuphoric, and has a longer effect after ingestion so that users will not need to (1) disrupt productive lifestyles by reporting to treatment programs to receive daily medication and (2) take home and self-administer medication. The use of LAAM, a long-lasting substitute for methadone, has been proposed as such a substance. The Domestic Council's Drug Abuse Task Force, in its September 1975 report to the President, recommended switching from methadone to LAAM as soon as its safety and efficacy had been determined. NIDA is sponsoring clinical trials to determine LAAM's safety and efficacy.

WHY SO MANY METHADONE DEATHS IN NEW YORK CITY?

The specific reasons for the high incidence of methadone deaths in New York City cannot be determined with certainty. However, there are indications that an important factor is the high density of methadone treatment programs and patients. With the large-scale use of methadone in treatment programs, a corresponding illicit methadone market could develop possibly because of inadequate controls and precautions to prevent diversion. Further, the methadone diversion problem in New York City is given a low law enforcement priority because it is viewed as primarily involved with unorganized diversion by a large number of patients.

The uniqueness of New York City's methadone problem is density of programs, patients, and addicts. New York City had about 33,000 patients at June 30, 1976, in an area of

^{1/}From 1970 to 1974, Boston's unemployment rate steadily rose from 3.9 percent to 7.5 percent.

300 square miles. The map on page 14 shows that the concentration is even greater than the figures indicate. Most of the treatment programs are clustered in a 12-square-mile area of Manhattan.

The availability of illicit methadone appears to be a direct consequence of the number and clustering of treatment programs in the city. The Fordham study found that in New York City nearly all of the street addicts interviewed considered illicit methadone to be available. It is estimated that at least 12,000 take-home methadone dosages are given in New York City every day. Although most of these probably do not find their way into illegal traffic, much does, and it represents a formidable supply of a commodity in demand and therefore easily marketable.

These elements--plentiful supply, substantial demand, and the concentration of buyers and sellers in small areas--create a marketplace atmosphere. Such illegal transactions are further facilitated by the low enforcement priority given by the local police. This environment affords diversion opportunities which probably contribute to the high rate of methadone deaths.

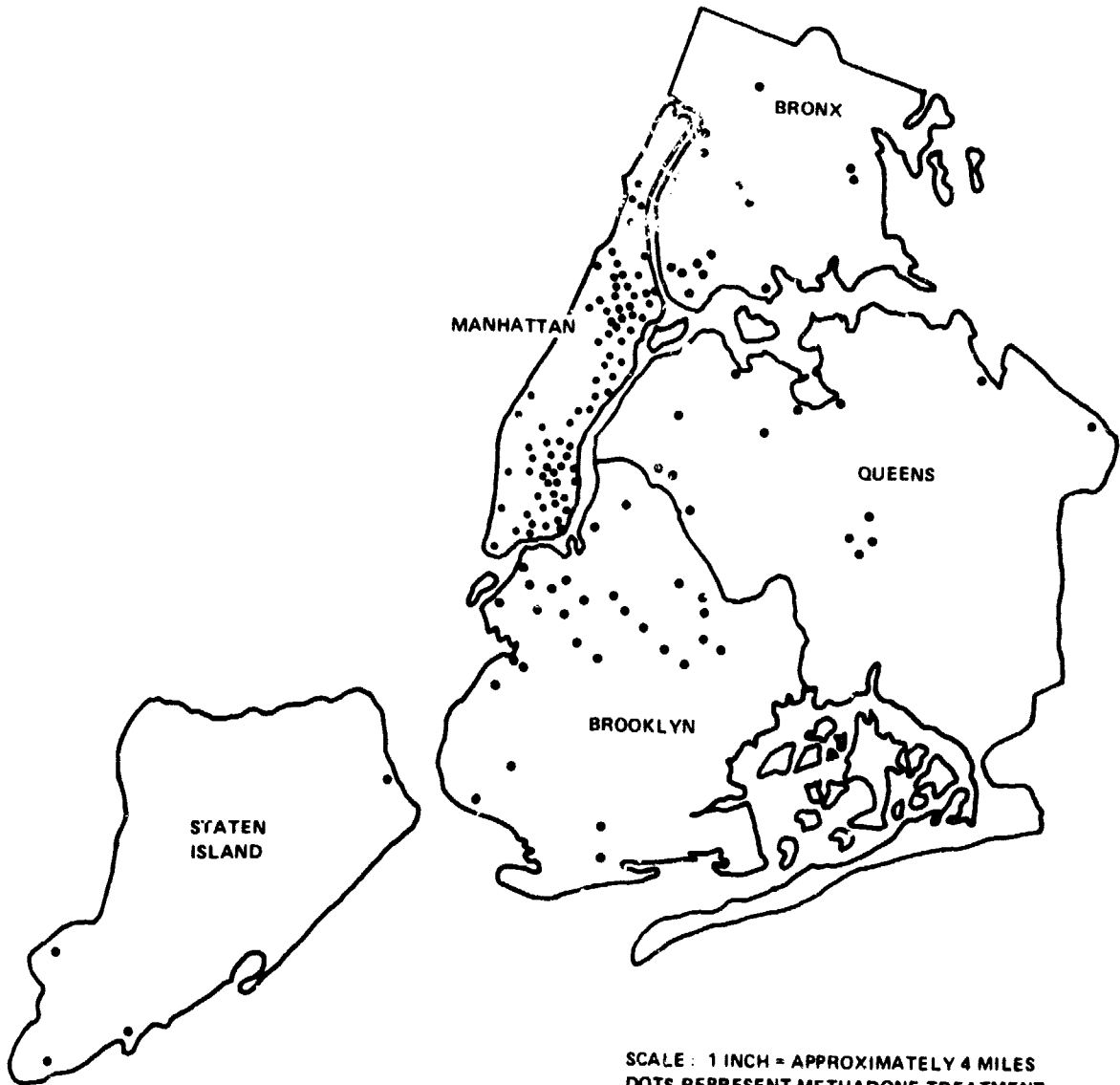
Law enforcement activity concerning methadone diversion

DEA's drug law enforcement policy is aimed at identifying and combating high-level diversion; however, according to its New York region compliance director, DEA has not identified any organized methadone diversion. DEA maintains that it cannot materially affect methadone diversion through criminal investigation at the patient level, believing the local police can better handle such investigations. Accordingly, DEA directs its efforts to insuring compliance by treatment programs with Federal requirements. (See ch. 3.)

A representative of the narcotics division of the New York City Police Department confirmed that methadone diversion has a low enforcement priority. In the department's view, the major source of diversion was patient take-home dosages.

The Fordham study concluded that police arrests of individual patients offer little hope for effectively combating the methadone diversion problem. The patients are widely spread geographically; leaving the police no clear target. The study concluded that if a solution to the diversion problem exists, it will not be found in law enforcement.

**LOCATION OF METHADONE TREATMENT PROGRAMS
IN NEW YORK CITY**



**SCALE : 1 INCH = APPROXIMATELY 4 MILES
DOTS REPRESENT METHADONE TREATMENT
PROGRAMS
LAND AREA OF NEW YORK CITY IS 299.7 SQUARE
MILES**

CONCLUSIONS

Methadone abuse and its consequences are a serious problem in New York City. Abuse sometimes means death for drug addicts, including patients in methadone maintenance programs and individuals who experiment with it. The large number of methadone deaths in the city apparently result from the improper or illegal use of methadone which is legally dispensed.

A major factor contributing to methadone diversion seems to be the take-home dosage. Elimination of take-home privileges could result in much less diversion and, consequently, fewer methadone deaths. Such benefits, however, must be weighed against possible drawbacks in treatment--large-scale dropouts leading to relapses into drug abuse and addiction.

AGENCY COMMENTS AND OUR RESPONSE

The Department of Justice expressed concern with the overall perspective of our proposed report because it believed that the report implies that DEA has the authority to correct the diversion of take-home supplies of treatment patients when, in fact, this authority lies with FDA. As the Department noted, such an impression would be wrong, and pages 2 through 4 discuss the authorities and responsibilities of Federal agencies in regulating treatment programs. Also shown for reference purposes are our previous reports dealing with these regulatory activities.

The Department believes that methadone take-home supplies are the true cause of methadone diversion and that, therefore, our report should identify this as the true cause and contain recommendations regarding the (1) established take-home dosage limits, (2) elimination of take-home privileges, and (3) development of LAAM as a methadone substitute.

Principally our report cites a body of studies, experiences, and opinions which indicate that patients' abuse of take-home privileges is a major factor contributing to methadone diversion. As stated above, elimination of take-home privileges could result in much less diversion, but there may be treatment drawbacks to this action. The Department noted that the Methadone Policy Review Board, at DEA's request, had initiated a study of the take-home policy. This study should assess all the pros and cons and produce appropriate recommendations.

Regarding the development of LAAM, HEW has informed us that clinical trials sponsored by NIDA are currently underway to determine the safety and efficacy of LAAM in the treatment of heroin addiction. We have no reason to believe that this project will not be carried through to completion; therefore, a recommendation by us on its further development would be superfluous.

The Department noted a recent court decision which creates a significant new potential for methadone diversion by allowing pharmacies to stock methadone to fill prescriptions for analgesia. Concerning this ruling that FDA lacks the authority to limit methadone distribution only to approved treatment centers, hospitals and selected pharmacies, the Department stated that potentially about 63,000 registrants will be authorized to stock methadone. According to the Department, DEA recognizes this as a significant new potential for diversion which will require additional compliance investigators and related resources to meet the threat.

CHAPTER 3

DEA ACTIVITIES UNDER THE NARCOTIC ADDICT TREATMENT ACT

The Narcotic Addict Treatment Act of 1974 (Public Law 93-281, May 1974) gave DEA authority to register methadone treatment programs and to suspend or revoke a program's registration for noncompliance with standards. The act also gives DEA authority to establish and enforce stringent security and recordkeeping standards for treatment programs.

To enforce the standards DEA makes

--preregistration investigations: brief visits to a treatment program to determine its fitness to operate by verifying that it is properly licensed and by evaluating the basic adequacy of its security and recordkeeping.

--regulatory investigations: scheduled at least once every 3 years to insure compliance with standards by a treatment program; these consist of a review of the adequacy of a program's security and recordkeeping and an indepth drug accountability audit of its methadone stocks.

PROBLEMS IN IMPLEMENTING REGULATORY ENFORCEMENT PROGRAM

During our review, we noted that DEA appeared slow in implementing an aggressive regulatory enforcement program in New York City under the 1974 act.

In November 1974 DEA headquarters instructed its regional offices to make preregistration investigations of all existing treatment programs by July 1, 1975. By that date, DEA's New York regional office (DEA-NY) had completed preregistration investigations of only about 60 of the city's 169 methadone clinics and, according to the Department of Justice, had inspected 60 other programs which had not yet come into full compliance. The DEA-NY compliance director told us that by December 31, 1975, about 100 preregistration investigations had been completed and another 47 were in process.

We noted that without informing DEA-NY, DEA headquarters approved the registration applications for 24 programs in New York City without the benefit of a preregistration

investigation. FDA had previously found 3 of these 24 programs to be seriously violative, and 1 of the 3 had also been found violative by DEA-NY. 1/

Regarding regulatory investigations, DEA-NY completed three scheduled investigations of New York City treatment programs from November 1974 through June 30, 1975. Nine investigations were in process at June 30, 1975; investigations were scheduled for 15 additional programs in the city for the 6-month period ended December 31, 1975. In comparison, to reach its goal of inspecting each program at least once every 3 years, DEA-NY should visit about 50 programs annually, about twice as many as were scheduled.

In two of the three regulatory investigations completed, DEA found such violations as

- too much methadone in stock,
- dosage changes not properly authenticated,
- failure to provide effective controls to prevent theft and diversion (the program needed three more holdup alarm buttons), and
- failure to take required inventory of controlled substances.

For one of the programs found in violation, an administrative hearing was held with the program director, who signed an agreement promising corrective action. However, there was no evidence that DEA planned to reinspect the program to see if agreed changes were made. At the other violative program, DEA recommended that an administrative hearing be held, but this action was delayed pending the resolution of an FDA hearing for violation of FDA regulations.

CONCLUSIONS

DEA's regulatory enforcement activities under the act can be an effective tool in preventing diversion, such as

1/Our report entitled, "More Effective Action Needed to Control Abuse and Diversion in Methadone Treatment Programs," (GGD-76-51, Mar. 9, 1976) discussed FDA and DEA coordination and presented recommendations with which the agencies agreed.

could occur from poorly operated and loosely controlled treatment programs. Such enforcement could insure adequate security against theft and encourage proper dispensing and accountability practices to guard against diversion. Because of the importance of DEA's antidiversion role, we proposed that the DEA administrator (1) establish controls to insure completing enough regulatory investigations to meet the once-per-3 years requirement and (2) take action to identify treatment programs not registered under the new legislation and give priority to completing preregistration investigations of all treatment programs.

AGENCY COMMENTS

The Department of Justice (see app. I) told us that had DEA conducted an aggressive regulatory enforcement program during the period covered by our review numerous methadone treatment programs would have been closed. According to the Department, this would have been contrary to the political and societal intent to support the methadone treatment concept and would have fostered adversary situations within the Federal Government and between State and city governments and the Federal Government.

The Department, however, acknowledged that indepth investigations of registered programs got off to a slow start and said that as the result of efforts made since January 1, 1976, the number of investigations was almost on schedule. The slow start was attributed to other workload priorities and a policy decision to emphasize preregistrant investigations.

Concerning the identification of, and emphasis on, programs not registered, the Department said that, nationally, all known treatment programs which existed before the 1974 act have now been inspected and only a small number have yet to come into compliance. Also, the Department said no new programs--those which have come into existence since the 1974 act--have been registered without completed preregistration investigations; according to the Department, five or six such programs exist in the DEA-NY.

The Department said that the report gives the erroneous impression that the corrective action needed (on methadone deaths) is more stringent regulatory enforcement by DEA-NY. The Department maintained that this is clearly not the case because the amount of diversion from treatment program stocks is infinitesimal. We agree that the major diversion appears to come from take-home supplies. Regulatory

enforcement, however, does have a role in minimizing illicit diversion of drugs.

Since DEA has taken actions to get the unregistered programs inspected and to get its regulatory investigations of registered programs on schedule, we are not making any recommendations.



Address Reply to the
Division Indicated
and Refer to Initials and Number

UNITED STATES DEPARTMENT OF JUSTICE

WASHINGTON, D.C. 20530

DEC 6 1976

Mr. Victor L. Lowe
Director
General Government Division
United States General Accounting Office
Washington, D. C. 20548

Dear Mr. Lowe:

This letter is in response to your request for comments on the draft report entitled "Methadone Deaths in New York City."

We are strongly concerned with the overall perspective of this report. Specifically, the recommendations are not consistent with the findings and conclusions in that the Drug Enforcement Administration (DEA), as well as any casual reader, is left with the erroneous impression that DEA has the authority to correct the diversion of take-home supplies of treatment patients when, in fact, this authority lies with the Food and Drug Administration (FDA). In addition, there needs to be a more balanced presentation of corrective actions to be taken as a result of the conditions noted in the report.

Based on our review, we noted that three major areas are addressed in the report relating directly to methadone overdose deaths in New York City for which no recommendations are developed. The only finding and recommendation of the report, which is applicable to DEA, has the least impact on the problem of methadone overdose deaths, yet it is singled out as the overall causal factor.

The three significant areas addressed in the report pertinent to methadone overdose deaths but not given the status of recommendations are identified below:

- Daily dosage and take-home dosage limits established by the Department of Health, Education and Welfare (HEW) appear to be too high. The basis for the excessive dosages is to block euphoric effects of heroin; however, under a self-administered program, the patient can reduce his dosage to ward off withdrawal and still take heroin



to achieve the desired euphoric effect. Thus, a patient can find a lower, but still comfortable, dosage level and sell the excess, thereby negating the benefits of larger dosages. The desirability of smaller dosages or other alternative dispensing methods should be considered as a report recommendation.

- Washington, D. C. and Boston had outstanding results in the reduction of methadone deaths after the take-home program was eliminated. A GAO recommendation is warranted in this area.
- GAO reported on the use of methadone substitutes, notably LAAM, but failed to give an up-to-date status regarding its use and development. As a conclusion, GAO agrees that further LAAM development should be continued but failed to grant it the status of a recommendation.

With respect to the daily and take-home dosages established by HEW, the report should reflect the true cause of methadone diversion in New York City, which is the "skimming" and selling by treatment program patients of take-home supplies of methadone. By identifying this cause, a specific and factual basis will have been cited for taking appropriate action to rectify the serious problem of methadone overdose deaths in New York City. As the report is currently written, the erroneous impression can be drawn that the corrective action needed is more stringent regulatory enforcement by the New York Region of DEA. This is clearly not the case, as a close analysis of the details of the report show. The real problem on which action needs to be taken is the diversion of take-home supplies by patients in treatment. Whether DEA conducted an effective regulatory program in New York City during the period indicated is not the issue, because the amount of diversion from treatment program stocks is infinitesimal. The authority to determine dosage sizes and decide whether or not there are to be take-home privileges rests with FDA.

Missing from the report is any comment regarding enforcement of 21 CFR Subchapter C, Part 130, which is enforced by FDA. These regulations establish standards and guidelines for clinics giving take-home supplies of methadone. Since the report recognizes that the illegal sale of take-home

supplies is the primary cause of methadone diversion and methadone deaths, it is incongruous that this aspect of Federal regulation was not included in the GAO review.

The report also discusses the positive results achieved through elimination of take-home privileges in two major cities--Washington, D. C. and Boston. Despite the fact the draft report clearly recognizes that diversion of take-home supplies of methadone is the major source of illicit methadone and the major cause of methadone deaths, GAO is reluctant to make a definitive recommendation concerning the elimination of take-home supplies. The final report should also include DEA's position on take-home privileges--a position which should have been known by GAO. DEA is a member of the Methadone Policy Review Board, along with FDA, the National Institute of Drug Abuse, and the Veterans Administration. DEA requested that a study, under the auspices of the Board, be made of the take-home policy. That study is nearing completion. If the study confirms DEA's position that the take-home policy is counterproductive, DEA will recommend the institution of a "nontake-home" policy. Such a decision would, of course, require approval by FDA as a good medical practice.

Related to the take-home policy is another very significant development which only recently occurred and should be included in the final report. Effective July 10, 1976, as a result of a decision of the U. S. Court of Appeals for the District of Columbia--which decision the Department of Justice has elected not to appeal--methadone may now be stocked in pharmacies in order to fill prescriptions for analgesia. Along with hospitals and other institutions, this will provide a potential of approximately 68,000 registrants authorized to stock methadone. Prior to the Narcotic Addict Treatment Act (NATA) and FDA regulations, we found that many practitioners were maintaining addicts by writing prescriptions for methadone which were filled in community pharmacies. Diversion through forged prescriptions, thefts, and illegal sales was also a problem. Now that FDA's regulations to remove methadone from retail outlets have been invalidated, an increased monitoring program to police the handling of methadone at the retail level is essential in order to prevent a recurrence of diversion problems with this potent and popular drug. DEA recognizes this as a significant new potential for diversion which will require additional compliance investigators and related resources to meet the threat.

The draft report fails to give an up-to-date status on LAAM, which the Domestic Council's Drug Abuse Task Force has recommended as a long lasting substitute for methadone as soon as its safety and efficacy has been determined. Since GAO is of the opinion that the Government should give high priority to the development of such methadone substitutes as a solution to the take-home dilemma, we believe GAO should have granted it the status of a recommendation.

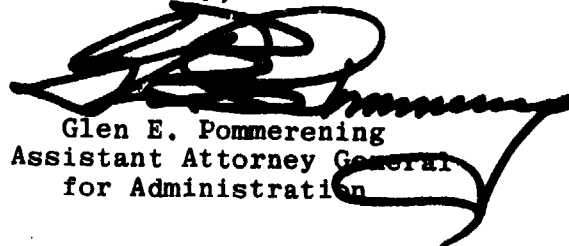
GAO states that DEA was slow in implementing an aggressive regulatory enforcement program in New York, and that this slowness allowed for the possibility that some violative programs may have continued in operation for lengthy periods of time. We are in substantial disagreement with GAO's judgment in this matter. Had DEA conducted an "aggressive regulatory enforcement program" during the time period covered by the GAO study, the result would have been the closing of numerous methadone treatment programs, particularly in New York City. Such a course of action would have been directly contrary to the demonstrated political and societal intent to support the methadone treatment concept. It would have created turmoil and fostered adversary situations within the Federal Government and between the Federal Government and State and city governments--particularly the State and city of New York in the case of this report.

In response to the recommendations that were directed at DEA, the first recommendation suggests that DEA "establish controls to assure that DEA regions schedule and complete sufficient investigations to meet the once-per-3-years requirement." Initially, in order to make the best use of available manpower, DEA made the policy decision to emphasize pre-registrant investigations in an effort to bring existing programs into compliance with the requirements of the NATA and get them registered prior to initiating in-depth investigations of the registered programs on a regular basis. As a consequence of this decision, as well as other workload priorities, in-depth investigations of registered programs got off to a slow start. However, during the period January 1, 1976, to date, the New York Regional Office has completed 33 in-depth investigations of programs, making a total of 38 completed since July 1975. This effort has brought the number of investigations almost on schedule, particularly in light of the fact that many programs have ceased operation due to city and State of New York financial cutbacks. As of June 30, 1976, there were only 139 registered programs in the entire State of New York as compared to GAO's June 30, 1975 figure of 169 city programs.

GAO also recommends that DEA "identify treatment programs which have not registered under the new legislation and give immediate priority to completing pre-registration investigations of all treatment programs." Nationally, all known treatment programs which existed prior to NATA have been inspected and only a small number have yet to come into full compliance. The GAO report leaves the erroneous impression that as of June 30, 1975, DEA had conducted only 60 pre-registrant investigations of the 169 treatment programs located in New York City, whereas, in the relatively short period from October 1974 to June 30, 1975, DEA had conducted on-site investigations of approximately 120 of the 169 programs. Of the 120 programs, 60 (as indicated by GAO) were completed in all respects and the remainder were primarily incomplete (i.e., registration had not been granted) because they had not yet come into compliance. As of December 31, 1975, 100 of the treatment programs had fully completed pre-registration investigations, and 47 others had been investigated but were incomplete because they had not yet come into compliance. By the end of March 1976, all programs had onsite investigations conducted. Currently, there are approximately 18 treatment programs in New York City that have not completed pre-registration investigations only in the sense that they have not yet come into full compliance. These are primarily separate-site clinics of which two are under the auspices of the city of New York and 16 under the auspices of Beth Israel Hospital. Also of significance is the fact that no new programs--programs which have come into existence since NATA--have been registered without completed pre-registration investigations. In the entire New York Region there have only been five or six to date.

We appreciate the opportunity given us to comment on the draft report. Should you have any further questions, please feel free to contact us.

Sincerely,



Glen E. Pommerening
Assistant Attorney General
for Administration

PRINCIPAL OFFICIALS
RESPONSIBLE FOR ADMINISTERING
ACTIVITIES DISCUSSED IN THIS REPORT

Tenure of office
From To

DEPARTMENT OF JUSTICE

ATTORNEY GENERAL OF THE UNITED STATES:

Griffin B. Bell	Jan. 1977	Present
Richard L. Thornburgh (acting)	Jan. 1977	Jan. 1977
Edward H. Levi	Feb. 1975	Jan. 1977
William B. Saxbe	Jan. 1974	Feb. 1975

ADMINISTRATOR, DRUG ENFORCEMENT ADMINISTRATION:

Peter B. Bensinger	Feb. 1976	Present
Peter B. Bensinger (acting)	Jan. 1976	Feb. 1976
Henry S. Dogin (acting)	May 1975	Jan. 1976
John R. Bartels, Jr.	Oct. 1973	May 1975

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SECRETARY OF HEALTH, EDUCATION, AND WELFARE:

Joseph Califano	Jan. 1977	Present
David Mathews	Aug. 1975	Jan. 1977
Caspar W. Weinberger	Feb. 1973	Aug. 1975

COMMISSIONER, FOOD AND DRUG ADMINISTRATION:

Sherwin Gardiner (acting)	Dec. 1976	Present
Alexander M. Schmidt	July 1973	Dec. 1976

ADMINISTRATOR, ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION:

James D. Isbister	Aug. 1975	Present
James D. Isbister (acting)	Sept. 1974	Aug. 1975
Robert L. DuPont (acting)	July 1974	Sept. 1974
Roger Egeberg (acting)	Oct. 1973	June 1974

<u>Tenure of office</u>	
<u>From</u>	<u>To</u>

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE (continued)

DIRECTOR, NATIONAL INSTITUTE

ON DRUG ABUSE:

Robert L. DuPont	Sept. 1974	Present
Karft J. Besteman (acting)	June 1974	Sept. 1974
Robert L. DuPont (acting)	Sept. 1973	June 1974