National Institute on Drug Abuse

Research 34

MONOGRAPH SERIES

Problems of Drug Dependence 1980

Proceedings of the 42nd Annual Scientific Meeting

Committee on Problems rug Dependence, Inc.

AND HUMAN SERVICES • Public Health Service • Alcohol, Drug Abuse, and Mental Health Administration

Problems of Drug Dependence, 1980

Proceedings of the 42nd Annual Scientific Meeting, The Committee on Problems of Drug Dependence, Inc.

Editor: Louis S. Harris, Ph.D.

NIDA Research Monograph 34
February 1981

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Alcohol, Drug Abuse, and Mental Health Administration

National Institute on Drug Abuse
Division of Research
5600 Fishers Lane
Rockville, Maryland 20857

For sale by the Superintendent of Documents, U.S. Government Printing Office
Washington, D.C. 20402

78715

Compliance and Enforcement Programs of the Drug Enforcement Administration

R. W. Buzzeo

It is indeed a pleasure and an honor to be with you at this your 42nd Annual Scientific Meeting of the Committee on Problems of Drug Dependence, Inc., and to represent Mr. Peter B. Bensinger, Administrator of the Drug Enforcement Administration.

I want to emphasize that DEA considers it absolutely essential to establish and maintain a close relationship with organizations such as this. The membership which you represent forms a vital partnership with DEA in monitoring over 600,000 registrants, both practitioner and nonpractitioner.

Our sincere desire is to remain approachable and responsive to the needs of these many registrants. Little progress would be made if the DEA were to remain aloof, issuing edicts, regulations and policies from Washington. We need to monitor the registrants and we need to work closely with all groups in preventing diversion. We must understand that enforcement or medical programs going off in separate directions is a simplistic approach -- we need to work together in addressing a common problem.

I would like to highlight briefly with you today the Drug Enforcement Administration and its Compliance and Enforcement Programs, which include DEA activities in State-Federal cooperation and with professional licensing boards, and then close with a major problem which faces this country.

The DEA is the lead Federal law enforcement agency charged with combatting drug abuse and the drug traffic. We have both an enforcement and a prevention responsibility.

The Controlled Substances Act of 1970, which we enforce, is designed to improve the administration and regulation of manufacturing, distribution, and the dispensing of controlled substances by providing a "closed" system for legitimate

handlers of these drugs. The idea of a closed system, through which flow 20,000 brand named products controlled under our current law, is to reduce the widespread diversion of these drugs from legitimate channels into the illicit market.

Often the public associates DEA with its better known role of criminal drug investigation. The resultant arrests and seizures of illicit drugs make daily headlines around the nation.

Perhaps less colorful, but no less important, is our compliance work in which we enforce those portions of the Controlled Substances Act that apply to the manufacturers, distributors, prescribers, and dispensers.

The DEA has about 4,200 employees worldwide -- most of them operating under five regional offices in the United States.

Approximately 2,000 of our employees are Special Agents, and about 200 are Compliance Investigators. These 200 investigators, working closely with 7,000 State investigators, are responsible for monitoring a market which, for comparison, is reached by some 26,000 medical service representatives of the pharmaceutical industry.

DEA's regulatory mission is performed by its Office of Compliance and Regulatory Affairs. Under it, we carry out such major responsibilities as registration, import and export monitoring, voluntary compliance, scheduling, quotas, regulatory investigations, State assistance programs, pharmacy theft prevention, DAWN, and the ARCOS system, which helps us spot problems and abuses in the distribution of controlled substances.

Our Compliance Program is concerned with the registrant who criminally diverts controlled substances into the illicit market. Although these are in the minority, the damage resulting to our society from such diversion can be most serious. These criminal diverters are no better than the individual who deals in heroin; even worse, since they have abused the trust placed in them by society.

Diversion has been reduced at the manufacturer/distributor level as a direct result of regulatory requirements under the Controlled Substances Act and Federal and State efforts. I am sorry to say the same results have not been achieved at the practitioner level, which includes physicians, pharmacies, researchers, hospitals, and clinics. Currently, the sources of diversion at this level are forged prescriptions, indiscriminate prescribing, thefts, and illegal sales. We estimate that 300 million dosage units are diverted annually, with 70 to 90 percent coming from the retail level. Primary responsibility at this level falls to the States under the Controlled Substances Act which requires DEA to register every professional who possesses a valid State license unless he has a drug felony conviction or materially falsifies his registration application.

It is entirely true that only a minority of practitioners are deliberately engaged in drug diversion; however, this minority can, and does, create serious drug problems in many parts of the country. In light of this problem, DEA embarked on a program called "Operation Script," a cooperative effort which combines the resources of both DEA and State drug agencies, which targeted 94 preselected pharmacies (44) and physicians (50) in 22 States for extensive investigation.

This increase in effort has focused DEA technical, investigative and legal expertise against preselected retail violators to produce high impact investigations.

This increase in effort will be valuable in:

(1) decreasing diversion,
(2) demonstrating the Federal Government's concern,
(3) increasing public awareness of the diversion and abuse of legitimately manufactured controlled substances,
(4) encouraging S[illegible]s to address practitioner diversion,
(5) demonstrat[illegible]e need for additional and continuing Diversion [illegible]estigative Units (DIU's),
(6) giving impetus to potential Federal legislation,
(7) supporting possible FDA actions regarding indications and uses of controlled substances,
(8) obtaining information which may be utilized in decreasing quotas and/or restricting imports.

At this point, indictments have been returned in seven of these cases and fifteen more are pending. Eight convictions have already been obtained for the illegal sale of controlled substances.

These eight (two pharmacists and six physicians) were responsible for an estimated diversion of 15.4 million d.u. per year.

Clearly, with 600,000 practitioners and only 2,000 agents/investigators, we must concentrate our efforts on practitioners who are strongly suspected of criminality.

For example, in FY '79, as part of our regular Compliance and Enforcement Investigative Program we were able to conduct only 129 practitioner complaint investigations (62 pharmacists, 42 practitioners and 25 others), while DEA arrested 4,900 nonprofessionals.

As part of our State assistance, we have developed a State criminal investigation operation aimed at prosecuting willful retail registrant diverters. We call it the Diversion Investigative Unit Program. DEA supports these State-run, State-manned units by providing 18- to 24-month seed funding, regulatory training, a full-time DEA representative working in the unit and investigative support. In addition to the DEA representative, the unit and its overseeing policy board are composed of personnel from the State's various regulatory

boards and its law enforcement agencies. This blend of expertise and the flexibility provided have had a beneficial impact in the nineteen States (Massachusetts, New Hampshire, New Jersey, North Carolina, Georgia, Hawaii, Washington, Oklahoma, Michigan, Pennsylvania, Nevada, Illinois, Texas, California, Alabama, Maine, Arkansas, Utah, New Mexico and the District of Columbia) where the units now exist. Perhaps the best measure of the DIU Program's success has been the willingness of State governments to continue these units with State funding.

Since the program's inception in 1972, these DIU's have accounted for approximately 3,000 arrests. In Calendar Year '79, these units made 450 arrests, including 170 registrants and removed 750,000 dosage units of controlled substances from the illicit market.

A spin-off of the DIU Program is our application of computer technology to identify problem drugs and problem registrants for investigation. In a pilot program in San Francisco, we utilized our Drug Abuse Warning Network (DAWN) to identify legitimate drugs appearing most frequently in the hands of abusers and our Automation of Reports and Consolidated Orders System (ARCOS) to pinpoint registrants excessively purchasing these drugs. This project, in conjunction with the California DIU, resulted in the criminal indictment of nine physicians and civil actions directed toward 21 pharmacies, with administrative actions against an additional 10 physicians and 16 pharmacies.

Additional progress in curbing diversion at the retail level has been made with the development and implementation of a program to address pharmacy thefts. Thefts from pharmacies and practitioners accounted for the loss of over 34 million (out of 43 million) dosage units of controlled substances in 1978, and in 1979 a projected 40 million (out of 52 million) dosage units. I might add that retail pharmacies are subjected to theft more than any other pharmaceutical business category. In the first six months of 1979, 73.5 percent of all thefts reported to DEA were reported by pharmacies. During this same time period 64.4 percent of all controlled substances diverted by theft were stolen from pharmacies.

In order to assist pharmacists who are concerned about this alarming increase in pharmacy thefts, the DEA initiated a Pharmacy Theft Prevention (PTP) Program which is available to all communities. DEA's PTP Program is a community action approach to pharmacy theft.

The nucleus of a PTP Program is the leadership in a community. These leaders form an executive committee which includes representatives from the police department, DEA and the professional associations.

The DEA currently has eleven active PTP cities and three that are in the developmental stages. The active programs are:

Philadelphia, Pennsylvania; Milwaukee, Wisconsin; Nashville, Tennessee; Johnson County, Kansas; Dallas, Texas; Denver, Colorado; Seattle, Washington; San Diego, California; Rhode Island State; Utah State; and Clark County, Nevada. Programs are developing in Louisville, Kentucky; San Juan, Puerto Rico; and Pittsburgh, Pennsylvania.

In addition, DEA has been working with the various medical associations in developing prescribing guidelines that provide and establish acceptable professional responses to guard against contribution to drug abuse through indiscriminate prescribing of drugs or the acquiescence by practitioners to unwarranted demands of some patients. These guidelines will also work to ensure that multiple prescription orders are not being obtained by the patient from different physicians, that prescriptions only provide enough of a drug to carry the patient to his next scheduled appointment, and that prescriptions are alteration-proof.

While progress is being made, the curbing of retail diversion in the future will require substantial increases in State and professional monitoring of practitioners in order to identify the problem areas and to develop solutions.

Before I discuss a major area of concern, I first wish to address some additional items of interest --

Dextropropoxyphene

Pursuant to a recent UN decision to add dextropropoxyphene to Schedule II, the DEA has determined that the placing of bulk dextropropoxyphene into Schedule II and the leaving of all dosage units in Schedule IV will meet our international obligation as required by the Single Convention and our domestic needs. In addition, a recent recommendation by FDA that propoxyphene be classified as a narcotic will require practitioners using dextropropoxyphene in maintenance or detoxification programs to register as NTP's.

Clandestine Laboratories

Another area of interest is DEA's Clandestine Laboratory seizures. In 1979, 237 labs were seized in the U.S. This includes 10 amphetamine producing labs; 137 methamphetamine and 53 PCP labs. Already for the first quarter of 1980, 74 labs have been seized. This figure is 31 percent of all labs removed last year.

International Diversion

Another major drug abuse concern of the DEA is the diversion of legitimate pharmaceuticals from international commerce. Many of the manufacturers of pharmaceuticals are located in Europe, where regulatory controls are quite different from those of the

United States. Several drugs, such as methaqualone, secobarbital and methamphetamine, which are tightly controlled in the U.S. because of high abuse levels, have not historically been considered a problem in some European countries and therefore have not been or have only recently been controlled. These conditions afford drug traffickers opportunity for diversion. Using various means of ordering and employing complex shipping routes, drug traffickers are diverting large quantities of drugs of abuse.

In response to this growing U.S. and potential worldwide problem, the DEA has initiated a program in cooperation with host governments to establish a voluntary program of soliciting cooperation from various manufacturers and pharmaceutical firms in Europe. Firms are encouraged to watch for and report unusual or suspicious orders from customers, requests for unusual or suspicious labelling or shipping instructions, and excessive orders.

It appears the long-range solution to this problem of drug diversion from legitimate sources will require the enactment of additional legal controls over nonnarcotic controlled substances. Additionally, it is necessary to ensure the application of adequate criminal or civil penalties to those firms or individuals that violate legal requirements.

Only through extensive international cooperation and sharing of information can countries effectively curtail the illegal international movement of abusable pharmaceuticals.

Southwest Asian Heroin

In many respects, DEA has seen considerable progress in its efforts, but the instabilities of the governments of Southwest Asia are having a dramatic adverse impact on the dimensions of the world drug situation. This area -- Iran, Afghanistan, and Pakistan -- is capable of producing many times over the amount of opium needed to satisfy world demand. This gives us cause for concern. The consequences of excessive opium production there have already been experienced in Europe, and now are being felt in the United States as well.

It is estimated that in 1978 Afghanistan produced 300 metric tons of opium and Pakistan produced approximately 400 metric tons, for a regional total of about 700 metric tons. Iran cannot be included in the 1978 total because at that time opium cultivation in Iran was legal and controlled. In 1979, however, opium production in all three of these countries in Southwest Asia is believed to have increased to a maximum of 1,600 metric tons.

We estimate a regional consumption of 1,000 metric tons of opium, leaving 60 metric tons of heroin available for worldwide distribution from this one area of the world.

Of course, these are "guesstimates." As you can well imagine, intelligence-gathering in that part of the world is, at best, very difficult. Our agents stationed abroad are our primary intelligence

source. However, DEA has had to close its offices in Iran and Afghanistan. Our efforts in Pakistan have been disrupted extensively, and still have not returned to the levels of previous years.

Foreign governments are often a secondary intelligence source, but we do not have ongoing enforcement and intelligence exchange in Iran and Afghanistan, and these countries have lost a number of their career drug law enforcement officials.

The high quality and availability of Southwest Asian heroin has made it a very marketable commodity. By mid-1977, West Germany was inundated with this high-quality Southwest Asian heroin. The problem has since spread to other West European markets which traditionally have been and continue to be outlets for Southeast Asian heroin. Despite sincere attempts by European governments to control the narcotics addiction problem, the situation has continued to worsen.

Throughout 1979, Western Europe served as a "sponge," absorbing the increased Southwest Asian heroin production. Approximately 2.5 metric tons of heroin were consumed in Western Europe that year. By way of contrast, a recent intelligence study estimates that in 1978 0.6-0.8 metric tons of Southwest Asian heroin, representing 17 percent of the total market, entered the United States. I expect that proportion to have doubled during 1979.

Although the heroin picture in Western Europe may be stabilizing, the situation still is not good. Drug overdose deaths in West Germany, for example, are almost double those of this country and yet their population is one-fourth of ours. In West Germany, street-level purity is currently between 20 and 40 percent and prices in some European cities have dropped to as low as $25,000-$35,000 per kilogram. According to our latest figures, that same kilogram would sell for about six times as much in New York City.

DEA intelligence reflects that some Iranian citizens, unable to move cash out of that country because of the currency regulations, have "converted" their cash to narcotics and have smuggled their assets out in that fashion. The profit motive has enticed numerous black, Hispanic, Italian, Iranian and other traffickers to enter the Southwest Asian heroin trade in the United States. Although at present this trade is best characterized as fragmented, there are indications that in the future it will be dominated increasingly by cohesive criminal groups.

Over the past two years, there has been a rising number of seizures and resulting investigations. During 1977 and 1978, small quantities of Southwest Asian heroin appeared in the U.S. and were confined to the New York/Washington, D. C. corridor. Since then, undercover purchases of Southwest Asian heroin also have been made in Chicago, Detroit, San Francisco and Los Angeles.

339-844 0 - 81 - 4

Seizures of heroin in this quantity and purity have not been experienced in several years.

Given the magnitude of recent developments, the question then becomes, "What plans are there for coping with this new presence and accelerating problem?" Unfortunately, there are no easy answers.

The United States Government has developed initiatives to attack the Southwest Asian heroin problem. The Administration is making the Southwest Asian heroin effort a high priority and is coordinating efforts of the Departments of Justice, State, Treasury, Defense, and Health and Human Services.

The Department of State is seeking international cooperation, not only through contacts with individual nations, but also by raising the issue in international forums such as NATO. We are accelerating the enforcement activities of the U.S. Customs Service and DEA both in the U.S. and abroad. Additionally, New York, Philadelphia, Boston, Newark, Baltimore and Washington are being designated target cities where major efforts are needed most to fight the flow of Southwest Asian heroin. The State and local law enforcement agencies are being involved in the antiheroin effort to the maximum extent. As you can see, the Drug Enforcement Administration is involved in the forefront of this action plan.

On February 28, 1980, President Carter and Attorney General Civiletti hosted approximately 120 law enforcement officials including all State attorneys general and several police chiefs and prosecutors. At this meeting, a five-point program to address the threat of Southwest Asian heroin was discussed with these enforcement officials and their cooperation and participation were encouraged.

Both Attorney General Civiletti and Mr. Bensinger have met with the Italian Prime Minister and Minister of the Interior of the Federal Republic of Germany to discuss mutual concerns regarding the Southwest Asian heroin problem. We intend to continue to assist foreign law enforcement agencies with support services directed at identifying and immobilizing major drug trafficking networks.

In all cases, our preference is to work as close to the source as possible; but, in the case of Southwest Asia, that door has virtually been slammed shut. Consequently, we have accelerated our efforts as close to the source as we can get -- through our agents and country attaches stationed along the transshipment and destination corridor in Western Europe.

DEA has recently established a Special Action Office/Southwest Asian Heroin to meet the imposing threat of renewed heroin production, transshipment and trafficking in and from Europe, the Middle East, and parts of Southwest Asia's opium producing countries.

SAO/SWA will address this serious situation on both the European and North American continents in a coordinated, directed, high-priority enforcement effort.

All of these actions are designed to counter the increasing availability that could cause Southwest Asian heroin to reach epidemic proportions. We believe that for the present our initial measures will blunt this threat to the best extent possible.

In closing, let me leave you with the following thoughts. The DEA is committed to preventing diversion. However, you, too, must be conscious of your responsibilities in the fight against drug diversion and abuse.

I am confident that the application of your know-how and resources to the abuse problem will have significant results. The urgent need to effectively curtail drug abuse and prevent diversion cannot be overemphasized. DEA has assigned the problem a high national priority. You can help by giving your utmost attention to the abuse of controlled substances.

AUTHOR

Ronald W. Buzzeo
Bachelor of Science in Pharmacy
Chief, Compliance Division
Drug Enforcement Administration
1405 Eye Street, Northwest
Washington, D. C. 20537

END