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STATEMENT OF

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BEFORE THE

SUBCOMMITTEE ON CRIME

HOUSE COMMITTEE ON THE JUDICIARY

ON

NEED TO CONTROL PRESCRIPTION DRUG ABUSE

Mr. Chairman and Members of the subcommittee, we are pleased to be here today to discuss our October 1982 report on prescription drug abuse. [1]/ Since that time, the Drug Enforcement Administration (DEA) has taken actions on the recommendations in our report. These actions will help but will not fully solve the problem.

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[1]/"Comprehensive Approach Needed to Help Control Prescription Drug Abuse" (GAO/GGD-83-2; Oct. 29, 1982)

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THE ABUSE OF PRESCRIPTION DRUGS IS A BIG PROBLEM

Prescription drug 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. National drug abuse statistics identify prescription drugs in drug-related deaths and emergency medical situations more often than all illegal drugs combined. The Drug Abuse Warning Network (DAWN), which is a nationwide program that gathers data on drug abuse, shows that prescription drugs are predominant in reported medical emergencies and deaths involving controlled drugs. For example, in 1980, 15 of the 20 most frequently mentioned drugs in DAWN's emergency room reports were prescription drugs. Also, prescription drugs made up 75 percent of the drugs identified in deaths reported to DAWN by medical examiners. In other words, of every four drugs involved in death or emergency treatment, three were prescription drugs.

Regulating prescription drugs to prevent their diversion is a tremendous task. Legitimate channels of distribution involve over 625,000 registered manufacturers, distributors, and dispensers nationwide. Of these, about 616,000 are at the retail level. Controlling prescription drugs is the responsibility of both the Federal Government and the States. Federal controls, authorized by the Controlled Substances Act, are focused at the wholesale level (manufacturers and distributors) while States are primarily responsible for controlling the retail, or dispensing level.

Although the Federal Government has the authority to enforce criminal laws against 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.

Manufacturers and distributors of drugs and DEA have taken steps to stop the diversion of licit drugs from the wholesale level sources. DEA's regulatory activities 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 estimates that 80 to 90 percent of abused prescription drugs come from the retail level. This is a tough problem to solve.

THE BEST WAY TO FIGHT THE PROBLEM

Solving such a problem will require cooperative efforts from a number of sources. The problem is beyond the reach of law enforcement, that is, law enforcement cannot solve it alone. Law enforcement agencies have a definite role when legally manufactured prescription drugs are diverted for illegal use through pharmacy thefts, illegal sales, and forged prescriptions. However, law enforcement cannot do much about legally and properly prescribed drugs that get abused. Also, there are other sources of abused prescription drugs which fall into a gray area--instances where physicians misprescribe drugs through carelessness and are unaware that the drugs will be misused.

Even if practitioners apparently violate the law, criminal intent often would be difficult to prove.

Because of these numerous ways--both legal and illegal--to obtain prescription drugs a comprehensive approach is necessary. This approach would involve participation of law enforcement agencies, regulatory boards, professional associations, and others as well.

The need for a comprehensive approach was recognized as far back as 1967. At an American Medical Association (AMA) conference attended by physicians and representatives of law enforcement and licensing agencies there was a general agreement that committees should be created at State and local levels to strengthen liaison among medical, law enforcement, and regulatory bodies to prevent and control the abuse of drugs. However, it seems that this effort never got off the ground.

Twelve years later, in September 1979, the topic arose again. The White House Drug Policy Office sponsored a meeting to discuss possible courses of action to solve the problem of diversion of prescription drugs. The participants agreed that no one agency, either Federal or State, could effectively deal with the problem. It was recognized that coordinated efforts involving Federal, State, and local agencies in cooperation with professional, educational, and trade organizations were needed.

It was also noted that several States had successful programs which contained some common elements--specifically law enforcement, regulatory and licensing activities, professional education, and professional peer pressure.

More progress was made in November 1980, when the White House convened a conference on prescription drug misuse, abuse, and diversion to highlight cooperative steps which would reduce the abuse of prescription drugs and to share information on State initiatives. A number of recommendations came out of the conference to improve and better coordinate prevention/education, peer review, regulation/licensing, and law enforcement. Conference participants agreed that coordination at the national level was needed and that concerned national organizations and Federal agencies needed to talk to one another more.

Several States have developed comprehensive plans to fight the problem of diversion of prescription drugs. For example:

--Wisconsin, through data provided by DEA and audits of pharmacies by the State regulatory board, revealed some extraordinary prescribing and dispensing patterns for amphetamines. Some investigations and arrests of physicians resulted. Also, the State discontinued Medicaid reimbursements for amphetamines unless prior authorization was obtained, and it placed restrictions on the use of amphetamines for treating obesity. As a result, retail purchases of amphetamines reportedly dropped by more than 90 percent.

Recent AMA Efforts

In addition, AMA has taken some positive steps that warrant recognition. In a June 1981 report, the AMA recognized that prescription drug abuse results from both intentional and unintentional actions of physicians and called on State medical societies to take a leading role in their jurisdictions. Specifically, the AMA report recommended that State medical societies institute a comprehensive State-wide program to:

--Find out how bad the prescription drug abuse problem is;

--Cooperate with law enforcement, regulatory agencies, pharmacists, and other professional groups to identify and bring to justice doctors who willfully misprescribe drugs for profit and to educate doctors who unwittingly misprescribe drugs; and

--Provide educational materials to all doctors and medical students on appropriate prescribing of controlled drugs.

The AMA also recognized that even under optimal prescribing practices, problems would continue. So, AMA also recommended that State medical societies work to

--educate patients and the public on the appropriate uses of controlled drugs, and

--help physicians in treating drug abuse and drug dependence.

In November 1981, the AMA met with representatives from various Federal, State, and private organizations to discuss the

report's recommendations and how to implement them. As a result, the National Steering Committee on Prescription Drug Abuse was formed. The Steering Committee has been working to make all those involved with prescription drugs aware of the problems and how to deal with them. A noteworthy project of the Steering Committee is the Prescription Abuse Data Synthesis Model, referred to as PADS, which is now being developed. The project involves a model approach to pull together a variety of local, State, and Federal information systems so that prescription drug abuse and diversion activities can be identified at the State level.

The Federal Government Can Help Too

Several Federal agencies are in a position to contribute significantly to achieving the Steering Committee's goals. The DEA, the Food and Drug Administration, the National Institute on Drug Abuse, and the White House Drug Abuse Policy Office are members of the Committee. The White House Office is especially well suited to coordinate the drug abuse functions of all Federal executive agencies to support the goals of the Steering Committee.

In commenting on our report, Justice agreed that the comprehensive approach was the best hope for controlling prescription drug abuse. The AMA commented that it is going forward with efforts to encourage improved drug prescribing practices and to foster the kind of cooperation at both national and State levels needed to implement the comprehensive approach. We

believe the White House Drug Abuse Policy Office can play a major role in working with AMA to foster the comprehensive approach, especially at the national level, and is in a unique position to direct and coordinate Federal drug activities and encourage the commitment of State governments to a comprehensive approach.

ONE FEDERAL AGENCY--DEA--IS IN A PARTICULARLY GOOD POSITION TO HELP

As stated in our report, one Federal agency--DEA--is in an excellent position to help the States locate sources of highly abused prescription drugs.

Traditionally, DEA has viewed its role in controlling prescription drugs at the retail level as one of motivating and assisting the States. Under agreements entered into with numerous States, DEA is responsible for monitoring manufacturers and distributors and the States are responsible for monitoring retail practitioners. However, by 1979 problems at the wholesale level had been alleviated and DEA started to shift its compliance investigation resources from the wholesale to the retail level. Although these investigations are to focus on the high-level retail violators, we found this was not always the case. Because of poor targeting, the results of these efforts had not been impressive.

At the same time that DEA was using its resources on these retail investigations, it was claiming that it did not have sufficient staff to fulfill an important requirement of the Infant

Formula Act. By law, controlled substances are separated into five schedules on the basis of their potential for abuse, accepted medical use, and accepted safety under medical supervision. Schedule II includes substances, such as morphine, barbiturates, and amphetamines, that have accepted medical uses but also have a high abuse potential.

The Infant Formula Act requires DEA to determine which schedule II drugs have the highest rates of abuse, prepare analytical reports on the distribution patterns of each such drug, and provide these 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 DAWN, which, as mentioned earlier, contains nationwide data on drug abuse and a second source called ARCOS. This source is a comprehensive drug tracking system which monitors the flow of selected drugs from the point of import or manufacture to the point of sale, export, or other distribution.

When used together, these two systems can provide an indepth profile of a geographical area. DAWN can be used to identify drugs being abused and abuse trends and ARCOS can show the distribution of certain drugs and identify potential excessive purchasers. An important point is that the eventual success of PADS--the project of the Steering Committee that I mentioned earlier--will depend on existing systems such as DAWN and ARCOS.

In our report, we recommended that since retail investigations were primarily a State responsibility, DEA reallocate staff to those activities that would enable it to provide analytical reports to the States as required by the Infant Formula Act. The Department of Justice, in responding to our report, said that improvements in computer utilization have offset but not eliminated the need for additional DEA personnel to meet the requirements of the Act. It said that, in 1982, DEA provided the required data to 26 States. On June 19, 1983, DEA officials told us that they were capable of providing the required data to all 50 States.

We also recommended that DEA monitor the use of staff resources in its effort to focus its investigations on a limited number of high-level retail violators. In response to that recommendation, the Department of Justice said that a DEA reorganization had increased the number of personnel who monitor DEA's investigations aimed at high-level traffickers.

DEA IS NOT RECOVERING ENOUGH OF ITS COSTS FOR CONTROLLING DRUGS

The last topic I will discuss deals with DEA's fees to recover costs of controlling drugs.

The Controlled Substances Act authorizes the Attorney General to establish reasonable fees to recover Federal costs for registering and controlling the manufacture, distribution, and dispensing of controlled substances. Presently the fees, which

have not been increased since they were established in 1971, recover only a small portion of the costs.

The law allows a great deal of discretion in deciding what costs to recover and in establishing the fees. DEA has set the fees at a level to recover only the costs of processing registrations and providing drug order forms to registrants. Existing fees are $50 for manufacturers, $25 for distributors, and $5 for retailers, such as pharmacies and practitioners.

From 1977 through 1980, DEA collected about $11.4 million which was only about one-fourth of the costs for DEA's compliance and regulatory functions. We felt that more costs should be recovered and recommended that DEA increase the fees. On April 5, 1983, DEA announced in the Federal Register its proposal to increase the fees. The cut-off date for comments was June 6, 1983. On June 22, 1983, a DEA official told us that a preliminary review of the comments, including those from AMA, disclosed nothing that would preclude DEA from increasing the fees.

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Mr. Chairman, that concludes my statement. We will be happy to respond to questions.