Security Controls For Methadone Distribution Need Improving

Department of Justice
Department of Health, Education and Welfare

BY THE COMPTROLLER GENERAL OF THE UNITED STATES

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Contents

ABBREVIATIONS

CSA	Controlled Substances Act of 1970
DEA	Drug Enforcement Administration
FBI	Federal Bureau of Investigation
FDA	Food and Drug Administration
GAO	General Accounting Office

COMPTROLLER GENERAL'S
REPORT TO THE HONORABLE
CHARLES B. RANGEL
HOUSE OF REPRESENTATIVES

SECURITY CONTROLS FOR METHADONE DISTRIBUTION NEED IMPROVING

Department of Justice
Department of Health, Education, and Welfare

D I G E S T

WHY THE REVIEW WAS MADE

Congressman Charles B. Rangel asked GAO to review the security procedures for transporting methadone and other drugs having a high potential for abuse.

Methadone is an addictive, synthetic narcotic produced primarily for treating and rehabilitating narcotic addicts. Some methadone has been diverted from legitimate distribution into the illicit market--resulting in many deaths.

The contents of this report were discussed with the Department of Justice but, in accordance with Congressman Rangel's wishes, GAO did not request the Department's written comments on this report.

FINDINGS AND CONCLUSIONS

The quantity of methadone and other controlled substances entering the illicit market as a result of diversions from manufacturers, distributors, and dispensers is substantial.

Although the methadone lost or stolen represents only a small part of the total diversions of controlled drugs, the actions GAO recommends for preventing illegal diversion of methadone are largely applicable to the entire range of similar drugs.

During fiscal year 1973, 6,382 drug thefts or losses, accounting for over 50 million "dosage units," were reported to the Drug Enforcement Administration, Department of Justice.

For methadone, 1,488 thefts or losses--totaling about 1,741,256 dosage units--were reported. Night break-ins and armed robberies accounted for most of these diversions.

For the 18-month period ending June 30, 1973, 153 intransit thefts or losses involving similar type drugs occurred. Fourteen of the thefts and losses--totaling 54,866 dosage units--were for methadone. (See p. 5.)

Three companies are authorized to manufacture methadone from raw materials. They produced about 1,600 kilograms of methadone during 1973.

The number of facilities approved to receive methadone from the manufacturers for either further processing, distribution, or

dispensing consisted of 5 manufacturers, 366 wholesalers, 14 community pharmacies, 2,783 hospitals, and 731 treatment programs.

The Drug Enforcement Administration annually registers approved manufacturers, distributors, and dispensers (registrants) of methadone and other controlled substances and is responsible for preventing their diversion.

The Food and Drug Administration, Department of Health, Education, and Welfare, is responsible for overseeing the medical uses of methadone.

Storage and shipping controls of manufacturers and wholesalers

Security controls for storing and shipping methadone orders at 5 manufacturers and 14 wholesalers appeared adequate. (See p. 7.)

Shipments to unauthorized retail pharmacies

Regulations prohibit shipping methadone to retail pharmacies after March 15, 1973, without approval of the Food and Drug Administration. Two of the 14 wholesalers visited made 13 shipments to 8 unapproved pharmacies during a 4-month period after the effective date of the regulations. The wholesalers admitted error in making these shipments and agreed to prevent shipments to unauthorized pharmacies. (See p. 10.)

Address labels identify methadone shipments

As required by Federal regulations, manufacturers and wholesalers shipping methadone did not mark the outside container or package to indicate that controlled substances were being shipped. However, address labels of shipments may suggest that controlled substances are being shipped because language such as "methadone maintenance" or "methadone treatment" may be part of the address of shipments to methadone dispensing programs. This occurs because the address on the Federal order form must be used in addressing shipments. (See p. 11.)

Controls over methadone transportation

Manufacturers, distributors, and dispensers shipping controlled substances are required to select carriers which provide adequate security from thefts and losses.

The Drug Enforcement Administration has not issued detailed guidelines to assist registrants in selecting carriers which provide adequate security over the transportation of controlled substances. As a result some registrants are not using the most secure means of shipping methadone. (See p. 14.)

Receipt of methadone

Security procedures over the receipt of methadone at State distribution facilities, hospitals, and treatment programs generally were adequate.

However, some registrants receiving methadone from manufacturers and wholesalers need to improve their receiving procedures to be sure that only authorized doctors, nurses, or pharmacists are permitted to sign for and accept methadone deliveries as required by Federal regulations.

At seven hospitals, methadone shipments were signed for and opened by receiving department personnel or warehousemen before being sent to the hospital pharmacy. At five treatment programs, program administrators, directors, and others who were not licensed practitioners were designated to receive methadone shipments. (See p. 17.)

Monitoring intransit thefts and losses

Federal regulations require registrants to report all thefts and significant losses of controlled substances to the Drug Enforcement Administration. The regulations do not specify the type of information that is to be reported for intransit thefts and losses, and the Drug Enforcement Administration has not issued guidelines to registrants clarifying what should be reported. As a result registrants often omitted information relevant to an intransit theft or loss.

Improvements are also needed in the reporting system for intransit thefts and losses to identify those carriers which are prone to thefts and losses and to provide a basis for initiating action when registrants have experienced a number of thefts and losses. A timely review of registrants' shipping or receiving procedures could assist the Drug Enforcement Administration in carrying out its compliance investigation program.

Registrants should, but in many cases did not, report thefts or losses to other law enforcement agencies, such as the Federal Bureau of Investigation. Further, in cases where thefts and losses were reported to other law enforcement agencies, the Drug Enforcement Administration generally did not follow up with these agencies. GAO believes that information obtained from other law enforcement agencies on their investigations of drug thefts and losses could help the Drug Enforcement Administration carry out its compliance investigation and criminal enforcement programs. (See pp. 19 and 20.)

RECOMMENDATIONS

GAO recommends that the Attorney General have the Drug Enforcement Administration:

--Encourage methadone dispensing organizations to modify their organizational titles on the Federal order forms so that the contents of methadone shipments are not inadvertently disclosed.

--Establish detailed guidelines to assist registrants in selecting carriers for shipping controlled substances.

--Revise the regulations on reporting thefts and significant losses of controlled substances to clarify what is meant by "significant losses" and what information should be reported to the Drug Enforcement Administration when an intransit theft or loss of a controlled substance occurs.

--Insure that thefts and losses are reported to appropriate law enforcement agencies.

--Develop procedures for following up and coordinating with other law enforcement agencies investigating intransit thefts or losses.

--Establish procedures for monitoring reported intransit thefts and losses to identify registrants which should have their shipping or receiving practices reviewed.

AGENCY ACTIONS

GAO discussed its findings with Drug Enforcement Administration officials. They agreed with GAO's conclusions and recommendations. They said that revisions are being made to applicable Federal regulations and to the drug theft report form which should improve and clarify the reporting of drug thefts and losses. Also, the officials said that other recommendations were being studied to determine their feasibility.

CHAPTER 1

INTRODUCTION

Congressman Charles B. Rangel requested that we review security procedures covering the transportation of methadone and other Schedule II controlled substances. Because Schedule II drugs comprise a large number of controlled substances, it was subsequently agreed that our review was to be directed to the security controls covering methadone distribution--from the manufacturers to the ultimate dispensers. We found that the security controls exercised over methadone were generally the same as for other controlled substances.

Methadone is an addictive, synthetic narcotic produced primarily for use in the treatment of narcotic addiction. Because of its high abuse potential, methadone has been designated a Schedule II controlled substance under the Controlled Substances Act of 1970 (CSA) (21 U.S.C. 801 et. seq.).

Schedule II controlled substances have an accepted medical use but have a high potential for abuse which may lead to severe psychological or physical dependence. In addition there are four other schedules of controlled substances classified according to abuse potential, accepted medical use, and accepted safety. Schedule I substances have a high potential for abuse and no accepted medical use; Schedule III through Schedule V substances have an accepted medical use and decreasing potential for abuse.

Methadone is used to treat and rehabilitate narcotic addicts through either maintenance or detoxification. Under maintenance treatment an addict receives a daily oral dosage of methadone for an indefinite period to block the craving for narcotics so that the addict may receive further rehabilitation and attain social adjustment. Under detoxification treatment an addict is given methadone in decreasing dosages for a period not exceeding 21 days with the objective of alleviating withdrawal pains and achieving a drug-free state.

Methadone may also be used as a primary drug of addiction, as a substitute for heroin, or in combination with other drugs. Some methadone has been diverted into the illicit market from legitimate distribution sources and has caused many deaths.

REGULATORY CONTROL OVER METHADONE DISTRIBUTION

The Drug Enforcement Administration (DEA), Department of Justice, and the Food and Drug Administration (FDA), Department of Health, Education, and Welfare, provide Federal regulatory control over methadone. FDA is responsible for overseeing the medical uses of methadone under the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301 et. seq.), and DEA is responsible for preventing its diversion under CSA.

Under CSA, DEA is responsible for enforcing the regulatory controls over the manufacture, distribution, and dispensing of methadone and other drugs. DEA annually registers methadone manufacturers, distributors, and dispensers--called registrants.

Each year DEA also establishes the aggregate methadone production quota to meet medical and research needs and approves individual manufacturing quotas for bulk raw material manufacturers.

Additionally, DEA requires that manufacturers and distributors sell methadone only to approved registrants. Further, DEA requires periodic reports from manufacturers and distributors accounting for all receipts, dispositions, and inventories of methadone.

Federal regulations (21 CFR 1301)--referred to as DEA's regulations--state that registrants shipping methadone and other controlled substances are responsible for selecting carriers which provide adequate security to guard against intransit losses. To minimize the diversion and abuse of methadone, FDA and DEA issued joint Federal regulations (21 CFR 310.505, at 39 F.R. 11680 (1974)) effective March 15, 1973--referred to as the Federal methadone regulations--which provide for a distribution system limiting the number of persons handling methadone. The Federal methadone regulations provide that manufacturers ship methadone directly to approved treatment programs, hospitals, and selected community pharmacies unless FDA and DEA approve an alternative method of distribution.

DEA extended its authority over the regulation of methadone treatment programs and methadone use under the Narcotic Addict Treatment Act of 1974 (Public Law 93-281). The act provides for more stringent registration requirements for treatment programs. The act also provides that DEA may prescribe increased security and recordkeeping requirements for treatment programs.

DISTRIBUTION SYSTEM FOR METHADONE

During 1973 the three manufacturers authorized to manufacture bulk methadone produced about 1,600 kilograms of methadone from raw materials. The methadone produced by these manufacturers was either further processed into a dosage form, such as a tablet or a syrup, or distributed for further processing, distribution, and/or dispensing by approved registrants.

In addition to the 3 raw material manufacturers, the registrants, as of July 19, 1974, authorized to receive methadone for further processing, distribution, or dispensing were

--5 dosage manufacturers approved to receive methadone for further processing into dosage form or for repackaging and relabeling;

--366 wholesalers, which were approved as an exception to the Federal methadone regulations;

--14 community pharmacies administering or dispensing methadone for analgesic purposes in remote areas or under exceptional circumstances;

--2,783 hospitals approved to receive methadone for analgesic use, detoxification, and temporary maintenance treatment; and

--731 treatment programs providing methadone maintenance and detoxification treatment to about 78,000 patients.

Treatment programs may receive methadone either directly from a manufacturer or through a multilevel distribution system of manufacturers and wholesalers. Also, in some States and localities a central distribution facility may exist to distribute methadone to some treatment programs. The central distribution facility receives the methadone and prepares the daily dose of methadone to be dispensed to each addict receiving treatment. Methadone not dispensed during the day by the treatment program is returned to the distribution facility if the program lacks secure storage facilities.

A treatment program may be affiliated with a hospital through which it receives methadone. The hospital's pharmacy receives methadone from a manufacturer or wholesaler for further distribution to the treatment program.

CHAPTER 2

ANALYSIS OF REPORTED THEFTS AND LOSSES OF CONTROLLED SUBSTANCES

The quantity of controlled substances entering the illicit market as a result of diversions from registrants is substantial. Although the methadone dosage units lost or stolen represent only a small part of total diversions of controlled substances, the corrective actions we are recommending for methadone are largely applicable to the entire range of controlled substances.

During fiscal year 1973 registrants reported to DEA 6,382 drug thefts and losses of controlled substances--totaling over 50 million dosage units. DEA's analysis categorized these thefts and losses as follows:

Type	Number	Percent
Night break-in	4,410	69
Armed robbery	1,057	17
Employee theft	221	3
Customer pilferage	108	2
Other (note a)	586	9
Total	6,382	100

a/Includes intransit thefts and losses and losses of undetermined cause.

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

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

As indicated by the above tabulation, night break-ins and armed robberies accounted for most of the reported methadone diversions. The 1,741,256 dosage units of methadone represented about 3 percent of the total dosage units of controlled substances reported stolen or lost during the fiscal year.

The dosage units of other controlled substances which entered the illicit market during fiscal year 1973, as indicated by DEA's drug theft analysis report, were as follows:

Drug category	Dosage units
Other narcotics (note a)	18,117,415
Amphetamine	15,398,776
Barbiturate	14,043,265
Cocaine	825,720
Total	48,385,176

a/Includes codeine and other opium derivatives.

DEA drug theft analysis reports do not identify reported in-transit thefts or losses as a separate item but generally include them in the "other" category. To determine the extent of in-transit thefts and losses (those occurring either during shipping, transporting, or receiving) for methadone and other Schedule II drugs, we reviewed registrants' drug thefts and losses reported to DEA for an 18-month period ending June 30, 1973. We classified 153 incidents reported during that period as intransit thefts or losses of a Schedule II drug. For Schedule II drugs other than methadone, there were 139 diversions, totaling about 189,000 dosage units, reported by registrants.

We categorized 14 reported losses or thefts, totaling 54,866 dosage units, as being for methadone. The thefts or losses ranged from 27 to 28,800 dosage units. The losses or thefts of methadone were reported by registrants to have occurred as follows:

	Number of reports	Dosage units
Lost, stolen, or pilfered while in the possession of the carrier	9	49,177
Armed robbery of driver making delivery from hospital to treatment program	1	627
Unaccountable shortage in shipment at time of delivery	2	2,750
Theft from vehicle making delivery from a State distribution facility to a treatment program	1	1,600
In registrant's automobile which was stolen	1	712
Total	14	54,866

Available DEA records indicate that 28,800 of the foregoing dosage units, diverted in a single theft, were later recovered.

CHAPTER 3

MANUFACTURERS' AND WHOLESALERS' SECURITY CONTROLS FOR FILLING AND SHIPPING ORDERS

The security controls for storing and shipping methadone at the 5 manufacturers and 14 wholesalers visited appeared adequate to prevent diversion. However, some improvements are needed to insure that methadone shipments are not disclosed by information on the address labels and that shipments are not made to unapproved retail pharmacies. The procedures and security controls followed for methadone were generally the same as for other Schedule II drugs.

STORAGE AND ORDER FILLING

Methadone in the possession of the 5 manufacturers and 14 wholesalers was stored in vaults or safes protected by alarm systems, and only authorized employees were permitted access to the vaults or safes. Further, DEA periodically reviewed the physical security over methadone and other controlled substances at manufacturers' and wholesalers' plants. During its reviews of the plants in our review, DEA found the security controls for Schedule II drugs generally adequate.

The internal shipping procedures at manufacturers and wholesalers, in most cases, provided for segregation of employee responsibilities and independent cross-checks in preparing methadone orders for shipment. As a result, two or more employees were usually involved in preparing orders for shipment. For example, one employee would be responsible for filling the orders from inventory while other employees would independently verify the order filling when packing the order. Also, packing and shipping areas at manufacturers and wholesalers were generally secured areas restricted to authorized employees.

A DEA order form is provided to approved registrants for ordering methadone and other Schedule II drugs from manufacturers and wholesalers. The order forms have serial numbers, contain a DEA registration number and the name and address of the registrant, and require the signature of an individual authorized to order the drugs. Orders must be sent to the address indicated on the order form.

TRANSPORTATION USED BY MANUFACTURERS

The five manufacturers visited, three of which manufactured bulk methadone, account for most of the shipments by methadone manufacturers. During the 18-month period ended June 30, 1973,

the 5 manufacturers reported 7 methadone shipments, totaling 1.8 kilograms, lost or stolen out of a total of 4,098 shipments involving 2,980.8 kilograms. One stolen shipment of approximately 1 kilogram was recovered. The other six shipments were reported as lost or pilfered while being transported or as short on delivery.

Two of the manufacturers that produced bulk methadone each used two carriers and the Postal Service to ship methadone. These two manufacturers distributed methadone primarily to treatment programs and State and local distribution facilities and limited quantities to other manufacturers for further processing and distribution.

The other manufacturer of bulk methadone which also further processed it into a dosage form used a number of carriers and the Postal Service to ship methadone. During a 3-month period ending June 30, 1973, the manufacturer used 20 carriers and the Postal Service to make 239 shipments of methadone. Officials of the manufacturer said that a number of carriers were used to initially stock wholesalers and that in the future private trucking firms would primarily be used.

The two dosage-form manufacturers visited primarily used the Postal Service to ship methadone. One dosage manufacturer processed bulk methadone into tablets for distribution primarily to hospitals and treatment programs in the New York City metropolitan area. The other dosage manufacturer combined methadone with another controlled substance for distribution to clinical researchers.

Although the manufacturers generally did not provide specific advance notice to purchasers that methadone was being shipped, the manufacturers did send an invoice billing the purchaser. It is possible that the invoice could arrive before delivery of the shipment and could provide advance notice. However, officials at one manufacturer said that no advance notice of a shipment was necessary because their customers generally requested that methadone be delivered on a specified date.

The manufacturers received a signed receipt from the carrier or the Postal Service when a shipment was turned over for delivery to the purchaser. The manufacturers generally requested a return receipt signed by the purchaser to show that the methadone had been received.

WHOLESALERS' SECURITY MEASURES

The 14 wholesalers generally used their own delivery vehicles and employees to make local deliveries of methadone and other controlled substances and pharmaceutical products. The wholesalers, at times, also used the Postal Service and hired carriers to ship controlled substances. In shipping methadone the wholesalers generally did not require that any special security precautions be followed which differed from those used for other controlled substances and products being delivered. None of the wholesalers visited experienced any shipment losses or thefts of methadone during our review.

According to wholesaler officials, methadone was received from the manufacturer in unmarked packages or containers. Packages and containers containing methadone were delivered by carriers to the receiving area of the wholesaler. At the time of delivery, a receiving clerk generally signed the bill of lading for the number of packages and containers delivered.

Personnel of the wholesalers' receiving departments generally opened the shipments and verified that the contents matched the packing lists or purchase orders. The receiving departments transferred the methadone to the wholesalers' vaults or safes for safekeeping. Some of the wholesalers also required shipments to be verified again by other wholesaler employees before the methadone was placed in storage.

In preparing methadone for delivery, wholesalers either packaged it separately, for example in an unmarked paper bag, or packaged it with other controlled substances using an outer wrapper to conceal the identity of the contents. The outer packaging was not marked to indicate that methadone or a controlled substance was being shipped. The wholesalers generally included a list of what was being shipped.

Delivery employees of the wholesalers were generally aware that they were handling controlled substances, and they often knew the specific controlled substances that they were handling. Some wholesalers followed such security procedures as (1) concealing packages containing methadone and other Schedule II drugs among other products carried in delivery vehicles, (2) using delivery vehicles equipped with burglar alarms, or (3) using vehicles marked in a manner not to disclose that drugs were being transported.

Wholesaler delivery personnel generally obtained a signed receipt to substantiate the delivery of methadone. Wholesaler officials informed us that methadone was generally not delivered

to the individuals authorized to receive methadone at treatment programs or hospitals.

SHIPMENTS TO UNAPPROVED RETAIL PHARMACIES

Under Federal methadone regulations retail pharmacies have been prohibited, since March 15, 1973, from handling methadone unless they are approved by FDA as a community pharmacy and authorized to dispense methadone as an analgesic. There were 14 approved community pharmacies as of July 19, 1974.

Two of the 14 wholesalers visited made 13 methadone shipments to 8 unapproved retail pharmacies during the 4-month period we reviewed. The methadone shipped was produced for analgesic use and consisted of 5 and 10 milligram tablets and of ampoules used for hypodermic injection. On October 9, 1973, we informed FDA of the shipments made by the two wholesalers.

An FDA official, on October 11, 1973, said that in cases where such shipments have been made FDA could require the manufacturer to recall all stocks of methadone from the wholesaler and its unapproved customers and rescind the wholesaler's access to methadone. If shipments of methadone were made with intentional disregard to the regulations, FDA would consider such enforcement actions as seizure, prosecution, or injunction.

FDA investigated the two wholesalers during October 1973. FDA reported that one of the wholesalers had inadvertently made a single shipment of methadone to an unapproved retail pharmacy. The pharmacy's methadone was destroyed under FDA's supervision.

The other wholesaler replied, in response to FDA inquiries, that it had erred in interpreting Federal methadone regulations and that it had established tighter controls to insure that methadone would be shipped only to approved facilities. The wholesaler reported that the methadone at the retail pharmacies had either been destroyed, returned to the manufacturer, or dispensed by physicians to patients. FDA informed us that they planned to take no further followup action.

An association of retail druggists has contested FDA's authority to establish regulations prohibiting the distribution of methadone to retail pharmacies. The U.S. district court, in June 1974, ruled in favor of the drug association; however, the decision was stayed pending FDA's appeal to the court of appeals. In the interim FDA plans to continue enforcing the regulations.

SHIPMENTS IDENTIFIED BY ADDRESS LABEL INFORMATION

DEA regulations provide that registrants must employ precaution to guard against intransit losses of controlled substances. One of the precautions is to insure that shipping containers do not indicate that they contain controlled substances.

The manufacturers and wholesalers we visited did not mark the outside container or package to indicate that controlled substances were being shipped. Address labels, however, sometimes suggest that controlled substances are being shipped. For example, a shipment of methadone was sent through the mail from a manufacturer to a "Methadone Maintenance Treatment Program." According to DEA's regulations the name and address shown on the Federal order form must also be used in directing shipments to the purchaser. However, treatment program names containing phrases such as "Methadone Treatment Program" or "Drug Abuse Treatment Clinic" might disclose the contents of methadone shipments.

CONCLUSIONS

We are not presently proposing corrective actions to prevent shipments to unapproved pharmacies because FDA's authority to restrict the distribution of methadone to retail pharmacies is being determined by the courts. However, if the courts rule favorably for FDA, we believe the monitoring of this restriction would be best carried out through FDA's compliance program.

DEA regulations provide that containers used for controlled substances should not disclose the contents. Additionally, the regulations require that the name and address appearing on the shipping label agree with the name and address appearing on the Federal order form. Consequently, when a drug dispensing organization with a title such as "Methadone Maintenance Treatment Program" places an order for methadone, the contents of shipments can be inferred from the shipping label.

We believe that, for ordering methadone, registrants should be permitted to use organizational names which will provide anonymity for the shipments. For example, methadone ordered by the Methadone Maintenance Treatment Program might be shipped to MMTP.

RECOMMENDATION TO THE ATTORNEY GENERAL

We recommend that DEA encourage methadone dispensing organizations to modify their organizational titles on the Federal order forms so that the contents of methadone shipments are not inadvertently disclosed.

CHAPTER 4

SECURITY CONTROLS OVER METHADONE TRANSPORTATION

Registrants shipping controlled substances are required to select carriers providing adequate security to prevent thefts and losses. To determine the adequacy of security controls over methadone transportation we visited 8 carriers--7 contract and commercial carriers and 3 offices of the U.S. Postal Service--which shipped methadone.

The extent of the security provided by the carriers varied, depending on the carriers' standard security procedures and the services requested by registrants. Some carriers provided extensive security over methadone shipments at additional costs to the registrants. Other carriers transporting methadone, however, were not requested to provide any special security controls over methadone shipments. Carriers used by registrants usually were not informed that shipments contained methadone.

The bill of lading does not indicate that the packages or containers being shipped contain methadone but may indicate that drugs or medical products are being shipped. Carriers deliver methadone shipments to the addresses indicated on the packages or bills of lading. At the time of delivery, the carrier obtains a signed receipt indicating the number of packages or containers delivered. The bills of lading generally do not indicate that deliveries are to be made to specified authorized individuals. The carriers have no knowledge of who is authorized to receive and sign for shipments containing methadone.

Carriers transporting methadone are not required to register with DEA under CSA and are therefore not subject to DEA regulatory control. As a result DEA does not conduct periodic reviews of the security controls exercised by carriers in transporting methadone.

In selecting carriers to ship methadone, officials at manufacturers said that they considered the reputation and reliability of the carrier and/or the security services offered by the carrier in handling shipments. The officials also stated that for shipments containing narcotics or methadone under 20 ounces the Postal Service was used for delivery in accordance with guidelines issued by a predecessor agency of DEA.

Wholesalers' selections of carriers for methadone transportation were based primarily on the geographic area serviced by the carrier. Wholesaler officials said that consideration was given to the delivery service provided and reliability of the carrier.

Registrants do not obtain detailed information from carriers about their security procedures in handling controlled substances. Some carriers are reluctant to provide detailed information on their security procedures.

Two carriers visited handled methadone shipments in the same manner as money or other high value items. Their security services available for methadone shipments included armed guards, armored trucks, hand-to-hand receipt to fix accountability every time a shipment changed hands, and security protection during periods of layover.

The five other carriers we visited were not requested by registrants to provide any special security protection in handling shipments containing controlled substances. These carriers generally had no special procedures for handling methadone shipments.

Some registrants used the Postal Service to send shipments of methadone by insured parcel post with return receipt requested. Insured parcel post packages are handled by the Postal Service in the same manner as regular parcel post or first class mail. Insuring a parcel post package provides indemnification against loss but does not result in increased security protection.

DEA has not issued detailed guidelines for the shipping of controlled substances to assist registrants in selecting carriers which provide adequate security. DEA has issued general guidelines to registrants stating that (1) registrants are responsible for selecting carriers that provide adequate security and (2) if several quantities of controlled substances are lost or stolen when a particular carrier is used, the registrant is to take steps to use another carrier or means of transportation.

Registrants using the Postal Service's insured parcel post service did not use the most secure service provided by the Postal Service. Registered mail service provides features such as hand-to-hand receipt and security protection during shipment. DEA issued internal instructions to its compliance investigators that stated that manufacturers

and wholesalers should make shipments of methadone by registered mail. However, DEA has not directly notified registrants that this is one of the recommended means for making methadone shipments.

One of the carriers used to ship methadone offered additional security services that were not requested. During an 18-month period the carrier was involved in the loss or theft of five methadone shipments as well as a number of other controlled substance shipments. A DEA compliance investigator reported that once the carrier picked up controlled substances from the registrant no accountability documents were maintained to permit the tracing of shipments while in the possession of the carrier.

CONCLUSIONS

Although registrants are required to select carriers that provide adequate security to prevent diversion, DEA has not issued detailed guidelines to assist registrants in selecting carriers and the security services desirable for shipping methadone and other controlled substances. As a result, some registrants are not using the most secure service available from the Postal Service and some carriers.

RECOMMENDATION TO THE ATTORNEY GENERAL

We recommend that DEA establish detailed guidelines to assist registrants in selecting carriers for shipping controlled substances.

CHAPTER 5

SECURITY CONTROLS OVER THE RECEIPT OF METHADONE

To determine the adequacy of the controls over the receipt of methadone, we visited 2 State distribution facilities, 23 hospitals, and 29 treatment programs. The State distribution facilities and some of the hospitals further distributed methadone to approved treatment programs. Federal methadone regulations state that only licensed physicians, nurses, or pharmacists are to sign for and accept methadone deliveries.

The security procedures over the receipt and further distribution of methadone were generally adequate. However, some registrants receiving methadone from manufacturers or wholesalers need to improve their receiving procedures to insure that only authorized personnel are permitted to sign for and accept methadone deliveries. Our review, however, did not disclose any instances in which methadone was diverted because unauthorized persons signed for the receipt of methadone.

Methadone received from manufacturers and wholesalers at the facilities visited was usually stored in vaults or safes protected by alarm systems.

RECEIPT BY STATE DISTRIBUTION FACILITIES

The two State distribution facilities visited received methadone from bulk manufacturers for conversion into dosage form for ultimate distribution to affiliated treatment programs. Authorized pharmacists received and accepted methadone shipments at the facilities.

One of the State facilities prepared methadone dosages daily for dispensing by treatment programs. The other facility from time to time converted powdered methadone into a liquid for periodic delivery in gallon containers to the treatment programs. Methadone was shipped from the facilities to the programs in unmarked cardboard boxes or locked containers under the protection of armed guards. Delivery was made to an authorized nurse at the programs and a signed receipt was obtained and returned to the distribution facilities.

RECEIPT BY HOSPITALS

At the 23 hospitals visited, methadone was received for treating narcotic addiction and/or for analgesic purposes.

Four of the hospitals received methadone for analgesic purposes only, the other 19 hospitals received methadone for addicted patients. These 19 hospitals provided (1) inpatient narcotic addiction treatment, (2) further distribution of the methadone to hospital-affiliated treatment programs, or (3) both inpatient and outpatient treatment.

The hospital pharmacies maintained security and recordkeeping controls over the methadone received and distributed. The hospital pharmacies also prepared methadone dosages for dispensing to patients.

Methadone shipped to hospitals was generally delivered by carriers and was accepted in the receiving departments. Receiving department employees usually signed for the number of packages or containers delivered by the carrier. Four hospitals accepted methadone deliveries at their pharmacies; the other 19 hospitals generally accepted methadone deliveries at their receiving departments.

Receipt by unauthorized hospital personnel

Federal methadone regulations state that only authorized pharmacists are to receive and secure supplies of methadone at hospitals. At seven of the hospitals, receiving department personnel or warehousemen signed for and opened methadone shipments before sending them to the hospital pharmacy. Although pharmacy personnel verified most methadone shipments, the initial opening of methadone packages and containers by unauthorized personnel in the receiving department is contrary to regulations.

Federal methadone regulations require that the names of authorized pharmacists be submitted to FDA. Hospital officials at seven hospitals said that they were not aware of this requirement or had not filed such a list with FDA. Most hospitals visited did not maintain a list of pharmacists authorized to sign for methadone; however, the hospitals were able to provide such information on request.

RECEIPT BY TREATMENT PROGRAMS

At the 29 treatment programs visited, methadone was received either from a manufacturer or wholesaler or from the pharmacy of a hospital with which the program was affiliated. Nineteen of the treatment programs received methadone from hospitals. Discussions with officials of the 19 treatment programs indicated that varied security practices existed for transferring methadone from hospitals to treatment programs.

For 16 programs a hospital nurse or messenger, accompanied by an unarmed guard, delivered methadone to the programs--3 of these programs were located within hospital quarters. For two programs the hospital nurse or messenger was accompanied by an armed guard. For one program an unaccompanied hospital nurse delivered methadone to the treatment center located within the hospital.

Methadone was usually delivered to the treatment program or center in a locked, unmarked box. The hospital pharmacy obtained a signed receipt for the release of methadone delivered to the treatment program. Methadone remaining at the end of the day was returned to the pharmacy using the same security measures which were used earlier in the day unless the program had facilities to store unused methadone overnight.

Officials at six of the programs stated that they were not aware of the Federal methadone regulations requiring that only licensed practitioners receive methadone. At five of the treatment programs visited, program administrators, directors, and others who were not licensed practitioners were designated to receive methadone shipments. We noted, during our review, instances in which individuals other than licensed practitioners signed for the receipt of methadone.

CONCLUSIONS

At 11 hospitals and treatment programs, unauthorized persons signed for the receipt of methadone. Because our review was performed a few months after the Federal methadone regulations went into effect, it is possible that the newness of the regulations accounted in part for the unauthorized receipts. We believe that FDA and DEA should determine whether the unauthorized receipt of methadone is continuing and, if so, what educational or enforcement steps may be necessary to insure properly controlled receipt of methadone.

CHAPTER 6

IMPROVEMENTS NEEDED IN THE MONITORING OF INTRANSIT THEFTS AND LOSSES

DEA needs to improve the monitoring of intransit thefts and losses of controlled substances to identify registrants which need to improve their shipping or receiving procedures. To more effectively monitor intransit thefts and losses, DEA needs to improve its reporting system and develop procedures for following up on thefts and losses.

DEA regulations require registrants to report to the appropriate DEA regional office all thefts and significant losses of controlled substances. In reporting thefts and significant losses, registrants are to use a DEA Form 106 entitled "Report of Theft of Controlled Substance."

DEA regulations do not specify the type of information that is to be reported for intransit thefts and losses, and DEA has not issued any guidelines clarifying what should be reported. For example, DEA has not issued criteria to registrants defining what is meant by a "significant loss," leaving this to the registrant's interpretation. In addition the DEA data system does not systematically collect information on registrants and carriers experiencing intransit thefts or losses.

A review of drug theft reports indicated that registrants often omitted relevant information. The registrant frequently did not identify the carrier or the other registrant involved. Often, it was not readily discernible whether the registrant who submitted the report was the shipper or receiver. Other relevant information frequently omitted from reports was what precautions had been taken to prevent the theft or loss, what security procedures the carrier had been requested to provide, and what steps had been taken after the theft or loss or were being taken to prevent future thefts or losses.

DEA has issued revised regulations, effective August 15, 1974, that now require that the shipper report an intransit theft or loss. The revised regulations were issued because many intransit losses of controlled substances have not been reported to DEA and registrants were uncertain about who was to report an intransit loss.

As previously indicated, additional improvements in the reporting system are needed. Further, improved reporting procedures should provide DEA with the analytic capability needed to identify those carriers which are prone to thefts and losses and to initiate action in cases where registrants have experienced a number of intransit losses and thefts.

DEA requires that compliance investigations are to be conducted at manufacturers, distributors, and treatment programs at least once every 3 years, but there is no specific requirement that the shipping or receiving procedures of the registrant be reviewed. Our review of a number of DEA's compliance inspection reports did not specifically show whether shipping or receiving procedures had been reviewed. A timely review of shipping or receiving procedures could assist DEA in carrying out its compliance investigation program.

DEA has not developed procedures for its regional offices to monitor intransit thefts or losses or for following up with other law enforcement agencies.

DEA officials told us that DEA does not have the primary responsibility for investigating thefts or losses of controlled substances. However, the officials said that if a significant theft or loss were reported DEA would conduct an investigation or provide assistance to other law enforcement agencies. Although registrants should report thefts or losses occurring in interstate commerce to the Federal Bureau of Investigation (FBI), DEA has not issued instructions informing registrants to take this action.

A review of registrants' drug theft reports during the 18-month period reviewed showed that in 134 thefts or losses of controlled substances the registrant did not report the diversions to the FBI, postal inspectors, or local police.

DEA officials stated that they did not routinely request or obtain the investigative reports of other law enforcement agencies that may have investigated a theft or loss reported by a registrant. We believe such information could be useful to DEA in carrying out its compliance investigation and criminal enforcement programs.

The following examples are indicative of the need for improved followup procedures on intransit thefts and losses of controlled substances.

Example 1. A registrant, during a 3-month period in 1973, reported 6 barbiturate thefts or losses ranging from 100 to 1,000 dosage units. Four of the losses reported by the registrant were in shipments to the same purchaser. Of the six shipments, two were transported by the same carrier (carriers for the other losses were not identified). Three of the diversions were reported to the local police, but there was no indication that police investigations were conducted. Further, at the time of our review, DEA had not investigated any of the reported losses.

Example 2. A registrant reported to DEA eight intransit losses of a Schedule II controlled substance which occurred during a 13-month period. The losses ranged from 50 to 3,900 dosage units. There was no indication that the registrant reported the losses to a law enforcement agency other than DEA for investigation. DEA regional officials told us they had not investigated any of the losses.

CONCLUSIONS

The reporting system for intransit thefts and losses is not adequate for DEA to effectively monitor intransit thefts and losses and follow up on such diversions. Improvements in reporting are needed to identify registrants' shipping or receiving practices needing review. Some registrants have reported a number of intransit thefts and losses of controlled substances for which there were no investigations or followup actions by DEA. DEA has not developed procedures for regional monitoring of thefts and losses or for following up with other law enforcement agencies.

RECOMMENDATIONS TO THE ATTORNEY GENERAL

We recommend that DEA:

--Revise the regulations on reporting thefts and significant losses of controlled substances to clarify what is meant by "significant losses" and what information should be reported to DEA when an intransit theft or loss of a controlled substance occurs.

--Insure that thefts and losses are reported to appropriate law enforcement agencies.

--Develop procedures for following up and coordinating with other law enforcement agencies investigating intransit thefts or losses.

--Establish procedures for monitoring reported in-transit thefts and losses to identify registrants which should have their shipping or receiving practices reviewed.

CHAPTER 7

SCOPE OF REVIEW

We primarily reviewed the adequacy of security controls over methadone distribution. We reviewed the applicable shipping, transporting, and receiving procedures at 5 methadone manufacturers, 14 distributors, 2 State distribution facilities, 29 treatment programs, 23 hospitals, 7 carriers, and 3 post offices. At each of the facilities we interviewed officials; reviewed procedures and records; and, when possible, observed the shipping and receiving of methadone and other controlled substances.

The review was also conducted at DEA headquarters, Washington, D.C., and at DEA regional offices in Kansas City, Missouri; Detroit, Michigan; and New York, New York. We also did work at the DEA district offices in Indianapolis, Indiana, and Cincinnati, Ohio. We interviewed DEA and FDA headquarters officials and reviewed laws, regulations, procedures, and practices relating to the distribution and transportation of methadone and other controlled substances. We reviewed reported thefts and losses of methadone and other controlled substances for the 18-month period ended June 30, 1973.

CHARLES B. RANGEL
19TH CONGRESSIONAL DISTRICT
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GEORGE A. DALLEY
ADMINISTRATIVE ASSISTANT

Congress of the United States
House of Representatives
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DISTRICT OF COLUMBIA

DISTRICT OFFICE:
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NEW YORK, NEW YORK 10027
TELEPHONE: 212-866-8600

MRS. VIRGINIA L. BELL
DISTRICT ADMINISTRATOR

PLEASE RESPOND TO
OFFICE CHECKED:
☑ WASHINGTON
☐ NEW YORK

April 17, 1973

The Honorable Elmer Staats
Comptroller General
of the United States
General Accounting Office
441 G. Street, N.W.
Washington, D.C. 20548

Dear Mr. Comptroller General:

It has recently come to my attention that the security precautions in the transportation of methadone to medical and pharmaceutical institutions throughout the country are slipshod and incompetent. Various spokesmen have cited incidents of theft and misplacement of the narcotic. It is documented that over 12,000 methadone pills were lost in 1972.

The dangerous and illegal use of methadone approaches near-epidemic proportions. To exacerbate the situation by allowing lax security procedures to continue is truly absurd.

I ask the General Accounting Office to begin a thorough investigation of the security procedures used in the transportation of methadone and other schedule II drugs. I would hope that your investigation and the recommendations resulting therefrom would lead to a reform of existing security procedures, for to let the current situation continue would be unforgiveable.

I look forward to the start of your investigation.

Sincerely,

Charles B. Rangel
Member of Congress

APPENDIX II

PRINCIPAL OFFICIALS RESPONSIBLE FOR ACTIVITIES DISCUSSED IN THIS REPORT

	Tenure of office	
	From	To
DEPARTMENT OF JUSTICE		
ATTORNEY GENERAL OF THE UNITED STATES:		
William B. Saxbe	Jan. 1974	Present
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:		
John R. Bartels, Jr.	Oct. 1973	Present
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
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE		
SECRETARY OF HEALTH, EDUCATION, AND WELFARE:		
Casper W. Weinberger	Feb. 1973	Present
Frank C. Carlucci (acting)	Jan. 1973	Feb. 1973
Elliot L. Richardson	June 1970	Jan. 1973
ASSISTANT SECRETARY FOR HEALTH:		
Charles C. Edwards	Apr. 1973	Present
Richard L. Seggel (acting)	Dec. 1972	Apr. 1973
Merlin K. Duval, Jr.	July 1971	Dec. 1972
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

a/Effective July 1, 1973, the Bureau was merged with several other Federal agencies involved with drug law enforcement into the new DEA. All the functions of the Bureau were transferred to DEA.

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

B-164031(2)

The Honorable Charles B. Rangel
House of Representatives

Dear Mr. Rangel:

This is our report on the adequacy of security controls over the methadone distribution system. Both the Food and Drug Administration, Department of Health, Education, and Welfare, and the Drug Enforcement Administration, Department of Justice, are engaged in the regulatory control of methadone.

This review was made in accordance with your April 17, 1973, request. As requested by your office, we did not submit the report to the Federal agencies involved for their official comments. However, we did discuss our findings with officials of the Drug Enforcement Administration and have incorporated their comments.

We are sending copies of this report to the House and Senate Committees on Government Operations; the House and Senate Committees on Appropriations; the Director, Office of Management and Budget; and the Attorney General.

Sincerely yours,

Elmer B. Staats
Comptroller General
of the United States