REPORT TO THE CONGRESS

Efforts To Prevent Dangerous Drugs From Illicitly Reaching The Public B-175425

Bureau of Narcotics and Dangerous Drugs
Department of Justice

BY THE COMPTROLLER GENERAL OF THE UNITED STATES

APRIL 17, 1972

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 is our report on the efforts of the Bureau of Narcotics and Dangerous Drugs, Department of Justice, to prevent dangerous drugs from illicitly reaching the public.

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).

Copies of the report are being sent to the Director, Office of Management and Budget, and to the Attorney General of the United States.

Elmer B. Staats

Comptroller General
of the United States

Contents

ABBREVIATIONS

BNDD	Bureau of Narcotics and Dangerous Drugs
DPSC	Defense Personnel Support Center
GAO	General Accounting Office

COMPTROLLER GENERAL'S REPORT TO THE CONGRESS

EFFORTS TO PREVENT DANGEROUS DRUGS FROM ILLICITLY REACHING THE PUBLIC

Bureau of Narcotics and Dangerous Drugs
Department of Justice B-175425

D I G E S T

WHY THE REVIEW WAS MADE

Increasing numbers of young people and adults abuse drugs widely used in medical practice. This abuse has reached epidemic proportions. The General Accounting Office (GAO) wanted to know what the Bureau of Narcotics and Dangerous Drugs was doing to stop diversion of these drugs from legitimate sources into the hands of illicit dealers where they become available to anyone wanting to buy them.

FINDINGS AND CONCLUSIONS

The Bureau estimates that 90 percent of the dangerous drugs in the illicit market are diverted, intentionally or unintentionally, from licensed sources--manufacturers, distributors, doctors, and pharmacists.

Opportunities for this diversion appear to be endless. There are 450,000 registered drug handlers in the United States, and through them flow 8 billion doses of stimulants and depressants annually.

The Bureau is making some progress in curbing diversion, but much more needs to be done. (See p. 13.)

Information needed

The Bureau should be better informed. For example:

--Drugs seized by State and local enforcement groups were not always examined to determine the manufacturer; this information is helpful and sometimes vital to learn how the diversion occurred. (See p. 14.)

--Drug samples used to identify seized drugs were not obtained from all domestic and Mexican firms. (See p. 16.)

--The Bureau received tips from drug manufacturers about unusually large or suspicious orders or purchases of dangerous drugs but did not maintain enough records to follow up leads systematically. (See p. 16.)

--Procedures were not established requiring the military services to provide information to the Bureau on drug thefts and shortages. (See p. 18.)

APRIL 17, 1972

--State and local groups did not maintain uniform and reliable statistics on dangerous drug thefts, seizures, and arrests. These statistics would indicate the extent of the drug problem. (See p. 19.)

Drug industry compliance

The Bureau has responsibility for investigating about 6,000 drug manufacturers and wholesalers to see whether their safeguards over drugs are adequate and comply with Federal regulations. During fiscal year 1971 the Bureau's surveillance resulted in 151 seizures of drugs. This represented confiscation of over 100 million doses of stimulants and depressants, 64 arrests, and 27 convictions and brought about improved safeguards by some firms. (See p. 23.)

The Bureau has developed plans to increase its monitoring of the drug-manufacturing industry. If effective, this development should provide added compliance by industry. (See p. 24.)

Self-regulation by the drug industry

Self-regulation needs improvement. The drug industry has a public duty and--under Federal law--a legal responsibility to safeguard its products from illicit use. Industry has taken actions, and so has the Bureau, to reduce the potential for diversion of drugs to the illicit market. However, the continued diversion indicates a need for increased efforts. (See p. 28.)

Retail drug handlers

As of June 30, 1971, agreements had been signed between the Bureau and 45 States to share the responsibility for monitoring licensed drug retailers. Negotiations were under way with the other five States. (See p. 30.)

GAO's review of the activities of State enforcement agencies in California, New Jersey, and New York showed that they lacked both sufficient staff and authority to effectively monitor retailers and force corrective action. For example, the New Jersey Bureau of Drug Control had four investigators to oversee the activities of about 1,900 pharmacies and make investigations of private doctors. Many retailers were not covered adequately; therefore many diversions might not have been detected. (See p. 30.)

In August 1971 the Bureau began to evaluate systematically the capabilities of the States to carry out effective monitoring programs.

RECOMMENDATIONS

The Bureau should:

--Obtain information on drugs seized by State and local enforcement agencies.

--Make sure that samples of drugs are obtained from drug manufacturers.

--Establish a uniform information system that will show all drug firms in each of the Bureau's regions and will provide control over all reports received of unusual or suspicious purchases or orders of dangerous drugs.

--Obtain information on drug thefts and shortages within the military and meet with the military on a regular basis to find out how to better control diversion.

--Define better the type of information it desires from State and local enforcement groups.

--Direct its regional offices to obtain available information from State and local enforcement groups on dangerous drug thefts, seizures, and arrests.

--Work with industry to establish a program for better self-regulation. (See p. 29.)

AGENCY ACTIONS AND UNRESOLVED ISSUES

The Department of Justice agreed that GAO's recommendations were valid and said that they would be made effective, to the greatest extent possible, on a priority basis.

With respect to the need to better spell out the types of statistics needed, the Department said that the development of a uniform collection program would require extensive time, effort, and resources and would hamper present operations. The Bureau, the Federal Bureau of Investigation, and the Law Enforcement Assistance Administration, however, are establishing a task force to consider the entire matter. (See app. I, p. 37.)

MATTERS FOR CONSIDERATION BY THE CONGRESS

This report shows that much more needs to be done by the Bureau of Narcotics and Dangerous Drugs, the States, local agencies, and the industry to reduce the diversion of legitimately manufactured drugs into illicit channels where they become easily available to young people and adults.

The report is being sent to the Congress to keep it advised of the situation and because of increasing public concern with the problems caused by drug abuse.

CHAPTER 1

INTRODUCTION

The Bureau of Narcotics and Dangerous Drugs (BNDD) was established in the Department of Justice in April 1968 as the result of a merger of the former Bureau of Narcotics of the Treasury Department and the Bureau of Drug Abuse Control of the Food and Drug Adminstration, Department of Health, Education, and Welfare. BNDD has the responsibility for enforcing Federal laws relating to (1) narcotics, such as heroin and morphine, (2) marihuana, and (3) dangerous drugs, including depressants, stimulants, and hallucinogens. BNDD's activities are carried out in the central office in Washington, D.C.; 20 regional offices; and 78 district offices, of which seven regional and 27 district offices are in foreign countries.

The diversion of legally manufactured drugs into the illicit market has become a serious problem because of increased abuse of stimulants and depressants. Our review was directed primarily toward the manner in which BNDD was carrying out its responsibility to curb the flow of drugs (stimulants and depressants) from legitimate manufacturers to the illicit market.

DRUG ABUSE

Drug abuse in the United States has reached epidemic proportions. Various studies show that increasing numbers of young people and adults are ingesting and injecting drugs, which not only can ruin their lives but also can cause dire consequences for society. For example, arrests in California for sale and possession of dangerous drugs have increased from 7,071 in 1966 to 38,396 in 1970. Of those arrested in 1970, about 28 percent were juveniles.

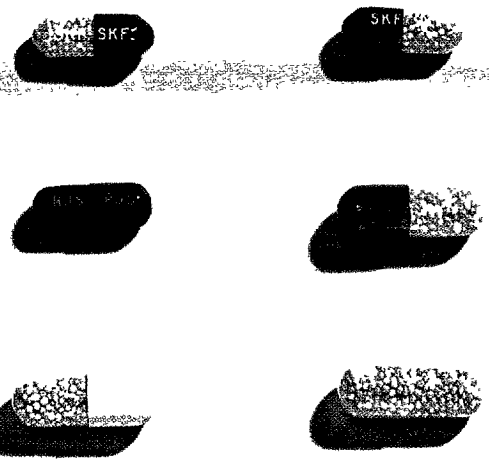
Stimulants and depressants often are prescribed in medical practice and, when taken under medical direction, are not considered dangerous. The most widely used and abused of the stimulants are amphetamines. Amphetamines are often called "diet pills," "pep pills," "uppers," "eye-openers," and "bennies." They cause central-nervous-system

stimulation and, in large doses, may cause overactiveness; release of inhibitions; and, in some cases, hallucinations.

Surveys conducted at various schools throughout the country indicate that amphetamines are abused widely by youths. One nationwide college survey revealed that about 13 percent of college students had used amphetamines. A survey of junior and senior high school students in Utah indicated that 10 percent had tried these drugs. A survey of California high school students in one county revealed that about 20 percent of the students had used amphetamines. (See p. 7 for BNDD-furnished photograph of stimulants.)

The most widely used and abused of the depressant drugs are the barbiturates. They often are called "sleeping pills," "reds," "downers," and "goofballs." They depress the central nervous system and sometimes cause death for the abuser. The nationwide college survey found that about 12 percent of the students had used barbiturates. A survey at several California high schools indicated that over 15 percent of the boys and 12 percent of the girls had used barbiturates. (See p. 9 for BNDD-furnished photograph of depressants.)

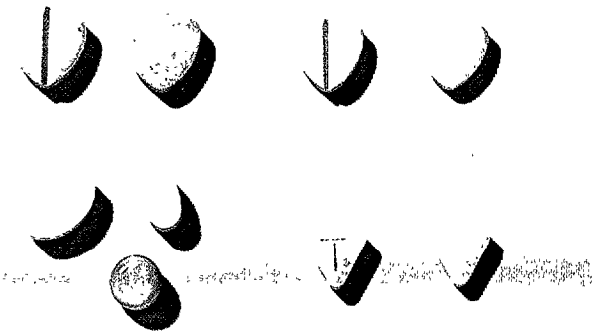
Stimulants



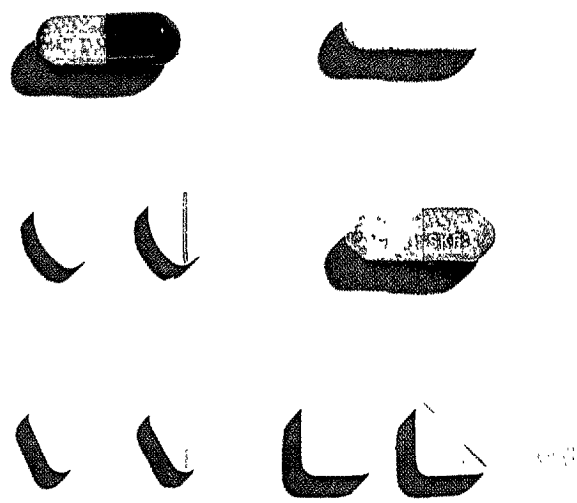
AMPHETAMINE CAPSULES

AMPHETAMINE TABLETS

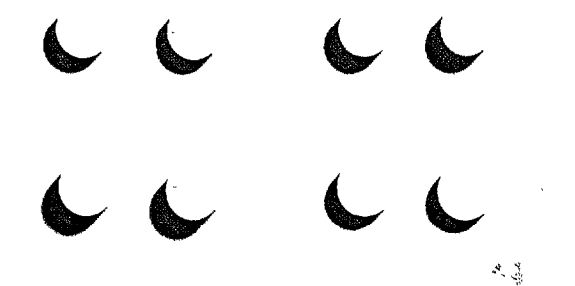
AMPHETAMINE TABLETS

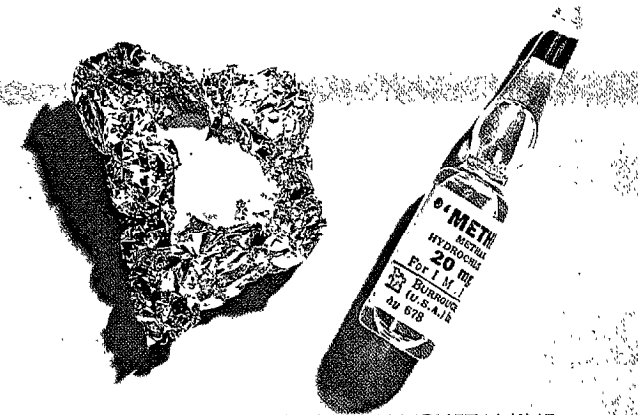


AMPHETAMINE TABLETS



AMPHETAMINE-BARBITURATE COMBINATIONS

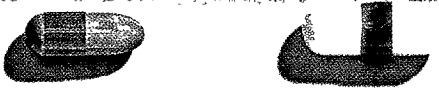




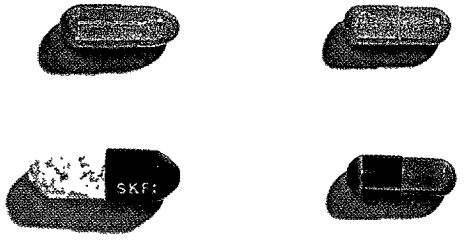
DOSAGE FORMS OF METHAMPHETAMINE

PHENMETRAZINE TABLETS

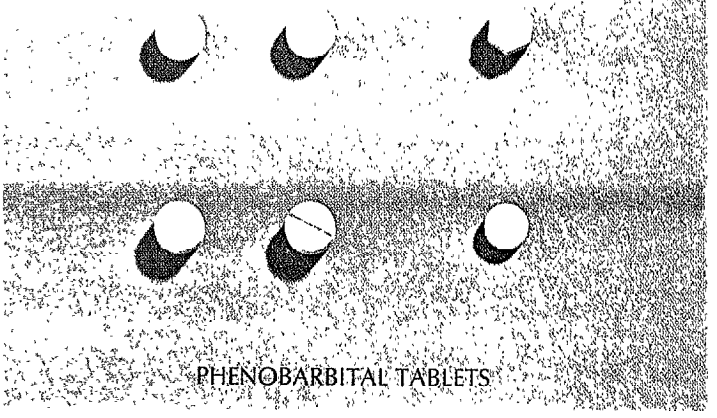
Depressants



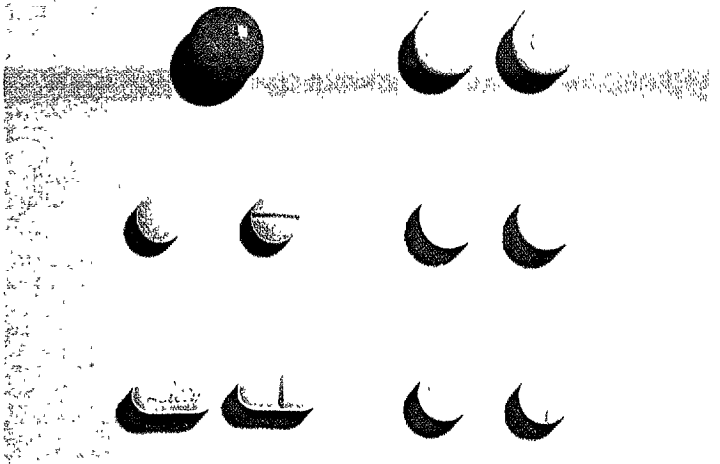
PENTOBARBITAL CAPSULES



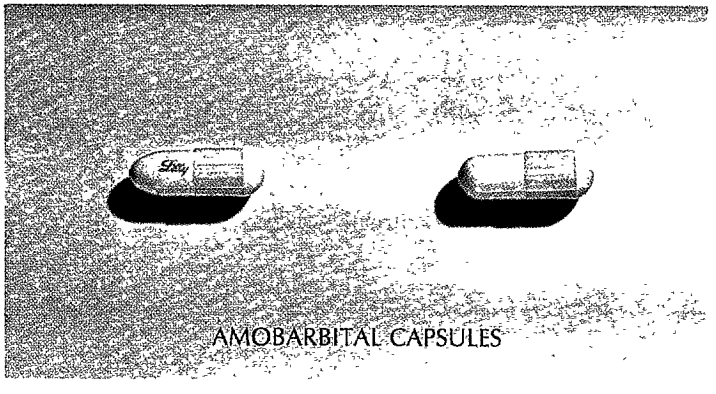
SECOBARBITAL CAPSULES



PHENOBARBITAL TABLETS



MISCELLANEOUS BARBITURATE TABLETS



AMOBARBITAL CAPSULES

AMOBARBITAL WITH SECOBARBITAL

OTHER DEPRESSANT DRUGS

CHAPTER 2

DIVERSION AS A CONTRIBUTING FACTOR TO ABUSE OF STIMULANTS AND DEPRESSANTS

BNDD estimates that about 90 percent of the drugs in the illicit market were manufactured by legitimate drug manufacturers. The chain for handling legitimate drugs (controlled substances) begins with the basic bulk raw-material manufacturer, links next to the dosage-form manufacturer, then to the wholesale distributor, and finally to the retail distributor. Through this chain of about 450,000 registered drug handlers, including prescribing physicians, flow about 8 billion dosage units of stimulants and depressants annually.

Diversion occurs when drugs find their way from legitimate drug handlers, either intentionally or unintentionally, into the hands of illicit dealers. "Diversion Analysis," a BNDD report, illustrates diversion at the different levels of distribution on the basis of an evaluation of seizures and prosecutions made between February 1966 and February 1970. Presented below are some of the observations made in the report.

1. Manufacturers--At this level of distribution there are very few instances in which management has been involved in overt illegal sales. The problem usually involves security lapses resulting in employee pilferage, break-ins, or filling of fraudulent orders.

2. Wholesalers--Some diversions are intentional, although the majority result from carelessness. Mail-order sales are a particular problem because of the difficulty of checking new customers, and the diversions usually occur because a firm fails to check properly its customers' credentials.

3. Retail pharmacies--This level is the most vulnerable to diversions because of the sheer number of handlers. Diversions are usually the result of illegal sales, that is, sales not pursuant to legal prescriptions, unauthorized

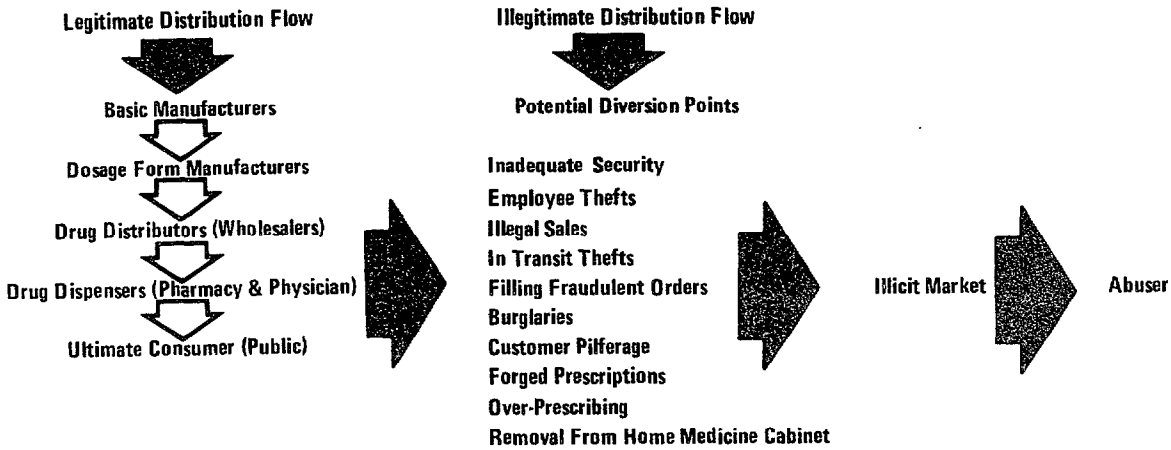
refills, and forging of prescriptions. Thefts are a significant and frequent problem due to the retailers' vulnerability in the area of security.

4. Practitioners--Diversions usually result from illegal sales, the use of drugs by the physician himself, or the nonmedical administration of drugs to others.

5. Researchers--Diversions are made by employees through unauthorized additions to company orders and through personal orders prepared on company forms.

The following chart, prepared by BNDD, illustrates some of the points of potential diversion.

DIVERSION OF LEGITIMATELY PRODUCED CONTROLLED SUBSTANCES



BNDD 1/72

BNDD has established an objective of curbing the flow of drugs from legitimate manufacturers to the illicit market. To accomplish this objective BNDD recognized the need for:

--Developing information to assess factually the diversion problem.

--Monitoring the drug industry's compliance with Federal laws.

--Promoting self-regulation by the drug industry.

--Cooperating with State agencies in combating drug diversions.

Our review indicated that, although BNDD was making progress toward meeting its objective, much more should be done. BNDD should improve its information system regarding drug diversions, increase its activity in monitoring the drug industry's compliance with Federal regulations, promote and encourage increased self-regulation on the part of the drug industry, and increase monitoring of retailers' activities. The Director, BNDD, agreed that much needed to be done and stated that plans were being made to implement our recommendations.

Our findings and recommendations are discussed in the following chapters.

CHAPTER 3

OPPORTUNITY TO OBTAIN ADDITIONAL INFORMATION ON DRUG DIVERSION

A comprehensive information system is a valuable tool for use in detecting and preventing drug diversion and in measuring the impact of enforcement and regulatory efforts. Our review revealed that BNDD had made some progress in developing such a system. We believe, however, that there are opportunities for BNDD to improve its system by developing (1) a procedure for obtaining information on drugs seized by State and local enforcement groups, (2) a more systematic method for obtaining information from drug manufacturers and distributors on suspected illegal drug purchases, and (3) a procedure for obtaining information from the military services on possible drug diversion.

We believe also that there is a need for BNDD to better define the type of information desired from State and local agencies on dangerous drug thefts, seizures, and arrests and to make its requirements known to Federal agencies who are assisting State and local agencies in upgrading their information systems.

DRUGS SEIZED BY STATE AND LOCAL ENFORCEMENT GROUPS NOT EXAMINED

BNDD, the Bureau of Customs, and State and local enforcement agencies seize large quantities of drugs. BNDD strives to identify the manufacturer of drugs seized by its agents and the Bureau of Customs, since the manufacturers' identity can be valuable in BNDD's investigations to determine the source and significance of the diversion. We found, however, that, although it had made some efforts to identify manufacturers of drugs seized by State and local enforcement agencies, BNDD had no formal procedures for obtaining such information and that informal requests for samples of seized drugs had produced few results.

Manufacturers of legally produced amphetamines and barbiturates can be identified by markings, such as trade names and trademarks, or by pillistics. (See photographs on pp. 7 and 9). Pillistics, a procedure similar to ballistics, identifies pills with the machines which produced them. BNDD has obtained samples (authentics) of pills from manufacturers which have been identified to specific machines. When the origin of seized pills is unknown, the pills can be compared with the authentics in an attempt to identify the manufacturers that produced them.

BNDD officials expressed the view that more complete information on the origin of drugs seized by State and local groups would be a valuable aid in their investigations. The value of this information is illustrated in a case involving amphetamine pills seized in California. Through its examination BNDD identified pills smuggled in from Mexico as being manufactured by a drug firm in the Midwest. Subsequent investigations at this firm revealed that large quantities of amphetamines were en route to a fictitious address in Mexico. This shipment was seized.

In our visits to 13 State and local enforcement groups in California, New Jersey, and New York, we learned that a number of large seizures had been made in the past year but that little attempt had been made to determine the origin of the drugs. Most officials were not aware of BNDD's efforts to identify manufacturers but were willing to cooperate with BNDD in establishing such a system.

In one large metropolitan police department, we found that over 1,358,000 pills were seized during 1970. Three of the seizures consisted of about 270,000, 95,000, and 68,000 pills and accounted for over 30 percent of the total seized. No attempt had been made by the police department to determine the origin of these drugs nor had BNDD obtained samples for this purpose.

In other enforcement agencies, we found also that no attempt had been made to determine the origin of many drug seizures ranging from 5,000 to over 100,000 pills. In addition, we found that none of the enforcement agencies had uniform procedures for recording statistics on drug seizures and, in several cases, no data was maintained.

We believe that BNDD should establish a procedure to obtain information on drugs seized by State and local enforcement groups. BNDD also should obtain samples of large drug seizures for its examination when the origin of the drugs is unknown. In addition, a uniform reporting format should be suggested to State and local enforcement groups so that data could be gathered systematically and uniformly and could be reported to BNDD.

NEED FOR MORE AUTHENTICS

BNDD did not have records that would provide assurance of the completeness of its file of authentics and had not obtained authentics from all domestic and Mexican drug firms.

BNDD officials advised us that they had obtained authentics from all major domestic drug manufacturers. BNDD did not maintain, however, records that would disclose the universe of firms and machines used in manufacturing drugs and had not identified the firms from whom authentics had not been obtained.

BNDD had a longstanding need for authentics of drugs manufactured by Mexican firms to help in identifying the source of drug seizures made along the Mexican border and throughout the United States. In June 1971, after 2 years of efforts, BNDD obtained samples from 33 Mexican drug firms; however, these authentics did not represent all Mexican firms manufacturing dangerous drugs. According to BNDD officials efforts will be made to obtain additional authentics.

NEED FOR A MORE SYSTEMATIC METHOD OF OBTAINING INFORMATION FROM DRUG FIRMS

Drug firms are in a unique position to provide BNDD with valuable information regarding suspected illegal drug purchases. BNDD has two programs which provide for drug firms to furnish such information. These programs were the excess-purchase program and the chemical-precursor control program. (Chemical precursors are basic ingredients required for the production of dangerous drugs.)

The objective of the excess-purchase program is to have manufacturers and wholesalers report all dangerous drugs

orders and all purchases which are unusual, suspicious, or unusually large. Such orders and purchases then are investigated to determine whether the disposition of the drugs was intended for legitimate use. The objective of the chemical-precursor program is to have chemical supply houses report unusual, suspicious, or large chemical-precursor sales in hope of identifying clandestine producers.

Both programs have provided leads to potential diversion and to clandestine producers. At the two BNDD regional offices we visited, however, we found that records were not maintained systematically on reported orders or purchases that appeared to be unusually large or suspicious or on the follow-up by BNDD of such reports. Officials of the regional offices advised us that data would be maintained in a manner which would enable BNDD to monitor participation.

We believe that BNDD should establish a uniform information system for each region that will (1) show all drug and chemical firms in the region and (2) provide control over all reports of unusual or suspicious orders or purchases received from firms and over the disposition of such reports.

NEED TO OBTAIN INFORMATION ON DRUG DIVERSIONS WITHIN THE MILITARY SERVICES

The military services purchase substantial quantities of dangerous drugs each year. For example, the Defense Personnel Support Center (DPSC), Philadelphia, Pennsylvania, purchased about 131 million pills and capsules of dangerous drugs during fiscal years 1970 and 1971. When large quantities of drugs which must be distributed to many locations are purchased, the possibility of diversion to the illicit market is increased greatly. We found, however, that procedures for the military services to provide information to BNDD on thefts and other shortages of dangerous drugs were not adequate.

Federal regulations implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 801) required the military services to begin reporting thefts of dangerous drugs to BNDD in May 1971. In September 1971 BNDD officials stated that the military services had not been contacted on the new reporting requirements and that they had not reported any thefts of dangerous drugs to BNDD headquarters. In our visit to DPSC, we found that DPSC Regulation 4158.6 dated May 21, 1971, required the reporting of narcotics thefts and shortages to BNDD but did not require the reporting of shortages of dangerous drugs. BNDD officials did state that some reports on shortages of dangerous drugs noted by the military during its periodic inventories had been sent to BNDD regional offices.

Timely reports on thefts and other shortages of drugs would be of value to BNDD in its enforcement efforts and would provide information on the extent of the diversion problem nationwide. BNDD officials agreed that there was a need to establish procedures for the military services to provide information to the BNDD central office and to regional offices on drug thefts and shortages. They further agreed that BNDD and the military should meet on a regular basis to discuss common problems and to exchange information on programs that are used to safeguard dangerous drugs.

NEED FOR BETTER INFORMATION TO MEASURE EXTENT OF PROBLEM AND IMPACT OF EFFORTS TO CURB IT

Information on dangerous drug thefts, seizures, and arrests is available from State and local enforcement groups and provides some indications of the extent of the drug diversion problem and success of efforts to curb it.

We found that many State and local groups had not maintained readily usable statistics on dangerous drug thefts, seizures, and arrests. We noted significant differences in the manner in which such statistics were recorded. For example, only three of the six law enforcement agencies we visited in New York and New Jersey had identified separately arrests for possession of stimulants and depressants and those for possession of hallucinogenic drugs. One agency used the category "other" as a catchall for all drug-related arrests, except those for narcotics. One police department did not distinguish between the types of drugs seized, and several did not even maintain seizure statistics.

BNDD officials advised us that several Federal agencies had programs aimed at assisting State and local enforcement agencies in developing information systems. We believe that BNDD should better define the type of information it desires and should provide its requirements to the Federal agencies to ensure that State and local systems being developed will be responsive to BNDD's needs. In the interim BNDD should require its regional offices to obtain available information on drug thefts, seizures, and arrests from State and local enforcement groups.

RECOMMENDATIONS TO THE DIRECTOR OF BNDD

We recommend that the Director of BNDD:

--Establish the necessary requirements to obtain information on drugs seized by State and local enforcement agencies.

--Increase efforts to obtain authentics from drug manufacturers and to maintain records to ensure that desired authentics have been obtained.

--Establish a uniform information system for each region that will show all drug firms in the region and will provide control over all reports of dangerous drug purchases and orders of an unusual or suspicious nature received from firms and over the disposition of such reports.

--Obtain information on drug thefts and shortages within the military supply system and establish a procedure for meeting with the military on a regular basis to exchange information on mutual problems in controlling diversion.

--Define better the type of information it desires from State and local enforcement groups to evaluate the drug problem; to measure enforcement efforts to control it; and, as new information systems are developed, to ensure that BNDD needs are considered.

--Direct, as an interim step, its regional offices to obtain available information from State and local enforcement groups on dangerous drug thefts, seizures, and arrests.

- - - -

The Department of Justice informed us (see app. I) that the recommendations for program improvement were valid and that they would be implemented, to the greatest extent possible, on a priority basis.

With respect to the recommendation to better define the types of statistics needed to evaluate the drug problem and measure the enforcement efforts, the Department stated that this recommendation:

> "*** concerns the need for a uniform collection program aimed at the collection of data on drug diversion or seizures and on arrests involving stimulants, depressants, hallucinogenic drugs, etc. In order to mount such an effort, extensive resources--human, material and time--will be required. LEAA [Law Enforcement Assistance Administration] has discussed the need for

collecting data on drug diversions or seizures with collection agencies in several States and there is unanimous opinion that the development of such data on dangerous drugs will entail serious dislocation to present operations. Of concern is the fact that there is already a large investment in the existing reporting systems. However, in order to fully assess the feasibility and cost of expanding the current program and establishing a new program, LEAA, BNDD and the FBI [Federal Bureau of Investigation] are arranging to establish a task force to examine the entire problem. This group will provide recommendations to the agencies involved for establishing a uniform collections program."

CHAPTER 4

INCREASED ACTIVITY TO MONITOR DRUG INDUSTRY COMPLIANCE WITH FEDERAL REGULATIONS

One of the major activities to detect and reduce diversion of dangerous drugs is the investigation of legitimate drug handlers for compliance with Federal regulations. We noted that there was a need for increased monitoring of the drug industry and that, as a result of recent congressional action, BNDD had developed plans to increase significantly its monitoring activities. We believe that BNDD's plans, if effectively carried out, will provide added assurance that drug firms are complying with Federal regulations.

BNDD COMPLIANCE PROGRAMS

BNDD is responsible for monitoring throughout the United States the activities of approximately 2,000 manufacturers and 4,000 wholesale distributors of drugs. BNDD has three types of investigations--routine, limited, and in-depth.

A routine investigation basically involves a background check of all applicants for Federal drug registration to ascertain that they are qualified or entitled under State laws to handle drugs. Included in this type of investigation is an inspection of premises to ensure that adequate storage and operational safeguards have been provided for stock.

The limited compliance investigation is an abbreviated investigation which involves a check of key indicators to determine whether a firm is complying with Federal regulations. Included in such an investigation is a check of the firm's registration and its controlled-drug security; a spot check of receipt, production, and distribution records; and a physical inventory of a representative number of controlled drugs.

The in-depth compliance investigation expands the limited investigation by including comparisons of transaction records for selected drugs with physical inventories of those drugs. This comparison, called an accountability, is performed to determine whether records of quantities of drugs on hand are accurate and reliable.

During fiscal years 1969 through 1971, BNDD performed 2,270 compliance investigations, as shown below.

	Fiscal year 1969	Fiscal year 1970	Fiscal year 1971	Total
Compliance investigations:				
Limited	739	533	-	1,272
In-depth	265	183	550	998
Total	1,004	716	550	2,270

Many of the 6,000 firms BNDD was responsible for monitoring were not investigated. Officials of BNDD explained that they did not have sufficient manpower to conduct investigations at all firms.

Our review showed that BNDD did have some degree of success as a result of the investigations it performed. During fiscal year 1971, BNDD's 550 investigations resulted in 151 seizures of drugs, which included 48 million dosage units of stimulants and 62 million dosage units of depressants, and in 64 arrests and 27 convictions. The investigations also caused some firms to change their practices to comply with Federal regulations.

RECENT LEGISLATIVE AND AGENCY ACTIONS

Recent legislative and agency actions have affected the drug industry and BNDD's monitoring activities. Most significant was the enactment of the Comprehensive Drug Abuse Prevention and Control Act of 1970 which required the drug industry to improve its physical security and recordkeeping over certain types of drugs.

Under the act controlled substances (narcotics and dangerous drugs) have been divided into five schedules on the basis of their potential for abuse, accepted medical use, and accepted safety under medical supervision. Substances included in schedule I are those with a high potential for abuse, no accepted medical use, and a lack of accepted safety. Those in schedules II through V decrease in potential for abuse and increase in accepted medical use. The placement of a drug in any one of these schedules determines the nature and level of control that must be exercised in preventing its abuse.

Amphetamines and barbiturates were placed in schedule III by the act. In July 1971 amphetamines were transferred from schedule III to schedule II. Drug firms handling amphetamines now are required to provide a higher degree of physical security for the drugs and to maintain separate records for transactions. They may also be subject to production quotas which can be established by the Attorney General.

The Director, BNDD, under the authority vested in the Attorney General, established 1972 production quotas for amphetamines and methamphetamines. The production quotas were set at 2,533 kilograms for 1972, a substantial reduction from the 1971 production of 14,282 kilograms and from the 1972 requests to produce 28,897 kilograms.

Federal regulations implementing the act provide for periodic investigation of all manufacturers and wholesale distributors of controlled drugs. BNDD plans to conduct annual in-depth investigations of all manufacturers of schedule I and II drugs and of wholesale distributors of schedule I drugs. BNDD plans to make in-depth investigations of all other firms once every 3 years. To accomplish this, and to continue following up on leads and complaints, BNDD increased its compliance staff from 82 in April 1971 to 164 at June 30, 1971. A staff of 290 was projected for January 31, 1972.

In view of BNDD's plans to increase significantly its investigations, we are not making any recommendations on this matter.

CHAPTER 5

IMPROVED SELF-REGULATION NEEDED BY DRUG INDUSTRY

Drug firms, in addition to meeting regulatory requirements, can take further actions in the public interest to reduce the potential for diversion of drugs. BNDD encourages such self-regulation as part of its program and has made some progress in its promotion. The continued diversion of legally manufactured drugs, however, indicates a need for increasing self-regulation, including the development and dissemination of self-regulation guidelines to all members of the drug industry and feedback from the industry on the self-regulation techniques that are successful in limiting diversions.

Hearings on the Drug Abuse Control Amendments of 1965 revealed a lack of self-regulation programs by the drug industry. The report on amphetamines issued on January 2, 1971, by the Select Committee on Crime, House of Representatives, restated the need for increased self-regulation by the drug industry, as follows:

> "No amount of Government regulation can be as effective as private enterprise carefully monitoring its own sales. Manufacturers, distributors, and dispensers, realizing the dangerousness of their products when abused, have a duty to the public to see that those products are put to their intended legitimate use. ***
>
> "We would hope in the future that the Nation's drug industry individually and collectively, will do a better job in seeing that their dangerous drugs are used legitimately and properly."

EFFORTS TO PROMOTE INDUSTRY PROGRAMS

BNDD's program to encourage the drug industry to help in the control of diversion consists of two phases. In the first phase, referred to as voluntary compliance, BNDD

encourages the drug industry to establish controls to ensure that its activities are in compliance with Federal regulations. The second phase, self-regulation, is based on the premise that regulations are not the complete answer. BNDD encourages the drug industry to install tighter controls when compliance with Federal regulations is insufficient to stop diversion.

In August 1969, as part of its operating plan, BNDD established several targets concerned with voluntary compliance and self-regulation, which were (1) to invite officials of the drug industry to form an advisory council, (2) to contact all distributors to familiarize them with laws and penalties and to maintain this contact on a regular basis, (3) to develop a program for promoting professional respect for regulatory programs through personal contact and correspondence with professional schools and associations, and (4) to publish a comprehensive booklet on voluntary compliance for distribution to the drug industry.

With the passage of the Comprehensive Drug Abuse Prevention and Control Act in October 1970, BNDD's primary emphasis was to provide the industry with information concerning the requirements of the new law. This was BNDD's main effort during the period of our review.

Voluntary compliance

BNDD made some progress in encouraging the drug industry to establish voluntary controls and undertook many projects to inform them about the new law and implementing regulations. BNDD and industry officials met to exchange ideas on how to curb diversion, and BNDD officials made numerous speeches on diversion to representatives of the industry. BNDD participated in national conferences of most industry groups, sponsored three conferences on the drug problem, and held seminars in various cities throughout the United States.

BNDD officials informed us that compliance agents had made numerous contacts with firms by telephone or letter. Also, in accordance with guidelines for performing compliance investigations, the agents discussed voluntary compliance with officials of each drug firm where an investigation was made.

In 1972 BNDD published a booklet on drug security measures and a booklet for pharmacists on the new law and how it affected them. A booklet for physicians is being printed, and we were informed that similar booklets were being prepared for wholesalers and manufacturers.

Self-regulation

During a September 1971 meeting with BNDD officials, we were informed that, because of limited resources, BNDD's main effort had been concentrated on informing the drug industry of requirements under the new law. Officials expressed an awareness of the need to encourage the drug industry to self-regulate and stated that various ideas concerning industry actions were under consideration. These ideas, however, had not been organized into a formal plan.

Drug industry associations

We visited four national drug associations and were informed that they had been active in developing and promoting compliance and self-regulation. They cited examples of their activities, such as participating in meetings and seminars with BNDD and other law enforcement officials and publishing articles in their trade publications. None of the associations had developed guidelines on the elements of an effective self-regulation program for use by their members and others in the industry. One of the associations mentioned that it had participated actively with BNDD in developing controls over mail-order distribution, security, and warehousing of dangerous drugs.

Drug wholesalers

We visited eleven major drug wholesalers in California, New Jersey, and New York and were informed by each that it had instituted in-house security measures designed to prevent the diversion of drugs and self-regulation systems to monitor its sales. Several firms actively participated in the excess-purchase program and regularly reported suspicious, large, and unusual orders to BNDD. Officials of six of the 11 firms informed us that they had not been approached by BNDD regarding voluntary compliance or self-regulation. Several officials indicated that, other than

suggestions read in trade publications, they had not received guidelines from their associations on self-regulation.

Bulk manufacturer

We visited one of the four major manufacturers of bulk amphetamines in the United States. This company also produces a large number of dosage-form amphetamine and barbiturate drugs. Company officials stated that they cooperate with BNDD, provide training to law enforcement officials, offer laboratory services to identify and analyze drugs, and had embarked on a number of drug education programs.

This firm sells its dosage-form drugs exclusively under yearly sales contracts and has approximately 400 wholesalers throughout the country. It has established an elaborate system for the selection of wholesalers, and its contracts contain a clause which stipulates that unlawful handling of drugs by the wholesalers is grounds for contract termination. Officials of the manufacturer informed us that (1) wholesalers' drug-buying patterns were monitored, (2) all large orders were questioned, and (3) precautions were taken to prevent theft and pilferage of the drugs during shipment.

CONCLUSIONS

The drug industry has a public duty and a legal responsibility to safeguard its products from illicit use. Although the industry has taken some actions and BNDD has taken numerous actions, more actions are needed to encourage and promote a program of self-regulation. If self-regulation is to be effective, information on such programs or techniques must reach all members of the industry. BNDD, jointly with the drug industry, should develop formal guidelines on what constitutes an effective self-regulation program and on the specific elements to be included in a program.

Also a system should be developed that will provide for dissemination of pertinent information to all members of the drug industry. BNDD, in conjunction with compliance visits to drug firms, should obtain information on (1) how well self-regulation information is being disseminated, (2) the types of actions firms have taken as a result of

information disseminated, and (3) techniques utilized by a firm that may be beneficial to other members of the industry.

RECOMMENDATION TO THE DIRECTOR OF BNDD

We recommend that the Director of BNDD work with drug associations to establish self-regulation guidelines for members of the industry, develop a means to disseminate self-regulation information to all members, and establish a procedure for gathering information on self-regulation measures taken by firms.

- - - -

The Department of Justice informed us (see app. I) that the recommendation was valid and would be implemented, to the greatest extent possible, on a priority basis.

CHAPTER 6

NEED FOR INCREASED MONITORING OF RETAILERS' ACTIVITIES

BNDD has responsibility for monitoring the activities of drug handlers and for suppressing diversion of dangerous drugs at all levels of distribution. In connection with this responsibility, BNDD is establishing agreements with States to share the monitoring of licensed drug retailers. The purpose of these agreements, called memorandums of understanding, is to eliminate duplicate effort that otherwise might arise from overlapping investigational activities. Under these agreements, BNDD is responsible for monitoring manufacturers and wholesale distributors, and the States are responsible for monitoring retailers. As of June 30, 1971, agreements had been signed with 45 States and negotiations were under way with the other States.

The States had been monitoring the drug industry to enforce their laws which generally were not as comprehensive as Federal legislation. BNDD had not evaluated fully, however, the capabilities of the States to effectively handle the increased responsibility assumed under the agreements. Our review showed that State agencies in California, New Jersey, and New York were not equipped to effectively monitor retailers because they did not have sufficient staffs. As a result, a large number of retailers were not monitored adequately, and diversions might not have been detected. On the basis of our observations in these three States, we believe that BNDD must evaluate the capabilities of the States and must assist them in maximizing the use of their available staffs to monitor retailers.

LACK OF PROGRAMS AND MANPOWER

BNDD's compliance investigation program was directed at the manufacturing and wholesale distributing levels. BNDD generally did not perform investigations at the retail level but did refer leads on possible diversions to State agencies. BNDD was aware of manpower limitations in many States and, on occasion, augmented a State's capability to follow up diversion leads.

BNDD had not made a systematic evaluation of the adequacy of investigation programs of State agencies, including the manpower resources necessary to execute effective programs at the retail level. BNDD attempted to make such an evaluation in 1970, but data was received from only a few States. Recently BNDD initiated a program to obtain complete data on State agencies to evaluate their capabilities, but sufficient data had not yet been received to enable us to evaluate the results of the program.

Following is the data we found on three States.

CALIFORNIA

The agency responsible for monitoring activities of retail drug handlers in California is the California State Board of Pharmacy. The board had 11 field agents in May 1971 to monitor the activities of approximately 5,000 retail and hospital pharmacies and 125 doctors who were dispensing large amounts of drugs. The agents also follow up on drug violation complaints made against doctors, dentists, and veterinarians.

The California board's monitoring activity consists of two types of inspections--surveys and in-depth investigations. Surveys involve examinations of pharmacies' premises and licenses and take 1 or 2 hours a pharmacy. In-depth investigations involve comparisons of pharmacies' records for selected drugs with physical inventories. Officials of the board informed us that an in-depth investigation was the only type of investigation that could detect inadequate recordkeeping and possible shortages of drugs.

The board had no formal plan directed at detecting and curbing diversion at the retail level but had set a goal of performing yearly inspection at each of the 5,000 pharmacies. Following is a summary of their inspection activities in fiscal years 1969 and 1970.

	1969	1970
Surveys	3,966	2,451
In-depth investigations	51	45
Totals	4,017	2,496

As shown above, the Board did not meet its goal, and only a small number of pharmacies were inspected in the depth believed necessary to detect diversions. Board officials informed us that they were unable to follow up on leads from BNDD on possible retail diversion because their manpower had been committed to other activities.

NEW JERSEY

The New Jersey Bureau of Drug Control is responsible for monitoring activities of retail drug handlers in the State. The bureau had four investigators in May 1971 to monitor the activities of approximately 1,900 pharmacies and to investigate practitioners against whom complaints on drug handling activities had been made. The bureau's investigators performs in-depth investigations which are similar to the type performed in California.

The bureau has a goal of investigating each pharmacy once every 3 years. During the 3-year period 1968 to 1970, only 283 pharmacies, or about 15 percent of the pharmacies in the State, were investigated. Officials of the bureau stated that four investigators were not enough to give coverage to each pharmacy once every 3 years. At one time the bureau had 11 investigators, but, because of budget limitations, the staff was reduced. Contingent upon budget limitations, present plans call for increasing the investigative staff to 27.

NEW YORK

The New York State Bureau of Narcotic Control is responsible for monitoring activities of retail drug handlers in the State. In May 1971 the bureau had 28 investigators to monitor the activities of about 80,000 registered handlers of controlled drugs, including 6,500 pharmacies. Monitoring activity consists of two types of investigations--routine and in depth. The in-depth investigation (similar to the type performed in California) program investigates drug handlers on a complaint basis rather than on a periodic basis.

The bureau's compliance program calls for an investigation, by one of the two types, of all hospitals, pharmacies,

and registered handlers once every 2 years. In calendar years 1969 and 1970, the bureau performed 71 in-depth investigations. Data on the number of routine investigations performed was not maintained.

Because of lack of data on the routine inspections, we were unable to determine the extent to which the bureau was meeting its goal of biennial investigation of hospitals, pharmacies, and registered handlers. Officials of the bureau informed us, however, that, because of manpower limitations, the agency was not meeting this goal and could not monitor adequately all of its registrants. Officials stated that requests for additional manpower had been unsuccessful and pointed out that the bureau lacked manpower to perform in-depth reviews.

LACK OF UNIFORM DRUG LAWS

State agencies monitoring the activities of retailers operate under State laws that generally are not as comprehensive as Federal legislation. Federal officials recognized the need for uniform and complementary laws at the State level to enable Government at all levels to more effectively deal with the drug problem. In response to this need, BNDD drafted model State legislation which was revised and adopted as the Uniform Controlled Substance Act by the National Conference of Commissioners on Uniform State Laws in August 1970.

The main objective of the Uniform Controlled Substances Act is to create a coordinated and codified system of drug control, similar to that required by Federal legislation. Another objective of the act is to establish a regulatory system for the legitimate handlers of controlled drugs to curtail diversion, which will require these individuals to register with a designated State agency, to maintain records, and to make biennial inventories of all controlled-drug stocks. The act sets out prohibited activities in detail but does not prescribe fines or sentences for violations of requirements. This is left to the discretion of the individual States.

BNDD officials have met with the Governors in 45 of the 50 States to encourage passage of the Uniform Controlled

Substances Act in each State. The reaction to the proposed act has been excellent. As of December 6, 1971, 25 States and three territories had enacted it and a number of States were considering its passage.

We noted that New Jersey had passed the Uniform Controlled Substances Act and that New York and California were considering its passage. We were informed by officials of the State agencies and BNDD that, due to the limitations of State laws, BNDD had been requested, in many cases, to investigate flagrant violators because of its ability to take quick enforcement actions not available to the State agencies.

As mentioned on page 30, BNDD initiated a program to evaluate the ability of the States to effectively monitor retailers; therefore we are making no recommendation on this matter.

CHAPTER 7

SCOPE OF REVIEW

Our review primarily was directed toward an examination into BNDD's compliance activities to reduce the diversion of legitimate drugs to the illicit market. It also included an examination into the compliance activities of three State agencies and the drug industry's activities to implement self-regulation measures. Our review was conducted at:

--Headquarters, Bureau of Narcotics and Dangerous Drugs, Washington, D.C.

--Bureau of Narcotics and Dangerous Drugs, New York Regional Office, New York, N.Y.

--Bureau of Narcotics and Dangerous Drugs, Los Angeles Regional Office, Los Angeles, California.

We made visits to State enforcement agencies in California, New Jersey, and New York and to certain local enforcement agencies in California and New York. We also visited members of the drug industry, including four trade associations, one bulk manufacturer, and 11 wholesale distributors.

In performing our review we examined Federal and State drug legislation; pertinent policies, procedures, correspondence, and documentation relating to compliance activities; and reports of drug arrests and seizures. We interviewed BNDD, State, and local agency officials responsible for administering compliance or enforcement programs. We also interviewed officials of trade associations and members of the drug industry regarding self-regulation programs.

UNITED STATES DEPARTMENT OF JUSTICE

WASHINGTON, D.C. 20530

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

February 18, 1972

Mr. Irvine M. Crawford
Associate Director, Civil Division
United States General Accounting Office
Washington, D. C. 20548

Dear Mr. Crawford:

This is in response to your request for comments on the draft report titled "Efforts to Combat the Diversion of Dangerous Drugs, Bureau of Narcotics and Dangerous Drugs."

The recommendations and suggestions for program improvement contained in the report are valid and they will be implemented to the greatest possible extent on a priority basis. As the draft report notes, some of the steps recommended were initiated while the audit was still in progress.

One of the major recommendations cited in the report concerns the need for a uniform collection program aimed at the collection of data on drug diversion or seizures and on arrests involving stimulants, depressants, hallucinogenic drugs, etc. In order to mount such an effort, extensive resources--human, material and time--will be required. LEAA has discussed the need for collecting data on drug diversions or seizures with collection agencies in several States and there is unanimous opinion that the development of such data on dangerous drugs will entail serious dislocation to present operations. Of concern is the fact that there is already a large investment in the existing reporting systems. However, in order to fully assess the feasibility and cost of expanding the current program and establishing a new program, LEAA, BNDD and the FBI are arranging to establish a task force to examine the entire problem. This group will provide recommendations to the agencies involved for establishing a uniform collections program.

Inasmuch as the report accurately and fairly presents the facts and we concur with the recommendations, an item by item response appears unnecessary.

[See GAO note.]

We appreciate the opportunity given us to comment on your proposed report to the Congress.

Sincerely,

L. M. Pellerzi
Assistant Attorney General
for Administration

GAO note: Deleted comments pertain to material presented in the draft report which has not been included in the final report.

PRINCIPAL OFFICIALS OF THE DEPARTMENT OF JUSTICE

RESPONSIBLE FOR THE ADMINISTRATION OF ACTIVITIES

DISCUSSED IN THIS REPORT

	Tenure of office	
	From	To
ATTORNEY GENERAL OF THE UNITED STATES:		
Richard G. Kleindienst (acting)	(Nominated Feb. 1972)	
John N. Mitchell	Jan. 1969	Feb. 1972
Ramsey Clark	Oct. 1966	Jan. 1969
DIRECTOR, BUREAU OF NARCOTICS AND DANGEROUS DRUGS:		
John E. Ingersoll	Aug. 1968	Present

Copies of this report are available from the U. S. General Accounting Office, Room 6417, 441 G Street, N W., Washington, D.C., 20548.

Copies are provided without charge to Members of Congress, congressional committee staff members, Government officials, members of the press, college libraries, faculty members and students. The price to the general public is $1.00 a copy. Orders should be accompanied by cash or check.