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Because of the growing abuse of legitimate drugs and the potential for diversion by those who dispense drugs, an examination was made of the Federal and State preventive efforts at the retail level. Under the Controlled Substances Act, the Drug Enforcement Administration (DEA) is provided with extensive authority to register and regulate drug manufacturers and distributors but not practitioners. The act authorizes the agency to register practitioners authorized under State laws to dispense and prescribe controlled substances. Security regulations for safeguarding drugs are virtually nonexistent, and the agency lacks statutory authority to establish stronger ones. Findings/Conclusions: The Drug Enforcement Administration is trying to assess and upgrade State capabilities to evaluate practitioners. Its largest effort involves diversion investigation units composed of State investigators and Federal agents who emphasize criminal investigations of practitioners. From 1972 to June 30, 1976, about 1,200 arrests have resulted from the activities of 11 of these units. Two basic approaches to solving the problem are by strengthening the direct role of the DEA or by continuing and accelerating the agency's role to help States carry the major burden. Recommendations: Congress should change the DEA's role by authorizing it to either exercise direct regulatory authority over retail-level practitioners or implement grant programs for assisting States in controlling diversion. Because of the potentially great cost of a change in the DEA's mission, the Attorney General should study the costs and benefits of these approaches or any other method to combat this problem. (Author/DB)

5658

# *REPORT TO THE CONGRESS*

## *BY THE COMPTROLLER GENERAL OF THE UNITED STATES*

# Retail Diversion Of Legal Drugs-- A Major Problem With No Easy Solution


Diversion and abuse of legal drugs may be involved in as many as 7 out of every 10 drugs reportedly being abused or resulting in deaths. Most of these drugs are diverted from the dispensing or retail level by practitioners such as physicians and pharmacists.

The Drug Enforcement Administration is unable to control retail diversion because of a lack of statutory authority, weak regulatory requirements, and inadequate resources. States are not equipped to combat diversion because of shortcomings in legislation, organization, and resources.

GAO recommends several actions that could reduce such diversion.



GGD-78-22

MARCH 10, 1978

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

B-175425

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

This report discusses the problem of legal drugs being diverted from the dispensing level of the drug distribution system and suggests several actions to help Federal and State agencies reduce this diversion.

Our review was made 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).

We are sending copies of this report to the Acting Director, Office of Management and Budget; the Attorney General; and the Secretary, Department of Health, Education, and Welfare.

Comptroller General
of the United States

COMPTROLLER GENERAL'S
REPORT TO THE CONGRESS

# RETAIL DIVERSION OF LEGAL DRUGS--A MAJOR PROBLEM WITH NO EASY SOLUTION

## D I G E S T

About 7 million Americans use legal drugs such as barbiturates, tranquilizers, and amphetamines, for nonmedical purposes--often with disastrous results. Used alone or with other drugs including alcohol, the legal drugs may be involved in as many as 7 out of every 10 drugs reportedly being abused or resulting in deaths. Yet, control of these drugs at the dispensing or retail level, their major point of diversion, by responsible Federal and State agencies, has been largely nonexistent.

More than a half-million practitioners, mainly physicians and pharmacists, are registered with the Drug Enforcement Administration to prescribe, dispense, or administer drugs. While the vast majority of these practitioners are law abiding, an estimated 200 to 243 million dosage units are diverted annually from retail distribution. Although thefts account for some of the loss, most diversions seem to come from false prescriptions, illegal sales, and overprescribing. A physician, for example, can sell drugs or prescriptions to individuals for profit. Or a pharmacist may knowingly fill a forged prescription or sell drugs without a prescription. (See p. 3 and pp. 5 to 11.)

The Drug Enforcement Administration's efforts to control retail diversion are severely restricted because of inadequate statutory authority, weak regulatory requirements, and inadequate resources. The Controlled Substances Act provides the agency with extensive authority to register and regulate drug manufacturers and distributors, but not practitioners. Under the act, the agency merely registers practitioners authorized under State laws to dispense and prescribe controlled substances. Security regulations for safeguarding drugs are virtually nonexistent, and the agency lacks statutory authority to establish stronger ones. (See pp. 12 to 14.)

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Since Federal authority to deny registrations is limited, practitioners have little to fear from violating regulatory requirements. The Drug Enforcement Administration can suspend or revoke a practitioner's registration for misrepresentation, loss of a State license, or a drug-related felony conviction. Yet this authority does little in regulating practitioners since it depends on State agencies which generally are reluctant to take disciplinary measures. Most States do not consider a practitioner's conviction for violating drug laws as grounds for action against his or her license. Further, when actions are taken, the Drug Enforcement Administration generally is not informed. (See pp. 14 to 15.)

Given this situation, the problem of diversion requires a criminal approach toward the diverters. This is a difficult way to get results because of the numerous and stringent evidence requirements needed to prove that the practitioner's intent was criminal. (See pp. 15 to 17.)

If stronger regulatory requirements were established for practitioners, the Drug Enforcement Administration would need additional resources to effectively monitor the dispensing of drugs at the retail level. Its 197 compliance investigators are fully occupied in monitoring drug manufacturers and distributors. (See pp. 18 to 19.)

Because of these constraints, the agency can merely assist States to control retail diversion. But most States are incapable of dealing with the problem because of inadequate legislation, ineffective organization, and inadequate resources. (See pp. 19 to 24.)

The Drug Enforcement Administration is trying to assess and upgrade State capabilities to evaluate practitioners. The agency's largest effort involves diversion investigation units--enforcement teams composed of State investigators and Federal agents--which emphasize criminal investigations of practitioners. Of the 14 units established since 1972, 12 are

still operating. From 1972 to June 30, 1976, about 1,300 arrests have resulted from the activities of 11 units that became operational during this period. (See pp. 25 to 28.)

Most of the Drug Enforcement Administration's other efforts provide no immediate relief since they stress planning, experimental projects, and long-term solutions to the problem rather than the present need to investigate violators. (See pp. 28 to 32.)

There are two basic approaches to solving the problem--strengthening the direct role of the Drug Enforcement Administration until it parallels its role with respect to manufacturers and distributors, or continuing and accelerating the agency's assistance role to help States carry the major burden. Regardless of the approach taken, controlling retail diversion will be a time-consuming task and will require legislative changes and increased resources. (See pp. 33 to 35.)

The Congress should change the Drug Enforcement Administration's role by authorizing it to either

--exercise direct regulatory authority over retail-level practitioners or

--implement grant programs for assisting States in controlling diversion.

Because of the potentially great cost of a change in the Drug Enforcement Administration's mission, GAO recommends that the Attorney General study the costs and benefits of these approaches or any other methods to combat this problem.

The Department of Justice told GAO that "in general" it believes that this report provided "an accurate description of the retail diversion problem facing the Drug Enforcement Administration." Concerning the alternative approaches to combating the problem, Justice favored the State-assistance approach rather than a stronger, more direct role. (See app. I.) The Department of Health, Education, and

Welfare said it had no substantive comments on the matters discussed in the report. (See app. II.)

# Contents

## ABBREVIATIONS

| | |
|---|---|
| DAWN | Drug Abuse Warning Network |
| DEA | Drug Enforcement Administration |
| FDA | Food and Drug Administration |
| GAO | General Accounting Office |
| HEW | Department of Health, Education, and Welfare |
| LEAA | Law Enforcement Assistance Administration |
| NIDA | National Institute on Drug Abuse |

# CHAPTER 1

## INTRODUCTION

The traditional drug problem in our society--abuse of opiates, cocaine, and other drugs imported, produced, and distributed illegally--has been widely documented and publicized. Less recognized, however, is the diversion and abuse of legal drugs distributed and dispensed legitimately through manufacturers, packagers, distributors, and retail-level practitioners.

For some time, we have recognized the need for increased monitoring of drug distribution activities. We previously reported on Federal efforts to prevent diversion of legal drugs by manufacturers and distributors. 1/ Because of the growing abuse of legitimate drugs and the potential for diversion by those who dispense drugs, we examined Federal and State preventive efforts at the retail level.

## THE REGULATION OF CONTROLLED SUBSTANCES

A primary responsibility of the Department of Justice's Drug Enforcement Administration (DEA) is preventing the diversion of legal controlled substances, such as narcotics and dangerous drugs (stimulants, depressants, and hallucinogens), into the illicit market. Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 801 *et seq.*), referred to as the Controlled Substances Act, authorizes the Attorney General to regulate the manufacturing, distributing, and dispensing of controlled substances. The Attorney General has given this authority to the DEA Administrator.

The Controlled Substances Act and the Code of Federal Regulations (21 C.F.R. 1301) attempt to create a closed distribution system extending from the manufacturer to the ultimate user. A regulatory system was established to prevent diversion of controlled substances while assuring an adequate supply for legitimate medical, research, and industrial needs.

Under the act, controlled substances are divided into

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1/ "Efforts to Prevent Dangerous Drugs From Illicitly Reaching the Public," (B-175425, Apr. 17, 1972), and "Improvements Needed In Regulating and Monitoring the Manufacturing and Distribution of Licit Narcotics," (GGD-75-102, Aug. 28, 1975).

five schedules based on their potential for abuse, accepted medical use, and accepted safety under medical supervision. Schedule I includes substances without accepted medical use or safety and with high abuse potential, such as heroin. Schedule II includes substances with accepted medical uses, but with a high abuse potential, such as morphine, barbiturates, and amphetamines. Schedules III through V include substances with accepted medical uses and a decreasing abuse potential, such as paregoric and cough syrups containing codeine. The placement of a drug in any one of these schedules determines the nature and level of control exercised to prevent its abuse and diversion. Schedules I and II controlled substances are more strictly controlled than schedules III through V substances.

DEA, with the help of the Food and Drug Administration (FDA), Department of Health, Education, and Welfare (HEW), enforces and administers the regulatory controls prescribed by the act and the Code of Federal Regulations. These controls include:

--Registration: All manufacturers, distributors, and dispensers of controlled substances register annually with DEA and are referred to as registrants.

--Quotas: For each basic class of controlled substances in schedules I and II, DEA, with FDA's assistance, establishes (1) a production quota for the industry, (2) a manufacturing quota for each bulk manufacturer, and (3) a procurement quota for each dosage manufacturer.

--Recordkeeping: Except for limited exemptions available to physicians and researchers, handlers keep full records of all manufacturing, purchases, sales, and inventories of controlled substances.

--Distribution: Manufacturers and distributors sell schedules I and II drugs only upon receiving an approved DEA order form. For other scheduled drugs, the supplier is obligated to verify the customer's registration number with DEA records.

--Dispensing to patients: Schedule I drugs are to be used only in research situations. Prescriptions are required by FDA for most schedules II, III, and IV drugs, and restrictions are placed on obtaining prescriptions and refills.

--Security: Registrants comply with certain security

requirements.

--Investigations: DEA conducts periodic compliance investigations of registrants.

In addition, penalties are provided and provisions are established to deny, revoke, or suspend registrations.

As of October 1976, more than 540,000 manufacturers, distributors, and dispensers were registered with DEA. As shown below, 532,408, or 98 percent, were at the dispensing or retail level--physicians, dentists, veterinarians, retail pharmacies, hospitals, and teaching institutions--and were collectively called "practitioners."

| Registrant | | Number |
|---|---|---|
| Manufacturers | | 515 |
| Distributors | | 1,660 |
| Researchers, laboratories, importers, exporters, and narcotic treatment programs | | 6,144 |
| Retail dispensers: | | |
| Doctors | 464,405 | |
| Retail pharmacies | 53,713 | |
| Hospitals/clinics | 13,553 | |
| Teaching institutions | 737 | |
| Total | | 532,408 |
| Total registrants | | 540,727 |

Under its scheduled investigation program, DEA's plan is to make at least one compliance investigation every 3 years at manufacturers, distributors, and methadone treatment programs. At the retail level of the distribution system, DEA performs compliance investigations when it gets a complaint or a lead and cooperates with individual State authorities in their regulatory control.

Individual States control practitioners, primarily through licensing and professional boards which monitor the qualifications and conduct of the various types of practitioners. Most States also have some type of controlled substances act aimed at preventing diversion.

According to DEA, about 30,000 drug products are subject to the Controlled Substances Act, and about 15 billion dosage units are manufactured each year. For these

legitimate drugs, practitioners are the final link in the distribution chain since they prescribe, administer, or dispense controlled substances to the ultimate users.

SCOPE OF REVIEW

We examined the efforts being made to prevent diversion of controlled substances at the retail level. Most of our work focused on diversion by doctors and pharmacists.

We examined applicable laws, regulations, procedures, and records and interviewed responsible representatives of DEA, FDA, HEW's National Institute on Drug Abuse (NIDA), the Law Enforcement Assistance Administration (LEAA), and officials of licensing and/or regulatory agencies in four States. We also reviewed a study of State capabilities to control practitioners, prepared for DEA by Arthur Young and Company. 1/ Because of the study's depth and comprehensiveness, its findings have been considered in this report.

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1/ This $225,000 study of professional licensing boards and professional associations was commissioned by DEA, FDA, and NIDA in 1974.

## CHAPTER 2

## DRUG DIVERSION AT THE RETAIL LEVEL: NATURE AND EXTENT OF THE PROBLEM

In November 1976, the President's Strategy Council on Drug Abuse reported that 7 million people used prescribed drugs, such as barbiturates, tranquilizers, and amphetamines, for nonmedical purposes. The use of barbiturates and tranquilizers was ranked with heroin use as a major social problem, and unsupervised amphetamine use was also considered serious.

DEA believes that diversion from legal suppliers is the primary barbiturate source and that amphetamine use is sustained through diversion and illegal production. Reports show that barbiturates and tranquilizers were involved in more drug abuse and death incidents than heroin and its metabolized form, morphine.

Although the exact amounts and sources of controlled substances being abused are unknown, much information shows that a large part of the Nation's drug abuse problem stems from the diversion of legal drugs. DEA believes that the retail level is the greatest source of diversion in the drug distribution system.

### THE RETAIL LEVEL IS THE MAJOR SOURCE OF DIVERSION

Based on estimates and reported drug thefts, DEA estimates that diversion of controlled substances from all sources is about 250 to 270 million dosage units annually, with the retail level accounting for approximately 80 to 90 percent of the total--200 to 243 million dosage units. Opportunity for diversion appears greatest at the retail level because of the large number of practitioners.

There is currently no system capable of quantifying the total illicit drug market in terms of illegal production and diversion from domestic and foreign sources. Accordingly, no definitive statistics exist which show the amount of diversion occurring at the manufacturing, distribution, and retail levels. However, indications are that much of the abuse involves legal drugs diverted at the retail level.

### The abuse of legal drugs

During the fiscal years 1974-76, DEA's Drug Abuse

Warning Network (DAWN) 1/ reported over 706,000 drug abuse mentions, about 34,000 of which were involved in drug deaths. The statistics showed that 51 percent of the mentions concerned polydrug abuse--the use of a combination of drugs or drugs and alcohol. For drug death mentions the polydrug abuse rate rose to almost 73 percent. Of the 35 leading drugs of abuse reported by DAWN, drugs which were legally available were present in about 70 percent of the drug abuse and death mentions. 2/

It is not possible to accurately determine how many of these drug mentions can be attributed to drugs diverted at the retail level. This is because the abuser may not know the source of the drug or, in the case of drug deaths, it is not possibile to discriminate between a legally produced drug and one produced in an illegal laboratory.

Some indication of diversion at the retail level can be obtained, however, from a DAWN report on drug abuse for April 1974 to April 1975. During this period, DAWN reported 192,000 episodes 3/ of drug abuse, including 7,176 deaths. This report showed that of the 15 leading drugs of abuse, 10 were legally controlled substances which are prescribed, dispensed, and/or administered by physicians and pharmacies.

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1/DAWN is a nationwide program to identify drug abuse. Selected hospitals, medical examiners, and crisis centers in 24 of the more than 250 standard metropolitan statistical areas report drug deaths and instances in which an abuser sought treatment or other help. The substances involved in the abuse are called "drug mentions." Noncontrolled substances such as alcohol are included in the program.

2/Morphine and cocaine were considered to be illicit drugs in our computation since (1) most DAWN morphine mentions by medical examiners are a result of heroin abuse (heroin is metabolized by the body into morphine), and DEA makes no distinction in its published statistics between heroin/morphine death and/or injuries and (2) DEA has reported that virtually all available cocaine is of illicit origin. If these drugs were considered legal substances, the percentage of licit drug abuse would increase.

3/An episode is a visit to a hospital or a crisis center or a death reported by a medical examiner.

The order of use of these controlled substances follows.

1. Diazepam--the tranquilizer "valium," the most abused drug in the Nation.
2. Secobarbital--the sedative "seconal."
3. d-Propoxyphene--the synthetic analgesic "darvon."
4. Chlordiazepoxide--the tranquilizer "librium."
5. Methadone--the narcotic analgesic heroin substitute.
6. Speed--stimulants such as desozyn.
7. Amphetamine--stimulants such as benzedrine.
8. Flurazapam--a sedative.
9. Secobarbital/Amobarbital--the barbiturate sedative "tuinal."
10. Methaqualone--nonbarbiturate sedatives such as "quaalude."

The report identified the sources for 5 of the 10 substances as follows.

| Source | Drug mentions | Percent |
|---|---|---|
| Legal prescription | 24,296 | 49.9 |
| Street buy | 3,664 | 7.5 |
| Gift | 1,072 | 2.2 |
| Stolen | 942 | 2.0 |
| Forged prescription | 379 | 0.8 |
| Other | 110 | 0.2 |
| Unknown | 18,206 | 37.4 |
| Total | 48,669 | 100.0 |

As can be seen from the above table, the predominant source for those drug mentions where the source could be identified was the retail level.

Significant retail diversion--additional indicators

Since the enactment of the Controlled Substances Act, DEA has concentrated its efforts on manufacturers and wholesalers, each of which has been investigated at least once, and for many, two or three times. DEA contends that (1) security and recordkeeping have improved greatly for manufacturers and wholesalers, so that robberies and diversion have been minimal and (2) complaints and leads regarding diversion relate almost entirely to retail sources.

The results of DEA's emphasis on manufacturers and wholesalers are reflected in the distribution of drugs in the illicit market. In 1975, the Domestic Council Drug Abuse Task Force reported that if wholesale diversion were the major source of supply, the distribution of brands in the illegal market would be skewed in some manner. Because the distribution of brands in the illegal market paralleled the distribution of brands in the legal market, the Council's report concluded that retail diversion was predominant.

In terms of magnitude, the only hard data available on retail diversion are thefts reported by registrants to DEA. As shown below, 123.6 million dosage units of various controlled substances were diverted in 26,877 thefts during fiscal years 1974-76. Most of these thefts occurred at the retail level.

| Type of registrant | No. of thefts | Dosage units stolen (millions) |
|---|---|---|
| Pharmacies | 20,172 | 96.2 |
| Practitioners | 1,229 | 4.5 |
| Manufacturer/distributor | 3,261 | 19.3 |
| Other | 2,215 | 3.6 |
| Total | 26,877 | 123.6 |

Opinions differ on the most likely source of retail diversion. DEA contends, without documentary support, that drug thefts account for no more than 20 percent of the total diversion. One DEA official believes that unintentional diversion by physicians is the major source, citing that diazepam--the largest selling tranquilizer and the most commonly prescribed drug in the Western World--is the leading drug of abuse.

In a recent State survey, regulatory boards thought that pharmacy thefts were the major source of diversion while professional health associations listed multiple prescriptions as the major source. Compliance investigation units felt that forged prescriptions and excessive prescriptions were also major problem areas.

Fourteen special investigative units were formed at the State and local level to look at retail diversion, primarily illegal distribution. One unit was not formed until 1977. As indicated below, special investigative projects show that a problem exists beyond that reflected

by theft statistics.

--According to DEA, a study of prescriptions issued by 200 doctors concluded that 25 were overprescribing.

--Project Script, a DEA study of pharmacist practices, showed that 56 percent of the forged prescriptions were filled.

--A DEA official stated that an investigation covering 70 pharmacies and physicians in the San Francisco area showed that the most prevalent method of diversion was practitioners selling prescriptions for profit.

--In a study on the pharmacy theft situation, DEA believed that most of the legal dosages being abused were obtained by means other than theft.

## HOW RETAIL DIVERSION OCCURS

Retail diversion of legally produced controlled substances occurs through thefts and the improper activities of (1) physicians in private practice, hospitals, and medical schools, (2) pharmacists in retail and institutional pharmacies, and (3) the general public. The diversion can be intentional for profit and abuse, intentional in a misguided effort to help those in need, or unintentional due to carelessness.

### Thefts

Aside from armed robberies, thefts of drugs and prescription pads can be committed by registrants' employees, drug addicts and abusers, and "pushers" for either their own use or distribution to others. Individuals can also steal controlled substances and prescriptions from those who had legally received them.

For example, a physician's nurse and the nurse's husband in Michigan pleaded guilty to charges of stealing 287,251 pills from her employer and selling them for $25,000 to an undercover agent posing as a dealer. The pills cost $9,762 wholesale and could have been sold on the street for about $250,000. Two women in Illinois were arrested for illegal possession after receiving controlled substances obtained by a forged prescription. The investigation revealed they were part of a burglary ring specializing in stealing blank prescription pads from physicians' offices.

## Diversion by physicians

Physicians can engage in intentional diversion for profit by selling controlled substances or prescriptions to individuals who have no legitimate medical need. For example, a New Jersey physician was arrested for the alleged sale of 2,200 dosage units of controlled substances. A New York physician was arrested for allegedly writing 5,000 illegal prescriptions in 3 months. Law enforcement officials estimated he made $100,000 profit.

Physicians can also intentionally divert drugs to support their own addiction. An investigation undertaken at the request of a New York physician's wife disclosed that the doctor had stopped practicing medicine and was personally consuming all the controlled substances he ordered. He would write prescriptions in the names of his wife and children and keep the drugs for his own use.

Physicians can unintentionally divert controlled substances by carelessly prescribing and dispensing them in an effort to satisfy their patients' needs. For example, they can prescribe or dispense narcotics or dangerous drugs when a nonprescription medication or an uncontrolled substance could serve the same purposes. Physicians could prescribe or dispense an excessive quantity so the patient does not have to return frequently.

## Diversion by pharmacists

Pharmacists can intentionally divert controlled substances for profit by illegally selling them. For example, law enforcement officials estimate that a New Jersey pharmacist diverted approximately 8,000 bottles of schedule V codeine cough syrup yearly.

Pharmacists can both knowingly and unknowingly fill false prescriptions. Under the Controlled Substances Act, the pharmacist is responsible for filling proper prescriptions. In Washington, D.C., three pharmacies filled prescriptions that had been forged, mechanically copied, or incompletely written. They were charged with a total of 1,178 separate violations.

Pharmacists may feel pressured to illegally dispense controlled substances. For example, a North Carolina pharmacist admitted selling a controlled substance to an undercover agent without a prescription. The pharmacist testified he was alarmed by the agent's long hair, beard, and shabby clothes and wanted "to get rid of him." The

pharmacist may also intentionally illegally dispense drugs to help or satisfy a customer, friend, or relative who does not have a prescription or has one that is obviously invalid.

Diversion by the public

In addition to the theft of drugs and prescription pads, the public can improperly obtain controlled substances at the legitimate retail level in a number of ways. For example, individuals can

--print their own prescription pads,

--obtain prescriptions and controlled substances by feigning a medical need, or

--obtain multiple prescriptions from different physicians.

## CHAPTER 3

## PROBLEMS IN CONTROLLING RETAIL DIVERSION

Retail diversion has been a neglected problem at the Federal and State levels. Limited statutory authority and resources, weak regulatory requirements, and the large number of retail outlets restrict DEA's efforts to control retail diversion. As a result this responsibility has been given to the States, which generally do not have the capability or, in some cases, the desire to provide aggressive antidiversion programs.

Under the Controlled Substances Act, DEA is not limited solely to interstate enforcement of controlled substances. Although it has the authority to inspect registrants, DEA does not directly control retail diversion. Under the act, there are significant differences in its regulatory authority among the various handlers of licit drugs, and thus differences in its power to motivate compliance. DEA has extensive authority over manufacturers and distributors in the registration process, to deny, revoke, and suspend registrations, and concerning security and recordkeeping. These provisions are weaker for retail registrants; DEA has little regulatory authority and therefore cannot effectively deal with retail diversion. In addition, DEA's resources are inadequate to insure that established controls are being followed by the vast number of registrants.

Because of these constraints, DEA concentrates on the wholesale levels. It views its role as motivating and assisting States to suppress retail diversion and becoming directly involved only when necessary.

### DEA's REGULATORY AUTHORITY OVER RETAIL-LEVEL REGISTRANTS IS LIMITED

Under the act's registration provisions, DEA's authority to regulate the various handlers of legal drugs differs significantly. DEA can grant or deny registration for manufacturers and distributors under many conditions, and thus the act's registration provisions are a basic regulatory tool. However, the act's provisions do not allow DEA to similarly regulate practitioners.

Under the act's registration provisions for manufacturers and distributors, DEA must determine whether the registration would be consistent with the public interest and with U.S. international obligations. In determining

public interest, the act lists the following factors which DEA must consider.

--Maintenance of effective controls against diversion.

--Compliance with applicable State and local law.

--Previous Federal or State conviction relating to the manufacture, distribution, or dispensing of controlled substances.

--Past experience in the manufacture, distribution, and dispensing of controlled substances and in the establishment of effective controls against diversion.

--Such other factors as may be relevant to and consistent with the public health and safety.

In addition, the promotion of technical advances in manufacturing these substances and the development of new substances are considered in the public interest determination for manufacturers.

None of these provisions apply to registrations at the retail level. Practitioners are entitled to be registered merely if they are authorized to handle controlled substances by the State in which they practice. No positive or negative findings by DEA are required before registration.

As with registrations, DEA has limited statutory authority to impose physical security requirements on practitioners. DEA can specify detailed physical security requirements for manufacturers and distributors which include (1) construction specifications for safes, cabinets, and vaults, (2) alarm systems, (3) accessibility to storage areas, and (4) manufacturing, processing, packaging, labeling, and distributing activities. However, DEA cannot require practitioners to maintain effective security controls under the registration provision in the act.

Federal regulations issued by DEA require only that (1) a practitioner not allow access to controlled substances to any employee who has been denied a DEA registration and (2) controlled substances be stored in a "securely locked, substantially constructed cabinet." These regulations permit pharmacies and institutional practitioners to disperse certain controlled substances throughout the stock of noncontrolled substances to obstruct theft.

These minimal requirements show the limited authority of DEA and even these requirements may not be binding on practitioners. For example, an assistant U.S. attorney wanted to file a class action suit so that pharmacies would provide better security to prevent the various types of thefts occurring in his district. In May 1976 DEA reported that it was against this approach because the promulgated regulations were "ultra vires acts" 1/ and such a suit would reveal DEA's weak legal authority.

These differences in authority give DEA greater leverage at the upper distribution levels in generating compliance than at the retail level. DEA can deny reregistration for manufacturers and distributors if it decides that the registrant's continued noncompliance is not in the public interest. On the other hand, DEA cannot deny registration for practitioners since practitioners are entitled to registration if they are authorized to handle controlled substances by the States.

DEA can revoke or suspend registration but only under the extreme conditions specified in the act. A registrant must have

--materially falsified a registration application,

--been convicted of a drug felony, or

--had his or her State license or registration suspended, revoked, or denied.

From January 1973 to May 1976, records provided by DEA showed that only about 64 physicians and pharmacies in 28 States had their registrations suspended or revoked.

The limitations in DEA's statutory authority severely restrict its ability to regulate practitioners. This situation is aggravated because:

--State agencies have shown a reluctance to revoke a license or prosecute a violator.

--Felony convictions are difficult to obtain.

--Revocation proceedings are time consuming.

--DEA lacks the resources to monitor practitioners.

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1/Acts beyond the scope or in excess of legal power or authority.

State agencies' reluctance to discipline practitioners

State boards have shown reluctance to discipline violators. For example, DEA stated that in one State, the boards appeared to have sufficient legal authority to enforce the laws but would rather "slap hands" than take affirmative action. In another State the board could revoke and suspend licenses but, according to DEA, political and professional considerations often precluded any strong action against all but the most flagrant violators. Where action was taken, the penalty was usually 1 year's probation.

One DEA regional director reported that a medical board in one State and a pharmacy board in another believed that the boards should not be required to take disciplinary action against their members. The boards felt that a doctor's or pharmacist's license should be revoked only upon their conviction in a Federal court. Also, the director reported that the State attorney general's office in one of the States expressed a similar opinion. It believed that the State court or licensing agency would not take civil or criminal action until the U.S. attorney secured a conviction.

Even under these conditions, disciplinary measures are not always taken. According to the Young study (see p. 4), about 78 percent of the boards did not consider a conviction for violating a State or Federal drug law as grounds for action against a license. When action was taken, such as a State drug registration revocation and conviction of drug crimes, over two-thirds of the regulatory agencies did not inform DEA. In agreements with DEA or predecessor agencies, State agencies responsible for retail diversion had agreed to provide such information following their investigations and termination of legal or administrative actions. (State capabilities are further discussed on p. 19.)

Felony convictions are difficult to obtain

If State regulatory agencies do not take licensing actions, DEA and State agencies may initiate a civil action or criminally prosecute the registrant. In some cases, registrants have voluntarily surrendered their registrations in lieu of criminal prosecution. In others involving civil sanctions--which according to DEA are relatively difficult to apply--huge fines have resulted

in closing a business.

The decision to prosecute criminally or initiate a civil action generally stems from the different record-keeping requirements for pharmacies and physicians. Different enforcement approaches are used, and securing felony convictions is often difficult because of the numerous and stringent evidence requirements needed to prove criminal intent on the part of the practitioner. Often prosecutors refuse to prosecute cases because of these requirements.

Manufacturers and distributors are required to keep extensive records on inventories, purchases, and sales of controlled substances. At the retail level, pharmacists are also required to keep extensive records. Physicians are generally exempt if they prescribe or administer a narcotic controlled substance or regularly dispense non-narcotic controlled substances without charging the patient.

Because of the detailed records required for pharmacies, a regulatory civil prosecution approach is generally used. To civilly prosecute a pharmacist, a regulatory investigation must show that recordkeeping requirements have not been adhered to. The records examination may show that a pharmacist could not account for all the drugs he or she dispensed. However, establishing criminal intent using records and thus forming a basis for registration revocation is difficult. It was not until 1976 that a registrant, the owner of a pharmacy, was convicted of illegal sales of controlled substances based on a regulatory investigation.

Since physicians keep fewer and less detailed records than pharmacists, proving willful diversion based on a regulatory investigation is usually not feasible. Other problems arise because of the gray area between legitimate and illegitimate practice. In diagnosing various illnesses and prescribing or dispensing the type and amount of drug for treatment, physicians necessarily have wide latitude in judgment. To prove that this judgment involves criminal intent is difficult.

To overcome these problems, diversion cases generally are developed by criminal investigations using undercover buys. The following case illustrates the necessity of such an approach. A DEA compliance investigator spent at least 125 days contacting pharmacies and interviewing witnesses to establish that a physician was excessively prescribing controlled substances without having legitimate medical

purposes. Because there were no undercover buys, the attorney refused to criminally prosecute the physician.

To prove that a physician is selling drugs or prescriptions merely for profit, it is usually necessary for an undercover agent to obtain the drug/prescription under the following circumstances:

--No discussion of symptoms takes place.

--The physician does not attempt to make an examination or obtain a medical history.

--The agent makes statements indicating that the drugs will be used for abuse.

Moreover, several undercover buys may be needed to show that the illegal prescribing or dispensing was not an isolated instance. Even with several buys, obtaining a criminal prosecution is difficult. In one case, undercover agents and informants made 10 purchases of controlled substances from a suspect; however, the U.S. attorney's office declined to prosecute the physician because of a lack of incriminating conversation between the buyers and the physician.

Revocation proceedings are time consuming

When a basis for revocation exists, the revocation is carried out with due process, including notice and hearings. If a hearing is desired, it is held before an administrative law judge who makes a recommended decision to the Administrator of DEA. Sometimes it takes years and in the meantime the registrant can still order and dispense controlled substances if he or she has a State license. For example, sometimes a registrant obtains a temporary restraining order against State licensing actions.

Also, delays are sometimes experienced in DEA regions and at DEA headquarters. In one case, a State licensing board summarily suspended a physician's license in November 1973, and a State court convicted him for a felony violation in March 1974. Yet it wasn't until September 1974 that DEA's Compliance Division requested a show cause order 1/ and until November 1975 that DEA revoked his registration.

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1/Orders notifying individuals that they have the opportunity to show why their application for registration should not be denied or why their registrations should not be suspended or revoked.

The final result may be a revocation or a decision to restrict the type of controlled substances a registrant can handle. A revocation does not prevent a practitioner from submitting a new application at a later time and becoming registered again.

Concerning the delays in the revocation process, DEA said that in most cases a definitive action must be initiated and completed by the State before DEA can act. However, in cases in which the registrant can be proven to be a danger to the public health and safety, DEA can immediately suspend a registration pending a show cause proceeding. Although DEA stated that it used this procedure without reservation whenever circumstances warranted, this authority was rarely used in the past.

DEA lacks adequate resources

In addition to a lack of authority and weak regulatory requirements, inadequate resources preclude DEA from pursuing an extensive regulatory program at the retail level.

DEA's compliance investigators are primarily responsible for monitoring registrants to insure compliance with regulations. As of June 1, 1977, DEA employed 197 compliance investigators, about 5 percent of its total work force. Their efforts were concentrated on approximately 3,300 manufacturers, distributors, importers, exporters, and narcotic treatment programs, where large stocks of drugs and the potential for large-scale diversion were present. Regulatory investigations of these registrants were generally lengthy and detailed, and DEA strived to visit each one every 3 years. Accordingly, there was little opportunity to provide coverage of any significance to the retail level. In fiscal year 1976, for example, DEA investigated about 1,300 upper-level registrants and 400 retail-level registrants.

DEA believes that because of its focus at the upper level, it has greatly reduced diversion in manufacturing and distribution; DEA says that redirecting its efforts toward the retail level could compromise these successes. For fiscal year 1978, DEA requested and was authorized 21 additional compliance investigators to (1) perform more detailed inspections at the upper levels, (2) conduct special surveys, (3) perform targeted investigations, (4) develop conspiracy cases, and (5) reduce diverted drugs coming from foreign countries.

DEA directly monitors practitioners by (1) reviewing practitioners' order forms to determine if excessive quan-

tities of schedule II drugs are being purchased and (2) making regulatory investigations on a complaint or request basis only.

DEA regional personnel informally review order forms for discrepancies. In addition suppliers are to notify DEA of excess purchases. In DEA's New York region, for instance, orders of 5,000 dosage units are considered excessive. DEA has not established formal policy for this activity, and regional personnel were unable to tell us when the practice was initiated or by whom. Although we observed a good deal of participation by suppliers in New York, our review did not indicate that significant excessive purchases were disclosed.

DEA has no systematic program of regulatory investigations of practitioners. Investigations are usually made only (1) at the request of State authorities, (2) in response to a specific complaint, or (3) as a part of a special survey to document drug abuse in a particular geographic area. The amount of time a DEA regional office can devote to these investigations depends on (1) the number of compliance investigators and their workload associated with upper-level registrants, (2) the significance of retail diversion, (3) State capabilities, and (4) whether there are special DEA/State investigative units.

DEA officials estimate that to adequately monitor the retail level through a systematic program of regulatory investigations, about 1,000 additional compliance investigators would be required--nearly five times the current number and an increase of almost 25 percent of DEA's total work force.

## STATES' ABILITY TO CONTROL RETAIL DIVERSION QUESTIONABLE

Although the control of retail-level diversion has been relegated to the States, most have not shown the capability to deal with it. DEA believes that three out of every four States are unable to control retail diversion.

State responsibility for controlling retail diversion has been outlined in memorandums of understanding--agreements between DEA and one or more State agencies. In addition to their licensing responsibilities, the States agreed to investigate suspected diversion, conduct compliance audits, and coordinate their activities with DEA. Since the passage of the Controlled Substances Act, most States have

also passed legislation modeled after the Federal act. However, the organization and scope of the States' activities vary greatly, and DEA believes that, in general, State programs are not adequately handling the problem.

DEA, at our request, estimated the amount of diversion in each State and the District of Columbia and assessed the individual States' capability to control it. Although the extent of diversion could not be explicitly defined and measured, DEA, based on its knowledge of the diversion problem and State and local regulatory and enforcement groups, provided the following information.

| Extent of retail diversion problem | No. of States (note a) | Able to control diversion: No. of States (note a) | Able to control diversion: No. of retail registrants | Unable to control diversion: No. of States (note a) | Unable to control diversion: No. of retail registrants |
|---|---|---|---|---|---|
| Large | 15 | 3 | 70,740 | 12 | 229,792 |
| Large to medium | 21 | 9 | 112,899 | 12 | 70,332 |
| Medium | 9 | - | - | 9 | 35,007 |
| Medium to small | 3 | - | - | 3 | 5,872 |
| Small | 3 | - | - | 3 | 3,206 |
| Total | 51 | 12 | 183,639 | 39 | 344,210 |

a/Includes District of Columbia.

Those States which DEA believes unable to control retail diversion have 65 percent of the total retail-level registrants. For the 12 States which were considered capable and willing to control diversion, 8 had special DEA/State enforcement groups aimed specifically at retail diversion.

We did not analyze the other elements that determine a State's capability to control retail diversion; at the time of our review, DEA and the Young study had assessed State operations, and DEA was starting a pilot program to increase State effectiveness. The problems discussed below show many of the elements which hinder the States and DEA in their efforts to prevent violators from handling controlled substances.

## Problems in State activities

The Controlled Substances Act reserves to the States the authority to practice and thus, the right to prescribe, dispense, and administer controlled substances. Within the various States, several separate agencies usually monitor retail points of diversion of controlled substances. State licensing boards for the various professions are primarily responsible for enforcing drug compliance by practitioners. The boards usually have sole authority for licensing health professionals, and they can remove an offender from a

position of responsibility. Compliance investigation units are usually affiliated with one of the State licensing boards. The investigation units are responsible for enforcing Federal and State drug laws specifically as the laws relate to drug diversion by practitioners.

State and local law enforcement agencies provide information regarding diversion. However, they generally do not regulate practitioners, and they usually become involved only after diverted drugs have reached the streets.

For the most part, State efforts to control retail diversion are hampered by inadequacies in legislation, organization, and resources.

Legislative deficiencies

State laws do not always provide the legislative foundation and authority to effectively control practitioner diversion. DEA said that in most cases the State controlled substances act was only a general law and without specific regulations, such as expressed in Title 21 of the Code of Federal Regulations, and therefore effective control was hampered. Although 44 States have adopted a controlled substances act modeled after the Federal Controlled Substances Act, many of the State laws are deficient in one or more respects and in some cases are not totally consistent with the Federal act. DEA's analyses of these laws have indicated that the following shortcomings, among others, exist in the laws of one or more States.

--Omitting drugs from State drug schedules contained in the Federal drug schedules.

--Failing to establish separate systems registering practitioners to handle controlled substances; that is, their license to practice constitutes authority to use controlled substances.

---Placing authority to suspend or revoke registrations in State courts rather than a regulatory agency.

Additionally, State licensing boards may be governed by other State laws. The Young study noted that numerous omissions from these laws hinder effective regulatory and enforcement activities, including the following:

--The lack of statutory authority to employ investigators. In 55 percent of the States, pharmacy boards do not possess such explicit statutory authority; in

80 percent of the States medical boards do not have this authority.

--An overall lack of clarity in statutory provisions outlining the grounds for license revocation and suspension.

--Statutes do not directly specify that professional boards have authority to promulgate rules and regulations concerning the licensing process in about 41 percent of the States.

--Responsibility for investigating misconduct or allegations of misconduct is not specified in an average of 59 percent of the statutes.

--An average of 54 percent of all State boards have no statutory provisions granting subpoena powers to the boards.

--For about 27 percent of the licensing boards, statutes do not specify whether they are authorized to set license qualifications.

--It is often unclear from statutory provisions what procedures are followed in holding disciplinary hearings.

--An average of 77 percent of the State boards exercise discretion in suspending licenses of practitioners who have met the grounds for suspension; only a few have statutory requirements which force the board to impose mandatory suspension penalties upon licenses.

--In 65 percent of the States, the statutes do not specify the status of a licensee pending appeal; the restrictions and regulations are vague and subject to variations in interpretation.

--Seventy-two percent of the statutes did not authorize full-time legal counsel to the boards.

Organizational and resource problems

According to the Young study, State licensing boards see their primary role as determining fitness to practice and view their responsibilities regarding controlled substances as only a part of their primary role. In general, the boards are concerned with all aspects of a practitioner's behavior. Misuse of controlled substances

generally has no special priority among the unprofessional conduct a practitioner could be guilty of.

The organization of the boards tends to give the appearance of compromising interests and reluctance to prosecute. In most States, boards are specialized; that is, each profession is under the control of a different board. According to the Young study, over 65 percent of the boards hold their own disciplinary hearings. Few States have central agencies which control the licensing functions of boards and which are responsible for disciplining practitioners.

The Young study also reported that State boards generally have no members outside the profession. Board members are usually appointed by the State governor as his or her choice or by the governor from a list of nominees recommended by State professional associations; all members have a practitioner's license. This interaction between the boards and the professional associations represents an area of possible public perception of conflict of interest.

Inadequate resources can hinder the effectiveness of State regulatory activities, particularly the investigative aspects. Many of the licensing boards are funded totally out of licensing fees, which often prevents adequate investigations. In fact, DEA considers viable State regulatory organizations with adequate resources a very difficult goal to achieve.

The State boards' compliance investigation units have a key role in controlling diversion since they handle the problem of drug diversion and/or abuse by health professionals. Generally, they investigate practitioners periodically or upon referral by another agency. Their investigations include audits of practitioner drug supplies or prescription files and undercover work. According to the Young study, the annual budgets for 21 of the units generally ranged from $26,000 to $250,000. In at least six States, however, budgets were less than $26,000. As a result, even where statutes permit, many State boards either have no investigators or have an inadequate investigative staff. Of 32 States which provided data for the Young study, 5 reported that they had no investigators and most of the others had four or fewer investigators.

Broad investigative responsibilities and lack of staff often result in uneven patterns of investigation. Because the pharmacy board is usually responsible for investigating retail diversion, the Young study stated that other

professionals, such as physicians, nurses, and dentists, may not be monitored at all or only when they use pharmacies. According to the study, pharmacies were monitored by compliance investigation units in all of the 34 States that responded to their questionnaire, while other professions were monitored less than half the time.

# CHAPTER 4

## EFFORTS TC CONTROL RETAIL DIVERSION

DEA's efforts to control retail diversion center on assessing and upgrading State capabilities and educating practitioners. Overall, this approach has had little impact on the diversion problem because (1) efforts so far have stressed planning, experimental projects, and long-term solutions to the problem rather than the present need to investigate violators and (2) some potentially effective activities, such as the training of State personnel, have not been fully taken advantage of. This situation is influenced by DEA's own enforcement priorities, the dependence on Law Enforcement Assistance Administration funding, and the degree of commitment by States.

The President, recognizing the great abuse of licit drugs, has recently directed several actions which will directly affect retail diversion.

## EFFORTS TO IMPROVE STATE CAPABILITIES

Federal-State cooperation in controlling retail diversion began in 1966 with the first memorandum of understanding by a State and a predecessor agency of DEA. Since then, a total of 45 States and the District of Columbia have entered into memorandums of understanding with DEA or predecessor agencies. Because the memorandums define Federal and State regulatory responsibilities, they have effectively directed Federal resources towards targets which potentially can divert large amounts of controlled substances. However, the memorandums do not insure that State agencies will take aggressive action in apprehending and punishing violators.

### Assessment of State capabilities

Although it has been several years since State agencies became responsible for controlling retail diversion of controlled substances, DEA has only recently tried to determine States' capabilities and to suggest needed improvements.

In 1974, DEA began to assess State capabilities and shortcomings to devise a State-by-State action plan to combat diversion. DEA officials told us that work on State assessments had a low priority. Assessment reports were due from the regions at the end of 1974, but of the assessments we sampled, most were received during January to

September 1975. Although the assessments were to cover specific subject areas, such as State laws and enforcement agencies, the quality and completeness of the assessments varied. Areas unaddressed included State court decisions, prosecution problems, and ways to improve a State's ability to control diversion. In addition, the reports did not consistently provide information on liaison activities, funding, the scope and quality of investigations, and licensing board disciplinary measures. A DEA official said that sometimes the reports were misleading because State operations appeared good, but headquarters followup showed otherwise.

State licensing board effectiveness project

The State licensing board effectiveness project will implement selected Young study recommendations in three pilot States to serve as a basis for developing a prototype program. To encourage implementing the specific operational plans in each State, DEA is exploring the following incentives, some of which require LEAA funding:

--Provide special inspector training schools.

--Encourage and foster cooperative investigations.

--Assign compliance investigators to State licensing boards.

--Provide a special attorney for the State attorney general's offices.

--Fund additional State inspectors.

--Fund additional staff.

Since many of the improvements require State legislative approval, DEA said it does not expect any changes until 1978 and that an evaluation of the program's effectiveness would take at least a year after the program was implemented.

Diversion investigation units

The most substantial program in the State assistance effort is the diversion investigation units which are staffed by investigators from various State agencies having drug enforcement responsibilities and DEA agents. Of the 14 units established since 1972, 12 are still operating. From 1972 to June 30, 1976, about 1,300 arrests

have resulted from the activities of 11 units that became operational during this period. One-third of the arrests, or about 400, involved registrants.

The units are unique because they emphasize criminal investigations by using undercover buys; this method minimizes the difficulties imposed by regulatory investigations--establishing criminal intent based on records. This program also provides the opportunity to apprehend the diverting practitioner in States where a street pusher or user is arrested by State or local police. Often the referral to the State licensing board for an investigation of the practitioner receives no action because the board has no investigators. Where a diversion investigation unit exists, such referrals would be acted upon.

LEAA and DEA provided $4.6 million in seed money for 13 of the units, ranging from $116,000 in New Hampshire to $420,000 in California. Funding was limited to 90 percent of the total program costs, while the States were required to provide 10-percent matching funds and, generally, continued funding after the initial 1-year period. As of March, 1977, Florida had been the only State to close its unit. New York City, which did not receive LEAA or DEA funds, closed its unit in June 1975 because of lack of funds and personnel. We were informed that other States have continued to fund the program with LEAA block grant funds.

Although there has been enthusiasm for the program, its expansion has been restricted by Federal funding restrictions and enforcement priorities. In 1975 lack of LEAA funds prevented units from being established in six States. In fiscal year 1976 LEAA planned to fund the program with $1.5 million, but because of DEA priorities, DEA chose to rechannel $1 million into another program unconnected with retail diversion. The program was funded as a line item in DEA's budget in fiscal year 1977, but since DEA lacked granting authority, LEAA had to award the grants and be reimbursed by DEA. Additionally, DEA said that beginning October 1, 1977, reimbursement agreements with primary State enforcement agencies will be used. To overcome problems with this funding approach, DEA submitted a legislative proposal to the Department of Justice calling for grant authority.

State agencies and professional groups must be committed to combating retail diversion and must be willing to supply the necessary personnel and funds. Some States have difficulty meeting these requirements. Since November

1974, only New Hampshire, Georgia, and Nevada have established units.

We did not evaluate the effectiveness of the units because at the time of our review Department of Justice auditors were reviewing the program. They reported that methods used to compile statistics varied and data concerning convictions was lacking. However, they believed that the program focused an enforcement effort in this area and was effective.

Liaison with State agencies

In December 1974 DEA headquarters suggested that each region assign a compliance investigator to serve as a liaison with the States and try to get State regulatory agencies and licensing authorities to discipline practitioners who violate the law. The investigator would (1) be a source of expertise and investigative support, (2) document cases or leads referred by DEA to the States, and (3) monitor the progress of State actions.

Dallas and New York assigned compliance investigators to be liaison officers with State agencies. In New York, however, the program never got off the ground because (1) the assigned compliance investigator had no time to do liaison work and (2) there were administrative problems. As a result, no formal liaison procedures were established with the State, and referrals to State agencies were not coordinated at DEA.

A DEA official said that other regions maintain liaison as part of their regular duties but that staffing and funding limitations prevented the program from fully developing.

Targeting violators

In December 1975 DEA started an experiment to reduce diversion in a specific geographic area. The project emphasized shifting away from routine investigations to targeting specific doctors and pharmacies in an area where diversion was occurring. To select these targets, DEA identified (1) abuse patterns through the Drug Abuse Warning Network and (2) practitioners receiving schedule II drugs through its automated order system. DEA selected the San Francisco area because of the high incidence of abuse of depressants and stimulants. Initial targets consisted of 19 pharmacies and 14 physicians, but since fraudulent prescriptions and illegal sales by practitioners were a large part of the diversion problem in this area, additional targets were later selected.

Using the California diversion investigation unit and selected DEA personnel, investigations resulted in the possible civil prosecution of 27 pharmacies, while 18 others were to receive various administrative actions. Based on 234 violations, 17 doctors may face criminal prosecution and/or may have to surrender their registrations.

At the end of the project, DEA evaluated whether the project reduced the abuse of selected drugs in San Francisco and tried to identify the major diversion source. According to a DEA official, the project showed that the primary diversion source was physicians writing prescriptions for profit.

The project cost DEA about $17,000 and DEA considered it to be a success. We did not follow up on the actions taken since August 1976, but we learned that DEA was experiencing difficulties in filing the proposed civil actions.

Training State personnel

Although the Young study recognized a need for compliance and enforcement training on retail-level diversion, the States have asked DEA to provide training for their own drug enforcement priorities--control of illegal traffic in hard drugs. Consequently, DEA provided training in criminal drug law enforcement to about 10,000 State and local personnel in fiscal years 1974-76.

Because of these priorities and funding limitations, a DEA official informed us that the States have not requested DEA to provide compliance and regulatory training. The only retail-level training available to the States is that financed by the diversion investigation unit program. In fiscal years 1974-76, DEA had eight schools for 210 State participants costing DEA about $9,000. DEA also cosponsored eight prosecuting-attorney seminars to promote successful prosecution of diverting practitioners. DEA estimates that 800 to 1,000 prosecutors and other personnel have attended these seminars. Because the cost of the seminars is paid by the State law association or with an LEAA grant, DEA has incurred only nominal costs.

EFFORTS TO EDUCATE PRACTITIONERS

Educating practitioners to increase awareness of diversion and encourage self-regulation is promoted by DEA,

NIDA, and FDA through various publications, conferences, and working groups. There are also special projects to confront specific problem areas such as pharmacy thefts and physician-prescribing practices.

Voluntary compliance

DEA has worked closely with the health professions in publishing and distributing information which may help reduce diversion and drug abuse. With DEA participation, seminars and working groups have been organized to provide a forum for discussing regulatory problems and to make the professions aware of DEA's regulatory functions. Some methods include:

--A quarterly newsletter sent to 5,000 State and national professional associations, schools, licensing boards, and other Government officials.

--Working committees which meet quarterly to discuss various problem areas with registered groups, including practitioners.

--Conferences of concerned professionals bringing together key leaders and policymakers from the regulated professionals.

Pharmacy theft prevention program

In response to the nationwide rise in pharmacy thefts in 1974 and the demand to make thefts of controlled substances a Federal crime, DEA launched a pilot program in St. Louis; the project was to determine the nature of such thefts and to establish a preventive program throughout the country. According to the DEA study, the analysis of the legal situation did not justify Federal legislation because:

--Burglarized pharmacies had a lower level of security than those which were not victimized.

--The most significant difference between those victimized and those not was their geographic location.

--Drugs were not the prime motivating factor in the commission of these crimes.

--The high pharmacy crime rate did not appear to stem from a deficiency in law enforcement.

--The increase in pharmacy crimes could not be traced to any glaring deficiency in the courts.

--For the most part, defendants were not drug addicts.

Based on the above DEA implemented a pharmacy theft prevention program in St. Louis emphasizing greater police involvement, increased security within the pharmacies, and greater communication among local police, pharmacies, wholesalers, and DEA. By 1976 DEA concluded that the program was successful since armed robberies and burglaries had decreased over 28 percent during calendar year 1975.

Although the program in St. Louis has been discontinued, DEA plans to implement similar community action programs in 13 other cities. Funding has not yet been established, but DEA believes that support may be available through State planning agencies.

Improving physicians' prescribing practices

DEA, FDA, NIDA, and medical associations have implemented programs or developed guidelines to improve physicians' prescribing practices. Health professionals are becoming aware of the dangers of overprescribing, multiple prescribing, and improper drug use through NIDA's physician education program, DEA's prescribing working committee, and various publications. FDA is drafting regulations on prescriptive drug inserts and labeling, and NIDA plans to issue a medical monograph on prescribing guidelines for physicians in 1977.

Some guidelines have been developed for assuring control over prescriptions and controlled substances and for properly prescribing and administering amphetamines, barbiturates, sedatives, and other drugs. DEA, for example, recommends that prescription pads should not be signed in advance nor be used for writing notes or memos and should be kept in a safe place. Like writing checks, the amount of drugs prescribed should be spelled out, as well as the numerical quantity, to discourage alterations.

The American Medical Association's guidelines for barbiturates recommend that (1) barbiturates and sedative-hypnotics should not be prescribed for minor complaints, (2) the susceptibility of the patient to drug abuse should be assessed, and (3) the patient should be counseled on proper use of medications. A local medical society recommended a ban on prescriptive amphetamines except under very

limited conditions.

## RECENT DEVELOPMENTS TO CONTROL THE ABUSE OF LEGAL DRUGS

During fiscal year 1977, a congressional committee and the Office of Drug Abuse Policy--which makes recommendations to the President regarding Federal drug abuse activities--considered restricting the use of amphetamines and barbiturates because their abuse had become so serious. On August 2, 1977, President Carter recommended that the Federal Government give greater attention to the abuse of licit drugs, primarily barbiturates, and emphasized several actions which would directly affect retail diversion.

In his message to the Congress, the President stated that DEA will continue giving priority attention to barbiturate cases and will conduct a special audit of 120 companies lawfully manufacturing barbiturates. The President planned to:

--Instruct the Secretary of HEW to study barbiturates and other sedative-hypnotic drugs to determine the conditions under which they can be most safely used.

--Instruct the Secretary of Defense, the Secretary of HEW, and the Administrator of Veterans' Affairs to review the prescribing practices of physicians under their jurisdiction and to discourage the medical use of barbiturates and sedative-hypnotics except in cases where it is unmistakably justified.

The President stated that he supported legislation giving the Food and Drug Administration the authority to apply standards of safety and efficacy to all drugs by repealing laws exempting drugs placed on the market before a certain date. In addition, the President directed:

--The Secretary of HEW to review those sedative-hypnotic drugs particularly subject to abuse to determine whether any should be removed from the market; the Secretary should consider not only their safety to the individual but also the dangers they pose to the public at large.

--The Attorney General, in full cooperation with State officials, to begin a concerted drive to identify and prosecute physicians who deliberately misprescribe barbiturates and other drugs.

# CHAPTER 5

## ALTERNATIVE APPROACHES TO COMBATING RETAIL DIVERSION

Retail diversion is a serious health and law enforcement problem. DEA is unable to play a direct role in solving the problem because of the provisions of the Controlled Substances Act, and the States, on the other hand, have not established effective programs.

While the abuse of licit drugs has recently caused the President to have several Federal agencies implement additional administrative and enforcement actions, other changes are needed. To effectively deal with retail diversion, which DEA believes is the largest source of diversion in the drug distribution system, requires a stronger, more direct DEA role or an assistance role in which DEA motivates and helps States to carry the major burden.

### THE DIRECT APPROACH

DEA's drug enforcement efforts have been mainly directed toward large-scale trafficking in narcotics and dangerous drugs, such as heroin and cocaine and drugs diverted by manufacturers and distributors. Under the direct approach, which differs from DEA's traditional enforcement role, DEA would have more responsibility over retail-level practitioners like it currently exercises over manufacturers and distributors. As such, DEA would not be as dependent on State licensing actions, and it would have the necessary tools to compel practitioner compliance.

With a stronger DEA role, significant legislative changes would be necessary giving DEA increased authority to register practitioners, deny registrations, prescribe security controls, and impose more stringent prescription and recordkeeping requirements.

DEA has considered revisions to the Controlled Substances Act to strengthen retail controls over security and prescription requirements. A DEA official estimated that stronger security requirements, similar to those required for manufacturers and distributors, could reduce thefts by 30 to 40 percent. DEA has not proposed authorizing legislation because it would be costly for retailers and because the authority and responsibility has been given to the States. DEA stated that it provided general minimum standards for practitioner security but that the States should outline specific security measures.

Similarly, DEA has not requested authority to require physicians to forward copies of prescriptions to it. This procedure would allow DEA to monitor practitioners liberally dispensing drugs and individuals securing multiple prescriptions from numerous practitioners. DEA believes that to be effective such a procedure would require disclosing and reporting information that may involve the privileged doctor-patient relationship. For example, a Federal District Court has declared unconstitutional a section of a New York State law requiring triplicate prescriptions; under the law physicians would have to forward a copy of each prescription they write for certain specified drugs to a State agency for recordation on a centralized computer file. The District Court's decision was later reversed on appeal to the Supreme Court.

This approach involves substantial costs. To implement, monitor, and enforce additional controls, large increases in DEA's resources and in the operating costs of practitioners would be required. There is also an intangible drawback--a vastly increased Federal presence in the medical profession. Moreover, even with a greatly expanded DEA role, there is no guarantee of quick results, and great reductions in diversion will most likely take a long time.

## THE ASSISTANCE APPROACH

The assistance approach would essentially be continuing the current situation in which the States have the primary responsibility for controlling retail-level diversion. DEA, however, would assume a more active role in assisting States.

A critical element in this approach is the States' recognizing their responsibilities. While DEA might begin action, the States would necessarily bear the major burden for establishing aggressive antidiversion programs. Unfortunately, other national problems have shown that States are often reluctant or unable to become involved without adequate Federal funding. Accordingly, the Government would likely have to financially support State efforts far beyond what has been previously provided.

Since States have not recognized the severity of retail-level diversion nor their responsibility to combat it, one approach may be to tie Federal support to federally approved activities as is currently done, for example, with LEAA grants. DEA, however, rather than LEAA, would award the grants so that DEA programs could be readily implemented in States having the greatest needs. Or, to

insure State involvement, a grant program could be implemented similar to the ones under the Clean Air Act or the Federal Water Pollution Control Act. DEA would establish mandatory standards for controlling retail-level diversion. States would submit detailed plans to DEA on how they expect to meet the standards and, upon DEA approval, would receive funds to implement their plans.

The assistance approach would be costly and would require legislative authority for DEA to embark on a new grant program. But retail-level diversion could be expected to continue until State capabilities are sufficiently upgraded.

We did not examine the costs of the two approaches discussed above. We believe, however, that DEA should study in detail the costs and benefits of each alternative.

## RECOMMENDATIONS

The Congress should change DEA's role by authorizing it to either

--exercise direct regulatory authority over retail-level practitioners or

--implement grant programs for assisting States in controlling diversion.

Because of the potentially large expenditures which would result from a change in DEA's role, we recommend that the Attorney General study the costs and benefits of these approaches or any other methods to combat this problem.

## CHAPTER 6

## AGENCY COMMENTS

In general, the Department of Justice believed that the report accurately described the retail diversion problem and fairly presented DEA's efforts and successes. In commenting on the alternatives on pages 33-35, for improving controls over retail-level diversion, Justice stated that the direct approach would be "a deviation from DEA's traditional enforcement role" and "would require significant legislative changes and manpower increases." While the assistance approach would be costly and require additional legislative authority, Justice stated that DEA endorsed this approach and believed that over the long run the approach would significantly reduce the retail diversion problem. (See. app. I.)

HEW said it had no substantive comments to make on the matters discussed. HEW said it was working with DEA on a project to match DEA distribution records with Medicaid and Medicare distribution records. (See app. II.)

APPENDIX I

UNITED STATES DEPARTMENT OF JUSTICE

WASHINGTON, D.C. 20530

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

JAN . 1978

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 "Retail Diversion of Legal Drugs--A Major Problem With No Easy Solution."

In general, we believe the report provides an accurate description of the retail diversion problem facing the Drug Enforcement Administration (DEA)--inadequate statutory authority, weak regulatory requirements, and inadequate resources. We also believe the report gives a fair presentation of DEA's efforts and successes in spite of the adversities cited above.

The report presents two alternative approaches to combating and controlling the retail diversion of legal drugs--the "Direct Approach" and the "Assistance Approach." GAO has aptly defined the advantages and disadvantages of the "Direct Approach." We agree with their assessment that direct DEA involvement at the retail level was not the intent of Congress as expressed in the provisions of the Controlled Substances Act (CSA) and that the Federal government could not properly assume the functions of State Regulatory and Licensing Boards. In addition to being a deviation from DEA's traditional enforcement role in this area, the "Direct Approach" would require significant legislative changes and manpower increases.

As an alternative, GAO recommends the "State Assistance Approach," which is essentially an enhancement of the present DEA approach of lending expertise and assistance to the States on a regular case-by-case basis, as permitted by time and manpower, in an effort to upgrade the capabilities

APPENDIX I

of the States to regulate their professionals. GAO indicates that the retail diversion problem could be more effectively attacked by strengthening DEA's role in assisting the States through the establishment of mandatory standards for their guidance in controlling retail diversion. The States would then submit plans to DEA explaining how they expect to meet the established standards and, upon DEA approval, would receive funds to implement their plans. GAO acknowledges that DEA is pursuing a modified, but somewhat limited, "State Assistance Approach," and points out that this effort is not totally successful due to the limitation of current resources.

The assistance approach GAO suggests would embody a full-scale grant-in-aid program, would be costly, and would require additional legislative authority. In addition to granting legislative authority, DEA would need specialists in contracting and grants, increased manpower for formulating initial standards and reviewing plans submitted by the States, and increased manpower to provide technical assistance in the field. Furthermore, attorneys at the State level would be needed to assist in formulating and supporting drug legislation through the State governments. However, it is anticipated that these resource requirements would be substantially less than those required in the "Direct Approach."

In summary, DEA endorses the "State Assistance Approach" and will continue this endeavor to the extent possible within the framework of its existing resources. A more active DEA role in assisting the States would significantly decrease the retail diversion problem over the long run, but would require the resolution of the above legislative and resource requirements.

General Comments on Findings and Recommendations

The following comments are intended to clarify certain statements contained in the report.

1. Cover Digest - The statement is made in the Cover Digest and throughout the report that DEA "is unable to control retail diversion because of a lack of authority," etc. A more accurate statement would be "...because of a lack of statutory authority."

2. Page iii, Paragraph 2 - The use of the term "ineffective organization" is addressed to the State governments; however the sentence as written is misleading in that it indicates this condition is also true of DEA operations. No indication is given in the body of the report that DEA has an "ineffective organization."

3. Page 23, Paragraph 2 - Concerning delays in the revocation process, DEA cannot revoke a retail registration unless such registrant has (1) been convicted of a drug-related felony, (2) had his State license revoked, or (3) falsified an application. Since the authority to control retailers has been relegated to the States, the overriding question concerning a revocation is "How is the firm or individual registered by the respective State?" Therefore, in most cases, a definitive action must be initiated and completed by the State before DEA can act. In those cases where the registrant can be proven as a danger to public health and safety, DEA has the authority to immediately suspend a registration pending Show Cause proceedings. This procedure is used by DEA without reservation whenever circumstances warrant such need.

4. Page 26, Paragraph 2 - It is true that a large number of States have passed similar CSA legislation. However, in most cases this is only general law, and without specific regulations, such as expressed in Title 21, CFR, Part 1300 to End, effective control is hampered.

5. Page 46, Last Sentence - Although cost is a consideration, it is not the overriding reason. DEA has not proposed authorizing legislation because the authority and responsibility has been relegated to the States. DEA provides general, minimum standards for practitioner security, but leaves the tailoring of specific security measures up to the States.

6. Page 47, Paragraph 1 - The Federal District Court did, in fact, declare unconstitutional a section of a New York law requiring triplicate prescriptions. However, the 2nd Circuit Court of Appeals reversed the Federal District Court's decision, and the United States Supreme Court sustained the 2nd Circuit Court of Appeals' decision. Therefore, the New York triplicate prescription requirement continues to be in effect.

7. General - The report contains a number of references to drug investigation unit (DIU) projects. The total number of operational DIU's is 12. Also, the current number of States that have adopted the model CSA is 44 rather than 43, and this does not include the District of Columbia, which has not yet passed such legislation.

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,

Kevin D. Rooney
Assistant Attorney General
for Administration

GAO note: The page numbers referred to do not necessarily correspond to those in the final report.

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

JAN 5 1979

Mr. Gregory J. Ahart
Director, Human Resources
Division
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Ahart:

The Secretary asked that I respond to your letter of October 18, 1977 asking for our comments on your draft report, "Retail Diversion of Legal Drugs--A Major Problem With No Easy Solution." Responsible Department officials who have reviewed your report have no substantive comments to make on the matters discussed. They would like, however, to offer the following remarks for your consideration when you develop the final version of this report:

- It might be noted that we are working with DEA Compliance on a project to match their distribution records with our Medicaid and Medicare disbursement records in order to determine whether a pharmacist may be dispensing through normal channels fewer doses that he is receiving. In addition, such comparisions, if more drugs are being dispensed than are being received, may show that the Medicaid or Medicare program is being defrauded.

- Secondly, rewards for information would probably produce results in the health care field since the transactions which result in diversion or abuse usually have some visibility within the health care community; i.e., pharmacists usually know Doctors who are overprescribing and distributors know practitioners who are overbuying. Rewards must be substantial and results oriented to be effective.

We appreciate the opportunity to comment on this report in its draft form.

Sincerely yours,

Thomas D. Morris
Inspector General

APPENDIX III

## PRINCIPAL OFFICIALS RESPONSIBLE FOR ADMINISTERING ACTIVITIES DISCUSSED IN THIS REPORT

| | Tenure of office | |
|---|---|---|
| | From | To |
| **DEPARTMENT OF JUSTICE** | | |
| ATTORNEY GENERAL OF THE UNITED STATES: | | |
| Griffin B. Bell | Jan. 1977 | Present |
| Richard L. Thornburgh (acting) | Jan. 1977 | Jan. 1977 |
| Edward H. Levi | Feb. 1975 | Jan. 1977 |
| William B. Saxbe | Jan. 1974 | Feb. 1975 |
| Robert H. Bork, Jr. (acting) | Oct. 1973 | Jan. 1974 |
| Elliot L. Richardson | May 1973 | Oct. 1973 |
| ADMINISTRATOR, DRUG ENFORCEMENT ADMINISTRATION: | | |
| Peter B. Bensinger | Feb. 1975 | Present |
| Peter B. Bensinger (acting) | Jan. 1975 | Feb. 1975 |
| Henry S. Dogin (acting) | June 1975 | Jan. 1975 |
| John R. Bartels, Jr. | Oct. 1973 | May 1975 |
| John R. Bartels, Jr. (acting) | July 1973 | Oct. 1973 |
| ADMINISTRATOR, LAW ENFORCEMENT ASSISTANCE ADMINISTRATION: | | |
| James Gregg (acting) | Feb. 1977 | Present |
| Richard W. Velde | Sept. 1974 | Feb. 1977 |
| Donald E. Santarelli | Apr. 1973 | Aug. 1974 |
| **DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE** | | |
| SECRETARY OF HEALTH, EDUCATION, AND WELFARE: | | |
| Joseph Califano | Jan. 1977 | Present |
| David Mathews | Aug. 1975 | Jan. 1977 |
| Caspar W. Weinberger | Feb. 1973 | Aug. 1975 |
| COMMISSIONER, FOOD AND DRUG ADMINISTRATION: | | |
| Donald Kennedy | Apr. 1977 | Present |
| Sherwin Gardiner (acting) | Dec. 1976 | Apr. 1977 |
| Alexander M. Schmidt | July 1973 | Dec. 1976 |

APPENDIX III

| | Tenure of office | |
|---|---|---|
| | From | To |
| **DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE (cont.)** | | |
| ADMINISTRATOR, ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION: | | |
| Jerald Klerman (acting) | Jan. 1977 | Present |
| James D. Isbister | Aug. 1975 | Jan. 1977 |
| James D. Isbister (acting) | Sept. 1974 | Aug. 1975 |
| Robert L. DuPont (acting) | July 1974 | Sept. 1974 |
| Roger Egeberg (acting) | Oct. 1973 | June 1974 |
| DIRECTOR, NATIONAL INSTITUTE ON DRUG ABUSE: | | |
| Robert L. DuPont | Sept. 1974 | Present |
| Karft J. Besteman (acting) | June 1974 | Sept. 1974 |
| Robert L. DuPont (acting) | Sept. 1973 | June 1974 |

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