GGD-76
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REPORT TO THE CONGRESS

093

BY THE COMPTROLLER GENERAL OF THE UNITED STATES

More Effective Action Needed To Control Abuse And Diversion in Methadone Treatment Programs

Food and Drug Administration
Department of Health, Education, and Welfare
Drug Enforcement Administration
Department of Justice

Methadone--a synthetic narcotic with a high potential for abuse--has been used increasingly in treatment programs. Its diversion and abuse has resulted in a number of deaths. Some of the treatment programs seriously and persistently violate Federal regulations.

GAO concludes that improvements are needed:

--In the Food and Drug Administration's program for compliance investigations at treatment programs.

--In the Food and Drug Administration's mechanism for taking enforcement action against treatment programs violating Federal regulations.

--In coordinating the Food and Drug and Drug Enforcement Administrations' efforts to regulate treatment programs.

GGD-76-51

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

B-164031(5)

To the President of the Senate and the
Speaker of the House of Representatives

We have evaluated the effectiveness of Federal agencies in regulating the use of methadone to treat heroin addicts and in preventing its abuse and diversion. Our review was made because of the widespread use of methadone and the hazards it presents when abused or diverted.

We made our review pursuant to the Budget and Accounting Act, 1921 (31 U.S.C. 53), and the Accounting and Auditing Act of 1950 (31 U.S.C. 67).

Copies of this report are being sent to the Director, Office of Management and Budget; the Secretary of Health, Education, and Welfare; and the Attorney General.

Comptroller General
of the United States

COMPTROLLER GENERAL'S
REPORT TO THE CONGRESS

MORE EFFECTIVE ACTION NEEDED TO CONTROL ABUSE AND DIVERSION IN METHADONE TREATMENT PROGRAMS

Food and Drug Administration
Department of Health, Education, and Welfare
Drug Enforcement Administration
Department of Justice

D I G E S T

The synthetic narcotic methadone, used primarily in treating heroin addiction, can be medically beneficial or, when abused, cause injury and death.

Eight hundred and one deaths involving methadone, either alone or in combination with other drugs, reported for 22 standard metropolitan statistical areas in fiscal year 1975 provide strong evidence that the illicit use of methadone is a serious problem. (See p. 7.)

Two Federal agencies are responsible for regulating and controlling methadone use.

The Drug Enforcement Administration has been unable to carry out an effective methadone anti-diversion program because its authority was inadequate to regulate and enforce activities aimed at controlling diversion from treatment programs. This weakness has apparently been corrected. (See p. 29.)

The Food and Drug Administration needs to act more decisively against methadone treatment programs violating Federal regulations and to otherwise improve its inspection program. (See p. 11.)

The Food and Drug Administration should

--act firmly and decisively against programs violating regulations (see pp. 11 and 16),

--evaluate inspection reports more quickly (see p. 20), and

--withhold final approval of new programs until they have passed inspection (see p. 21).

Since these agencies share the responsibility for controlling and regulating methadone use, their work should be coordinated. (See p. 29.) Because of the dangers inherent in the illicit use of methadone, only efficient, compliant treatment programs should be operated.

The Department of Health, Education, and Welfare stated that it has begun action (1) to establish criteria and procedures for using administrative and regulatory sanctions against methadone programs seriously in violation of regulations and (2) to decentralize the report evaluation function. (See app. II.)

The Department felt regulatory control would not be improved by conditionally approving new programs because of the due process requirements of the Administrative Procedure Act but said it was taking several other steps to expedite correction of violative programs.

GAO believes that granting conditional approval to programs is without legal objection since the due process requirements of the act do not apply to conditional licenses. (See p. 27.)

The Department of Justice generally agreed with the report as it applied to the Drug Enforcement Administration and said an agreement was being developed with the Food and Drug Administration to establish closer coordination over methadone treatment programs. (See app. III.)

Contents

ABBREVIATIONS

CSA	The Controlled Substances Act
DEA	Drug Enforcement Administration
DMM	Division of Methadone Monitoring, Food and Drug Administration
FDA	Food and Drug Administration
GAO	General Accounting Office
HEW	Department of Health, Education, and Welfare
IND	investigational new drug
NDA	new drug application
SMSA	standard metropolitan statistical area

CHAPTER 1

INTRODUCTION

METHADONE USE

Methadone is an addictive synthetic drug with a high potential for abuse, used primarily in treating heroin addiction. It also is used as an analgesic to treat certain painful illnesses. In treating heroin addiction, methadone is used for either detoxification or maintenance.

In detoxification, the traditional method of treating narcotic addicts, methadone is administered in declining dosages for 1 to 3 weeks to alleviate withdrawal pains. At the end of treatment, the patient presumably is no longer physically dependent on either the narcotic drug he has been using or the methadone, and the dosage is terminated.

Methadone maintenance is a relatively new concept. Experiments in New York in the mid-1960s showed that methadone satisfies the addict's physical craving for heroin and other narcotics while blocking the euphoria associated with these drugs. In maintenance treatment, the addict receives a fixed dosage of methadone daily for an indefinite period to achieve a level of methadone dependence. The patient is maintained at a level sufficient to eliminate some of the more undesirable characteristics of heroin addiction, thereby enabling the patient to benefit from nondrug therapeutic techniques. The success of early experiments in methadone maintenance led to the establishment of many treatment programs throughout the Nation.

Merely dispensing methadone is not the only, or even the primary, objective of such treatment programs. The goal is to make the addict a useful, productive member of society by providing medical and psychiatric care, assistance in finding employment or completing schooling, counseling on family and other problems, and guidance to reduce criminal or other antisocial behavior. A program's overall activities are supervised by a director, who is often a physician. The director of a program's medical activities must be a physician.

Once admitted to a program, an addict is to report daily to receive his dosage of methadone and any needed rehabilitative services. After spending some time in the program, the addict is no longer required to visit the program every day but may be allowed to take home up to a 3-day supply of methadone for self-administration. The amount of the take-home supply depends on the length of time spent in the program and the amount of progress made.

A methadone treatment program may be funded and operated by public or private sources and may be located in a hospital, behind a storefront, or elsewhere.

As of December 31, 1974, 739 methadone programs provided maintenance and detoxification treatment to about 115,000 patients.

FEDERAL CONTROL RESPONSIBILITIES

The use of methadone for treating narcotic addiction is subject to regulation and control by:

--The Food and Drug Administration (FDA), Department of Health, Education, and Welfare (HEW), 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)).

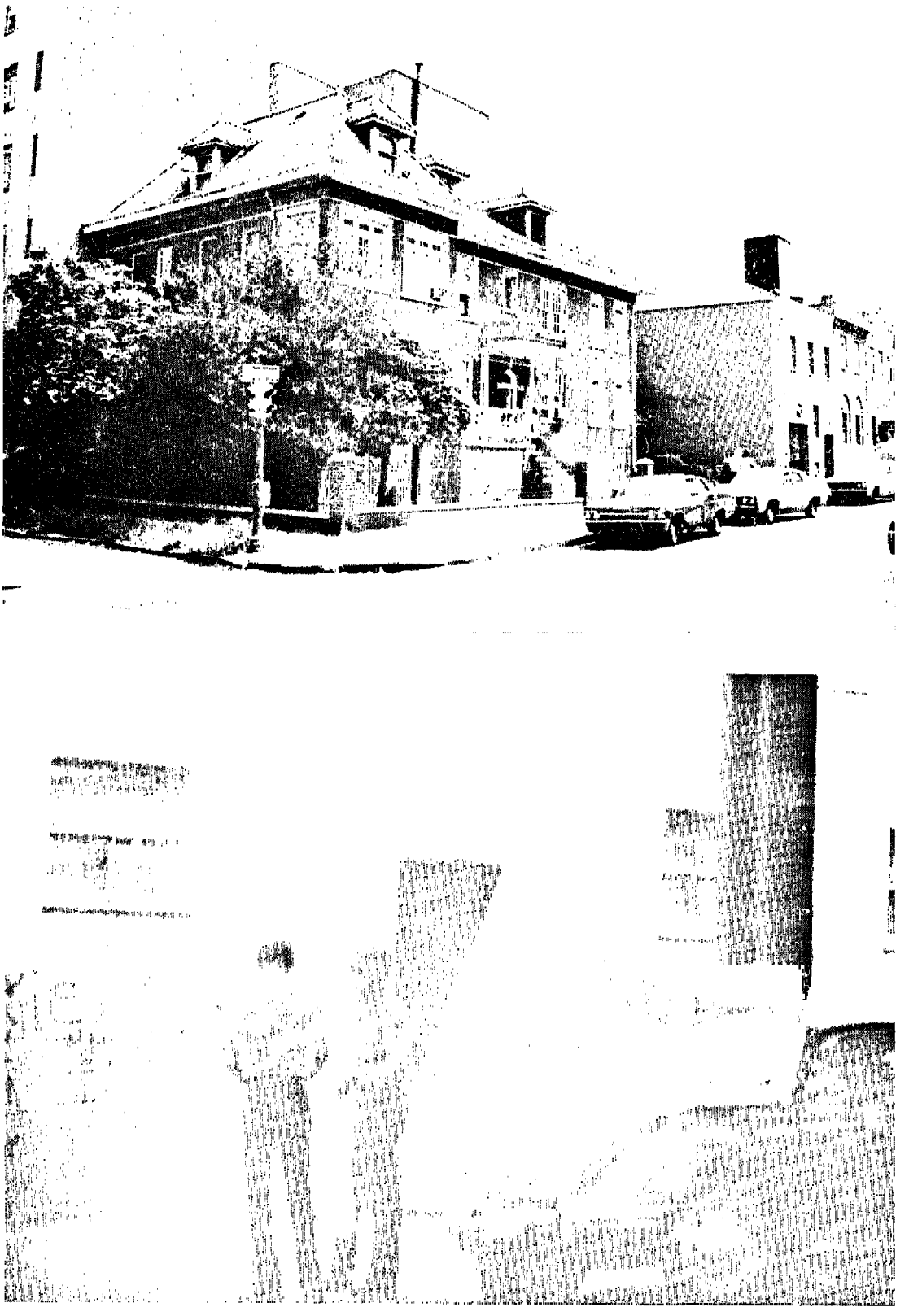
--The Drug Enforcement Administration (DEA), Department of Justice, under title II of the Comprehensive Drug Abuse Prevention and Control Act (21 U.S.C. 801) (known as the Controlled Substances Act (CSA)), as amended by the Narcotic Addict Treatment Act (Public Law 93-281, May 1974).

Before June 1975 the Special Action Office for Drug Abuse Prevention, Executive Office of the President, had overall responsibility for developing policy and coordinating Federal efforts in drug abuse prevention and treatment. Since July 1975 many of the Special Action Office's functions have been assumed by HEW's National Institute on Drug Abuse.

Representatives of the above agencies serve on the interagency Methadone Treatment Policy Review Board, which monitors the implementation of Federal methadone guidelines.

FDA is responsible for the treatment standards governing the use of methadone in programs under Federal regulations developed jointly with member agencies of the Policy Review Board. DEA is responsible for preventing the diversion of methadone; it prescribes and monitors drug security and drug accountability recordkeeping practices. DEA also regulates the manufacture and distribution of methadone as a controlled substance under CSA.

Each treatment program must be approved by FDA with DEA's advice and must also register with, and be approved by, DEA. Both agencies can deny approval to, or revoke approval of, programs that do not comply with regulations. Periodic onsite inspections at treatment programs insure compliance.



DIVERSITY AMONG TREATMENT PROGRAM LOCATIONS IS ILLUSTRATED BY THE IMPOSING STRUCTURE IN THE TOP PHOTO AND THE NONDESCRIPT BUILDING IN AN INDUSTRIAL/COMMERCIAL AREA IN THE BOTTOM PHOTO.

Most States have also passed legislation and created agencies to control abuse and diversion of drugs, including methadone.

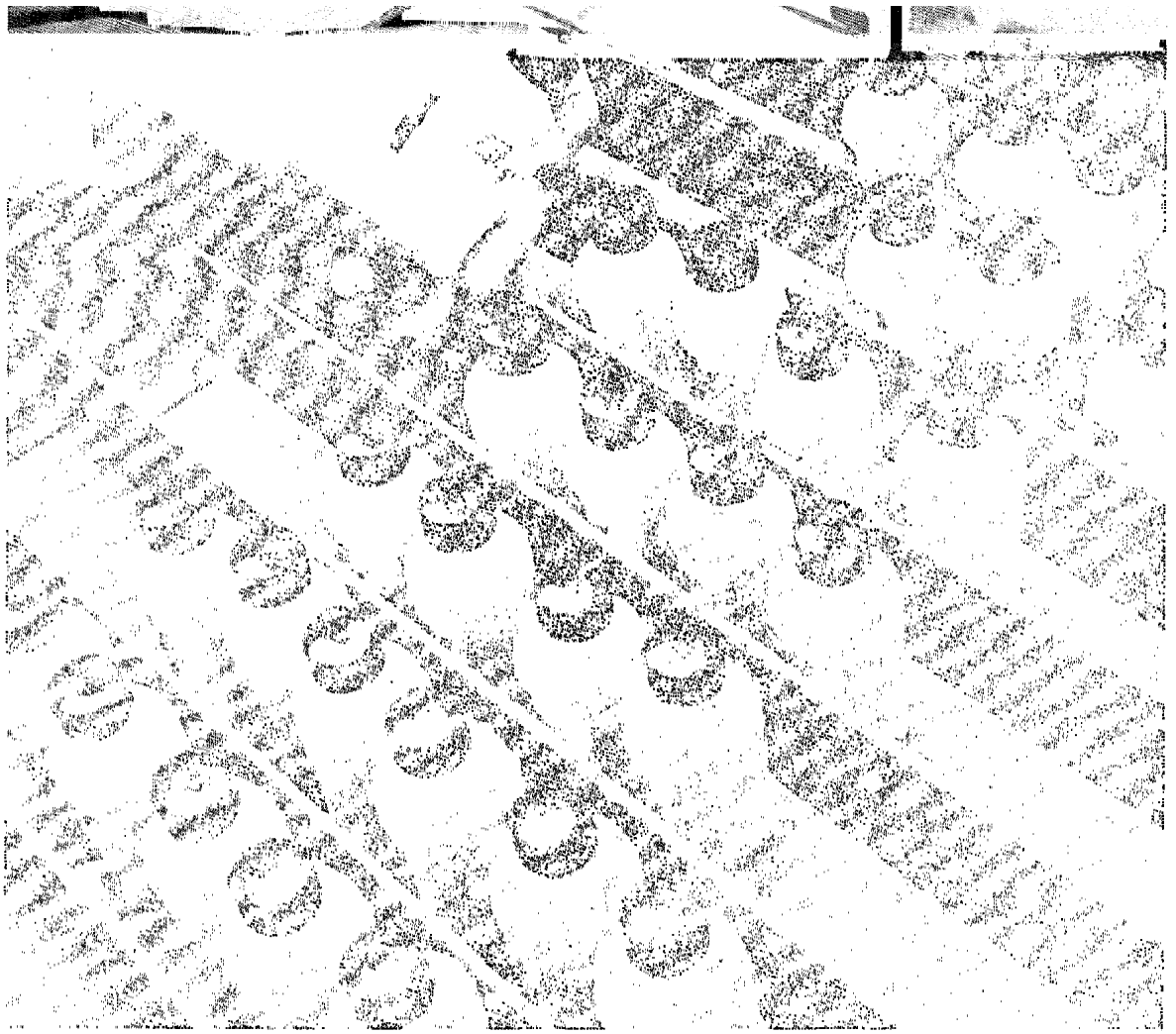
Regulatory history

The Federal Government was late in gaining authority to regulate methadone treatment programs. The use of methadone for maintenance began in the mid-1960s. FDA considered methadone used in maintenance treatment for heroin addiction to be in a research status and classified it as an investigational new drug (IND). Practitioners using methadone for maintenance treatment had only to register with FDA and maintain records showing the distribution of the drug. Some treatment programs which sprang up were not engaged in legitimate treatment, but the Federal Government could not regulate their activity because methadone was approved for other purposes and its distribution was not restricted.

Not until enactment of the Comprehensive Drug Abuse Prevention and Control Act of 1970 did legal authority exist for Federal regulation of the use of methadone for maintenance treatment. Until passage of the Narcotic Addict Treatment Act of 1974, DEA had only limited authority to control methadone diversion from treatment programs.

The first Federal regulations governing the use of methadone for maintenance treatment were issued in April 1971, when about 300 programs with 25,000 patients already existed. The regulations required that each maintenance program be approved by FDA for scientific merit and by DEA for drug control. The regulations included a model operating procedure, covering program objectives, admission criteria and evaluation, and dosage levels to meet Government acceptance. By the time they were issued, the regulations were virtually obsolete because the scope of and number of people involved in maintenance programs had far exceeded anything permitted under the concept of research.

Because of the regulations' weaknesses in controlling methadone abuse and diversion, FDA indicated in April 1972 its intention to publish new regulations governing methadone use. The new regulations, effective in March 1973, changed the status of methadone from an IND for maintenance treatment research to an approved new drug application (NDA) but made it subject to strict controls not normally applied to NDAs. By then, 585 treatment programs were in operation.



METHADONE DOSAGES READY FOR DISPENSING. (Photo by FDA.)

The regulations prescribed medical and control standards to insure proper treatment and to reduce the possibility of abuse and diversion. The regulations also provided for a distribution system limiting 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 alternative method of distribution.

The problem of delayed regulatory authority also affected those aspects of methadone treatment programs of concern to DEA--drug security and recordkeeping. Under CSA, DEA had some authority to control methadone, but this authority proved inadequate to combat the new and unusual problems presented by the large-scale dispensing of a drug with abuse potential to addicts in treatment programs. Not until May 1974 was CSA amended by the Narcotic Addict Treatment Act to increase DEA's regulatory and enforcement authority over treatment programs.

SCOPE OF REVIEW

We reviewed FDA's and DEA's effectiveness in carrying out their responsibilities to regulate the use of methadone in treatment programs and prevent its abuse and diversion.

We examined applicable laws, regulations, procedures, and records and interviewed representatives at headquarters and regional offices of FDA and DEA, selected treatment programs, and selected State and local regulatory and enforcement agencies.

This is our eighth report dealing either wholly or partly with methadone. Previous reports dealt with (1) narcotic addiction treatment and rehabilitation programs in five cities (see app. I), (2) security controls used in transporting methadone (GGD-75-50, Jan. 30, 1975), and (3) improvements needed in regulating and monitoring the manufacture and distribution of methadone and various opium derivatives (GGD-75-102, Aug. 28, 1975).

CHAPTER 2

ABUSE AND DIVERSION

Like many drugs, methadone has a dual nature--it can be medically beneficial or cause great harm, even death. The methods and conditions of use, of course, determine what its effect will be.

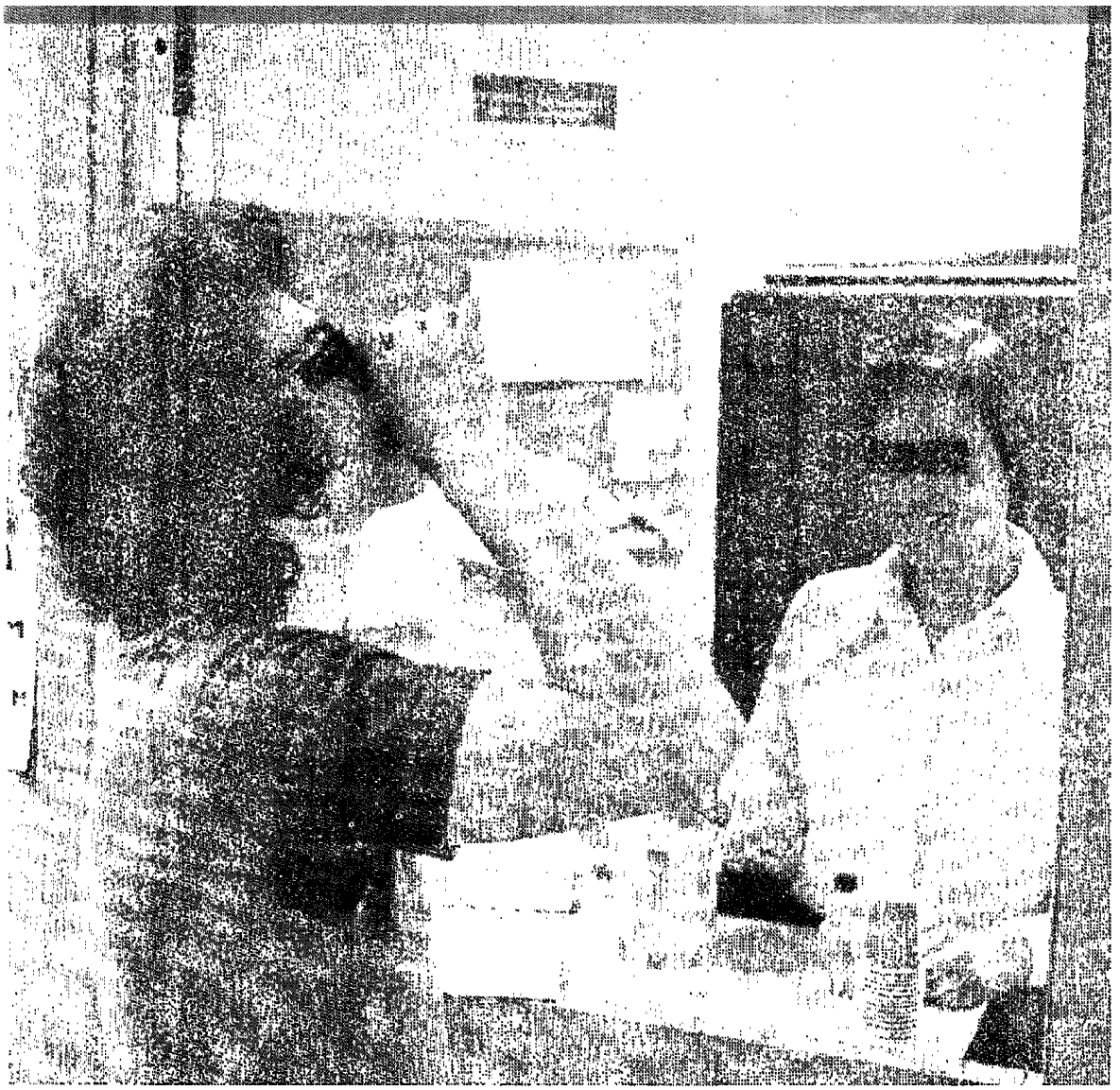
Diverted methadone has a variety of uses. Some addicts may prefer methadone to heroin because it may be easier to obtain or cheaper. Others may buy it illegally to insure against withdrawal, especially during heroin shortages. Many abusers use other depressant drugs, including alcohol, to increase the effects of methadone. Multidrug abusers have been found among the regular purchasers of illegal methadone.

The growing problem of methadone abuse and diversion paralleled the growing legitimate use of the drug. In 1971 about 300 programs provided treatment to about 25,000 patients. At the end of 1974, 739 programs were providing maintenance and detoxification treatment to about 115,000 patients

With the increased use of methadone, DEA seizures of illicit methadone increased dramatically, from 3,700 dosage units in fiscal year 1971 to more than 202,000 dosage units in fiscal year 1973. In New York City, nearly 1,200 arrests were made for illicit possession of methadone during the year ended May 30, 1972. Most involved persons under 19 years old.

The most distressing evidence of abuse and diversion is the number of deaths caused by methadone. From October 1972 through June 1973, selected coroners and medical examiners in 24 standard metropolitan statistical areas (SMSAs) sampled by DEA reported 191 deaths in which methadone (alone or in combination with other drugs) was involved. During fiscal year 1974, selected coroners and medical examiners in 23 of those SMSAs reported 910 deaths and 2,648 injuries involving methadone. In the following fiscal year, 22 of the SMSAs reported 801 deaths and 2,659 injuries involving methadone.

In the New York City area, where about half of the Nation's methadone patients are located, the problem is particularly acute. In 1972, 175 deaths were attributed to methadone overdoses; in 1973, 181 deaths were attributed to methadone and another 401 to a combination of methadone and some other drug; and in fiscal year 1974, 834 deaths were attributed to methadone. Neighboring New Jersey reported 88 methadone overdose deaths in 1973.



PATIENT DRINKS METHADONE UNDER NURSE'S OBSERVATION.
(Photo by FDA.)

DEA has found the major sources of diverted methadone to be unscrupulous practitioners, well-intentioned but poorly operated treatment programs, and patients.

Unscrupulous or unethical practitioners have operated methadone programs for profit with little, if any, intention of treating patients. They dispense methadone to anyone able to pay the price. One physician charged up to $75 for the 200 methadone tablets he gave weekly to each of several hundred addicts. Many of these addicts would resell the methadone for profit. That physician was arrested and convicted for the criminal distribution of methadone.

Poorly organized or loosely operated and controlled programs can be another source of methadone finding its way into illicit traffic. Such diversion may be allowed by such factors as (1) a failure to adequately safeguard and account for the methadone supply, (2) a failure to observe the patient to insure that he actually consumes his methadone dosage, or (3) faulty recordkeeping practices which provide no check against patients receiving more than their allotted dosage or take-home supply of methadone.

Some addicts in treatment programs sell all or part of the methadone dispensed to them and use the profits to buy other drugs. DEA calculated that as of July 1975 a dosage unit of illicit methadone sold for $5.42 on the streets. These illicit sales may lead other persons to addiction.

According to a nationwide DEA survey in March and April 1974, methadone sales in the illicit market were declining. Most local police departments contacted by DEA reported few, if any, arrests involving methadone. DEA informants reported no large-scale trafficking in methadone. Also, most of DEA's attempts to make undercover purchases of methadone failed. In general, DEA concluded that any diversion taking place consisted of small quantities of take-home dosages. However, in view of the large numbers of reported deaths and injuries in 1974 and 1975 resulting from methadone abuse, methadone diversion presents a significant social and regulatory control problem.

Only time will tell how successful Federal efforts have been in preventing conditions which give rise to abuse and diversion. Meanwhile, methadone distribution displays the signs of being a major medical and law enforcement problem--an ample supply of an addictive drug of abuse and a receptive market. Although methadone treatment tries to bridge this

gap legally, some still look to accumulate a supply and satisfy demand by extra-legal means. As long as methadone is made available on a large scale, abuse and diversion will be potential problems.

CHAPTER 3

FDA NEEDS TO IMPROVE ENFORCEMENT EFFORTS

Treatment programs that severely and persistently violate Federal regulations are a major source--actual and potential--of abuse and diversion. FDA has allowed treatment programs which are known violators to operate for prolonged periods and has failed to act effectively to insure compliance with Federal standards. Also, some FDA procedures for identifying potential violators in a timely manner are inadequate.

Certain administrative problems contributed to FDA's delays in taking effective enforcement action. For example, before the March 1973 regulations were issued, FDA had begun proceedings to terminate some treatment programs which had seriously violated prior regulations. To be effective, the termination process had to be completed before the new regulations went into effect because the new regulations granted interim approval to all ongoing programs that properly applied for approval. Since FDA was unable to complete termination before March 1973, it had to drop termination proceedings against these programs.

In addition, when the March 1973 regulations were issued, FDA faced the administrative task of reviewing the applications for registration of all existing programs under the new regulations. The regulations terminated the IND registration of all programs and required them to reapply to FDA for registration to use methadone as an NDA. FDA, however, found nearly all applications for registration then submitted by the programs to be inadequate and had to request additional information.

In addition, the Division of Methadone Monitoring (DMM) at FDA headquarters relocated several times. Because FDA's regulation of methadone is highly centralized, these relocations greatly disrupted normal procedures.

However, the chief problem is FDA's failure to take decisive, aggressive enforcement action against violative treatment programs.

SERIOUSLY VIOLATIVE PROGRAMS OPERATE FOR PROLONGED PERIODS

FDA, primarily on the basis of its inspections, identified 51 treatment programs as seriously violative because of problems such as

--lack of control over the quantity of methadone dispensed,

--dosage level changes without physician's consent,

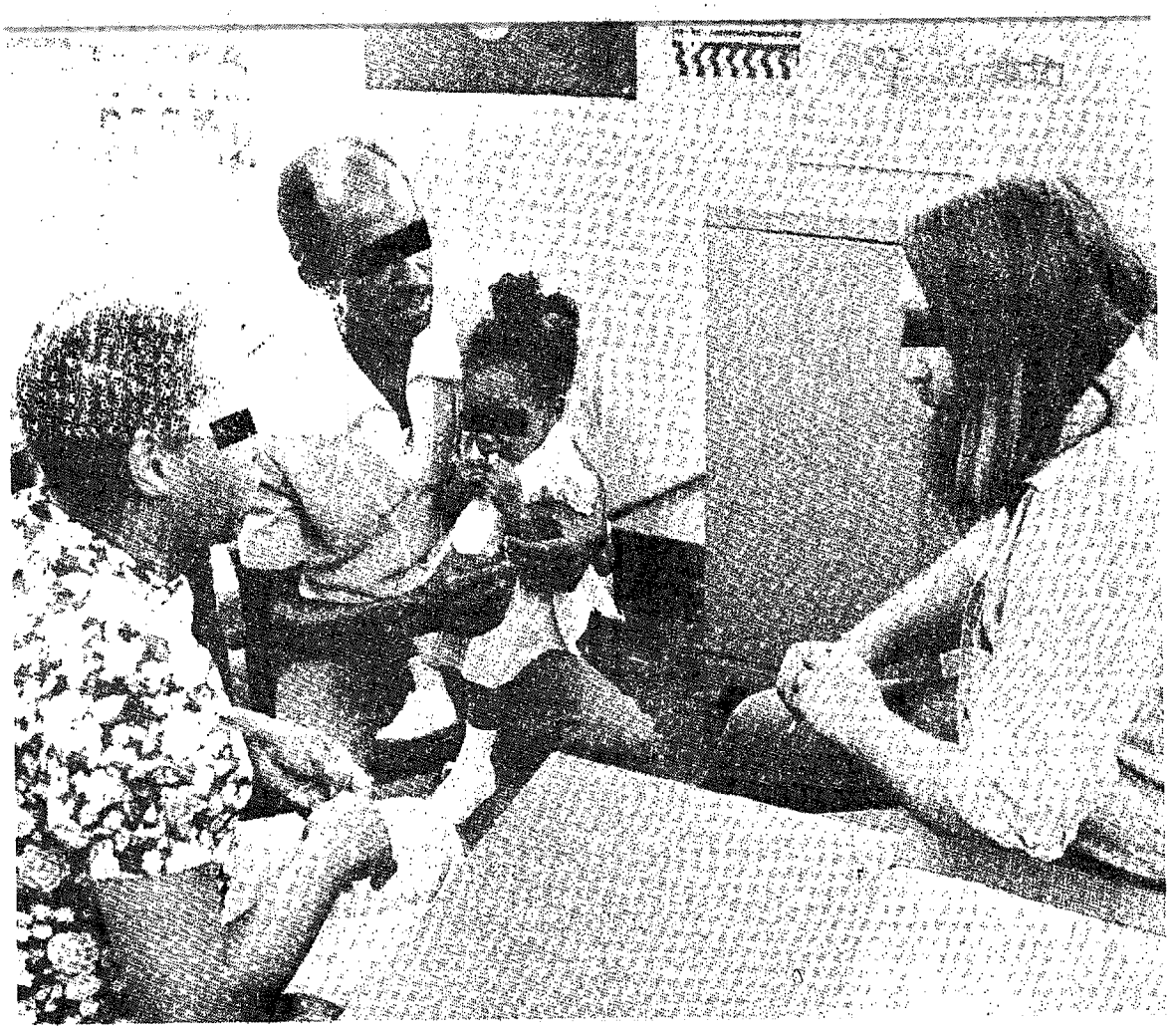
--failure to observe drug intake,

--poor packaging of take-home medication,

--too much take-home medication dispensed,

--no annual evaluation of addiction problem,

--no weekly screening of urine to detect opiate use,



TREATMENT PROGRAM COUNSELING SESSION. (Photo by FDA.)

--failure to determine the true addiction history of new patients, and

--failure to obtain patient consent to receive methadone.

FDA was slow in taking action against these problem programs--some of which had violations dating back to 1971--either by obtaining compliance or by closing them down. As of February 28, 1974, 28 of the programs were still operatin without FDA having taken final action. In June 1975, 2 of the 51 were still considered to be seriously violative and awaiting action. Of the remainder, 17 had closed voluntaril and 32 had corrected their violative practices. However, mos of these had operated in a violative state for prolonged per iods, in some cases 1 to 2 years after the violations were detected.

The following example, although not typical of most cas illustrates FDA's time-consuming procedures and lack of deci sive action in obtaining compliance from seriously violative treatment programs. The program used in the example began operations early in 1971 in New York City. The chronology o events follows.

Date	Event
April 1971	FDA approved the program's IND applicatio
March 1972	FDA's first inspection found violations, including (1) excessive take-home dosages (2) patients under 18 years old, and (3) urine collections not observed.
June 1972	FDA evaluated the inspection report.
July 1972	FDA sent a 30-day letter of admonition and the program responded.
September 1972	FDA's second inspection again disclosed a serious deficiency; nothing in FDA files indicated that the inspection report was evaluated or that a letter of admonition was sent.
February 1973	The program submitted an NDA application.
March 1973	FDA granted interim approval.

Date	Event
March 1973	DEA's preapproval inspection disclosed inadequate security and recordkeeping practices.
May 1973	FDA completed its third inspection--a preapproval inspection because the program had not complied with significant requirements of previous regulations identical or similar to those in the new regulations. The inspection disclosed the following violations: --lack of patient consent forms; --lack of patient medical history records; --lack of records evidencing patient physical dependence on heroin and 2-year addiction; --lack of records of patient's treatment dates, amounts of dosage dispensed, or results of urine test; --changes in patient's dosages not recorded or signed by a doctor; --new patients allowed take-home dosages; --one patient, not a heroin addict, receiving methadone regularly for analgesic purposes; and --insufficient staff to provide adequate services.
June 1973	FDA evaluated the inspection report.
July 1973	FDA sent a 10-day letter of intent to deny or revoke approval unless deficient conditions were corrected.
July 1973	FDA received DEA's preapproval inspection report recommending denial of approval because of deficient security and recordkeeping practices.

Date	Event
July 1973	The program responded to the 10-day letter of intent.
July 1973	FDA decided that the program's reply was unacceptable because it did not respond to many of the violations and lacked assurances that they would be corrected.
September 1973	FDA sent the program a 10-day letter of intent requesting explanations of the violations found by DEA.
September 1973	The program replied to the 10-day letter indicating that corrective action had been taken.
October 1973	DEA's second preapproval inspection noted improved security and recordkeeping, and DEA recommended approval.
January 1974	FDA notified the program (1) of specific shortcomings in the latter's reply to the July 1973 10-day letter of intent and (2) that because of the time elapsed since July 1973, a decision on whether to hold a hearing to deny approval would be postponed until after another inspection.
May 1974	FDA made its fourth inspection, noting deficiencies similar to those found in the May 1973 inspection.
July 1974	FDA evaluated the inspection report.
November 1974	FDA sent the program a 10-day letter of intent and the program responded.
January 1975	FDA accepted the program's response with reservation, subject to verification by inspection.
January 1975	FDA made its fifth inspection, which revealed several undisclosed deviations from regulations as well as violations of a continuing nature similar to those found in May 1973.

Date	Event
March 1975	FDA evaluated the inspection report and determined that the report did not permit a proper evaluation of the program's compliance with the regulations.
April 1975	FDA made its sixth inspection, noting deficiencies similar to those found in May 1973 and several other deviations from regulations.
May 1975	FDA evaluated the inspection report.
June 1975	FDA published a notice in the Federal Register of an opportunity for a formal hearing to show why the treatment program's application should not be denied.

Thus, as of July 1975--40 months after FDA found it to be in violation--this program was still operating. On December 15, 1975, at a prehearing conference, a hearing was scheduled to be held on January 28, 1976, before an administrative law judge.

Hesitancy in taking firm and decisive action

FDA's policy is to direct enforcement action primarily toward obtaining compliance from violative programs and, as a last resort, to terminate those programs which cannot be brought into compliance. FDA has several sanctions available to produce quicker results but has not used them.

According to FDA representatives, when an inspection of a treatment program discloses violations, FDA uses the following procedures. When violations are:

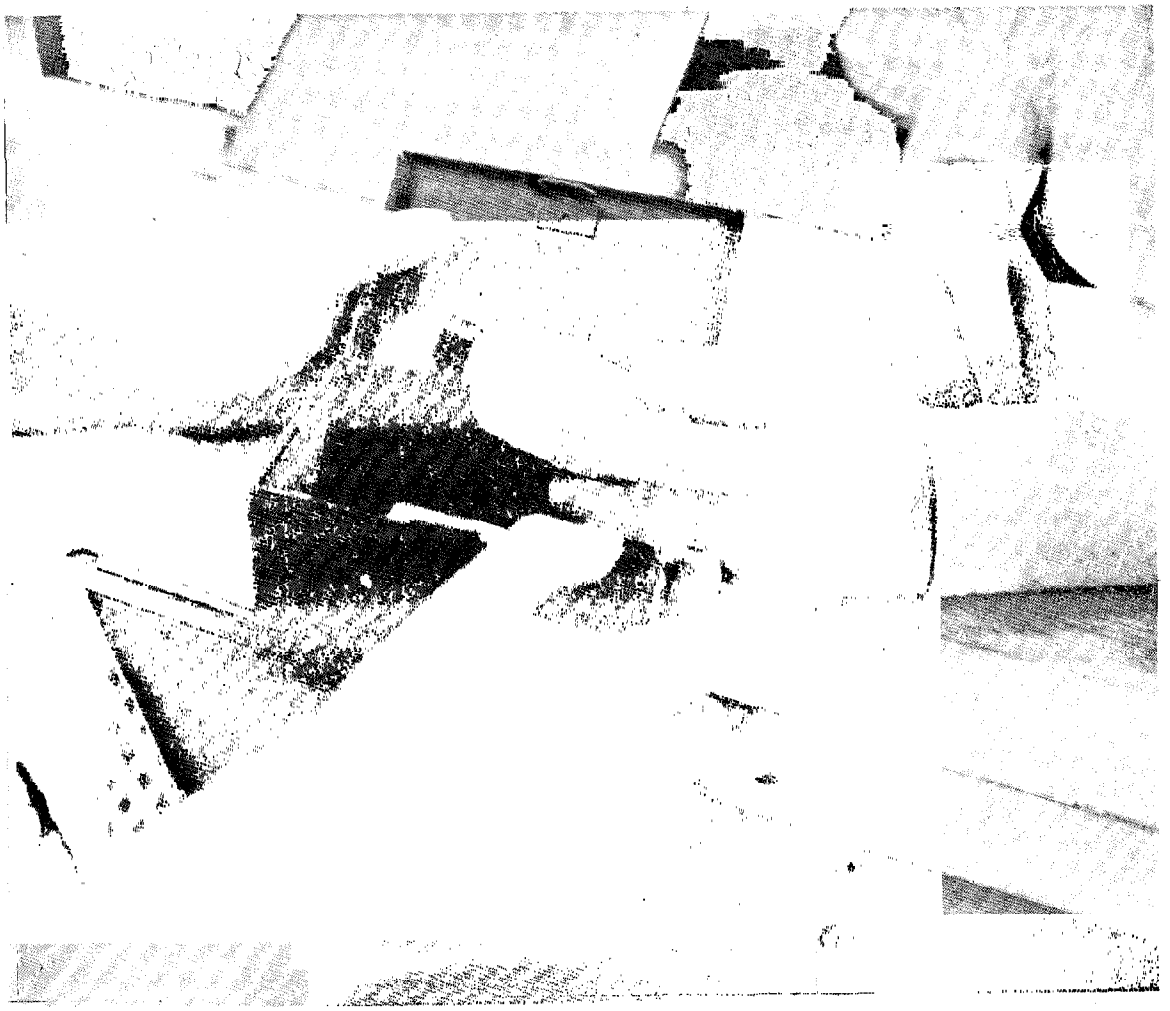
--Minor, a program's promise of voluntary corrective action is accepted without official action.

--More significant, a 30-day letter of admonition, discussing the violations and the need for corrective action, is sent to the program.

--Serious and 90 days have elapsed since the inspection, a 21-day letter of admonition is sent to the program. This letter discusses the violations and the need for corrective action, indicates that a reinspection will be made, and warns that termination proceedings will be instituted if the violations continue.

--Serious and 90 days have not elapsed since the inspection, a 10-day letter of intent to propose to the Commissioner of FDA denial or revocation of approval is sent to the program. This is the first step in termination.

In implementing these procedures, FDA sometimes seemed to be on a treadmill. An inspection would be made and violations detected. Several months would elapse before the inspection report was evaluated. A letter of admonition would be sent to the program, requesting an explanation of the



NURSE DISPENSES TAKE-HOME DOSAGE TO A PATIENT. THIS TREATMENT PROGRAM FURNISHES A METAL BOX FOR THE PATIENT TO LOCK THE MEDICATION AWAY FROM CHILDREN AT HOME. (Photo by FDA.)

violations and, in most cases, signifying the initiation of termination action. The program would respond. FDA would make another inspection and find the same and/or other violations. Months would elapse before the reinspection report was evaluated. FDA would send another letter requesting explanation of violations found during the reinspection, and the entire process would repeat itself.

Although FDA has brought programs into compliance using these practices, only after a prolonged period of time is the program finally persuaded to comply or is action taken to terminate it. While these programs are in violation, they are potential sources of abuse and diversion.

Recognizing the need for quick action against violative programs, the Commissioner of FDA has concluded that the following sanctions should be used to obtain immediate enforcement of regulations:

--Seizure of a program's drug stocks.

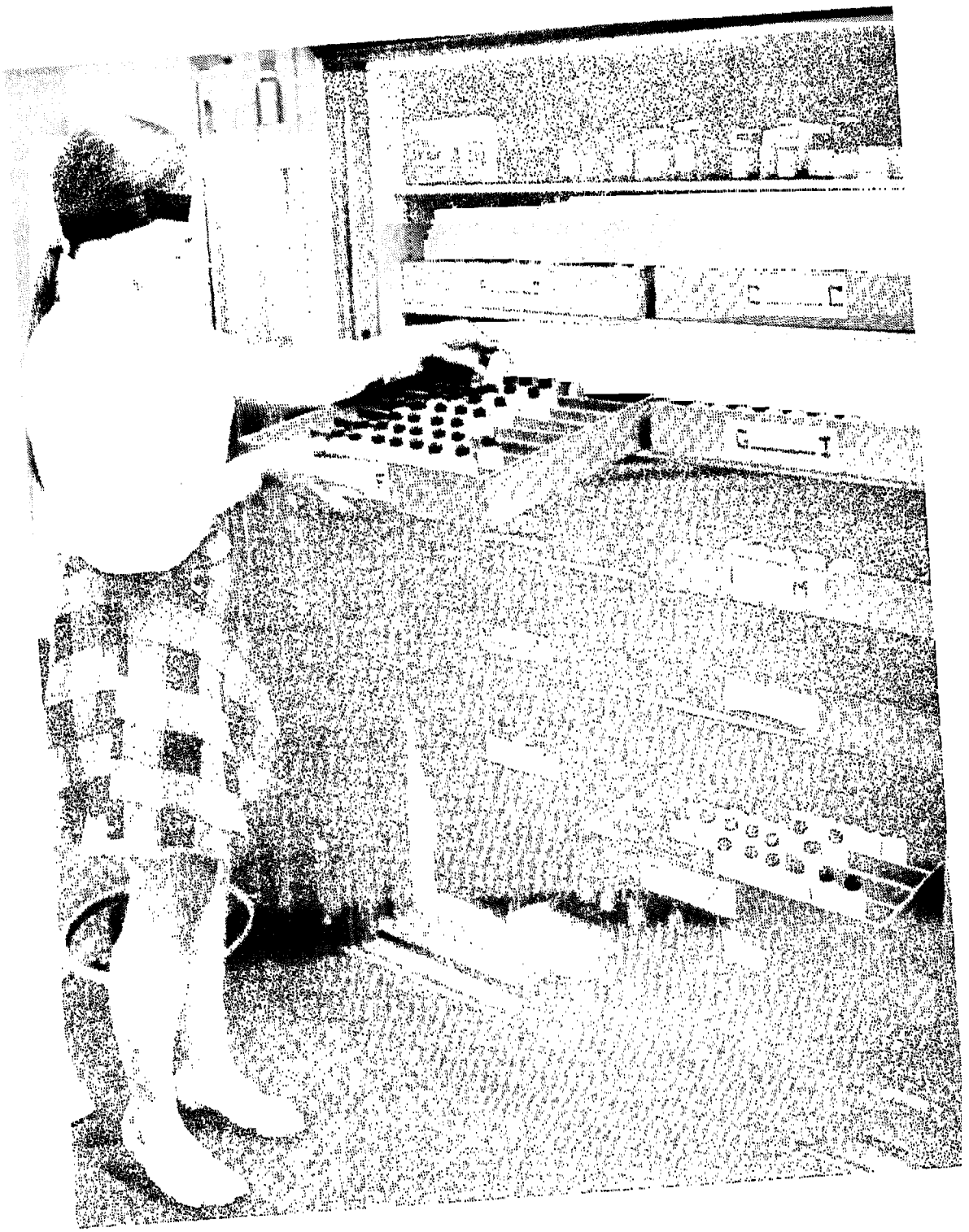
--Injunction against noncompliance.

--Criminal action against program management.

Each of these sanctions would at least partially terminate a program. Admittedly, operations would not necessarily cease, and those aspects of a program not affected by the sanction could continue. Imposing a sanction would, however, force a violative program to take FDA's findings of noncompliance more seriously. The program would then be more likely to take the remedial measures necessary to comply with regulations and resume full operation.

Despite the availability of these sanctions, the statement in the Federal regulations of FDA's intent to use them, and the FDA Commissioner's policy that they will be the primary enforcement tools, at the conclusion of our review none of them had been used since the March 1973 regulations went into effect.

According to FDA representatives, they have not established formal criteria to identify (1) the conditions and circumstances under which each sanction should be used or (2) the types of violations and violators which would be most effectively corrected by each of the available sanctions. Nor have procedures been established for implementing these sanctions (for example, should action be taken and who is responsible for taking it). Without formal criteria and procedures for selecting and implementing sanctions, properly using the sanctions to obtain correction of violative practices is difficult.



NURSE CHECKS METHADONE STOCKS IN THE TREATMENT PROGRAM'S SAFE.
(Photo by FDA.)

As a last resort, FDA may terminate a program by revoking approval of its application to operate. According to FDA, the termination process could take about 6 months.

Although the FDA Commissioner has recommended that the termination process be used when appropriate, FDA has been reluctant to do so. From March 1973 (when the new regulations took effect) to June 6, 1975, it had not been used to revoke any program's application. (Since FDA's entry into methadone regulation in 1971, it has been used only 11 times--all in connection with INDs.)

FDA representatives agreed that the practices for obtaining compliance are cumbersome and time consuming. Recognizing these weaknesses, FDA has begun applying pressure to seriously violative programs by warning them through telegrams to either comply immediately or cease operations. During the 22 months ended October 1975, 33 warning telegrams were sent for such violations as the lack of a full-time physician, the use of unapproved dispensing sites, and the distribution of methadone to unapproved sites. FDA officials indicated that the warnings were successful in obtaining program compliance.

Delays in evaluating inspection reports

A key factor in effective enforcement is timely evaluation of inspection reports. FDA has experienced significant and persistent delays in its evaluation process.

Regional FDA inspectors make onsite inspections of treatment programs and then obtain comments on their findings from program personnel. All inspection reports are submitted to DMM for review and evaluation. Centralized evaluation of reports is intended to provide uniformity in administering the regulations and initiating enforcement actions.

DMM recognizes that untimely evaluation of inspection reports delays the initiation of action against violative programs. Accordingly, DMM's practice is to scan inspection reports to identify apparent serious violators and to give such reports priority for detailed evaluation and prompt action. This practice has not been very successful. From March 1973 through February 1974, FDA inspected 350 treatment programs. As of April 1974, 226 of the inspection reports had been evaluated. An average of 1 month elapsed between completion of the inspection to receipt of the report by DMM, and an average of 3 months elapsed from receipt to DMM review.

Of the 350 inspection reports, 69 were found to have violations requiring the sending of a 10- or 21-day letter. Because of the delay in evaluating reports, the programs continued operating for an average of 5 months after the violations were detected before being notified by DMM of any official remedial action required of them.

Because of delays in evaluating inspection reports, DMM instituted a practice which further delayed decisive enforcement action. DMM contends that successful termination action against a program is less likely if violations are more than 90 days old. DMM believes that programs' compliance status may change quickly, that timely information is necessary to take appropriate legal action, and that inspection violations should therefore be as current as possible. Since more than 90 days usually elapsed before an inspection report was evaluated, DMM generally ordered reinspections to determine whether the violations still existed. Unfortunately, several more months usually elapsed before the reinspection was made, and further delays occurred in evaluating the reinspection report.

DMM representatives attribute the delays primarily to a shortage of personnel to process and evaluate inspection reports. Only four evaluators are available to review and process hundreds of reports. In addition, inspectors frequently fail to specifically identify in their reports violations which DMM considers significant. Thus, during DMM's initial scanning, these reports are not given priority for detailed evaluation.

At the conclusion of our review, DMM representatives indicated that they had virtually eliminated the backlog of inspection reports by using additional temporary personnel and authorizing overtime. DMM recognizes that this action was a one-time solution and that future backlogs could develo unless corrective measures are taken. Accordingly, DMM representatives are considering decentralized evaluation of inspection reports by regional personnel. They pointed out, however, the need for adequate training and formal instructions to insure that such personnel make proper evaluations.

New programs are approved without inspection

Enforcement problems could be lessened if treatment programs did not receive final approval before being inspected.

FDA approves new treatment programs based on a satisfactory application, DEA approval of security, and State

A PATIENT DISCUSSES PROBLEMS WITH REHABILITATION COUNSELOR (RIGHT). AT THIS TREATMENT PROGRAM, OUTPATIENTS WHO ARE PARENTS OF SMALL CHILDREN OFTEN BRING THEM ALONG DURING COUNSELING SESSIONS. (Photo by FDA.)

approval. Since the programs are not fully operational when approved, FDA allows them 6 to 9 months to operate before inspecting them. This enables new programs to develop some operating expertise and an operational history for FDA to inspect and evaluate.

FDA's policy of giving a program time to develop an operational history is reasonable. However, by approving programs before they are inspected, FDA incurs the risk that seriously violative programs may be approved and operate undetected for months. The likelihood of this happening is indicated by FDA's estimate that, upon initial inspection, 40 percent of all new programs are found violative to the extent that enforcement action is required. This high rate, moreover, is based on FDA's experience with treatment programs subject to requirements considerably less stringent and comprehensive than current regulations.

If FDA wishes to take enforcement action against a violative program which has already been approved, it must adhere to formally prescribed, often time-consuming hearing requirements. Enforcement action could be implemented more smoothly and quickly if the program had not already been approved. Regulations would have to be amended to allow FDA to grant tentative approval to new programs, with final approv contingent upon the program passing an onsite FDA inspection. To minimize the possibility of unwarranted action against a program, programs that have had their conditional approval terminated or denied should be given an opportunity to apply for final approval, denial of which would require a hearing with full due process. However, programs that apply for final approval in this manner would not be permitted to operate during the time-consuming hearing procedures.

SOME REGULATIONS LACK CLARITY

Some Federal methadone regulations lack clarity, making it difficult for FDA to determine whether a program is compliant in several important areas. As a result, programs with questionable operating procedures could continue to operate for prolonged periods without making corrections.

The following section of the regulations, dealing with ancillary services, is an example of vague requirements that cause FDA difficulty in regulating treatment programs.

> "A methadone treatment program, in addition to providing medication and/or evaluation, shall provide, as a minimum, counseling, rehabilitative, and other social services (e.g., vocational and educational guidance, employment placement), which will help the patient become a well functioning member of society."

FDA's ability to identify the seriousness of noncompliance with this requirement is hampered because the regulations do not provide specific standards for evaluating whether the ancillary services provided are adequate and consistent with the intent of the regulation. Clarity could be provided by specifying the basic information needed for a thorough and meaningful evaluation of services, such as

--qualifications that counselors should have in terms of formal education, experience, and training;

--recordkeeping and documentation to be maintained; and

--supervision to be provided.

Without such specific criteria, inspectors limit their efforts to determining whether counseling is available for patients and is being supplied to those who need it.

The inadequacies of such evaluations are illustrated by a report on the FDA inspection of a methadone maintenance program, which made the following findings on supportive services:

--The program had no full-time counselors. The head of the program, a physician/psychiatrist, said counseling was supplied to patients by him, two licensed practical nurses, and the program's administrator. According to the administrator, the counseling consisted of "rapping" informally in the waiting room. The head of the program said he had recently hired (1) two of his patients to provide limited counseling and (2) a professional counselor for referrals. Counseling services were not supplied to patients during the 6 days of the inspection.

--The program had no written records of counseling provided except for some nurses' notes on 4 of the 14 patient files reviewed.

--The program did not provide vocational, rehabilitative, or employment placement services.

--The program had no physical facilities for group counseling or for counseling more than one patient simultaneously.

After evaluating the inspection report, FDA sent the program a letter of admonition. Concerning supportive services, FDA noted only (1) the absence of counseling records for 10 of the 14 patient files reviewed, (2) that regulations

required more full-time counselors than the program actually employed, and (3) that no counseling was conducted during the 6-day inspection period.

The inspection and evaluation of the program's services indicated deficiencies, but did not provide insight into the seriousness of the deficiencies and the corrective actions needed. Such important considerations as the education, training, experience, and supervision of counselors; the sufficiency and accuracy of recordkeeping and documentation of services provided; and the lack of vocational rehabilitation services were not included in the inspection or evaluation process. Such a superficial evaluation fails to pinpoint significant shortcomings characterizing poorly operated programs.

FDA representatives, agreeing that the regulations need greater clarity and specificity, have identified about 40 areas requiring revision or clarification. About half of the areas appear to have a direct or indirect impact on FDA's ability to more effectively enforce regulatory requirements. Actions FDA believes necessary include:

--Clearer definition of the role of a program's medical director.

--Definition of what constitutes adequate physical facilities necessary to provide all services.

--Establishment of minimum time which physicians, nurses, and counselors must spend onsite (at the program).

--Clear definition of what constitutes a comprehensive range of medical and rehabilitation services.

--Definition of what constitutes a regular review of dosage level.

--Establishment of minimum standards to minimize falsification of urine samples.

The proposed revisions were turned over to the Methadone Treatment Policy Review Board for study. As of October 31, 1974, however, all action on the revisions had been postponed because of the Board's involvement in considering the impact on the FDA regulations of (1) new DEA regulations on methadone diversion and (2) regulations proposed by the Special Action Office for Drug Abuse Prevention regarding confidentiality of patient records. At the end of our review, the Board had not taken any final action on the proposed revisions.

CONCLUSIONS

Because of the dangers inherent in the misuse or poorly controlled use of methadone, the extensive system for dispensing it to heroin addicts--methadone treatment programs--must be effectively regulated so that only compliant treatment programs are allowed to operate. Because of FDA's enforcement practices, this goal is not being fully achieved.

We recognize that FDA experienced early problems because of factors largely beyond its control--the inappropriateness

REHABILITATION COUNSELOR (CENTER, AT DESK) PARTICIPATES IN GROUP THERAPY SESSION. (Photo by FDA.)

of the IND system to an expanding methadone treatment market and the time lost because of the Government's late entry into methadone regulation. But the major cause of FDA's failure to obtain timely program compliance has been its own failure to pursue an aggressive and decisive enforcement program. In view of the dangers--actual and potential--posed by the widespread use of methadone, we believe that further improvements are needed if FDA is to effectively control the use of methadone in treatment programs.

RECOMMENDATIONS

We recommend that the Secretary of HEW direct FDA to:

--Establish formal criteria and procedures to help personnel to use appropriate enforcement sanctions and initiate the swift, certain actions needed to carry out established enforcement policy.

--Reduce the period from inspection to report evaluation either by decentralizing the report evaluation function or by better implementing its system of priorities to insure that immediate attention is given to reports on seriously violative programs.

--Revise Federal regulations to provide new program applicants with conditional rather than final approval until they have passed a comprehensive onsite inspection as soon as possible after beginning operations.

AGENCY COMMENTS

HEW concurred with our first and second recommendations, stating (see app. II) that criteria and procedures establishing priorities and time factors for implementing the full range of administrative and regulatory sanctions for regulating methadone programs will be implemented during fiscal year 1976. In addition, plans were initiated in fiscal year 1975 to decentralize the report evaluation function, a task expected to be completed during fiscal year 1976.

HEW disagreed with our third recommendation. HEW said regulatory control would not be improved by conditionally approving new treatment programs because the due process requirements of the Administrative Procedure Act would still require following the same time-consuming procedures to terminate an approved program found to be violative.

In our opinion, granting conditional approval to programs is without legal objection since the due process requirements of that act do not apply to temporary licenses, which is what treatment programs granted conditional approval would have. Furthermore, even if the act did apply to the type of conditional approval or license we are recommending, terminating a methadone treatment program might be considered an exception to the due process requirements, since the act provides that notice and the opportunity to demonstrate or achieve compliance are not required before action is taken to withdraw, suspend, revoke, or annul a license when the public health, interest, or safety requires otherwise.

HEW did state, however, that FDA is taking steps to expedite correction of violative programs. Instructions have been issued to FDA inspectors to inspect, on a trial basis, programs after only 60 days of operation in order to more quickly detect violative programs and initiate corrective action. In addition, FDA plans to publish in the Federal Register proposals for revising procedures to reduce the time for denying or revoking the approval of a treatment program and for automatically revoking a program's FDA approval when either DEA or a State denies or revokes the program's registration.

CHAPTER 4

DEA'S EFFORTS TO CONTROL DIVERSION

DEA has been unable to carry out an effective enforcement program to prevent the diversion of methadone from treatment programs. DEA's authority to regulate and enforce activities aimed at controlling diversion from such programs has been inadequate; however, recent legislation appears to have corrected this situation. The new legislation dictates that DEA closely coordinate its activities with FDA.

Until CSA was amended in May 1974, DEA did not have adequate regulatory and enforcement authority to effectively control diversion from methadone treatment programs. The act and existing regulations did not, for example, give DEA authority to

--require treatment programs to register with DEA;

--establish strict security standards relating to the storage, receipt, handling, dispensing, and movement of methadone;

--require treatment programs to keep records of methadone administered; and

--suspend or revoke a treatment program's operation for violating regulations.

The Narcotic Addict Treatment Act of 1974, and the regulations issued under it, corrected these weaknesses and appear to provide DEA with sufficient regulatory authority to prevent diversion at treatment programs.

NEED FOR COORDINATION WITH FDA

Under the new legislation, the need for increased DEA-FDA coordination is particularly important because the agencies will be carrying out similar enforcement activities. In the past, coordination was sometimes inadequate.

After the first Federal regulations on methadone were issued in April 1971, DEA undertook compliance investigations at treatment programs. The investigations consisted of checks of security, recordkeeping, and protocol (operational procedures), as well as an accountability audit to insure proper accounting for all methadone stocks.

DEA did not ordinarily have the authority to suspend or terminate a program's operation, but it could recommend such action to FDA.

In DEA's New York region, where about half of the Nation's methadone patients reside, 55 compliance investigations were completed during 1971-73. All 55 investigations disclosed deficient practices in security, recordkeeping, program protocols, or accountability. Typical deficiencies reported included

--inadequate maintenance of, or failure to keep, required records;

--inadequate security;

--exceeding the take-home supply stipulated in the protocol; and

--discrepancies between the amount of methadone on hand and that shown on the records.

In 13 of the cases, DEA considered the detected discrepancies to be minor and recommended no action. Nearly all of the remaining 42 programs were sent a letter of admonition stating what violations or deficiencies were found and requesting a response concerning corrective action taken or planned. Only two cases were referred to FDA.

DEA did not usually make followup investigations to determine whether violative programs actually corrected deficiencies. DEA representatives believed that such investigations were impractical owing to the lack of strong enforcement authority. Further, DEA guidelines reportedly changed three times because of significant changes in FDA procedures, leaving doubt as to actions that could be taken on past deviations based on revised guidelines.

Any potential benefits from DEA's investigations were diluted by the general absence of coordination with FDA. DEA stated that, regarding security and accountability recordkeeping discrepancies, referral to FDA was of little value since neither agency had authority to act before the Narcotic Addict Treatment Act took effect. According to DEA, the only referrals that would have been useful to FDA were apparent violations of medical standards that DEA investigators may have noted but had no authority to act against.

At a minimum, however, investigative reports on all violative programs might have been routinely referred to FDA for consideration in its overall evaluations of a program's

fitness to continue operations. FDA did issue some 10-day letters of intent based on DEA referrals.

Effective coordination becomes more important in light of DEA's increased enforcement authority under the new law. DEA and FDA will be inspecting the same treatment programs, examining basically the same records and documents, and have similar authority to take strong enforcement action. When responsibilities are so similar, the potential for conflict is always present.

We have previously reported on the difficulties and conflicts which arose in a similar situation involving the former Bureau of Narcotics and Dangerous Drugs and the Bureau of Customs (B-164031(2), Dec. 7, 1972). In that report, we pointed out how the two agencies' overlapping jurisdications hindered Federal control of narcotics smuggling. Close coordination between FDA and DEA is essential to prevent similar problems from hindering the oversight of methadone treatment programs.

CONCLUSIONS

Because of DEA's lack of adequate regulatory and enforcement authority, its efforts to prevent methadone diversion have been less than effective. New legislation appears to have corrected this problem and has made DEA an equal partner with FDA in the Federal control of methadone treatment programs. However, DEA's new expanded authority necessitates close coordination of its activities with similar FDA activities.

RECOMMENDATION

We recommend that the Attorney General and the Secretary of HEW direct DEA and FDA, respectively, to enter into a coordinative agreement which includes formal procedures governing

--each agency's responsibilities,

--the interchange of information, and

--the resolution of disagreements.

AGENCY COMMENTS

HEW and the Department of Justice (see app. III) concurred in our recommendation and said they were developing an agreement to establish closer coordination. The

agreement will include procedures for making referrals and recommendations which may lead to the revocation, suspension, or denial of a program's registration under the Narcotic Addict Treatment Act.

The Department of Justice added that, although it believed that DEA had good coordination with FDA at the headquarters level, much closer coordination is being established to insure effective oversight of methadone treatment programs with passage of the Narcotic Addict Treatment Act.

GAO REPORTS ON NARCOTIC TREATMENT PROGRAMS IN SELECTED CITIES

Title	B-number	Date
Narcotic Addiction Treatment and Rehabilitation Programs in Washington, D.C.	B-166217	4/20/72
Narcotic Addiction Treatment and Rehabilitation Programs in the County of Los Angeles	B-166217	7/21/72
Narcotic Addiction Treatment and Rehabilitation Programs in San Francisco and Alameda Counties, California	B-166217	7/24/72
Narcotic Addiction Treatment and Rehabilitation Programs in Chicago, Illinois	B-166217	11/16/72
Narcotic Addiction Treatment and Rehabilitation Programs in New York City	B-166217	4/11/73

APPENDIX II

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

October 24, 1975

Mr. Gregory J. Ahart
Director
Manpower and Welfare
Division
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Ahart:

The Secretary asked that I respond to your request for our comments on your draft report to the Congress entitled, "More Effective Action Needed to Control Abuse and Diversion in Methadone Treatment Programs." They are enclosed.

We appreciate the opportunity to comment on this draft report before its publication.

Sincerely yours,

John D. Young
Assistant Secretary, Comptroller

Enclosure

DEPARTMENT COMMENTS TO GAO DRAFT REPORT ENTITLED, "MORE EFFECTIVE ACTION NEEDED TO CONTROL ABUSE AND DIVERSION IN METHADONE TREATMENT PROGRAMS"

GAO RECOMMENDATION:

Establish formal criteria and procedures to guide personnel in using appropriate enforcement sanctions and initiating the swift and certain actions needed to carry out established enforcement policy.

DEPARTMENT COMMENT:

We concur. FDA has drafted criteria and procedures establishing priorities and time factors to be used by the Agency in implementing the full range of administrative and regulatory sanctions available to the Agency for use in regulating the methadone program. The new criteria and procedures will be implemented during FY 1976.

GAO RECOMMENDATION:

Reduce the time period from inspection to report evaluation either by decentralizing the report evaluation function or by improving implementation of its system of priorities to assure immediate attention to reports on programs that are seriously violative.

DEPARTMENT COMMENT:

We concur. FDA initiated plans to decentralize the report evaluation function in FY 1975. Some decentralization such as the development of standardized criteria and procedures has begun. Decentralization of appropriate functions will be completed during FY 1976.

GAO RECOMMENDATION:

Revise Federal regulations to provide new program applicants with conditional rather than final approval, contingent upon passing a comprehensive on-site inspection as soon as possible after beginning operations.

DEPARTMENT COMMENT:

We do not believe this recommendation can achieve the intended result. Granting of approval to a treatment program is always contingent upon its continuing compliance with the requirements of applicable regulations. The Administrative Procedures Act requires that any adverse

action undertaken by the government must provide for legal due process for those who would be affected. Since this requirement would apply equally to a treatment program given conditional approval or to one given full approval, there would be no regulatory advantage in granting a conditional approval. An initial inspection of a new treatment program would be necessary in either case. If violations are found during the inspection, whether or not it is the initial inspection, uniform administrative and judicial procedures must be followed in applying sanctions. Adhering to due process is particularly important in dealing with treatment programs whose patients may be jeopardized by precipitous action on the part of the Agency. Due process in such cases serves the dual purposes of preventing unwarranted actions against a program and protecting the individual patients from the adverse effects of sudden withdrawal from a maintenance treatment regimen.

FDA is taking several steps to expedite correction of violative programs. The Agency has been allowing treatment programs a period of six months of operation after initial approval before an inspection is made. This procedure was designed to allow the program to develop a full patient load and work out any start-up problems prior to an evaluation. Instructions have been issued to FDA inspectors initiating on a trial basis inspections after only 60 days of operation. This action should allow FDA to more quickly detect violative programs and initiate appropriate corrective action. It will not, however, obviate the requirement for the Agency to follow the due process requirements. The Agency will also be publishing a Federal Register proposal revising procedures to reduce the time for denying or revoking approval of a treatment program. An additional proposal will be published providing for automatic revocation of approval when either DEA or a State denies or revokes registration to a program.

GAO RECOMMENDATION:

We recommend that the Administrator of DEA and the Commissioner of FDA enter into a coordinative agreement which includes formal procedures governing: (1) the respective responsibilities of each agency, (2) the interchange of information, and (3) the resolution of disagreements.

DEPARTMENT COMMENT:

We concur. DEA and FDA presently have an agreement in effect. It is under revision to incorporate provisions of the Narcotic Addict Treatment Act.

UNITED STATES DEPARTMENT OF JUSTICE

WASHINGTON, D.C. 20530

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

November 18, 1975

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 "More Effective Action Needed to Control Abuse and Diversion in Methadone Treatment Programs."

The major portion of the report is directed toward the need for the Food and Drug Administration (FDA) to take more decisive action against methadone treatment programs found to be in violation of Federal regulations. As the report also points out, the Drug Enforcement Administration (DEA) was initially "unable to carry out an effective methadone anti-diversion program because of its inadequate authority to regulate and enforce activities aimed at controlling diversion from treatment programs." As GAO indicated in the report, this condition was corrected by passage of the National Addict Treatment Act of 1974 (hereinafter referred to as the 1974 Act). The 1974 Act made DEA an equal partner with FDA in the Federal effort to control methadone treatment programs. Recognizing the need for close coordination between the two organizations following passage of the 1974 Act, GAO recommends that DEA and FDA enter into a coordinative agreement that will include formal procedures governing the respective responsibilities of each agency, the interchange of information, and the resolution of disagreements.

DEA agrees with the above recommendation and has taken steps to establish close coordination with FDA. Since passage of the 1974 Act, DEA and FDA have worked closely in promulgating regulations and defining appropriate enforcement authority responsibilities. Frequent meetings are held to discuss current and potential procedural problems between the DEA Regulatory Investigations Section and the FDA Division of Methadone Monitoring. In addition, the Chief of the DEA Regulatory Investigations Section participates in each session of the Methadone Policy Review Board. A draft Memorandum of Understanding between DEA and FDA has been developed to establish procedures for making referrals and recommendations which may lead to the revocation, suspension or denial of a program's registration under the 1974 Act. The memorandum is currently under review and revision by the legal offices of both agencies.

While we agree with the major issues of the report insofar as they pertain to DEA, several areas of the report leave misleading connotations which should be clarified. The statement that DEA has been unable to carry out an effective methadone anti-diversion program is overstated. Prior to the 1974 Act, DEA did take actions to prevent the diversion of methadone when such diversion was detected. Obviously, the lack of authority hampered our activities, but many of the actions taken were instrumental in reducing the abuse and diversion of methadone. The statements on pages i, 40 and 43 would more accurately reflect the efforts of DEA if phrased "Until the Controlled Substances Act was amended in May 1974, DEA's efforts to prevent the diversion of methadone from treatment programs were greatly hampered because of its inadequate regulatory and enforcement authority to effectively control diversion from methadone treatment programs."

Further clarification is needed to more clearly distinguish between the responsibilities of DEA and FDA. Several areas of the report appear to obscure rather than clarify these responsibilities. The last paragraph on page 4 could more clearly distinguish between DEA and FDA responsibilities by stating "FDA is responsible for establishing and monitoring the medical and counseling criteria under which methadone may be used and dispensed in treatment programs. This includes the establishment of treatment standards and patient review.

DEA is responsible for the prevention of diversion of methadone by establishing and monitoring drug security and drug accountability recordkeeping criteria."

Several clarifications are needed in the report to account for the actions taken by DEA on the 55 compliance investigations cited on pages 41 and 42 . The report points out that the 55 investigations were conducted over a 3 year period, but does not note that FDA procedures changed significantly three times during the period. As a consequence, DEA guidelines also changed three times because no other basis for regulatory authority existed, and the nature of the actions to be taken on past deviations based on the revised guidelines were left questionable. Also, of the four typical violations mentioned, the last two--exceeding take-home supplies and shortages or overages indicated by records--were only indicators of poor security or inadequate records, with no violations necessarily involved. The report states that "nearly all of the remaining 42 cases were considered serious enough by DEA to warrant a letter of admonition." This statement is very misleading for two reasons. First, other than an agent warning, which is no longer used, the Letter of Admonition is the lowest level of regulatory action used by DEA for notice of minor violations. This certainly does not warrant the "serious" discrepancy connotation implied in the report. Second, unless DEA took criminal action, or the program physician lost his state license, or submitted a false application, neither DEA nor FDA could take further action for security or accountability recordkeeping discrepancies. This dual lack of enforcement authority is also discussed in the next paragraph.

Page 42 of the report asserts that DEA's only enforcement tool was, in effect, the enforcement authority of FDA, and that DEA's investigative reports might have been referred to FDA for an evaluation of the programs' fitness to continue operations. This statement is misleading. During the period that methadone was classified as an investigational new drug (IND) and later as an approved new drug application (NDA), FDA could revoke program approval for discrepancies in the medical standards, but could not act on security or accountability recordkeeping discrepancies. Accordingly, referrals to FDA were of little value since neither agency had authority to take action for security and accountability recordkeeping discrepancies prior to the 1974 Act. The only DEA referrals that would have been useful to FDA were those apparent violations of medical standards which DEA investigators may have noted but had no authority to enforce. During

APPENDIX III

the period that methadone was designated as an approved NDA, DEA maintained a full-time staff assistant at Headquarters who reviewed all DEA reports of investigation involving methadone maintenance treatment programs and maintained almost daily contact with FDA concerning these programs. Overall, we believe that DEA has had very good coordination of program investigations with FDA at the Headquarters level and, in light of DEA's increased enforcement authority under the 1974 Act, much closer coordination is now being established to assure effective oversight of methadone treatment programs.

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

GAO note: Page references in this appendix may not correspond to page numbers in the final report.

PRINCIPAL OFFICIALS RESPONSIBLE FOR ADMINISTERING ACTIVITIES DISCUSSED IN THIS REPORT

	Tenure of office			
	From		To	
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE				
SECRETARY OF HEALTH, EDUCATION, AND WELFARE:				
David Mathews	Aug.	1975	Present	
Caspar W. Weinberger	Feb.	1973	Aug.	1975
Frank C. Carlucci (acting)	Jan.	1973	Feb.	1973
Elliot L. Richardson	June	1970	Jan.	1973
Robert H. Finch	Jan.	1969	June	1970
COMMISSIONER, FOOD AND DRUG ADMINISTRATION:				
Alexander M. Schmidt	July	1973	Present	
Sherwin Gardner (acting)	Mar.	1973	July	1973
Charles C. Edwards	Feb.	1970	Mar.	1973
DEPARTMENT OF JUSTICE				
ATTORNEY GENERAL:				
Edward H. Levi	Feb.	1975	Present	
William B. Saxbe	Jan.	1974	Feb.	1975
Robert H. Bork, Jr. (acting)	Oct.	1973	Jan.	1974
Elliot L. Richardson	May	1973	Oct.	1973
Richard G. Kleindienst	June	1972	Apr.	1973
Richard G. Kleindienst (acting)	Feb.	1972	June	1972
John N. Mitchell	Jan.	1969	Feb.	1972
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
John R. Bartels, Jr. (acting)	July	1973	Oct.	1973
DIRECTOR, BUREAU OF NARCOTICS AND DANGEROUS DRUGS (note a):				
John E. Ingersoll	Aug.	1968	July	1973

a/Effective July 1, 1973, the Bureau and other Federal agencies involved with drug enforcement merged to form DEA. All Bureau functions were transferred to DEA.

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