BY THE COMPTROLLER GENERAL

# Report To The Congress

OF THE UNITED STATES

## Comprehensive Approach Needed To Help Control Prescription Drug Abuse

The abuse of prescription drugs--most of which are obtained at the retail level--results in more injuries and deaths to Americans than all illegal drugs combined.

A comprehensive approach using law enforcement, regulation, education, and professional peer pressure is the best hope for controlling these drugs. This approach requires commitment by medical and pharmaceutical associations, State and local governments, and the Federal Government. Recent actions by the American Medical Association to implement this approach are steps in the right direction.

The Drug Enforcement Administration can contribute to the success of the comprehensive approach by increasing information to the States on areas of drug abuse and potential drug sources and effectively targeting high-level traffickers appropriate for Federal investigation. DEA also needs to increase the annual fees charged persons and firms who prescribe or handle prescription drugs and are required by law to be registered.

DEA agreed with the thrust of this report and stated that implementation of GAO's recommendations is a step in the right direction in dealing with the prescription drug abuse problem.



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

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

This report addresses the nature and extent of prescription drug abuse in the United States and actions which can be taken to better control the sources of supply. Our review was made because of long-standing congressional concern.

Copies of this report are being sent to the Director, Office of Management and Budget; the Attorney General; the Acting Administrator, Drug Enforcement Administration; and other interested parties.

Shelton J. Dorsen

Acting Comptroller General
of the United States

COMPTROLLER GENERAL'S
REPORT TO THE CONGRESS

# COMPREHENSIVE APPROACH NEEDED TO HELP CONTROL PRESCRIPTION DRUG ABUSE

## D I G E S T

Prescription drugs 1/, most of which are obtained at the retail level of the distribution chain--doctors, pharmacies, and clinics--where the States have the primary responsibility for control, ironically have been abused or misused by more Americans than cocaine, hallucinogens, or heroin. Prescription drugs are also identified in drug-related deaths and emergency medical situations more often than all illegal drugs combined. During 1980, prescription drugs accounted for 15 of the 20 controlled drugs reported most often to the Federal Government by hospital emergency rooms.

Because of long-standing congressional concern over the seriousness of prescription drug abuse, GAO examined efforts to control prescription drugs at the retail level. This report discusses the nature and extent of the prescription drug problem and actions needed to address it. To effectively deal with the problem will require the efforts of Federal, State, and local governments and professional associations. At the Federal level, the Drug Enforcement Administration (DEA) is in a position to provide direct assistance to the States on some efforts.

### PRESCRIPTION DRUGS OBTAINED LEGALLY AND ILLEGALLY

While no definitive statistics exist which show the amounts of abused prescription drugs coming from the various points in the legitimate drug distribution chain, available information indicates that most of the drugs are obtained at

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1/For simplicity, GAO refers to legally manufactured and distributed drugs that are controlled under Federal law as "prescription drugs."

the retail level. Unintentional misprescribing by doctors, intentional misprescribing by unscrupulous doctors, pharmacy thefts, illegal sales by pharmacists, and forged prescriptions are among the various ways by which abused prescription drugs are obtained. Legally obtained drugs appear to be involved in a major portion of the abuse taking place. However, the abuse of drugs properly obtained from legitimate channels is beyond the reach of law enforcement. (See pp. 7 to 9.)

COMPREHENSIVE APPROACH NEEDED TO CONTROL ABUSED DRUGS

Because of the enormity and complexity of the prescription drug abuse problem, law enforcement alone cannot combat it. Therefore, a comprehensive and coordinated response involving the Federal Government, State and local governments, and professional associations is needed. With Federal help, each State must assess its own prescription drug abuse problem and develop a plan of action that combines elements of law enforcement, regulation, education, and professional peer pressure. Such a response is needed to address all sources of abused prescription drugs, both legal and illegal.

The White House Drug Policy Office sponsored a national prescription drug conference in November 1980 to highlight cooperative activities which could reduce the abuse of prescription drugs. Conference participants discussed the need to improve cooperation and coordination among the various organizations involved in the States, and they generally agreed that national level coordination is needed. This conference was viewed as only a beginning in attempting to comprehensively deal with the prescription drug problem. Recently the American Medical Association has taken steps to implement a comprehensive approach to the problem. Federal Government agencies, such as the DEA, are in a position to contribute significantly to the success of this approach. (See pp. 12 to 16.)

## DEA NEEDS TO USE ITS RESOURCES BETTER

DEA recently reduced its oversight at the wholesale level (manufacturers and distributors) and increased its criminal investigations of retail practitioners. GAO found, however, that DEA's pilot program--Operation Script--targeted other than high-level violators although it was intended to target only that group. DEA officials said they recognized this problem and have taken steps to improve the targeting of violators under its Targeted Registrant Investigations Program, a permanent criminal investigations program concentrating on the retail level. Because of the targeting problem of Operation Script, DEA should closely monitor the program. (See p. 20.)

Although DEA has freed resources previously concentrated at the wholesale level, it has not allocated sufficient staff to adequately fulfill the requirements of the Infant Formula Act of 1980 to provide the States with analytical information to help locate sources of highly abused drugs. According to DEA, only four staff members are needed to adequately carry out this task. However, at the time of this review only two positions were filled, and both were scheduled to be abolished because of budget constraints. GAO believes the necessary staffing can be provided from the resources freed at the wholesale level. (See pp. 21 to 23.)

## REGISTRANTS' FEES ARE TOO LOW

Annual fees charged manufacturers, distributors, and dispensers registered under the Controlled Substances Act are too low. They have remained unchanged since first established by DEA over 10 years ago. Reasonable fees can be established under the act to recover Federal costs related to the registration and control of the manufacture, distribution, and dispensing of controlled substances.

However, because DEA has narrowly interpreted the types of costs to be recovered by the fees, the present fees recover only a small portion of these costs. GAO believes the Controlled Substances Act authorizes fees that will recover greater Federal costs than those now being recovered, and that the annual fees should be increased. (See pp. 26 to 29.)

RECOMMENDATIONS TO THE ATTORNEY GENERAL

To assist the States in their efforts to control prescription drug abuse at the retail level, GAO recommends that the Attorney General direct the Administrator of DEA to

--reallocate sufficient staff resources to fully implement the analytical reporting requirements of the Infant Formula Act and

--monitor the use of staff resources on the Targeted Registrant Investigations Program in terms of the program's success in targeting and immobilizing high-level traffickers appropriate for Federal investigation.

GAO also recommends that the Attorney General direct the Administrator of DEA to increase the fees charged to drug manufacturers, distributors, and dispensers under the Controlled Substances Act so that a greater portion of Federal costs of controlling prescription drugs is recovered. (See p. 24 and p. 29.)

AGENCY COMMENTS AND GAO'S EVALUATION

The Department of Justice said that implementing GAO's recommendations is a step in the right direction in effectively dealing with the problem of controlling diversion of prescription drugs. The American Medical Association assured GAO that it is going forward in its efforts to encourage improved drug prescribing practices and to foster inter-disciplinary cooperation on both national and State levels. (See apps. V and VI.)

Specifically, Justice said that DEA has been attempting to fully implement the Infant Formula Act requirements within currently available staff resources and has been able to increase its ability to meet the requirements of the act through the use of sophisticated computer techniques. GAO's concern is that the act's reporting requirements be fulfilled. If, in attempting to fulfill the requirements, computers can be utilized, negating the need to use additional staff resources, GAO's concern would be satisfied.

Regarding the investigative targeting of high-level traffickers, Justice said that DEA is now confident that it is focusing on the appropriate level of drug violator and the Targeted Registrants Investigations Program will continue to be monitored to assure that this objective is being achieved.

Regarding GAO's recommendation to increase the fees for DEA registrants, Justice said it has been discussing with the Office of Management and Budget the question of appropriate fees and that some form of fee proposal will be developed and published in the Federal Register after the discussions are concluded.

# Contents

## ABBREVIATIONS

| | |
|---|---|
| AMA | American Medical Association |
| ARCOS | Automation of Reports and Consolidated Orders System |
| CSA | Controlled Substances Act |
| DAWN | Drug Abuse Warning Network |
| DEA | Drug Enforcement Administration |
| DIU | Diversion Investigation Unit |
| FDA | Food and Drug Administration |
| GAO | General Accounting Office |

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| NASADAD | National Association of State Alcohol and Drug Abuse Directors |
| NIDA | National Institute on Drug Abuse |
| OMB | Office of Management and Budget |
| PMA | Pharmaceutical Manufacturers Association |
| TRIP | Targeted Registrant Investigations Program |

# CHAPTER 1

## THE PRESCRIPTION DRUG ABUSE PROBLEM IN THE UNITED STATES

Prescription drug 1/ abuse has been a widespread problem in this country for years, although not as well recognized as the abuse of heroin, cocaine, marijuana, and other illegal drugs. Prescription drugs such as stimulants, sedatives, tranquilizers, and analgesics have wide application and an important place in the practice of medicine. These drugs also have potential for abuse, however, and can cause great psychic and physical harm when used for nonmedical purposes. The health hazards are illustrated by national drug abuse statistics which identify prescription drugs in drug-related deaths and emergency medical situations more often than all illegal drugs combined.

Regulating prescription drugs to prevent their diversion for nonmedical use is a tremendous task. Approximately 20,000 drug products are controlled under Federal law, and over 20 billion dosage units of these products flow through the legitimate distribution chain each year. The drugs move from the manufacturer, to the wholesale distributor, to the retail outlet, and, finally, to the consumer. These legitimate channels of distribution involve over 625,000 registered manufacturers, distributors, and dispensers nationwide.

The abuse of prescription drugs has long been of concern to the Congress. Both the Senate and the House have held numerous hearings on the topic. In 1970, the Congress passed the Controlled Substances Act to control the quantity of drugs available and, therefore, reduce their potential for abuse. In 1978, and again in 1979, the House Select Committee on Narcotics Abuse and Control held hearings on prescription drug abuse and concluded that these drugs were being both overprescribed by doctors and diverted into the illegal market.

### ABUSE OF PRESCRIPTION DRUGS IS WIDESPREAD

Millions of Americans abuse prescription drugs, often with tragic results. A 1979 national survey sponsored by the National Institute on Drug Abuse (NIDA) showed that the nonmedical use of prescription drugs was second only to the use of marijuana/hashish. (See app. I.)

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1/For simplicity, we are referring to legally manufactured and distributed drugs that are controlled under Federal law as "prescription drugs."

The Drug Abuse Warning Network (DAWN) 1/ shows that prescription drugs dominate the statistics on reported drug episodes (emergency medical situations and deaths) involving controlled drugs. In 1980, 15 of the 20 most frequently mentioned controlled drugs in DAWN emergency room reports were prescription drugs. (See app. II for greater detail.)

Also during 1980, prescription drugs were identified in 3,535, or 74 percent, of the total (4,747) mentions of controlled drugs involving deaths reported by medical examiners. And, 71,431, or 75 percent, of the total (95,502) emergency room controlled drug mentions were prescription drugs.

## THE RETAIL LEVEL IS THE MAJOR SOURCE OF ABUSED PRESCRIPTION DRUGS

No definitive statistics exist to show the amounts of abused prescription drugs coming from the various points in the legitimate drug distribution chain. However, indications are that most of the drugs are obtained at the retail (dispensing) level.

Diversion from the wholesale level (manufacturers and distributors) was once considered to be a major source of abused prescription drugs. However, the regulatory activities of DEA plus improvements in the security and recordkeeping of drug inventories by manufacturers and distributors have significantly reduced opportunities for diversion from the wholesale level. DEA seldom uncovers significant violations of law in its periodic compliance investigations of manufacturers and distributors.

The retail level, on the other hand, has over 616,000 registered practitioners authorized to prescribe, administer, or dispense controlled drugs. 2/ DEA estimates that most--about 80 to 90 percent--abused prescription drugs coming from the legitimate domestic distribution chain are obtained at this level.

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1/DAWN is a nationwide program that gathers data on drug abuse from hospital emergency rooms and medical examiners in selected locations throughout the United States. Since each reported drug abuse episode may involve one or more drugs, DAWN compiles and analyzes the number of drug mentions (named substances).

2/As of September 1980, there were 625,804 manufacturers, distributors, and dispensers of controlled drugs registered under Federal law. Of these, 616,811, or 98.6 percent, were at the retail level--physicians, dentists, veterinarians, pharmacies, hospitals, and teaching institutions. These retail level registrants are collectively called "practitioners."

DAWN statistics also indicate that the retail level is the principal source of abused prescription drugs. For those cases reported by emergency rooms from March 1980 through April 1981, "legal prescription" was the predominant source identified--it was cited in 41 percent of the prescription drug mentions.

## THE NATION'S APPROACH TO CONTROLLING PRESCRIPTION DRUGS

Controlling prescription drugs is the responsibility of both the Federal Government and the States. Federal controls are focused at the wholesale level (manufacturers and distributors) of the legitimate distribution chain, while the States bear the primary responsibility for controlling the retail or dispensing level. The Controlled Substances Act defines Federal responsibilities. The Federal drug strategy for controlling prescription drugs was developed on the basis of this law.

While the Federal Government has the authority to enforce criminal laws against those retail practitioners who illegally divert drugs from legitimate channels, it has limited statutory authority to regulate the retail level. Licensing, regulating, and monitoring this level have traditionally been State responsibilities.

### Controlled Substances Act

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 (CSA), establishes the framework for controlling drugs that have a potential for abuse. The CSA provides for a closed drug distribution system extending from the manufacturer to the ultimate user. It established a regulatory system to prevent diversion of controlled drugs while ensuring an adequate supply for legitimate medical, research, and industrial needs. CSA controls include activities such as establishing production quotas for certain drugs, registering all those handling or prescribing controlled drugs, and inspecting drug manufacturers and distributors to ensure compliance with the CSA.

The CSA authorizes the Attorney General to regulate and control distribution of these drugs. It also authorizes the Attorney General to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances. The Attorney General has delegated authority under the act to the Administrator of DEA.

The CSA divides controlled substances into five schedules on the basis of their potential for abuse, accepted medical use, and accepted safety under medical supervision. Schedule I includes substances, such as heroin, that have no accepted medical uses and a high abuse potential. Schedule II includes substances, such as morphine, barbiturates, and amphetamines, that have accepted medical uses but also a high abuse potential. Schedules III through V include substances, such as diazepam (Valium) and cough syrups containing codeine, that have accepted medical uses and a decreasing abuse potential. 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 drugs are more strictly controlled than schedules III through V drugs.

Federal drug strategy

The Federal Strategy for Drug Abuse and Drug Traffic Prevention outlines the Nation's approach to controlling prescription drugs. The congressionally mandated strategy 1/ formulates Federal policy for drug abuse prevention and control. The strategy is also intended to serve as a foundation from which the Federal Government can proceed to reduce the effects of drug abuse in this country. Concerning the control of prescription drugs, the strategy emphasizes the division of responsibilities of the various entities involved and distinguishes the roles of each. It calls for the Federal Government to focus on the wholesale level of the distribution chain. It also calls for State and local agencies to concentrate on the retail level, and for the Federal Government to assist them by providing information, financial support, training, and technology. The strategy also notes that professional and business associations related to drugs should be encouraged to intensify the monitoring of their professions and industries and to impose swift and adequate penalties upon those members who violate their code of ethics, laws, or regulations.

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1/The Drug Abuse Office and Treatment Act of 1972 (Public Law 92-255) created the Strategy Council on Drug Abuse and required it to develop and publish a comprehensive long-term Federal strategy. The most recent strategy, Federal Strategy for Drug Abuse and Drug Traffic Prevention, was published in 1979. (U.S. Government Printing Office: 1979 0-284-561.)

## OBJECTIVES, SCOPE, AND METHODOLOGY

In view of the long-standing congressional concern over prescription drug abuse, we attempted to assess the nature and extent of the problem and to determine what actions can be taken to better control the sources of supply. In addition, we assessed the reasonableness of DEA's fees relating to the registration and control of the manufacture, distribution, and dispensing of prescription drugs.

This report deals with domestically manufactured and distributed legal drugs that are controlled under the CSA. Although we refer to these controlled substances as they are commonly described, as prescription drugs, they are only a portion of the drugs for which a prescription is needed, and some can be obtained without a prescription (for example, cough syrups containing codeine). This report is not concerned with uncontrolled legal drugs that are sold over-the-counter, such as aspirin, or drugs that require a prescription but are not controlled by the CSA, such as penicillin. Furthermore, the report does not deal with substances that are illegally manufactured 1/, or that are diverted from international commerce and smuggled into the country. Prescription drugs are included in schedules II through V of the CSA.

In conducting our evaluation, we reviewed laws, strategies, policies, procedures, practices, correspondence, and statistical data relating to prescription drug control efforts. Our evaluation included work in Washington, D.C., and in several locations across the country. In Washington, D.C., we

--discussed the prescription drug abuse problem and the various ways drugs are obtained with officials at DEA, NIDA, and the Food and Drug Administration (FDA);

--analyzed DEA's nationwide statistics on the nature and extent of prescription drug abuse and reviewed the results of DEA's nationwide efforts to prevent drug diversion from legitimate markets;

--analyzed summaries of DEA's Operation Script retail level investigations; and

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1/Illegally manufactured drugs are the subject of a recent GAO report, "Stronger Crackdown Needed On Clandestine Laboratories Manufacturing Dangerous Drugs" (GGD-82-6, Nov. 6, 1981).

--assessed DEA's assistance to States in preparing analytical reports on the distribution patterns of certain highly abused drugs.

To complete our understanding of prescription drug abuse and diversion, we performed further work in Chicago, Dallas, Los Angeles, Philadelphia, and San Francisco. We chose these locations because of their size, geographic dispersion, and the existence of ongoing or recently completed programs to reduce drug diversion. Work at these locations included:

--discussions of program results and local drug diversion problems with DEA regulatory compliance personnel;

--analysis of DEA drug diversion cases; and

--visits to State and local agencies to get their views on the extent of prescription drug abuse, the ways these drugs are obtained, and the efforts to control drug sources, as well as to obtain data concerning investigations of retail practitioners.

We also discussed the prescription drug abuse problem and control efforts with officials of the Pharmaceutical Manufacturers Association (PMA), the National Association of State Alcohol and Drug Abuse Directors (NASADAD) and the American Medical Association (AMA). Additionally, we attended the November 1980 White House Conference on Prescription Drug Misuse, Abuse, and Diversion, and we considered the recommendations of the conference participants.

We supplemented the work described above with information obtained in a variety of GAO, Department of Justice, congressional, and other reports. The primary reports we relied on are listed in appendix IV.

This review was performed in accordance with generally accepted Government auditing standards.

## CHAPTER 2

## A COMPREHENSIVE APPROACH IS NECESSARY TO SUCCESSFULLY COMBAT THE PRESCRIPTION DRUG ABUSE PROBLEM

Because heroin, cocaine, marijuana, and certain other dangerous drugs are illegal, curtailing their production and distribution constitutes a law enforcement problem. Controlling prescription drugs, however, extends beyond law enforcement. Although law enforcement agencies have a definite role in dealing with the diversion of legally manufactured prescription drugs for illegal use through activities such as pharmacy thefts, illegal sales, and forged prescriptions, law enforcement cannot do much about legally and properly prescribed drugs that get abused. There are also sources of abused prescription drugs which fall into a gray area--where the physician mispre-scribes drugs through carelessness but is unaware that the drugs will be misused. Even when practitioners apparently violate the law, their criminal intent is often very difficult to prove.

These factors have contributed to an increasing recognition that a comprehensive approach combining elements of law enforcement, regulation, education, and professional peer pressure is the key to long-term success in combatting prescription drug abuse. The need for such a comprehensive approach was recognized as far back as 1967, and national prescription drug conferences in 1979 and 1980 also highlighted this need. Recently, the AMA has taken steps to implement a comprehensive approach to the problem, and the Federal Government is in a position to contribute significantly to the success of this approach.

### PRESCRIPTION DRUG ABUSE IS MORE THAN A LAW ENFORCEMENT PROBLEM

Prescription drug abuse is more than a law enforcement problem. The numerous ways--both legally and illegally--by which abused prescription drugs are obtained make the control of this drug problem difficult and unique. Although opinions differ and virtually no reliable information exists on the relative size of the various means of obtaining prescription drugs, it is apparent that legally obtained drugs are involved in a major portion of the abuse which is occurring. However, the abuse of drugs properly obtained from legitimate channels is beyond the reach of law enforcement activities.

## Many abused prescription drugs are obtained legally

The DAWN system indicates that the prescription drugs mentioned most often in emergency room reports--schedule III and IV drugs together (see app. III)--are generally obtained through legitimate channels. The source most often cited in DAWN reports for these drugs is "legal prescription," and the predominant motivation reported in association with them is suicide. The more tightly controlled schedule II drugs, on the other hand, are generally reported as obtained in a "street buy," with psychic effect and dependence the most frequent motivations reported. 1/

These DAWN reports partially explain why schedule II drugs were involved much more often than schedule III or IV drugs in the retail level criminal investigations we reviewed at various law enforcement agencies. Another reason is that law enforcement agencies generally place greater priority on schedule II drugs because of their potential for abuse. For example, in DEA's Operation Script, an investigative effort started in August 1979 and directed against 94 retail level targets 2/, schedule II drugs accounted for 67 percent of the primary drugs involved in cases where convictions had resulted as of May 1981. Our work in Dallas, Philadelphia, Los Angeles, and San Francisco showed this same pattern:

--In 69 retail investigations we reviewed that were conducted by DEA's Dallas District Office and/or the Texas Department of Public Safety during 1979 and 1980, 75 percent of the drugs mentioned were schedule II drugs.

--DEA's Philadelphia Compliance Supervisor informed us that in 15 DEA retail investigations between July 1980 and January 1981, two of the four principal prescription drugs diverted were schedule II drugs.

--Our review of California Diversion Investigation Unit (DIU) cases reported in Los Angeles and San Francisco during 1979 showed that all six of the prescription drugs most often involved were schedule II drugs.

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1/Sources of drugs and motivations for taking them have a high "unknown/no response" rate in DAWN reports. Nevertheless, the reported information provides an indication of how and why various drugs are obtained.

2/See p. 20 for more details on this project.

It is entirely proper for law enforcement to concentrate on schedule II drugs. DAWN indicates that abused schedule II drugs are acquired predominantly through illegal means, and that abused schedule III and IV drugs are usually obtained legitimately. Further, schedule II drugs are considered to have a higher abuse potential. Nevertheless, schedule III and IV drugs together are mentioned most often in emergency medical situations. This means that law enforcement is unable to deal with a substantial portion of the prescription drug abuse problem.

Difficulties in proving willful diversion

The difficulty often faced in securing felony convictions of practitioners who willfully divert drugs further limits what law enforcement can accomplish. Often it is difficult to obtain the necessary evidence required to prove a practitioner's criminal intent and gain a conviction. Therefore, prosecutors frequently refuse to prosecute these cases.

Pharmacies are required to keep detailed records of drugs acquired and dispensed. In regulating pharmacies, States examine these records to determine whether recordkeeping requirements have been adhered to and whether a pharmacist can account for all the drugs he or she dispensed. However, establishing criminal intent using records is difficult. It was not until 1976 that a registrant, the owner of a pharmacy, was convicted under a criminal statute for the illegal sale of controlled drugs on the basis of the results of a regulatory investigation. Consequently, States generally use civil prosecution proceedings in pharmacy cases.

Physicians, on the other hand, keep fewer and less detailed records than pharmacists. Thus, proving willful diversion by a physician is even more difficult. 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 drugs for treatment, physicians necessarily have wide latitude in judgment. Proving that this judgment involves criminal intent is difficult.

To overcome these difficulties, an investigative approach generally used for developing criminal cases against physicians is undercover buys. 1/ Several undercover buys may be needed to

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1/An undercover buy involves a law enforcement agent making a drug purchase while posing as a drug user or customer.

show that the illegal prescribing or dispensing was not an isolated instance. Even with several buys, however, obtaining a criminal prosecution can be difficult. In order to obtain a conviction, it must be proven that a physician's activity was outside the scope of his or her legitimate medical practice. A major issue in these cases is whether a doctor/patient relationship existed. Whether this relationship existed is usually based on the degree of examination by the physician. According to DEA, some violators conduct examinations merely to give the appearance of legitimacy.

Another investigative approach is to make a "paper case" against a physician. This type of criminal investigation, which can support or be supported by undercover buys, relies on the analysis of such things as a doctor's prescribing or dispensing patterns, clinic records, and drug purchases. Paper cases, however, are very complex and time-consuming and the prosecution must satisfy a heavy burden of proof. DEA officials told us that prosecutors in some jurisdictions are therefore reluctant to accept paper cases.

## A COMPREHENSIVE APPROACH IS NOW WIDELY RECOGNIZED AS THE KEY TO SUCCESS

Controlling prescription drug abuse requires that law enforcement agencies, regulatory boards, professional associations, and others work together to address the various legal and illegal sources of prescription drugs. This need was recognized as far back as 1967. Most of the needed actions must be taken at the State level. Although actions have been taken in a few States, the need for further action is widely recognized.

### Better coordination of law enforcement, regulatory, and professional organizations' efforts is needed

At a 1967 AMA conference attended by physicians and representatives of law enforcement and licensing agencies, there was general agreement that committees should be created at State and local levels to strengthen liaison among medical, law enforcement, and regulatory bodies so as to prevent and control the abuse of drugs. Although it was recognized that liaison mechanisms would take on different forms in different States, conference attendees generally agreed that the principal functions of such committees should include:

--working with Federal, State, and local law enforcement and judicial agencies and State licensing bodies

to prevent misuse and abuse by physicians and to process, investigate, and adjudicate complaints;

--consulting with individual physicians on problems arising in their practices; and

--upgrading the skills and increasing the understanding of physicians in practice, physicians in training, and medical students with respect to narcotics abuse.

In addition, the conference proposed that a national committee be created to establish principles of proper medical use of narcotics.

More recently, the White House Drug Policy Office sponsored a meeting in September 1979 1/ to discuss possible courses of action to remedy the problem of diversion of prescription drugs to illicit use. The meeting was attended by representatives of various Federal and State agencies and professional, educational and trade associations. The participants concurred that no one agency, either Federal or State, could effectively deal with the problem. The need for coordinated efforts involving Federal, State, and local government agencies in cooperation with professional, educational, and trade organizations was repeatedly emphasized. It was noted that common elements of successful State programs include law enforcement, regulatory and licensing activities, professional education, and professional peer pressure. It was also noted that since the problems in each State are unique, there is probably no one model of coordination that will suffice.

The White House Associate Director for Drug Policy told the Congress in October 1979 2/ that while Federal and State governments must continue to prosecute practitioners illegally diverting drugs, the most effective way to deal with prescription drug abuse is to foster Federal-State cooperation in identifying sources of diversion and to use peer pressure and other noncriminal means of ensuring compliance with proper prescribing standards. He said that the States and concerned professionals must determine the type of program needed in light of their own

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1/U.S. Cong., Diversion of Licit Drugs to Illegal Markets, hearing before the select Committee on Narcotics Abuse and Control, House of Representatives, SCNAC-96-1-11, Oct. 31, 1979, pp. 71 to 78.

2/House, Diversion Hearing, pp. 67 to 69.

circumstances, and that the Federal Government would do everything possible to encourage the establishment of adequate systems for monitoring and control.

A step in the right direction was the White House's convening in November 1980 of the Conference on Prescription Drug Misuse, Abuse, and Diversion: Strategies for Prevention. The conference was held to highlight cooperative steps which would reduce the abuse of prescription drugs and to share information on existing State initiatives. Participants at the conference discussed the need for better coordination in the States and for more reliable and timely information to locate diversion problems. Recommendations were made to improve and better coordinate prevention/education, peer review, regulation/licensing, and law enforcement. Conference participants also generally agreed that coordination at the national level is needed (for example, a national steering committee or advisory group), including more frequent dialogue among the concerned national organizations and Federal agencies.

## Some States have successfully applied the comprehensive approach

A few States have developed comprehensive plans to combat particular prescription drug problems. Wisconsin and Florida are two good examples.

Wisconsin officials became concerned with reports of both the illicit availability and large purchases of amphetamines by physicians in 1976. The State then obtained computerized information from DEA's ARCOS system 1/ on purchases of amphetamines by all physicians and pharmacies in the State. Computer analysis of the ARCOS data, along with pharmacy audits by the State regulatory board, revealed some extraordinary prescribing and dispensing patterns. Numerous physicians were investigated and several were arrested. The State discontinued Medicaid reimbursement for amphetamines unless prior authorization was obtained and placed restrictions on the use of amphetamines in treating obesity. Wisconsin officials reported that by 1978, as a result of these actions, retail purchases fell by more than 90 percent, and various local law enforcement agencies reported sharp drops in the illicit availability of prescription amphetamines and in the number of amphetamine-related arrests.

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1/DEA's Automation of Reports and Consolidated Orders System (ARCOS) is a comprehensive drug tracking system which monitors the flow of selected drugs from point of import or manufacture to point of sale, export, or other distribution.

In 1977, the Duval County Medical Society, the Jacksonville Area Osteopathic Society, and the Duval County Pharmaceutical Association in Jacksonville, Florida, decided to act against the serious abuse of methaqualone and amphetamine that was taking place in the area. These professional organizations instituted a program designed to discourage physicians from prescribing these drugs and to reduce the incidence of stolen and forged prescriptions and pharmacy burglaries. Methaqualone and amphetamines are no longer to be stocked routinely by pharmacies in the area. A 48-hour delay in filling prescriptions for these drugs was created, during which time the pharmacist contacts the physician to verify the prescription. In addition, prescriptions are to be honored only in stock-size packages so partial packages are not left on pharmacy shelves. The medical society also kept its members informed about the drug abuse problem and applied peer pressure by contacting those few physicians believed to be abusing their prescription writing functions. These actions reportedly reduced the number of methaqualone and amphetamine prescriptions by more than 70 percent in Duval County. Similar programs have been implemented in other Florida counties, and the Dade County Medical Association has published guidelines for prescribing methaqualone and amphetamine. The Florida Medical Association recommended that each of its component medical societies institute such programs.

## THE AMA HAS TAKEN STEPS TO EXPAND APPLICATION OF THE COMPREHENSIVE APPROACH

The AMA has started expanding the establishment of comprehensive statewide programs involving professional groups, law enforcement, and regulatory agencies. The AMA has done this by inviting other interested organizations to join it in a National Steering Committee on Prescription Drug Abuse in which the parties can share their ideas and experiences and develop supportive relationships. The AMA is to be commended for its initiatives. Continued commitment to this approach is necessary to effectively deal with prescription drug abuse.

Until recently, the AMA did not actively encourage State medical societies to play a significant role in efforts to combat prescription drug abuse. In the past, the AMA took the position that the problem was predominantly a law enforcement one. In June 1981, the AMA adopted a report 1/ prepared by its special

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1/Council on Scientific Affairs, Drug Abuse Related to Prescribing Practice, June 1981.

drug abuse panel which recognized that prescription drug abuse can result from both intentional and unintentional actions of physicians. The report commended the activities of the Duval County Medical Society and the Florida Medical Association in significantly reducing inappropriate prescribing and illicit diversion of amphetamine and methaqualone. It noted that:

> "Each community and each state should assess its own drug abuse problems and options for remedial action in as direct and forthright a manner, and state medical societies should take a leading role in this cooperative process in their respective jurisdictions."

The AMA report recommended that State medical societies carry out the following specific actions:

1. To curtail prescription drug abuse and to promote appropriate prescribing practices, these societies should institute a comprehensive statewide program that incorporates the following elements:

   a. Determination of the nature and extent of the prescription drug abuse problem.

   b. Cooperative relationships with law enforcement, regulatory agencies, pharmacists, and other professional groups to identify "script doctors" 1/ and bring them to justice and to prevent other unlawful activities related to prescription drugs.

   c. Cooperative relationships with such bodies to provide education to "duped doctors" 1/ and "dated doctors" 1/ so their prescribing practices can be improved.

   d. Educational materials on appropriate prescribing of controlled drugs for all physicians and for medical students.

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1/The AMA report defines "script doctors" as physicians who willfully, consciously, and usually for profit, misprescribe drugs for drug abuse purposes; "duped doctors" as physicians who inappropriately misprescribe drugs because they unwittingly acquiesce to the demands of patients for medication; and "dated doctors" as physicians who engage in uninformed prescribing because they have not kept abreast of new pharmacology and drug therapy developments.

2. Recognizing the fact that even optimal prescribing practices will neither eliminate the availability of drugs for abuse purposes, nor appreciably affect the root causes of drug abuse, State medical societies should:

   a. Educate patients and the public on the appropriate medical uses of controlled drugs and the deleterious effects of the abuse of these substances.

   b. Provide instruction and consultation to practicing physicians on the treatment of drug abuse and drug dependence in its various forms.

In November 1981, the AMA held a meeting of representatives from various Federal, State, and private organizations to discuss specific recommendations in the report and how to implement them. To help implement the recommendations, the representatives formed the National Steering Committee on Prescription Drug Abuse. The members emphasized that only through a cooperative effort among the medical, pharmaceutical, and governmental organizations could these recommendations be carried out, and to that end uniformly pledged their support. The Committee has since taken steps toward achieving these recommendations, as described below.

Medical associations

Information developed in a survey of medical societies and supplied by members of the Steering Committee has been used to identify six States having a strong interest in reducing their prescription drug abuse problems. The Committee is encouraging the professional organizations in those States to convene conferences at the State level to identify the nature of the problem locally and to develop specific remediation programs. With the results of the first round of State meetings as a guideline, similar meetings are planned across the country over the next 2 years. These State level efforts could include a variety of activities depending upon the specific needs identified.

Pharmaceutical associations

Recognizing that the pharmaceutical profession can play a major role in combatting the problem, actions have been taken at the national, State, and local levels. At the national level, the American Pharmaceutical Association and the National Association of Boards of Pharmacy are devising a better way of preventing and detecting prescription forgeries and alterations, as well as sensitizing individual pharmacists to the seriousness of the problem.

At the State level, the Steering Committee is encouraging medical and pharmaceutical associations to develop formal avenues of communication on prescribing issues, as well as specific programs to reduce prescription drug abuse. For example, in Oregon the State medical society and State pharmacy association have developed a "hot line" system to alert members to the activities of drug hustlers.

At the local level, pharmacies are being encouraged to exchange information on suspicious individuals and outright thefts, and individual pharmacists are alerted to detect and question prescriptions that may be altered or forged and to observe and report serious deviations in physicians' prescribing practices.

### Federal agencies

Several Federal agencies are in a position to contribute significantly to achieving the Steering Committee's goals. Federal committee members are DEA, FDA, NIDA and the White House Drug Abuse Policy Office. Their contributions to providing a comprehensive approach include drug law enforcement, regulation, prevention, education, and treatment. Additionally, the White House Drug Abuse Policy Office occupies a unique position to coordinate the drug abuse functions of all these executive agencies to support the goals of the Steering Committee.

## CONCLUSIONS

Because law enforcement cannot combat all aspects of the prescription drug abuse problem, a comprehensive approach combining elements of law enforcement, regulation, education, and professional peer pressure is now widely recognized as the key to success. The AMA has recently taken steps to extend application of this comprehensive approach, which has been applied successfully in some States. Commitment to this approach by all involved parties--medical and pharmaceutical associations; trade organizations; and Federal, State, and local agencies--is essential for effective implementation of this approach. The Federal Government can contribute significantly to effective implementation in that Federal agencies, such as DEA, are in a position to perform functions which lie beyond the jurisdiction of individual States.

## AGENCY COMMENTS

Both the Department of Justice and the AMA commented on this chapter of the report. (See app. V and VI.) Justice agreed that the concept of a comprehensive approach involving law enforcement regulations, education, and professional peer pressure is the best hope for controlling prescription drug abuse. Justice said that DEA uses each of these levels of activities. The AMA assured us that it is going forward in its efforts to encourage improved

drug prescribing practices and to foster inter-disciplinary cooperation on both national and State levels.

The White House Drug Abuse Policy Office was provided a copy of our draft report for comment, but did not respond. The White House Drug Abuse Policy Office can play a major role in working with the AMA to foster inter-disciplinary cooperation, especially at the national level. This office is currently evaluating its role and developing a revised Federal strategy. At the time we completed our review, it had not yet specified its role regarding the prescription drug abuse problem. However, we believe this office is in a unique position to direct and coordinate Federal drug activities and encourage the commitment of State governments to a comprehensive approach.

## CHAPTER 3

## DEA NEEDS TO BETTER USE ITS RESOURCES TO HELP CONTROL PRESCRIPTION DRUG ABUSE

DEA's primary role at the retail level is to assist the States in their efforts to control prescription drug abuse. In the past, DEA concentrated its prescription drug control efforts on the wholesale level of the distribution chain. But, because of the drug industry's improved controls at the wholesale level (as discussed on p. 2), DEA has placed increased attention on conducting criminal investigations of drug violators at the retail level. The retail investigations that we reviewed, however, did not effectively focus on only high-level violators warranting Federal attention as DEA intended. DEA has recognized this problem and taken steps to correct it. There is a need to closely monitor DEA's current use of resources on retail level investigations to ensure that these efforts are directed only at high-level violators.

DEA is statutorily required to provide the States with analytical information to help locate sources of highly abused prescription drugs. Although only a small increase in staff is needed to adequately carry out this task, DEA has not devoted the necessary resources. These resources could be provided from those made available because of DEA's reduced oversight at the wholesale level.

### DEA'S PRIMARY ROLE AT THE RETAIL LEVEL HAS BEEN ASSISTANCE

Because DEA has traditionally viewed its primary role in controlling prescription drugs at the retail level as one of motivating and assisting the States, it generally has become directly involved only at their request. Since 1966, DEA and its predecessor agencies have entered into memorandums of understanding with 45 States and the District of Columbia. Under these agreements, which define Federal and State roles, DEA is responsible for monitoring manufacturers and distributors as provided in the CSA, and the States are responsible for monitoring retail practitioners. This division of responsibilities is also reflected in the Federal strategy. (See p. 4.) Accordingly, DEA's efforts involving the retail level, until recently, centered on assisting the States.

DEA's most substantial effort to assist States was the Diversion Investigation Unit (DIU) program. In this "seed" program, DEA acted as a catalyst in many States to bring funding, manpower, expertise, and various jurisdictions together into unified State efforts to investigate retail level diverters of prescription drugs. Although DIUs were staffed and managed by

State authorities, they were established with DEA assistance and training and direct Federal funding. The objective of the DIU program was to launch the participating States on a sound start and, ultimately, to have permanent State-sustained units. DEA believes that DIU's were successful and demonstrated that highly trained personnel can curtail diversion of drugs on a statewide basis. Because of recent budget constraints, however, DEA no longer funds DIUs.

DEA also assists States in other ways. For example, it participates in five informal "working committees" designed to improve communication with health care professionals, the related industry, and regulatory boards. As a result of one committee's efforts, DEA and the AMA jointly issued "Guidelines for Prescribers of Controlled Substances." 1/ In addition, DEA: established pilot programs in California and Pennsylvania to support improvement of State regulatory and enforcement capabilities; acted as a catalyst in various cities to mobilize pharmacists, police, government, and media into a joint community action approach designed to reduce pharmacy thefts (Pharmacy Theft Prevention project); and established a voluntary compliance program to support and foster self-regulation and self-enforcement among the health care professions and related groups such as State licensing boards and the pharmaceutical industry.

## DEA HAS SHIFTED RESOURCES TO RETAIL LEVEL INVESTIGATIONS WITH DISAPPOINTING RESULTS

In 1979, DEA started what has become a major shift of compliance investigative resources from the wholesale to the retail level. These retail investigations are designed to focus on high-level retail violators. 2/ Such cases can serve as models for State and local investigations and can demonstrate that the Federal Government will not tolerate doctors, pharmacists, and other practitioners violating the public trust. We found, however, that DEA's pilot program often targeted individuals who were not considered high-level violators by DEA's own standards.

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1/DEA-Registrant Facts, Vol. 6, No. 1, 1980.

2/DEA divides drug violators into four classes on the basis of certain criteria to help ensure that investigations are directed at the highest levels of drug trafficking. Class I and Class II are considered major or high-level violators. A registrant must illegally distribute 200,000 or more dosage units of schedule I, II, III, or IV drugs within 1 month to be considered a Class I violator, and 50,000 or more dosage units within 1 month to be considered a Class II violator.

DEA initiated Operation Script in August 1979 to supplement existing law enforcement efforts at the retail level and to produce high impact/high visibility criminal investigations of major practitioner violators. Operation Script focused DEA technical, investigative, intelligence, and legal resources on 94 suspected prescription drug diverters in 24 cities. The 94 targets were selected after a screening process intended to help ensure that the suspects were major violators appropriate for Federal investigation.

Our review of Operation Script showed that it did not entirely meet its objectives--many of the targets did not meet DEA's criteria for classification as high-level violators. DEA officials acknowledged there was mistargeting in Operation Script. They explained that the targeting was performed in a very short time frame and, therefore, was not as accurate as it should have been.

After more than 1-1/2 years of Operation Script, less than one-third of the targets had been convicted or had lost their medical or pharmacy licenses through revocation, suspension, or surrender. Some DEA offices had no success whatsoever. For example, the district offices we visited in Los Angeles, Dallas, and Philadelphia targeted a total of 18 practitioners with no results. DEA officials in those locations cited various reasons, including the inability to make a drug buy, insufficient evidence, targets reducing their activities, and unsuccessful investigative approaches.

With knowledge gained from Operation Script, DEA implemented its Targeted Registrant Investigations Program (TRIP) in fiscal year 1981. Similar in concept to Operation Script, this permanent program is designed to focus DEA investigations on a limited number of high-level retail violators. The assigned staff are, for the most part, compliance investigators who previously concentrated on monitoring regulatory activities at the wholesale level of the prescription drug distribution chain. According to DEA, improvements in recordkeeping and controls by the drug industry allowed DEA to reduce its oversight of the wholesale level and redirect some of its resources to the TRIP program. DEA has directed that at least 50 percent of its compliance investigative time in the field be spent on TRIP-type cases.

DEA officials told us they have taken action to improve the targeting of high-level violators for the TRIP program. If a DEA profile or preliminary investigation indicates a violator is not high-level, information will be given to the appropriate State for action. However, it is too early to evaluate whether the revised target selection procedures under TRIP will correct the targeting problems experienced under Operation Script.

## DEA IS NOT ADEQUATELY FULFILLING LEGISLATIVE REQUIREMENTS TO PROVIDE STATES ANALYTICAL REPORTS ON ABUSED DRUGS

DEA has not devoted sufficient staff resources to adequately fulfill the Infant Formula Act's requirements. These requirements state that DEA must provide analytical information to the States to assist them in identifying the sources of certain highly abused prescription drugs. Although the need for better analytical information has been recognized, DEA has not provided it to many of the States. DEA officials have acknowledged that the act's requirements have not been fulfilled and claim that a shortage of staff resources is the cause. However, they also told us that only a small staff increase is needed to meet the requirements.

The Infant Formula Act of 1980 (Public Law 96-359) amended the CSA to require that the Attorney General 1/ annually (1) determine which schedule II drugs have the highest rates of abuse, (2) prepare analytical reports on the actual distribution patterns of each such controlled drug, and (3) provide these analytical reports to State regulatory, licensing, and law enforcement agencies. DEA is in a unique position to fulfill these requirements because of its access to Federal information sources such as the Automation of Reports and Consolidated Orders System (ARCOS).

ARCOS is a comprehensive drug tracking system which monitors the flow of selected drugs from point of import or manufacture to point of sale, export, or other distribution. According to DEA, there are almost 1,500 companies (manufacturers, distributors, importers, and exporters) that are registered to handle controlled drugs and required to report to DEA on a monthly or quarterly basis. Reportable transactions consist of sales and purchases as well as other activities which affect the inventory of all schedule I and II drugs and narcotics in schedule III. Each reported transaction identifies the firm or individual with whom the reporting company is doing business. ARCOS can be used to identify actual or potential diversion within the legitimate distribution chain.

ARCOS is in a unique position to interact with other Federal information systems such as DAWN (see p. 2 for a description of DAWN). When used together, these two systems can provide an in-depth profile of a geographical area. For example, DAWN can be used to identify drugs currently being abused, determine existing

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1/The Attorney General has delegated his authority under the CSA to the Administrator of DEA.

abuse/abuser patterns, and identify abuse trends. ARCOS can show the distribution of certain drugs, including a comparison of State and total U.S. distribution patterns, and can identify potential excessive purchasers (that is, specific registrants such as pharmacies, physicians, and clinics).

In House and Senate reports 1/, the Congress expressed its belief that through vigorous and imaginative use of ARCOS in conjunction with other drug diversion/drug abuse indicators, such as DAWN, retail diversion activities can be identified and the diverters apprehended and prosecuted. The congressional reports also expressed the belief that the demonstrated effectiveness of this approach in States such as Wisconsin and Illinois would encourage similar efforts in other States. Unfortunately, the reports noted that even though ARCOS information was being provided to some States, it was not being provided in a timely fashion or in such form as to facilitate effective targeting of State diversion control activities. This situation prompted the amendment to the CSA, which was intended to correct the reported problems.

The need for better analytical information on the sources of highly abused prescription drugs was further highlighted during the 1980 White House Prescription Drug Conference. According to a summary report of the conference, there was general agreement that the States need reliable and timely information to locate diversion problems, since the types and levels of prescription drug problems vary from one location to another. Recommendations made at the conference to help correct this situation included the following.

--Use of DEA's ARCOS information should be increased to identify potential sources of diversion.

--Use of DAWN and mini-DAWN 2/ to measure the impact of prescription drug abuse on a locality.

--Analysis of DAWN and ARCOS should be integrated to enhance problem identification capability.

--ARCOS reporting to States and localities should be more timely, and adequate resources should be made available to do so.

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1/U.S. Cong., Infant Formula Act of 1980, Rept. 96-936, pp. 11 to 12, May 12, 1980, and Rept. 96-916, pp. 12 to 13, Aug. 26, 1980.

2/Mini-DAWN is a miniature DAWN system for use on a statewide, instead of nationwide, basis.

DEA has taken steps to correct some of the problems identified in the congressional and White House conference reports. For example, DEA officials told us ARCOS reporting is being changed from annually to quarterly so that more timely information can be provided to the States. DEA has also developed a "mapping" technique for targeting practitioners most likely to be diverting drugs. This procedure identifies "peak" geographical areas of drug distribution corrected for population differences. The drug distribution data, as well as the identification of individual registrants, is from ARCOS.

Unfortunately, even with these improvements, DEA has been unable to fully satisfy the act's analytical reporting requirements. For example, the mapping technique generates data which shows potential problem areas. However, this data must be combined with information from other sources and manually analyzed to determine if there is an explanation for the indicated problems.

DEA's ability to develop these analytical reports is essentially a function of the number of analysts on its staff. The DEA official responsible for preparing the analytical reports estimated that DEA would need four analysts in order to fulfill its requirements under the Infant Formula Act. However, at the time of our review, DEA employed only two analysts, and, because of budget constraints, both analyst positions were scheduled to be abolished.

Abolishing these analyst positions would further limit DEA's ability to meet its requirements under the Infant Formula Act. It would also be contrary to the House and Senate reports 1/ which state that the Attorney General is expected to ensure the allocation of additional analytical staff to DEA's ARCOS program to provide the necessary evaluation of drug distribution patterns.

## CONCLUSIONS

DEA recently reduced the amount of investigative time it spends to ensure compliance by manufacturers and distributors at the wholesale level. The resources made available as a result of this reduction were redirected to criminal investigations at the retail level. Although DEA's pilot program at the retail level (Operation Script) was meant to target only high-level

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1/See footnote 1 on page 22.

violators warranting Federal attention, many of the investigations failed to meet this objective. Subsequently, DEA developed TRIP, a permanent retail level investigation program. In this program, DEA has undertaken steps to prevent targeting problems experienced under Operation Script. However, it is too early to determine whether these steps will correct those targeting problems. Therefore, DEA should closely monitor TRIP.

DEA has not devoted sufficient staff to provide adequate analytical information to the States regarding the distribution patterns of certain highly abused prescription drugs. In view of the few resources needed, we believe that this task can be adequately carried out within DEA's current staffing level. One option is for DEA to reallocate a small portion of the resources now being used on retail level investigations.

## RECOMMENDATIONS

To assist the States in their efforts to control prescription drug abuse at the retail level, we recommend that the Attorney General direct the Administrator of DEA to

--reallocate sufficient staff resources to fully implement the analytical reporting requirements of the Infant Formula Act and

--monitor the use of staff resources on TRIP in terms of the program's success in targeting and immobilizing high-level traffickers appropriate for Federal investigation.

## AGENCY COMMENTS AND OUR EVALUATION

In commenting on our draft report, the Department of Justice said that it believes the implementation of our recommendations is a step in the right direction in effectively dealing with the prescription drug abuse problem. (See app. V.)

The Department of Justice stated that DEA has been attempting to fully implement the requirements of the Infant Formula Act within currently available staff resources. Justice noted that providing analytical information to the States is just one of many mandated drug enforcement activities to which DEA must distribute its limited resources and that DEA has increased its ability to meet the needs of the act through use of sophisticated computer techniques. Our concern is that the act's reporting requirements be fulfilled. If, in attempting to fulfill the requirements, computers can be utilized, negating the need to use additional staff resources, our concern would be satisfied.

Regarding our recommendation that attention be given to assuring the targeting of high-level retail drug diversion cases, Justice stated that DEA has refined the targeting process in TRIP and that the identification of appropriate cases continues to improve. DEA is now confident that it is focusing on high-level retail violators. Moreover, Justice said the program will continue to be monitored to assure that this objective is being achieved.

Justice disagreed, however, with our statement on page 19 that DEA has shifted resources to retail level investigations with disappointing results. The Department also said our statement on page 20 that: "After more than 1-1/2 years of Operation Script, less than one-third of the targets had been convicted . . .," is misleading. Justice argues that DEA was disappointed only with the quality of the information used to target high-level violators in Operation Script and not with the results of the investigations. According to Justice, DEA did not waste limited resources on inappropriate targets by pursuing Federal investigations, but referred to State agencies those targets that did not meet DEA's established criteria for classification as high-level violators.

Our review of Operation Script cases showed that DEA did spend investigative time on targets not classified as high-level, often in cooperation with State or local agencies. The use of investigative time in that manner, given the objective of Operation Script, can be considered a disappointment. We recognize, however, that the Script program, being new, may have had start-up problems, and we appreciate DEA's attempted solution. We believe that DEA's improved targeting procedures should provide better focused and more productive investigations in the future.

## CHAPTER 4

## FEES CHARGED REGISTRANTS TO RECOVER DRUG CONTROL COSTS ARE TOO LOW

Annual fees charged registrants under the CSA are too low. Although the CSA authorizes the Attorney General to establish reasonable fees to recover Federal costs for registering and controlling the manufacture, distribution, and dispensing of controlled substances, the present fees recover only a small portion of those costs. The fees have not been increased since they were established by DEA in 1971.

This situation exists because DEA has interpreted the CSA's fee authorization provision to cover only registration processing and drug order form costs. The CSA fee authorization provision is sufficiently broad to cover a greater portion of the Federal costs than now is covered by the existing fees; therefore, the annual fees should be increased.

### THE CSA AUTHORIZES REASONABLE FEES

The CSA authorizes the Attorney General to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances (21 U.S.C. 821). Neither the CSA nor its regulations describe the specific costs to be covered by the fees. Nor do they provide guidance for determining "reasonable fees." Consequently, the Attorney General has broad discretion in establishing the fees authorized in the CSA. The Attorney General has delegated this responsibility to the Administrator of DEA.

### FEDERAL POLICY FOR ESTABLISHING FEES

Office of Management and Budget (OMB) Circular A-25, "User Charges," dated September 23, 1959, sets forth the general user charge policy for charging fees for services provided by the Federal Government. Except for certain specifically excluded activities, the Circular applies to all Federal activities which convey special benefits to recipients above and beyond those accruing to the public at large. The activities performed under the CSA are not specifically excluded, nor does the CSA restrict the Attorney General from using the principles contained in the Circular in establishing CSA fees. The Circular states in part:

> "3. General policy
>
> A reasonable charge, as described below, should be made to each identifiable recipient for a measurable unit or

amount of Government service or property from which he derives a special benefit.

a. Special services

(1) Where a service (or privilege) provides special benefits to an identifiable recipient above and beyond those which accrue to the public at large, a charge should be imposed to recover the full cost to the Federal Government of rendering that service. For example, a special benefit will be considered to accrue and a charge should be imposed when a Government-rendered service:

(a) Enables the beneficiary to obtain more immediate or substantial gains or values (which may or may not be measurable in monetary terms) than those which accrue to the general public (e.g., receiving a patent, crop insurance, or a license to carry on a specific business)." (Emphasis added.)

OMB Circular A-25 also provides guidance for determining the Government costs to be recovered. It states that the cost computation shall cover the direct and indirect costs to the Government of carrying out the activity.

## FEES ESTABLISHED BY DEA SHOULD BE INCREASED

DEA sets its fees under the assumption that it should recover only the costs of processing registrations and providing drug order forms to registrants. These costs make up only a small portion of DEA's total compliance and regulatory budget. But, studies by the Department of Justice Internal Audit Staff and DEA's Management Analysis Division show that the fees are too low to recover even these relatively small costs.

Under the authority provided by the CSA, DEA has maintained the following annual fee schedule since 1971:

| | |
|---|---|
| Manufacturers | $50 |
| Distributors, importers/exporters, and brokers | $25 |
| Retail pharmacies, practitioners, teaching institutions, researchers, and analysis laboratories | $ 5 |

The following table shows the total amount of fees DEA has collected and DEA's compliance and regulation expenditures during fiscal years 1977 through 1980. As shown, the difference between what DEA has collected and what it has spent for this program is substantial.

| Fiscal Year | Registration fees deposited (note a) | Compliance/regulation actual expenditures | Unrecovered costs (note b) |
|---|---|---|---|
| | ----------millions---------- | | |
| 1977 | $2.78 | $ 8.67 | $ 5.89 |
| 1978 | $2.73 | $10.80 | $ 8.06 |
| 1979 | $2.85 | $13.10 | $10.25 |
| 1980 | $3.04 | $12.66 | $ 9.61 |

a/The registration fees are deposited in the U.S. Treasury.

b/Some amounts do not add due to rounding.

On June 19, 1981, we wrote a letter to DEA inquiring about the fees and the types of costs being recovered. DEA responded that when the fees were first established it was felt that they covered the total cost of processing registrations and providing drug order forms. According to DEA, the fees have not been changed because the costs directly related to processing registrations have decreased with the advent of faster and more efficient computer programs and hardware. Even so, this does not alter the fact that DEA has been recovering only about one-fourth of the costs it incurs in controlling the manufacture, distribution, and dispensing of controlled substances.

DEA stated that an increase to provide revenue sufficient to recover the cost of its entire regulatory effort would represent a position different from what it has heretofore perceived to be the purpose of the fees. DEA said that such a change in its position would raise questions of policy and economics which it has never previously addressed. DEA further stated that such a departure from its past position would require a congressional or executive mandate that does not exist now. As we previously stated, we feel the CSA authorizes DEA to collect reasonable fees that will recover a greater portion of the cost of its compliance and regulatory program.

We would expect that fee increases established by DEA would not impose an undue financial burden on registrants. Even if the fees were increased to recover all of the program costs, they could still remain inexpensive. For example--assuming that all fees are collected--if the existing fees had been five times greater (for example, manufacturers, $250; distributors, $125; retail practitioners, $25) DEA's entire 1980 compliance and regulatory program expenditures would have been more than covered.

## CONCLUSIONS

DEA's annual fees charged to manufacturers, distributors, and dispensers of controlled substances are too low and should therefore be increased. The fees were established in 1971 and have not been changed since.

DEA has authority under the CSA to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances. DEA believes that only the costs for registration processing and drug order forms should be recovered. These costs represent only a small percentage of DEA's total expenditures for its compliance and regulatory functions. OMB Circular A-25 provides a basis for determining the proper fees to be charged by an agency for services provided by the Federal Government to a recipient receiving a special benefit from that service. The guidance contained in Circular A-25 should be useful to DEA in determining the proper fees to be charged under the CSA. DEA's use of the criteria contained in Circular A-25 should result in increased fees which would recover a greater portion of the Federal costs than is now recovered by the existing fees.

## RECOMMENDATION

We recommend that the Attorney General direct the Administrator of DEA to increase the fees charged to drug manufacturers, distributors, and dispensers under the Controlled Substances Act

to recover a greater portion of Federal control costs. The DEA Administrator should determine the additional compliance and regulatory program costs to be recovered by the fees and establish fee amounts accordingly.

## AGENCY COMMENTS

In its comments on this report (see app. V), the Department of Justice said it has been in contact with OMB concerning the question of appropriate fees for DEA registrants. According to Justice, some form of fee proposal will be developed and published in the Federal Register after the discussions with OMB are concluded.

APPENDIX I

## NIDA'S 1979 NATIONAL SURVEY ON DRUG ABUSE
## PERCENT OF MAJOR AGE GROUPS
## THAT EVER USED EACH DRUG OR DRUG CLASS

| Drug/drug class | Youth (Age 12-17) | Young adults (Age 18-25) | Older adults (Age 26 & older) |
|---|---|---|---|
| Marijuana/hashish | 31 | 68 | 20 |
| Nonmedical RX (note a) | 7 | 30 | 9 |
| Cocaine | 5 | 28 | 4 |
| Hallucinogens | 7 | 25 | 5 |
| Heroin | 1 | 4 | 1 |

a/NIDA defines "nonmedical RX" as a drug class that includes the recreational or nonmedical use of stimulants, sedatives, tranquilizers, and/or analgesics that are legally obtainable only with a doctor's prescription.

APPENDIX II

## DRUG ABUSE WARNING NETWORK
## TOP 20 CONTROLLED DRUGS ABUSED
## Calendar year 1980

| Drug | Type | CSA schedule | Drug mentions reported by Emergency rooms Number | Drug mentions reported by Medical examiners Number |
|---|---|---|---|---|
| Diazepam | P | 4 | 16,603 | 346 |
| Heroin | I | 1 | 8,487 | 885 |
| Methaqualone | PT | 2 | 5,958 | 137 |
| Flurazepam | P | 4 | 4,538 | 92 |
| Marijuana | I | 1 | 4,513 | 10 |
| PCP | I | 2 | 4,441 | 43 |
| Cocaine | I | 2 | 4,153 | 265 |
| D-Propoxyphene | P | 4 | 2,964 | 326 |
| Phenobarbital | P | 4 | 2,861 | 225 |
| Amphetamine | PT | 2 | 2,658 | 37 |
| Chlordiazepoxide | P | 4 | 2,602 | 48 |
| Methadone | P | 2 | 2,500 | 376 |
| Secobarbital/ Amobarbital | P | 2 | 2,183 | 144 |
| Acetaminophen w/codeine | P | 3 | 1,980 | 5 |
| Pentazocine | P | 4 | 1,914 | 66 |
| Etchlorvynol | P | 4 | 1,834 | 103 |
| Speed | PT | 2 | 1,808 | 0 |
| Clorazepate | P | 4 | 1,719 | 5 |
| Oxycodone | P | 2 | 1,498 | 3 |
| LSD | I | 1 | 1,452 | 2 |
| Total P & PT | | | 53,620 | 1,913 |
| Total I | | | 23,046 | 1,205 |
| Total | | | 76,666 | 3,118 |

P - Prescription drug; normally found in the legitimate market.
PT - Prescription-type drug; significant origins outside legitimate domestic market.
I - Illegal drug

For the same year, the total number of mentions by emergency rooms was 95,502, and the total number of mentions by medical examiners was 4,747.

APPENDIX III

## DRUG ABUSE WARNING NETWORK
## DRUG SCHEDULES FOR ALL ABUSED CONTROLLED DRUGS REPORTED BY EMERGENCY ROOMS
## Calendar Year 1980

| Type of drug | Percent of total mentions |
|---|---|
| Prescription drugs (note a) | |
| Schedule II | 28 |
| Schedule III | 6 |
| Schedule IV | 41 |
| Schedule V | (less than 1%) |
| Illegal drugs (note b) | 25 |
| Total | 100 |

a/Includes methaqualone, amphetamine, and other drugs which often originate outside legitimate domestic channels; does not include cocaine or phencyclidine, which are schedule II drugs but are not considered prescription drugs.

b/Schedule I drugs plus cocaine and phencyclidine.

## LIST OF REPORTS CONCERNING PRESCRIPTION DRUG ABUSE AND RELATED TOPICS

GAO

Comptroller General's Report to the Congress, "Stronger Crackdown Needed On Clandestine Laboratories Manufacturing Dangerous Drugs" (GGD-82-6, Nov. 6, 1981).

Comptroller General's Report to the Congress, "Retail Diversion of Legal Drugs--A Major Problem With No Easy Solution" (GGD-78-22, Mar. 10, 1978).

GAO Report to the Attorney General, "Improvements Needed in Regulating and Monitoring the Manufacture and Distribution of Licit Narcotics" (GGD-75-102, Aug. 28, 1975).

Comptroller General's Report to the Congress, "Identifying and Eliminating Sources of Dangerous Drugs: Efforts Being Made, But Not Enough" (B-175425, June 7, 1974).

Comptroller General's Report to the Congress, "Efforts to Prevent Dangerous Drugs from Illicitly Reaching the Public" (B-175425, Apr. 17, 1972).

Department of Justice

"Internal Audit Report on the Drug Enforcement Administration's Controlled Substances Act Registration Records System," Internal Audit Staff, Justice Management Division (79-32, Mar. 1980).

U.S. Congress

"Psychoactive Drug Diversion," a report of the Select Committee on Narcotics Abuse and Control, House of Representatives, SCNAC-96-2-18, 1981.

"Drug Enforcement Administration Reauthorization," a hearing before the Subcommittee on Health and the Environment, Committee on Interstate and Foreign Commerce, House of Representatives, Serial No. 96-115, Mar. 10, 1980.

"Polydrug Abuse - The Response of the Medical Profession and the Pharmaceutical Industry," a report of the Select Committee on Narcotics Abuse and Control, House of Representatives, SCNAC-95-2-16.

APPENDIX IV

"Diversion of Licit Drugs to Illegal Markets," hearing before the Select Committee on Narcotics Abuse and Control, House of Representatives, SCNAC-96-1-11, Oct. 31, 1979.

"Abuse of Dangerous Licit and Illicit Drugs--Psychotropics, Phencyclidine (PCP), and Talwin," hearings before the Select Committee on Narcotics Abuse and Control, House of Representatives, SCNAC 5-2-22, Aug. 8 and 10, Sept. 19, and Oct. 6, 1978.

APPENDIX V

U.S. Department of Justice

*Washington, D.C. 20530*

SEP 9 1982

Mr. William J. Anderson
Director
General Government Division
United States General Accounting Office
Washington, D.C. 20548

Dear Mr. Anderson:

This letter is in response to your request to the Attorney General for the comments of the Department of Justice (Department) on your draft report entitled "Comprehensive Approach Needed to Help Control Prescription Drug Abuse."

As the draft report points out, the concept of a comprehensive approach involving law enforcement regulations, education and professional peer pressure is the best hope for controlling prescription drug abuse. The drug diversion program of the Drug Enforcement Administration (DEA) utilizes each of these levels of diversion control activities. In fact, the report notes that DEA has shifted substantial portions of its diversion investigation resources to high-level practitioner violators who are responsible for most drug diversion. This shift has been extremely successful and has resulted in the investigation and prosecution of increasing numbers of major drug diversion violators.

In contrast to the General Accounting Office's (GAO) statement on page 18 that DEA has shifted resources to retail level investigations with disappointing results, it is our conviction that the results of the shift in resources to the retail level has not been disappointing. It is true that DEA was disappointed with the first attempts at targeting, but this was because many of the practitioners identified, while involved in diversion, did not reach the level of diversion appropriate for Federal investigation under G-DEP I or II. Those practitioners who met G-DEP I or II levels were pursued with excellent results as acknowledged by GAO. In final analysis, DEA was not disappointed with the results of shifting resources to investigation at the retail level, only with the quality of the information used to identify major violators in the initial pilot program.

Similarly, the statement on page 19 that "After more than 1-1/2 years of Operation Script, less than one-third of the targets had been convicted . . . ." is also misleading. DEA did not waste limited resources on inappropriate targets. Those targets which did not meet G-DEP I or II levels were not pursued as Federal investigations but were referred to the appropriate State agencies.

In addition to its law enforcement activities, DEA has taken a number of regulatory steps to curtail diversion. These include drug scheduling actions, setting of stringent quotas for Schedule II drugs, pre-registrant screening of all applicants, and a number of other measures. In addition, we believe that DEA's "working committee" system is an excellent example of Government/Industry cooperation toward the common goal of reduced drug diversion. As the report points out, it was through one of these committee efforts that DEA and the American Medical Association jointly issued the "Guidelines for Prescribers of Controlled Substances." DEA plans to continue to build upon its successes involving the cooperation of peer groups.

In addressing the three specific recommendations of the report, GAO first recommends that DEA provide sufficient staff resources to more fully implement the analytical reporting requirements of the Infant Formula Act. DEA has been attempting to fully implement the requirements of the Infant Formula Act within currently available staff resources. The provision of this information to the States is just one of the many mandated drug enforcement activities to which DEA must distribute its limited resources. Through the use of sophisticated computer graphics, DEA has been able to increase its ability to meet the needs of the Act in spite of a decline in resources.

In its second recommendation, GAO suggests that DEA monitor the use of staff resources on the Targeted Registrant Investigations Program (TRIP) in terms of the program's success in targeting and immobilizing high-level traffickers appropriate for Federal investigation. GAO's recommendation that attention be given to assuring the targeting of high-level cases is well taken. DEA has refined the targeting process in TRIP, and as a result the identification of high-level (G-DEP I and II) cases continues to improve. Indication of the need to determine and refine the targeting process was first detected during the pilot program. DEA is now confident that it is focusing on high-level retail violators and the program will continue to be monitored to assure that this objective is being achieved.

In its final recommendation, GAO suggests that DEA increase the fees charged to drug manufacturers, distributors, and dispensers under the Controlled Substances Act so that a greater portion of Federal costs of controlling prescription drugs is recovered. The Department has been in contact with the Office of Management and Budget (OMB) concerning the question of appropriate fees for DEA registrants. Some form of registration fee proposal will be developed and published in the Federal Register following the conclusion of our discussions with OMB.

In summary, we recognize that the diversion of controlled prescription drugs and the efforts to control it present a major challenge. In an effort to effectively deal with the problem, we believe that implementation of GAO's recommendations is a step in the right direction.

APPENDIX V



We are pleased to have the opportunity to respond to the draft report. Should there be a need for additional information, please feel free to contact me.

Sincerely,

Kevin D. Rooney

Kevin D. Rooney
Assistant Attorney General
for Administration

APPENDIX VI

AMERICAN MEDICAL ASSOCIATION
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JAMES H SAMMONS, M D
Executive Vice President
(751 6200)

August 17, 1982

Mr. William J. Anderson
Director
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Anderson:

Thank you for sending me a draft copy of Chapter 2 of your proposed report to Congress on prescription drug abuse.

We are pleased that you have given due recognition to the activities of the AMA in this important problem area. Let me assure you that we are going forward in our efforts to encourage improved prescribing practices and to foster inter-disciplinary cooperation on both national and state levels.

Sincerely yours,

James H. Sammons, M.D.

JHS/ims

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