TAB K

State of Wisconsin \ DEPARTMENT OF HEALTH AND SOCIAL SERVICES

CONTROLLED SUBSTANCES BOARD
1 WEST WILSON STREET
P.O. BOX 7851
MADISON, WISCONSIN 53707
(608) 266-7586

Conference Synopsis

TITLE: Drug Diversion in the Health Professions: Progress, Issues, Directions (Wisconsin's third state conference on diversion)

DATE: May 17, 1983

LOCATION: Wingspread
Racine, Wisconsin

COSPONSORS: Wisconsin Controlled Substances Board
The Charitable, Educational, and Scientific Foundation of the State Medical Society of Wisconsin
Wisconsin Pharmaceutical Association
State Council on Alcohol and Other Drug Abuse
Wisconsin Office of Alcohol and Other Drug Abuse
Wisconsin Association of Alcoholism and Other Drug Abuse
The Johnson Foundation

ATTENDANCE: 90 maximum capacity, 89 participants

PROCEEDINGS: A conference proceedings is forthcoming and will be sent to participants; others may request a copy by corresponding with the Board.

PRINCIPAL PRESENTATIONS

KEYNOTE - National and International Aspects of Drug Diversion: The Federal Government's Response

Ron Buzzeo
Office of Diversion Control
Drug Enforcement Administration

NATIONAL PANEL - Responses to Drug Diversion and Prescription Drug Abuse from the Private Sector

Darold A. Treffert, M.D., Moderator
State Medical Society of Wisconsin

Emanuel M. Steindler
American Medical Association

James L. Williams
Pharmaceutical Manufacturers Association

Karen S. Gillespie
PRACON, Inc.

PLENARY - Drug Diversion: Progress in Wisconsin

David E. Joranson
Wisconsin Controlled Substances Board
Office of Alcohol and Other Drug Abuse

ENFORCEMENT
PANEL - Drug Diversion: Views from Enforcement

John W. Killian, Moderator
Narcotics and Vice Bureau
Wisconsin Department of Justice

James Hannon
Drug Enforcement Administration

John C. Temby
Wisconsin Department of Regulation and Licensing

Tom Casper
Narcotics Unit
Milwaukee Police Department

PLENARY - Historical Perspective on Prescription Drug Abuse and Diversion

Robert T. Angarola
Hyman and Phelps

PLENARY - Medical Assistance and Drug Diversion

Ted Collins
Medical Assistance Program
Wisconsin Department of Health and Social Services

REGULATORY
PANEL - Today's Diversion Problem: Issues and Directions for the Future

W. Allen Daniels, Moderator
Wisconsin Pharmaceutical Association

Walter L. Washburn, M.D.
Medical Examining Board

Vivian DeBack, R.N.
Board of Nursing

Meredith L. Nelson
Pharmacy Examining Board

Frank Shuler, D.D.S.
Dentistry Examining Board

James E. Helms, D.V.M.
Veterinary Examining Board

FINAL
PLENARY
SESSION - Key Issues and Directions for the Future

June L. Dahl, Ph.D., Conference Chairperson
Wisconsin Controlled Substances Board

innovations

PRESCRIPTION DRUG ABUSE CONTROL: THE WISCONSIN APPROACH

by Keon S. Chi

SUMMARY

Until recently, Wisconsin was no exception to the growing nationwide trend of growing prescription drug abuse and diversion. Today, however, Wisconsin is regarded as a model state in dealing with controlled substances and in helping federal agencies as well as other states. Wisconsin's programs and activities in reducing prescription drug abuse, especially amphetamine abuse, have received national attention. The model program was presented in 1979 to Congressional hearings and a special meeting sponsored by the White House. Congress adopted legislation in 1980 requiring the U.S. Attorney General to provide reports to all states based on the approach pioneered by Wisconsin; and the Wisconsin approach was featured in 1980 at the White House Conference on Prescription Drug Misuse, Abuse, and Diversion. The innovative aspect of the Wisconsin model lies in cooperative efforts among several regulatory agencies in the state to stop diversion of controlled substances by a small percentage of doctors and pharmacists. A comprehensive program has been coordinated by a state agency—the Controlled Substances Board—assisted by professional licensing boards and law enforcement agencies in the state. Subsequently, the sale and abuse of amphetamines has decreased drastically, by more than 90 percent, within a period of two to three years. During that period, the State Medical Society issued strict prescription guidelines for amphetamines; the Pharmacy Examining Board conducted an audit of pharmacies; the Medical Examining Board investigated physicians and promulgated an administrative rule; and the state Department of Health and Social Services restricted Medical Assistance payments for amphetamines to only a few legitimate uses.

The Wisconsin experience exemplifies what interagency cooperation can achieve in combating the prescription drug abuse problem. State-federal coordination has also helped a great deal. Equally significant has been reducing the sale of amphetamines without corresponding increases in sales of other controlled substances, at least during the period surveyed.

The author wishes to thank Robert T. Angarola, formerly with the White House Domestic Policy Staff, now a partner in the law firm of Hyman and Phelps, P.C., Washington, D.C.; W. Wayne Bohrer, Chief, State and Industry Unit, Drug Enforcement Administration; Charles E. Barner Jr., assistant secretary, Florida Department of Professional Regulation; Ernest Sjoblom, Director, Missouri Bureau of Narcotics and Dangerous Drugs; and especially David E. Joranson, drug abuse specialist and staff to the Wisconsin Controlled Substances Board, for their generous help in collecting data for this study. For further information on the Wisconsin approach to prescription drug abuse control, contact David Joranson (608) 267-7704, or the Innovations Transfer Program staff (606) 252-2291, The Council of State Governments, P.O. Box 11910, Iron Works Pike, Lexington, Kentucky 40578.

Controlling Amphetamine Abuse

Wisconsin, in the past, was similar to other states in the sizable number of prescription drugs sold on the street. In addition, Medicaid recipients were obtaining prescriptions, then selling drugs at a profit.

Wisconsin's comprehensive approach to control prescription drug abuse began in 1976 when the Controlled Substances Board (CSB), through the Drug Enforcement Administration (DEA), learned about physicians purchasing large quantities of amphetamines (Biphetamine 20). Biphetamine 20, available in the illicit market as "black Cadillac" or "black beauty," contains a combination of amphetamine and dextro amphetamine both of which were subject to the strict regulatory control of Schedule II of the state Controlled Substances Act.

The manufacturer's product information calls for Biphetamine 20 to be prescribed for exogenous obesity. The amphetamine product was chosen for investigation by the CSB for two reasons: first, the drug was widely available in the black market; and second, Wisconsin state officials were able to obtain the product's purchase data from the DEA's Automation of Reports and Consolidated Orders System (ARCOS), a computerized record of manufacturers' and distributors' reports of retail purchases.

The analysis of the 1975 purchase information on Biphetamine 20 showed that of 922,700 dosage units purchased by state practitioners, 26 individuals purchased 118,300 dosage units, or about 13 percent of the total purchases. The 26 included 20 physicians; three osteopaths; two dentists; and one podiatrist. The top five practitioners were connected with 71 percent of the purchases; and 10 of the 26 dispensing practitioners were from the urban Milwaukee area.

Concerned about such high concentrations of amphetamines in the Milwaukee area, the CSB in 1977 shared its analysis of the ARCOS data with the state pharmacy and medical licensing boards, requesting that they determine the legitimacy of the dispensing or prescription of the drugs. Specifically, the CSB asked the Pharmacy Examining Board (PEB) to review the physicians' prescription patterns. At the direction of the PEB, state pharmacy inspectors conducted an unprecedented prescription audit at 10 pharmacies that had purchased the largest quantities of Biphetamine 20. The results, which were subsequently sent to the Medical Examining Board (MEB), showed that of the total 10,202 prescriptions filled, approximately 83 percent or 8,432 prescriptions were written by eight physicians.

Utilizing these statistics, the CSB sponsored a symposium on "Diversion of Licit Controlled Substances" which was attended by state leadership of the medical, dental, nursing, and pharmacy professions and licensing authorities, and representatives of state and federal health and law enforcement agencies. The timely symposium in 1977 was widely publicized by the news media throughout the state.

The action taken by the Wisconsin MEB was equally swift. The board promptly initiated investigations of 60 physicians, while the board began to clarify its position on the medical safety and usefulness of amphetamines. The MEB concluded that there was no statistically reliable evidence showing that the drug had lasting positive effects in treating obesity and that there existed a high potential for abuse.

At the same time, it was acknowledged that amphetamines are medically useful for the treatment of some conditions such as narcolepsy and hyperkinesis. It was in this context that the state MEB issued an administrative rule under the state medical practice act which, in effect, made the prescribing of amphetamines, along with phenmetrazine, in the treatment of obesity, "unprofessional conduct." In addition, the rule was designed to permit the use of amphetamines in cases such as treatment of narcolepsy, hyperkinesis, drug-induced brain dysfunction, epilepsy, depression shown to be refractory to other therapeutic modalities, the differential diagnostic psychiatric evaluation of depression, or the clinical investigation of the effects of such drugs.

The MEB's initial administrative rule restricted all anorectic drugs in Schedules II, III and IV. But the rule was later amended to apply only to Schedule II drugs and took effect in 1977. Since 1977, the MEB has received only seven requests for exceptions to the new amphetamine rule. Of these requests, only three were granted: two relating to research and one for a patient with diabetic neuropathy.

Faced with the growing concern about amphetamines, the Wisconsin Department of Health and Social Services (DHSS) conducted an investigation of Title XIX (Medical Assistance) claims for amphetamine prescription. As a result of the investigation, the DHSS in 1977 stopped reimbursement of Title XIX claims for all Schedule II, III and IV amphetamine and anorectic products, unless a prior authorization had been approved. Title XIX prior authorization requests have been reviewed by the Bureau of Health Care Financing (BHCF) within the DHSS. Since the inception of the policy, according to the BHCF, only 10 to 15 requests have been received monthly, the majority from psychiatrists for depression ("unresponse to ordinary medications and treatment") and from pediatricians for the "hyperactive child." BHCF staff estimate that the annual Medicaid reimbursement level for amphetamines dropped from $100,000 in 1976 to approximately $1,000 in 1979.

Controlled Substances Board

The cooperative approach in controlling drug abuse, as described above, has been directed and coordinated by the Controlled Substances Board, an agency created

in 1970 by the state legislature. The Board, established by Chapter 161 of the Wisconsin Statutes, is authorized to administer certain provisions of the Controlled Substances Act (CSA), including proper placement of psychoactive drugs having abuse potential into the schedules of the act, and granting special authorizations to permit nonpractitioners involved in research, teaching and other functions to possess controlled substances.

The Board serves as an advisory agency on drug abuse to the public, the legislature, state departments and agencies, and to the State Council on Alcohol and Other Drug Abuse, of which the CSB is a member. The Board also provides technical assistance to various state agencies and individuals to interpret provisions of the CSA, and revises and publishes the schedules of controlled substances.

The Board membership consists of the state Attorney General; the Secretary of the Department of Health and Social Services; the Chairman of the Pharmacy Examining Board; the Secretary of the Department of Agriculture, Trade and Consumer Protection; a pharmacologist and a psychiatrist—the latter two appointed by the governor for three-year terms. Staff services for the six-member Board are provided by the DHSS' Office of Alcohol and Other Drug Abuse.

Since 1970, the CSB, in cooperative efforts, has conducted annual symposia to help public and professional understanding of drug abuse and controlled substance issues. Symposia topics have included the abuse of aerosols and inhalants; use of narcotic antagonists; the role of law in the social control of drugs; diversion of licit controlled substances; and use and diversion of sedative hypnotics. The CSB has also been involved in reviews of sale and control of "look-alikes," phencyclidine (PCP); and use of Delta 9-THC for cancer patients. Since 1976 the Board has paid most attention to control of diversion problems involving amphetamines, sedative-hypnotics, narcotics and "Ts and Blues."

Cooperative Approach

The cooperative effort undertaken by Wisconsin officials was subsequently formalized in a 1980 memorandum ("Memorandum of Cooperation for Controlling Diversion of Controlled Substances in Wisconsin"). A review of the memorandum will illustrate how the agencies have actually been able to realize interagency and state-federal cooperation.

Parties to the memorandum were the Controlled Substances Board, Pharmacy Examining Board, Medical Examining Board, Dentistry Examining Board (DEB), Veterinary Examining Board (VEB), and U.S. Drug Enforcement Administration. The memorandum was designed to develop and maintain a high degree of cooperation between state agencies and the federal government by strengthening working arrangements between them. In the memorandum they agreed that the CSB, because of its composition and its statutory relation to the Uniform Controlled Substances Act, would serve as a focal point for coordination of agency efforts, prepare reports for the public, state agencies and the DEA describing controlled substances distribution patterns and trends, monitor overall observance of state amphetamine regulations, and participate in periodic work-planning and coordinating meetings with state agencies and the DEA.

On the other hand, the PEB, MEB, DEB, and VEB reaffirmed their authorities and responsibilities for initiating investigations of their practitioners and adjudicating violations of the non-criminal ethical controlled substances law. They specifically agreed to: (1) participate in periodic work-planning and coordinating conferences with other state agencies and DEA; (2) provide the DEA with information on the initiation of results of any controlled substances and license investigations and of actions concerning Wisconsin practitioners; (3) regularly analyze controlled substances purchase reports from CSB and DEA and initiate investigative and regulatory actions; (4) undertake specialized projects to monitor and foster compliance with controlled substances law; (5) provide the DEA with complaints or any other information concerning registrants (manufacturers, distributors, etc.); and (6) report suspected criminal activities to enforcement agencies.

The Drug Enforcement Administration agreed to: (1) provide annual ARCOS reports (drug category, excess purchase, other special reports) to the CSB, MEB, and PEB; (2) review triplicate order forms routinely and provide reports to appropriate state licensing boards for follow-up; (3) refer all pertinent information and complaints concerning state-licensed registrants to the appropriate licensing board; (4) not conduct investigations of community level registrants unless in coordination with state boards; (5) notify state licensing boards of the initiation or results of regulatory or criminal investigations and actions against Wisconsin registrants; (6) conduct drug accountability investigations of drug manufacturers, wholesalers, distributors, and packagers to determine the adequacy of their reports; (7) routinely notify the appropriate state boards when excessive sales of controlled substances to Wisconsin registrants are discovered; (8) conduct joint field investigations or audit with personnel of state agencies; (9) provide assistance to state and local associations of Wisconsin pharmacists for the purpose of upgrading their approaches to the prevention of theft of controlled substances from pharmacies; (10) provide annual reports to CSB and PEB describing the previous year's experience concerning theft of controlled substances from Wisconsin pharmacies; and (11) participate in mutually arranged periodic work planning and coordinating conferences with state agencies.

In December 1981, the Wisconsin Legislature unanimously passed Assembly Bill 930, requiring the CSB to enter into formal agreements with state and federal

agencies to control the abuse of prescription drugs and to monitor cooperation between the agencies involved. The legislation recognized the value of interagency cooperation in diversion control and strengthened the CSB's authorities and responsibilities in further reducing drug abuse and diversion in Wisconsin.

Results

The results of Wisconsin's cooperative approach in controlling prescription drug abuse are surprising. The DEA's computerized data system, ARCOS, showed a sharp decline in amphetamine purchases in Wisconsin within the first two years: from approximately 40,000 grams in 1976 to under 4,000 grams in 1978. As shown in Figures 1 and 2, the sale of amphetamines between 1976 and 1980 to physicians, pharmacists and hospitals dropped by 92 percent. In 1976, Wisconsin ranked 26th among the states in per capita consumption of amphetamines; but by 1979 the state ranked 50th in the nation.

The decline in amphetamine purchases has also been correlated with a decrease in amphetamine-related arrest rates, as reflected in arrest data from police departments in the Milwaukee area (103 in 1976 to 76 in 1977, to 23 in 1978, to six in 1979, and nine in 1981). The decline in arrests for illegal sale of amphetamines was confirmed by a separate survey of law enforcement officials conducted by the state Justice Department. (Incidentally, the DEA arrested two physicians who were responsible for writing over 10,000 prescriptions. They were subsequently convicted in federal court for unlawful distribution of a controlled substance.)

Furthermore, amphetamine restrictions have received favorable reaction from drug abuse treatment providers in the state. Available statistics on amphetamine purchases in Wisconsin appear to substantiate the recent pronouncement to the CSB by David Joranson, a drug abuse specialist and CSB staffer: "The diversion of amphetamine-related drugs from legitimate sources—physicians and pharmacists—is all but gone."

A significant implication of the Wisconsin experience is that there has been no correspoding increase in purchases in drugs in Schedule III or IV. There has been, instead, an apparent decline in the sale of other drugs. Between 1976 and 1979, for instance, data from a small sample of Wisconsin drug distributors indicate that purchases of one Schedule IV anorectic decreased 77 percent, while purchases of another Schedule IV anorectic decreased 49 percent. Sale of methaqualone, a commonly abused sedative sold under brand names such as Quaaludes and Sopor, dropped 90 percent between 1976 and 1981; sale of amorbarbital decreased by 84 percent during the same period; and by 1982 the sale of phenmetrazine, a stimulant, dropped 99 percent.

It has been noted earlier that Wisconsin has drastically reduced reimbursement by the Medical Assistance Program for amphetamine prescriptions. It is also worth noting that the state has continued to take measures to curb drug abuse among recipients of the Medical Assistance Program. In 1981, for example, Wisconsin state

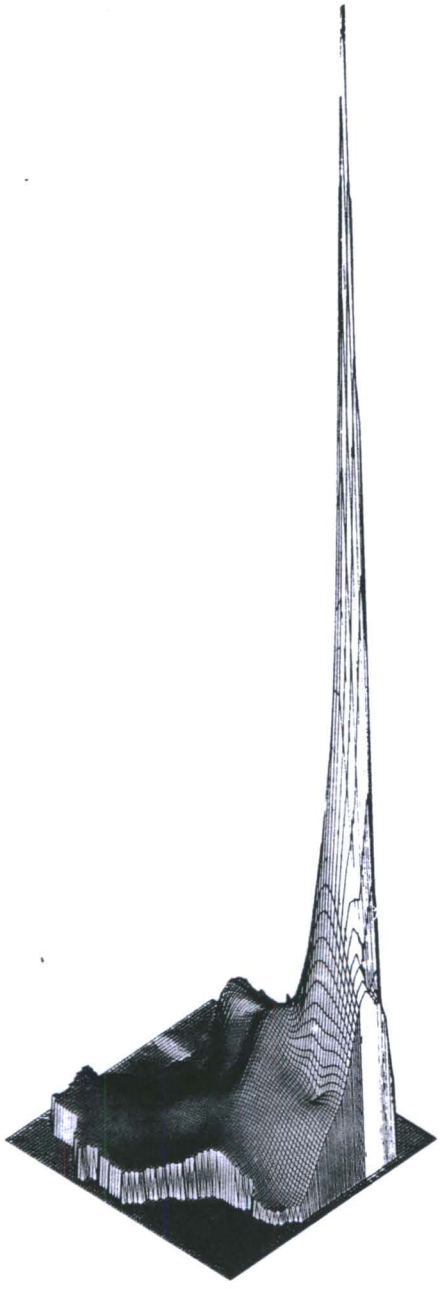

Fig. 1 Amphetamine Grams Purchased in 1975

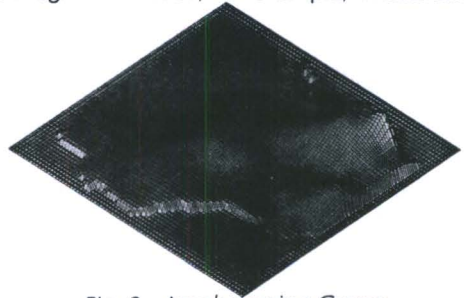

Fig. 2 Amphetamine Grams Purchased in 1980

officials, utilizing the Medicaid Management Information System, identified 140 Medicaid recipients who were charged with abusing drugs, including narcotics, sedatives, tranquilizers and soporifics.

Although a majority of drug recipients obtained prescriptions from a few physicians and pharmacists, some sought drugs from as many as 45 different physicians and 35 different pharmacies in 12 communities in the state. And it was found that over 38 percent of the total prescriptions were obtained from four physicians, who later were charged with drug abuse "for the price of an office call, a drug dispensing fee, or other gratuities." These findings are the result of cooperative efforts between Medicaid and other health insurance agencies. In addition, the Medical Assistance Program pharmacy consultant is a member of the CSB.

Although the Medicaid primary provider program in Wisconsin has contributed to helping the primary physicians and/or pharmacies manage the recipient's drug abuse problem, an alternative approach has been initiated in the state whereby pharmacists' dispensing practices are readily identifiable by the Medicaid program. The alternative—known as the Pharmacy Primary Provider Program—has proven to be more effective in controlling drug abuse; and the new program has eliminated legal problems associated with the Medicaid primary provider program, such as those involving recipients' civil liberties, confidentiality issues, and the time-consuming administrative appeal process.

Evaluation

Some national advisors consider the Wisconsin program "the most farsighted and innovative" in the nation, according to Robert T. Angarola, who served for several years in the White House Drug Policy Office. The success of Wisconsin's Controlled Substances Board is attributable to several factors, among them the positive attitudes and approaches of state government officials, cooperation among professional societies in the state, and the use of new techniques in data collection and analysis.

The CSB in Wisconsin has demonstrated that it has a lasting plan, instead of a "quick-fix" program, to reduce prescription drug abuse problems. State officials, supported by legislative measures, established a permanent government agency—the Controlled Substances Board—with broadly-defined authority to coordinate the prevention and control of prescription drug diversion, emphasizing interagency cooperation.

The Wisconsin experience might be looked at from another angle: that is, the CSB began with a cooperative approach and early recognition that prescription drug abuse was not merely a law enforcement issue. The CSB then devoted more attention to working within the regulatory and peer pressure framework.

Close cooperation among the regulatory agencies has been a major strength of the Wisconsin program. In particular, the willingness of the leaders of the MEB and the PEB to take preventive measures and to conduct self-evaluations and investigations has been an important source of the program's success. Further, state government officials, before taking action, have been receptive to ideas and concerns of various interest groups representing medical and pharmaceutical industries in the state.

The fact that Wisconsin was the first state to use the federal drug information system along with the state system as a source of information should be noted here in measuring the effectiveness of the Wisconsin approach. The ARCOS data, combined with the computer cartography technique developed in Wisconsin, provided a comprehensive picture for identifying the amphetamine problem areas.

As a result of the amphetamine control experience, the CSB has also been able to identify diversion problems involving other prescription drugs. The ARCOS data has provided necessary information on several drugs in Schedule II, and Wisconsin officials have been able to pinpoint suspected overprescriptions. Perhaps the Wisconsin program could not have been as efficient as it has been without direct communication and cooperation between the CSB and the DEA.

Initiatives at the National Level

Prescription drug abuse, although not as well recognized as illegal drug abuse, has been a nationwide problem in the United States for many years. A 1979 national survey showed that the use of prescription drugs was second to the use of marijuana. Moreover, health hazards are not less serious than those of illegal drug abuse. A recent GAO report shows, for instance, that 75 percent of the most frequently mentioned controlled drugs in the Drug Abuse Warning Network (DAWN) emergency room reports in 1980 were prescription drugs.

Currently over 20 billion dosage units of some 20,000 drug products, which are controlled under federal law, flow through over 625,000 registered manufacturers, distributors and dispensers. And, of those, nearly 99 percent involve retail level practitioners—physicians, dentists, pharmacies, veterinarians, hospitals and educational institutions.

Controlling prescription drugs is a joint responsibility of states and the federal government. At the federal level, the legal framework for controlling drug abuse was established by Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, commonly referred to as the Controlled Substances Act. Although the Drug Enforcement Administration, created in 1973, is the lead agency of the federal government in enforcing controlled substances laws and regulations, the DEA's administrator, since 1982, reports to the director of the FBI, who is authorized to supervise drug enforcement efforts. Currently, some 200 DEA diversion investi-

gators enforce regulation of the legal manufacture and distribution of prescription drugs.

Two pilot projects have been initiated recently by the DEA. Operation Script was begun in 1979 to identify high-level violators. Although the DEA concentrated nearly 500 prescription drug investigations in 24 cities, and although about one-third of the targets had been convicted or had lost their medical or pharmacy licenses through revocation, suspension or surrender, the project failed to meet its objectives, according to a 1982 GAO report. In 1981, the DEA initiated a permanent program, the Targeted Registrant Investigations Program (TRIP), designed to focus DEA investigations on retail violators.

According to a recent DEA survey of state health-care-related regulatory agencies and professional associations in 50 states, the most serious source of prescription drug diversion is pharmacy theft. Nationwide, the number of drug thefts reported to the DEA since 1976 has risen by 29 percent, and retail pharmacies account for most, if not all, of these thefts. To deal with drug thefts, the DEA, in addition to the Pharmacy Theft Prevention Program which became fully available in 1977, created the Registrant Drug Theft Program. Its purpose was to develop a proposed amendment to the 1970 Controlled Substances Act which would provide for mandatory minimum sentences in violent drug theft situations. Under that program, most states are expected to revise their statutes.

Between 1978 and 1980, two congressional hearings and a White House conference were held to discuss desirable courses of action to control the diversion and abuse of prescription drugs. Major themes of the hearings and conferences have centered around the need for coordinated efforts involving the three levels of government in cooperation with professional organizations and regulatory, licensing and law enforcement agencies.

The 1980 White House conference made specific recommendations so that states and localities would have more timely access to DEA's ARCOS information and use of DAWN or a statewide mini-DAWN system. Responding to these recommendations, DEA has changed ARCOS reporting from annually to quarterly, and the agency has also adopted Wisconsin's "mapping" technique for targeting practitioners most likely to be diverting drugs.

One significant development is that the American Medical Association (AMA) is currently in the process of devising a new model plan to help states determine the extent of drug abuse and diversion. The model plan is patterned after Wisconsin's approach and is known as Prescription Abuse Data Synthesis (PADS). The model synthesizes data from several different sources for use by states: Automated Reports and Consolidated Orders System (ARCOS); Drug Abuse Warning Network (DAWN), which is a record of drug mentions from drug-related emergency room visits in 26 major metropolitan areas; statistics on theft of controlled substances collected by the DEA; Medicaid Management Information System (MMIS) involving state records of reimbursement for medical assistance services; state crime laboratory reports regarding drug-related investigations; drug abuse treatment program admissions; and drug-related arrests by local law enforcement agencies. The AMA expects to complete the PADS model in 1983, and drug abuse agencies in each state will be able to have access to it.

Four Categories of Errant Prescribers

Joseph H. Skom, MD, clinical professor of medicine at Northwestern University Medical School, Chicago, and chairman of AMA's Steering Committee on Prescription Drug Abuse, offers four categories for doctors who misprescribe:

- Dishonest—or "script"—doctors probably represent no more than 1 percent of all practicing physicians, but they are responsible for the majority of prescription drugs earmarked for illegal use.
- Disabled doctors are those whose professional competance has been impaired by physical or emotional illness. Impaired physicians are not responsible for much misprescribing, according to available data.
- Dated doctors are poor prescribers because they have not kept pace with developments in pharmacology and drug therapy. They may prescribe excessive amounts of drugs for unusually long periods, prescribe drugs that are not appropriate for the condition being treated, or prescribe drugs when another type of therapy is indicated.
- Duped doctors have ethical intentions but misprescribe because they accede to pressure from patients who are drug abusers or who wish to obtain drugs for sale to others.*

*From *American Medical News*, November 12, 1982.

Transferability

The role of states in controlling prescription drug abuse should be reemphasized. The states are the most appropriate level of government to solve the prescription drug abuse problem since states, in addition to their enforcement capabilities, hold regulatory authority over the licenses of physicians, pharmacists, veterinarians and dentists who divert drugs into the illicit market.

Obviously, many states have not implemented effective methods of curbing drug problems. In fact, most states lack a single agency for administering a program of interagency diversion control and prevention. In Wisconsin, the addition of these new responsibilities to an interagency board already vested with controlled substances scheduling authority was a logical and practical choice.

States also administer the Medicaid program, sometimes abused by recipients but more often by providers. Many state governments have not been able to investigate Medicaid fraud, however. According to the U.S.

House of Representatives Select Committee on Aging's 1982 report on Medicaid Fraud Enforcement, many states need legislative measures—to subpoena, arrest, and seize evidence—before Medicaid Fraud Units can investigate and prosecute. The report found that state Medicaid Fraud Units have not been successful in getting interagency cooperation, and that as many as 20 states have not even applied for the 90 percent federal funding for Medicaid Fraud Units because of "the resistance of state Medicaid administrators who do not want to share their powers or have them taken away."

As demonstrated in the Wisconsin approach, additional legislative actions might be necessary to launch a comprehensive program. Presently, the AMA is considering drafting papers on this issue; there is a need to enact legislation to enable authorities to take regulatory and peer pressure action to deal with the diverters before having to go to the criminal justice system.

It appears that state legislators also need to be better informed about the activities of the substances abuse office. In Wisconsin, such knowledge prompted enactment of necessary legislation, since key legislative leaders had been informed of the situation.

Additionally, states can learn from Wisconsin some lessons having little to do with legal mechanisms. Professional organizations, for example, can initiate and implement various preventive measures to control prescription drugs; statewide or regional conferences and seminars can be held to educate state authorities to take steps to handle the drug abuse problem; and state drug abuse agencies might try to devise ways and means to have law enforcement and medical personnel work closely together in an atmosphere of trust and cooperation.

Other States

Florida is often cited as another model state with innovative programs to control prescription drug abuse. As a result of the 48-hour delay rule and educational programs initiated in 1977, for example, the number of methaqualone and amphetamine prescriptions was reduced by more than 70 percent. In 1980, the Florida legislature approved the creation of 12 investigator positions within the Department of Professional Regulation (DPR), which regulates 32 professions, including physicians, osteopaths, dentists, podiatrists, veterinarians, naturophathic physicians, nurses and pharmacists.

The investigators, through two surveys of pharmacies in 1980 and 1981, helped identify drug prescribers involved in the operation of so-called "stress clinics" in Southeast Florida. Those establishments prescribed methaqualone (Quaalude) to treat young persons with "stress problems." As a result of DPR actions against health care practitioners in "stress clinics," Florida officials report there are now no known "stress clinics" in the state.

The DPR has recently added another dimension to its ability to identify those involved in drug diversion. Through cooperation with the DEA, the DPR began to maintain copies of DEA 222 forms for all drug purchases in Florida. DEA 222 forms must be used by pharmacists when ordering Schedule II drugs from wholesale distributors or other pharmacies. Similarly, medical practitioners must utilize the 222 form when purchasing drugs for office use from pharmacies or wholesale distributors. Effective November 1982, this system enables the DPR to assess whether individual medical practitioners are purchasing Schedule II drugs beyond what is considered reasonable.

Missouri initiated the Controlled Substance Prescription Survey Program in 1981 to detect "inappropriate" prescribing and dispensing practices. Specifically, the survey's purposes are to identify practitioners who prescribe indiscriminately; identify pharmacies filling forged, altered or excessive prescriptions; and to identify "professional patients."

Under the program, prescriptions on file at pharmacies or physicians' dispensing records are hand-recorded by field representatives on forms submitted to electronic data processing. The data are used to generate specific information, such as prescriptions issued to patients by individual practitioners, individual patient records to detect persons obtaining prescriptions from several physicians, and information on files at particular pharmacies for audit purposes.

Administered by the Bureau of Narcotics and Dangerous Drugs within the Missouri Division of Health, the program has generated information used in actions against practitioners as well as patients. In the past two years, over 100 actions have been taken by the bureau, which currently uses four field investigators and two clerical assistants to check 16,000 practitioners.

Conclusion

Wisconsin has been able to eliminate "script doctors," who have been responsible for prescribing large quantities of drugs with abuse potential. The Wisconsin experience would indicate that elimination of sources of diversion has been largely responsible for sales reduction. Some questions still remain to be answered, however.

There could be, for example, more pressure on physicians to prescribe narcotics. The fact is that anyone in Wisconsin who tries to obtain amphetamines and other controlled substances could easily get them from practitioners in other states. And the effects of declining prescription drug abuse on the overall problem of drug abuse has yet to be measured. Nevertheless, the Wisconsin approach could be used as a model by other states contemplating a lasting, single state agency to curb prescription drug abuse and diversion.

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Notes

WORK GROUP ON PROFESSIONAL EDUCATION

Washington, D.C.
July 19, 1983

Jane Lee (Chairman) American Medical Association
Jim Callahan, National Institute on Drug Abuse
John Cifala, American Osteopathic Association
Karen Gillespie, Pracon Incorporated
Gail Jara, California Medical Association
Bill McGivney, American Medical Association
Stephanie Ross, Haight-Ashbury Training and Education Projects
Joel Solomon, Association for Medical Education and Research in Substance Abuse
Bonnie Wilford, American Medical Association

Identified Needs

1. *Educational programs to improve the prescribing and dispensing practices of all health professionals.*

2. *Programs adaptable to the special needs of practitioners whose prescribing or dispensing practices do not meet accepted or legal standards.*

Proposed Goal

To develop an educational effort for physicians and other prescribers of controlled substances aimed at

1. *improving prescribing and dispensing practices, patient assessment and diagnostic techniques, and good office management practices;*

2. *ensuring up-to-date knowledge of relevant legislation and regulations; and*

3. *improving interprofessional cooperation for the benefit of the public.*

Target Population

Group 1 (Prevention)	*Physicians who wish to obtain continuing education on prescribing laws, practices, and techniques.*
	Physicians whose prescribing practices may bring them to the attention of licensing or regulatory authorities.

Group 2 (Remediation)	*Physicians identified through PADS or other means as being in need of additional education on prescribing laws or practices.* *Physicians who seek additional education as an alternative to punitive action.*

Elements of Educational Program

Group 1 (Prevention)	*A packaged program containing a video-cassette, text, instructor's guide, pre- and post-test (for CME credit), and evaluation form. Presentation of the program would be accompanied by a local "expert" who will serve to clarify issues and facilitate discussion.*
Group 2 (Remediation)	*All of the above, supplemented by individual proctoring and sustained contact with a "consultant panel" which could advise on specific problems with prescribing decisions.*

General Educational Objectives

The nature of the general objectives is two-fold: prevention and remediation. The prevention objective should be met through the participation of prescribers whose prescribing practices are within the bounds of the law or are marginally within the law but have not come to the attention of law enforcement or licensing authorities. The remediation objective should be met through the participation of prescribers whose prescribing practices have or probably have violated relevant federal or state law, who have been contacted by law enforcement or licensing authorities, and who face the possibility of prosecution or disciplinary action.

All participants should achieve a sufficient level of knowledge as a result of their participation to ensure that their knowledge of relevant legislation and regulation is up-to-date; to recognize and handle more effectively patient assessment, diagnosis, and management; to revise their office or practice standards to safeguard against violations of the law, theft, forgery, or other avenues for diversion of prescription drugs; and to create a better understanding of the nature and consequences of prescription drug abuse, methods of prevention, and the need to cooperate with other prescribers, law enforcement officials, local authorities and health associations, etc.

Outline for Video Cassette Script/Text

I. Federal and State Law Governing Controlled Substances

A. *Brief History*
B. *Effects of Abuse - Need for Special Precautions*
C. *Dimensions of Prescription Drug Abuse Problem*
D. *Penalties for Violations of Relevant Drug Laws*
    1. *Loss of prescribing privileges*
    2. *Loss of license*
    3. *Criminal proceedings*

II. *Prescription Practices*

A. *Instructions for Patient*
    1. *Dosage*
    2. *Drug interactions*
    3. *Compliance*
    4. *Refills*
    5. *Accidental poisoning*

B. *Improper Prescription Practices*
    1. *Overmedication*
    2. *Undermedication*
    3. *Drug Abuse*
        a. *Willful and conscious misprescribing*
        b. *Inappropriate prescribing*
        c. *Uninformed prescribing*
        d. *Self-prescribing*

C. *Myths and Facts Concerning Commonly Abused or Misprescribed Drugs; Drug Classes (sedative/Hypnotics, CNS stimulants, narcotic analgesics, etc.) and Diagnoses (anxiety, stress, insomnia, obesity, clinically unverifiable or chronic pain) Requiring Special Caution*

III. *Prescribing Controlled Psychoactive Drugs*

A. *Indications for Use and Precautions (Abuse Potential and Dependence Liability)*
    1. *Opioids*
    2. *Antianxiety and Hypnotic Agents*
        a. *Benzodiazepines*
        b. *Barbiturates*
        c. *Nonbenzodiazepine/Nonbarbiturate drugs (e.g., Methaqualone)*
    3. *Central Nervous System Stimulants*
        a. *Amphetamines*
        b. *Other stimulants*

B. *Common Avenues of Prescription Drug Diversion*
    1. *Office thefts (drugs, prescription pads)*
    2. *Prescription thefts, forgeries and alterations*
    3. *Deceptive practices employed by "professional patients"*
    4. *Physical or emotional intimidation, social pressure, flattery, blackmail used against prescriber*

C. *How to Guard Against Victimization*
   1. *Office security*
   2. *Patient assessment techniques; recognition of deceptive practices*
   3. *Complete and accurate records (patient history, presenting symptoms, complaints, examinations and tests performed, consultations obtained, drugs ordered, etc.)*
   4. *Interprofessional cooperation (e.g., with pharmacists, enforcement officials, nursing staff)*
   5. *Responsibility to confront or report patients and professionals whose actions suggest improper prescribing or drug abuse.*

How to Reach Target Audiences

Group 1 (Prevention)	*State medical society meetings, hospital medical staff meetings (attendance mandatory), state or regional conferences on drug abuse, cable TV (CME channels).*
Group 2 (Remediation)	*Provide "incentives" (e.g., participation in an education program in lieu of licensure action).*

Possible Resources for Development

1. *Professional Education Work Group/Informal Steering Committee*
2. *AMA Staff (Health and Human Behavior, Medical Education, Drugs, Public and Federation Relations, Legislation, OGC, Washington Office, et al)*
3. *National Institute on Drug Abuse*
4. *Drug Enforcement Administration*
5. *National Association of Boards of Pharmacy*
6. *California Medical Association*
7. *Haight-Ashbury Training and Education Projects*
8. *Pharmaceutical manufacturers*

Possible Sources of Financial Support

1. *AMA*
2. *Pharmaceutical Manufacturers Association*
3. *Individual drug manufacturers*
4. *Insurance industry, particularly those professional liability companies formed by state medical societies*

Schedule for Development of an Educational Program

Begin immediately to work with Haight-Ashbury (script and production), NIDA, DEA, CMA and NABP (consultation, script review, written materials, possibility of joint CME and CEU credits to encourage interprofessional cooperation). Target: rough tape completed by December 1983; final program ready for distribution early 1984.

Related Activities of Other Organizations

The National Association of Boards of Pharmacy (NABP) is developing a video cassette series for pharmacists:

1. *"Professional and Legal Responsibilities in Pharmacy Practice: The Food, Drug, and Cosmetic Act" (completed)*

2. *"Professional and Legal Responsibilities in Pharmacy Practice: The Federal Controlled Substances Act" (scheduled for completion 10/83)*

3. *Disciplinary Actions Against Pharmacists (in early planning stages)*

The NABP program format includes a video cassette, script and instructor's guide. The package is available to all interested groups at nominal cost (postage and handling), but can be shown only if a member of the appropriate state board of pharmacy is present to facilitate the discussion and clarify relevant state law. The program caries 0.1 continuing education units in pharmacy.

The California Medical Association is planning a series of video cassettes for physicians:

1. *Prescribing for Insomnia and Anxiety*
2. *The Manipulative Patient*
3. *Guidelines for Prescribing Any Dependence-Producing Drug*

It is important that the physician education program be coordinated with the NABP program for pharmacists as the cornerstone of a comprehensive professional education package.

cc: Nancy Cahill
Dan Lambert
Manny Steindler

M

Notes

WORK GROUP ON PATIENT/PUBLIC EDUCATION

Washington, D.C.
July 20, 1983

Karen Gillespie (Chairman), Pracon Incopporated
Dorynne Czechowicz, M.D., National Institute on Drug Abuse
Mary Danaher, American Medical Association
Madeline Naegle, Ph.D., R.N., American Nurses Association
Karen Prupes, American Medical Association
Bonnie Wilford, American Medical Association

I. Strategy

The work group reviewed a number of recent reports on public and patient knowledge of prescription drugs and discussed several possible projects, including some designed for the elderly and for women in the child-bearing years. After considering these options, the group determined that a more productive course would be to (1) outline basic learning objectives for any patient or public education programs on prescription drugs and (2) assess programs now available that might meet those needs.

II. Assignments

The following assignments were agreed upon:

1. *B. Wilford will supply group members with DAWN data on drug-related morbidity and mortality for specific population groups.*

2. *K. Gillespie and M. Danaher will conduct a literature search to identify currently available educational materials.*

3. *R. Ashery will send K. Gillespie a list of publications available through the NIDA Clearinghouse.*

4. *K. Prupes will prepare a draft list of concepts that should be covered in any educational program.*

The group will meet again to prepare detailed learning objectives after the members have received and studied this information.

cc: Rebecca Ashery
Nancy Cahill
Manny Steindler

Study No. 812020

PATIENT INFORMATION AND PRESCRIPTION DRUGS: PARALLEL SURVEYS OF PHYSICIANS AND PHARMACISTS

Conducted by

LOUIS HARRIS AND ASSOCIATES

John M. Boyle, Ph.D.
Project Director

March 1983

for the

FOOD AND DRUG ADMINISTRATION

Louis Morris, Ph.D.
Steven R. Moore, M.P.H.
Project Officers

1: EXECUTIVE SUMMARY

The Food and Drug Administration (FDA) is charged with the responsibility for the safe and effective use of prescription drugs. Since safe and effective drug use depends on the user's understanding of the proper use, risks, and precautions associated with prescription medication, the FDA has undertaken a number of studies concerning patient education as it relates to prescription drugs. The nature and extent of communications between patients and health professionals about prescription drugs constitute one important area of patient education.

In February 1981, the Food and Drug Administration commissioned Louis Harris and Associates to conduct a national study of patient-professional communications about prescription drugs from the professional's perspective. Earlier studies of doctor-patient communications had been conducted by the FDA by means of consumer surveys. This study, however, involves parallel national samples of physicians and pharmacists who report their attitudes and experiences with patients and prescriptions. Fifteen-minute telephone interviews were conducted with 501 office-based primary care physicians and 500 dispensing pharmacists in community pharmacies. The surveys were conducted between September and December 1982.

The physician and pharmacist surveys confirm that a high volume of prescription drugs are being prescribed and dispensed. Office-based physicians engaged in the primary care of adults (i.e., general practitioners, family practitioners, internists, and obstetricians/gynecologists) report prescribing an average of 88.5 outpatient prescriptions during the last complete week of practice prior to their interview. Since the physicians

report an average of 86.4 outpatients and approximately 29.8 hours devoted to outpatient care during that last week of practice, this means that doctors write an average of 1 prescription per outpatient and 3 prescriptions per hour.

Pharmacists are equally busy. On average, pharmacists estimate that 526.6 prescriptions are filled each week in their pharmacy, yielding a national estimate of 1.38 billion prescriptions dispensed per year. The pharmacist personally dispenses 68.2 prescriptions during an average working day. Thus, the average pharmacist dispenses 7-9 prescriptions an hour.

If one considers the volume of drugs prescribed and dispensed, it is not surprising that doctors report that a number of problems occur frequently among patients taking prescription drugs. Seven out of ten doctors (72%) report that premature termination of medication by patients who are feeling better frequently occurs. Half of the doctors (50%) say neglect of the proper dosage schedule by the patient frequently occurs. In somewhat smaller proportions, 20% of doctors say patients frequently use someone else's drugs, 19% say suggestion-induced side effects occur frequently, and 12% report that patient resistance to drug therapy occurs frequently.

Interestingly, physicians see inappropriate prescribing by physicians as more common than serious adverse reactions to the drugs themselves. While only 1 in 100 physicians (1%) report that serious adverse drug reactions happen frequently, 1 out of 10 (10%) say that inappropriate prescribing occurs frequently. Indeed, a majority of doctors (56%) say that inappropriate prescribing by physicians happens at least occasionally.

The most common problems with prescription medications, however, are identified by physicians as issues of patient behavior -- noncompliance,

neglect of schedule, exchange of drugs -- not physician behavior. Indeed, doctors are quite satisfied with their own efforts to inform and educate their patients about the proper use of prescription drugs. Four out of five doctors (79%) feel they spend the right amount of time informing their patients about drug therapy, compared with 4% of doctors who feel they spend too much time informing patients, and 16% who feel they spend too little time. It is not surprising, then, that 32% of physicians say patients are very well informed, and another 56% say patients are adequately informed about the purpose and use of their prescription medications. Only 9% of doctors feel their patients are less than adequately informed, and only 1% feel their patients are very poorly informed about the purpose and use of prescriptions.

Four study drugs -- tetracycline, thiazides, benzodiazepines, and warfarin -- were selected for more detailed examination, in order to learn more about what health professionals tell their patients. Tetracycline is an antibiotic that requires short-term compliance. Thiazides are antihypertensive drugs that require long-term compliance. Benzodiazepines are a drug group usually prescribed as tranquilizers that are used symptomatically. Warfarin is an anticoagulant with potentially severe side effects that requires careful monitoring. These drugs represent a range of drug classes that raise different issues about physician disclosure and patient compliance. They also are drugs that are relatively frequently prescribed and dispensed. During an average week, physicians in office-based primary care of adults write, on average, 7.27 prescriptions for tetracycline, 13.91 prescriptions for thiazides, 5.42 prescriptions for benzodiazepines, and .94 prescriptions for warfarin. Pharmacists, who fill prescriptions for a much larger and somewhat different population of doctors, report dispensing,

on average, 24.2 new prescriptions for tetracycline, 31.5 new prescriptions for thiazides, 27.1 new prescriptions for benzodiazepines, and 5.0 new prescriptions for warfarin during an average week. Survey questions concerning the study drugs were directed to physicians and pharmacists who say they prescribe or dispense the drug at least once a week.

Physicians who prescribe the four study drugs report relatively few patient complaints about the drugs' side effects. These doctors report an average of 7.8 complaints from patients during the past year about side effects from tetracycline, 10.65 complaints about the side effects of thiazides, 10.55 complaints about the side effects of benzodiazepines, and 3.12 complaints about warfarin. Complaints about side effects represent 1.4% of thiazide prescriptions, 2.7% of tetracycline prescriptions, 3.7% of benzodiazepine prescriptions, and 6.3% of warfarin prescriptions.

Among those who prescribe each of the study drugs, physicians spend an average of 2.73 minutes discussing new prescriptions for tetracycline, 3.40 minutes discussing thiazides, 3.69 minutes discussing benzodiazepines, and 6.32 minutes discussing warfarin. What doctors say they tell patients about these prescription drugs includes directions for drug use, precautions, and side effects warnings. Nonetheless, there appear to be some striking omissions in what physicians say they tell a patient who has not taken one of the study drugs before. Although premature termination of antibiotics is reported as one of the most common problems of drug therapy, only 7% of doctors who prescribe tetracycline say they tell their patients to finish their prescription. Only 3% of doctors who prescribe benzodiazepines warn their patients not to give their medicine to anyone else, even though the use of drugs by individuals other than the patient is another problem recognized

by physicians. No doctors report that they told their thiazide patients that the drug therapy was long term or permanent. Furthermore, surprisingly few physicians report that they tell their patients what the medication is and what it is used for, unless it is likely to have physical manifestations (urination for thiazides, bleeding and bruising for warfarin).

Doctors may feel that patients are satisfied with the present level of doctor-patient communication about prescription drugs because of the limited number of questions patients ask about their prescriptions. When the doctors who prescribe the four study drugs were asked what kinds of questions patients usually ask about each drug, 54% of doctors prescribing tetracycline volunteered that patients receiving new tetracycline prescriptions usually ask no questions, 43% of new thiazide patients ask no questions, and 28% of new warfarin patients and 28% of new benzodiazepine patients ask no questions. Similarly, physicians report that they get 12.6 phone calls a week from patients concerning their prescriptions -- representing 14% of the average number of prescriptions per week. It should be noted, however, that 38% of physicians report that their staff screen out most or almost all of the phone calls from patients about their medication.

Pharmacists report more questions from patients about prescriptions, and they seem to be less satisfied with patient-professional communications. Pharmacists report an average of 25.2 questions of a professional nature from customers during an average day concerning prescription drugs. The pharmacists report that they are getting questions with 37% of the prescriptions they fill in an average day. Pharmacists report that in an average week, customers ask, on average, 29.3 questions about what a drug is used for, 28.1 questions about refills, 27.7 questions about side effects, 23 questions about drug or food interaction, and 13.3 questions about proper

dosage. Despite this fairly high level of customer questions, fully 82% of pharmacists say their customers ask too few questions about their prescriptions.

When filling a new prescription for one of the four study drugs, most pharmacists also say they normally speak to customers about the prescription. However, the likelihood of a pharmacist who dispenses a study drug speaking to the customer about a new prescription varies from 82% for tetracycline, to 79% for warfarin, to 67% for benzodiazepines, to 61% for thiazides. Moreover, the pharmacist spends considerably less time discussing prescriptions with customers than does the doctor. On average, pharmacists who dispense the study drugs say they spend, on average, 1.4 minutes discussing new prescriptions of thiazides, 1.5 minutes discussing new prescriptions of tetracycline, 1.6 minutes discussing benzodiazepines, and 1.7 minutes discussing new prescriptions of warfarin.

Both doctors and pharmacists report some positive changes over the last few years in patient-professional communications. Almost half (47%) of office-based doctors specializing in primary care for adults report they now spend more time discussing drug therapy with their patients than they did two years ago, while only 3% say they spend less time. Similarly, nearly three-quarters of pharmacists (74%) report that patients rely more on pharmacists for professional advice about medicine now than they did two years ago.

However, there appear to be important limits to the future expansion of patient-professional communications. As noted earlier, the vast majority of physicians (79%) say they are already spending the right amount of time on patient discussions. The relatively small number of doctors (16%) who think they spend too little time informing patients report that other practice demands and limited time are the reasons they don't spend more time in

discussions with patients. Pharmacists are less satisfied with the present level of pharmacist-patient communications than physicians are with physician-patient communications. Nearly three-quarters of pharmacists (73%) say they would prefer to spend a greater proportion of their workday on patient consultation. However, pharmacists report that their other duties prevent them from spending more time with patients.

The survey finds that both doctors and pharmacists have relatively long workweeks. Doctors spent an average of 46.6 hours in direct patient care activities during their last complete week of practice. Pharmacists work 45.2 hours a week, on average, as a dispensing pharmacist. During their outpatient office hours, doctors see an average of 3 patients per hour. Meanwhile, pharmacists dispense 7-9 prescriptions an hour during their workweek.

Increased patient load for either the doctor or the pharmacist limits patient-professional communications. The time doctors spend discussing with patients new prescriptions for the four test drugs is measurably less among high-prescribing physicians. Similarly, the time pharmacists spend discussing new prescriptions is measurably less among high-dispensing pharmacists. On the other hand, since both physicians' and pharmacists' earnings are dependent on the number of patients they serve, it is unrealistic to expect that they will reduce the number of patients they see in order to increase the time spent per patient.

Thus, the length and thoroughness of doctor-patient and pharmacist-patient communications are likely to improve dramatically only if patients ask more questions. Questions are the way the patient signals to the health professional that the level of communications is not adequate. There is no evidence that doctors or pharmacists discourage patient questions.

Quite the contrary, most pharmacists say patient questions interrupt their work only a little (26%) or not at all (45%).

It is also possible that patient-professional communications may be improved by reshaping the content of the 2-6 minutes the doctor spends and the 1-2 minutes the pharmacist spends discussing the study drugs. This possibility requires an assessment of the current components of those discussions in order to decide whether or not the time could be better spent on issues not currently being addressed.

Finally, written and audiovisual supplementary materials act as professional extenders in describing and explaining prescription medications. Virtually all pharmacists (96%) report that they currently provide auxiliary labels on prescriptions, although in the context of the four test drugs, the percentages vary from 87% of pharmacists for tetracycline, to 44% for thiazides. More than two-thirds of pharmacists (69%) report that they provide pamphlets about certain medications, 33% provide books about drugs for sale, and 30% provide books on display for reference purposes.

Doctors also use a variety of patient education materials to supplement their verbal discussions. On a daily basis, 37% of doctors give their patients materials that the doctors have prepared for their practice; 22% give out disease foundation brochures related to condition or treatment; 20% give out drug company pamphlets; 12% give out medical association publications; 11% give out government brochures; and 3% give out reprints of newspaper and journal articles. The survey also finds that doctors who are high prescribers are more likely to use these supplementary educational materials -- possibly to compensate for limits on their discussion time with patients.

Since any major changes in the availability of these secondary forms of patient education require the support and approval of the health professionals, doctors' attitudes toward alternative patient information choices are important. Most doctors view as helpful both patient consultation with pharmacists (81%) and books and pamphlets about prescription medication written for the layman (66%). However, only minorities of doctors believe that patient consultation of newspaper and magazine stories (35%), drug company advertising (32%), and the PDR or other professional texts (31%) is helpful, and nearly equal percentages believe that such consultation is harmful. Clearly, while doctors see health benefits to patients in supplemental education materials about prescriptions, physician approval depends considerably on the nature of those materials.

The main objective of this survey is to provide baseline data for the assessment of subsequent patient information efforts. Nonetheless, the study also provides important insights into the world of patient-professional communications -- from the professional's point of view.

FDA
TALK PAPER

FOOD AND DRUG ADMINISTRATION
U.S. Department of Health and Human Services
Public Health Service 5600 Fishers Lane Rockville, Maryland 20857

T82-78
Nov. 8, 1982

William Grigg
(301) 443-3285

ORAL DRUG INFO MORE LIKELY FROM DOCTORS

Consumers are nearly twice as likely to have their physician tell them about a drug as they are to get oral information from a pharmacist -- but nearly three times as likely to get written information from the pharmacist as from the doctor.

These are some of the preliminary results of FDA's consumer prescription drug information survey conducted by Chilton Research Inc. Chilton interviewed 1,104 persons who had filled prescriptions within four weeks.

The preliminary results were sent by Associate Commissioner for Planning and Evaluation Gerald L. Barkdoll to members of the privately supported Council on Patient Information and Education this week.

The preliminary results show:

-- About 65 percent of consumers reported getting some drug information -- how much to take, how often, when, or what problems to look out for -- from their physicians or others in the physicians' offices.

-- About 37 percent reported getting oral information from their pharmacists or others in the pharmacy. This figure and the 65 percent above include about 27 percent of consumers who report getting oral information from both the physicians' offices and the pharmacies.

-- The physician or his office was most commonly reported as the source of information on when to take a drug, 61 percent, and how much to take, 59 percent; about side effects by 26 percent, and about precautions to take by 32 percent. Most of the information was volunteered; only 2 to 4 percent of the consumers reported requesting the information.

-- Only about 6 percent of consumers were given written information in physicians' offices, about 15 percent at pharmacies.

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Ms. Gillespie:
Per telephone conversation.

Gerald F. Barkdoll 12/2/82

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
Rockville MD 20857

NOV 9 1982

The Honorable Paul Rogers
815 Connecticut Ave., NW
Suite 700
Washington, DC 20006

Dear Mr. Rogers:

The purpose of this letter is to relate to you some of the preliminary findings of FDA's consumer prescription drug information survey. A number of interested persons were previously asked to comment on the draft questionnaire to be used in this survey. Many of these individuals are now members of the National Council on Patient Information and Education (see Attachment A). The final questionnaire was the result of the substantive and useful comments we received.

The purpose of this survey is to establish initial benchmarks or reference points. Additional surveys will be conducted in the future and the results of this survey can then be used to determine changes in the consumers' experiences. This survey and the subsequent surveys are designed to measure the aggregate effect of the various patient information activities now underway or just getting started.

The survey was conducted by Chilton Research, Inc. The data was obtained from consumers, age 18 or over, who had filled a new prescription for themselves or someone in their household in the last four weeks. The consumers were chosen at random using a probability sample of adult subjects. The interviewing began on September 7, 1982, and ended the week of September 26, 1982. Chilton called almost 8000 households in order to locate 1104 individuals who met the survey criteria and agreed to be interviewed.

We just received a tape of the survey data and have done some preliminary analyses. We will, of course, be doing a substantial amount of additional analysis. However, we thought you would be interested in some of the preliminary findings to selected questions. These are presented in a question and answer format (see Attachment B). We are also preparing an FDA Talk Paper on these results.

As additional variables and combinations of variables are analyzed, we will make them available to the Council. Also, we are assembling a technical document which will include a description of the study methodology, copies of the questionnaire, the computer record format, and the "raw data." If you would like a copy of this document, please let us know. Copies of the data tapes will also be available for those who want to do their own analysis. I am very interested in any specific questions you or members of the Council would like to have answered from the data. We will attempt to answer all questions that are of interest.

Sincerely,

Gerald L. Barkdoll
Associate Commissioner for
Planning and Evaluation

Attachments

Attachment A

Individuals Invited to Participate in Questionnaire Design

Mr. Roger Tusken
Executive Vice President
American Academy of Family Physicians
Suite 2970
475 L'Enfant Plaza West
Washington, D.C. 20024

Mr. Fred Wagner
Pharmaceutical Specialist
American Association of Retired Persons
1901 K Street, N.W.
Washington, D.C. 20049

James H. Sammons, M.D.
Executive Vice President
American Medical Association
535 N. Dearborn Street
Chicago, IL 60610

William Apple, Ph.D.
President
American Pharmaceutical Association
2215 Constitution Ave., N.W.
Washington, D.C. 20034

Joseph Oddis, Ph.D.
Executive Vice President
American Society of Hospital Pharmacists
4630 Montgomery Ave.
Bethesda, MD 20814

Mr. Robert J. Bolger
President
National Association of Chain Drug Stores
413 North Lee Street
Alexandria, VA 22314

Mr. William E. Woods
Executive Vice President
National Association of Retail Druggists
1750 K Street, N.W.
Washington, D.C. 20006

Ms. Sandra Willet
Executive Vice President
National Consumers League
1522 K Street, N.W.
Suite 406
Washington, D.C. 20005

Frank Royal, M.D.
President
National Medical Association
1122 North 25th Street, Suite A
Richmond, VA 23223

Mr. James Tyson
Executive Secretary
National Pharmaceutical Association
Howard University, Box #934
Washington, D.C. 20059

Mr. Lewis A. Engman
President
Pharmaceutical Manufacturers Association
1155 15th Street, N.W.
Washington, D.C. 20005

William M. Heller, Ph.D.
Executive Director & Secretary
The United States Pharmacopeia
12601 Twinbrook Pkwy.
Rockville, MD 20852.

Mr. Felton Davis, Jr.
Senior Vice President
Government and Public Affairs
Pharmaceuticals Division
CIBA-GEIGY Corporation
Summit, NJ 07901

Ms. Anne S. Kasper
Women and Health Roundtable
2000 P Street, N.W.
Suite 403
Washington, D.C. 20036

Attachment B

PRELIMINARY SURVEY RESULTS

I. Question: What percentage of consumers get some oral information about drugs from their physician or pharmacist?

Answer: Consumers report getting a variety of oral information including how much medicine to take, how often to take it, if it can be refilled, precautions to follow, and possible side effects. About 65 percent of the consumers report getting some oral information on one or more of these topics from their physician or someone in the physician's office. About 37 percent report getting some oral information on one or more of these topics from their pharmacist or someone in the pharmacy. Incidentally, these figures include 27 percent of the consumers who get information from both sources.

II. Question: What oral information about drugs do consumers get from their physician or pharmacist?

Answer: The answer to the question depends on the type of information you're talking about. The table below summarizes the approximate percentage of consumers who get various types of oral information.

	Approximate Percentages of Consumers Who Get Oral Information From:		
Information About the Medicine	Physician or Someone in Physician's Office	Pharmacist or Someone in the Pharmacy	Both*
How much to take	59	25	19
How often to take it	61	26	19
If it can be refilled	31	15	9
Precautions	32	16	9
Possible side effects	26	11	4

*These percentages are also included in columns on physician and pharmacist.

III. Question: Are consumers offered oral information or do they request it?

Answer: Consumers are offered oral information much more often than they request it. About 58 percent of consumers are offered information about "how much medicine to take" and about 22 percent are offered information about "side effects" by the physician or someone in the physician's office. Only 2 to 4 percent request these types of information while in the physician's office.

Consumers are offered oral information about "how much medicine to take" and "side effects" 22 and 7 percent, respectively, while they are at the pharmacy. Only a small percent request such information while at the pharmacy.

IV. Question: What percentage of consumers report getting some written information about drugs from their physician or pharmacist?

Answer: About 6 percent of consumers were given some written information while in the physician's office. About 15 percent were given information while in the pharmacy. Included in these percentages (2 percentage points) are consumers who received written information in both places.

V. Question: Do consumers report getting information from sources other than their physician or pharmacist, e.g., reference books, friends, magazines, etc.?

Answer: Consumers report getting drug information from several sources including:

Source	Percentage of Consumers
Friends, relatives, or neighbors	14
Reference books	13
Magazines	4
Newspapers	3
Television	3

Less than 1 percent of the consumers reported getting information from any other specific source, e.g., radio.

Mc

Notes

WORK GROUP ON LEGISLATION

Washington, D.C.
July 19, 1983

Bob Angarola (Chairman), Hyman & Phelps, P.C.
Nancy Bannon, American Medical Association
Nancy Cahill, American Medical Association
Manny Steindler, American Medical Association
Bonnie Wilford, American Medical Association
Jim Williams, Pharmaceutical Manufacturers Association

I. Goals of the Work Group

The participants agreed that the general thrust of the initiative should be to identify legislative mechanisms which would allow state authorities, professional societies and manufacturers to work together to identify problem practitioners and to deal with them in a prompt and flexible manner. The aim was to avoid drug-specific actions as much as possible and to concentrate on those very few practitioners who cause problems.

Any legislative approach must balance the need to control certain substances with the need to have them available for legitimate therapeutic purposes. Federal and state legislation should not be so rigid that, in dealing with the small minority of problem prescribers and dispensers, the health of the public is negatively affected.

II. Strategies

At its meetings, the Legislation Work Group has discussed several areas of state legislation which require attention and strengthening to achieve the objective of an effective and flexible response to the diversion problem. Among the areas of the law that the group will review are professional practices acts, uniform controlled substances acts, statutes granting immunity to people who identify possible diverters, provisions which allow educational alternatives to disciplinary action, and laws setting up centralized controlled substances boards.

The Legislation Work Group is proceeding on two tracks. The first track will be the drafting of a model executive order or bill which would authorize a state to set up a task force on prescription drug abuse. Such legislation could be used to promote careful study of the problem and potential solutions, and thus avoid precipitous action in response to media attention

or ill-thought-out political pressure to "do something" about prescription drug abuse. The group considered whether this approach might lead some states to defer necessary action in the area; i.e. to study the problem rather than deal with it. The work group concluded that this could be avoided by using the model in conjunction with other necessary legislative measures, which would ensure that the state authorities could take steps to handle the problem.

The second track proposed by the work group is to prepare a check-list of legislative provisions which each state should have, or should consider adopting, to deal with the prescription drug diversion problem in a rational and prompt manner. The work group will develop this check-list over the next few months and a somewhat expanded group will review it in early October. Thereafter, the group will draft exemplary language for all of the provisions identified. This language will not be in the form of model legislation, but will be available to states that may wish some guidance in amending their laws.

The group plans to have a final report for review sometime around the first of 1984. Since legislation is the necessary underpinning of all actions in this area, the group is aiming to mesh its report with other Steering Committee initiatives, such as PADS.

BBW/mf

D-R-A-F-T

BILL OR EXECUTIVE ORDER

TASK FORCE ON PRESCRIPTION DRUG ABUSE

Central Authority A Task Force on Prescription Drug Abuse, to be convened by the Governor or his designee within 90 days.

Charge The Task Force shall: (a) identify existing prescription drug abuse problems in the state; (b) identify existing statutory and regulatory structures and provisions that may affect those problems and the professions involved; (c) identify voluntary practices or provisions among prescribers, dispensers and distributors of prescription drugs that may affect the problems and professions involved; and (d) identify remedies proposed or adopted in other jurisdictions.

The Task Force shall report to the Governor and Legislature within _____ (12 months suggested) and shall present recommendations, to include: (a) a description of the problems identified pursuant to the activities described in (a) through (d), above, and describe the proposed mechanism(s) and resources needed to remedy those problems.

Composition The Task Force shall include representatives of the following agencies, organizations and interests: medicine, pharmacy, dentistry, veterinary medicine, nursing, and all other health professions authorized to prescribe or dispense prescription drugs; professional licensure agencies; and principal entities that provide drug education and treatment services.

Appropriations Funds sufficient to meet the expenses and administrative costs of the Task Force are hereby authorized. Further, the Governor is specifically authorized to provide funds to reimburse the expenses of individuals who would be unable to participate in the Task Force without such assistance.

DRAFT: FOR DISCUSSION ONLY

Approaches to State Legislation on Prescription Drug Abuse And Diversion

I. Introduction

The abuse and diversion of prescription drugs result in more injuries and deaths to Americans than those caused by all so-called illegal drugs combined. On the other hand, the World Health Organization has determined that several controlled substances are "essential drugs" that every country should have available for therapeutic purposes. In fact, 10% of all drugs prescribed are psychotropic substances. State legislatures and the Congress have the responsibility of ensuring access to these needed medications while reducing the possibility of their diversion into illicit channels.

The Drug Enforcement Administration (DEA) has determined that most prescription drugs found in the illicit traffic are obtained at the retail, practitioner level. Retail diversion primarily comes from indiscriminate prescribing, "script" doctors, dishonest pharmacists, thefts from pharmacies, prescription shoppers, and prescription forgery.

The Federal Controlled Substances Act gives DEA the authority to monitor and take action against manufacturers, wholesalers and retailers who divert scheduled drugs. However, the statute is structured in such a manner as to focus primarily on the manufacturer and wholesaler levels

in the distribution chain. DEA has neither the authority nor the manpower to deal in a truly effective manner with the practitioner, physician/pharmacist diverter. This responsibility therefore falls mainly on the states. Unfortunately, legislatures often have not given the concerned state agencies adequate authority or guidance to take the necessary measures to halt retail diversion.

Almost all states have adopted the Uniform Controlled Substances Act. This statute is closely patterned after the Federal Controlled Substances Act. This being the case, most states have legislative structures which also focus mainly on the manufacturer and wholesaler levels. The Uniform Act does not set up mechanisms which will assist the authorities in dealing with the problem practitioner. Therefore, when faced with an outbreak of prescription drug abuse, states are forced to take "drug specific" actions such as imposing triplicate prescription requirements, rescheduling drugs at the state level or limiting Medicaid reimbursement for specific substances. Existing legislation often does not allow or encourage state agencies to identify retail level diverters and take actions to restrict or stop their prescribing or dispensing of controlled substances.

The aim of this paper is to present, in preliminary form, some approaches to state legislation which would allow and encourage a coordinated, flexible and rapid response

to diversion problems at the retail level. Its purpose is to stimulate discussion and raise issues. Criticism, particularly from state officials, is sought.

II. Existing Legislation

Every state has health professions practice acts which regulate individuals who prescribe and dispense pharmaceuticals. Typically these statutes cover physicians, pharmacists, veterinarians, and dentists, with varying authority over health service providers such as podiatrists, nurses and physical therapists. Often there will be a central licensing department, with separate boards having statutory responsibility to take disciplinary actions for unprofessional conduct against the individuals they regulate.

The authority given to licensing boards, and the resources available to them, vary significantly from state to state. In general, however, their responsibilities can be summarized as (1) monitoring the quality of care and standards of conduct of professionals under their jurisdiction; (2) investigating cases of possible unprofessional conduct; (3) administering and hearing disciplinary actions; and (4) ensuring enforcement of disciplinary actions. Clearly, the improper prescribing or dispensing of controlled substances is unprofessional conduct which would warrant action by a state licensing authority.

As mentioned above, almost all states have adopted the Uniform Controlled Substances Act which deals with criminal as well as regulatory matters. This law contains the schedules of controlled substances, a list of prohibited acts and requirements for registration of manufacturers, distributors and practitioners. The Act also grants the state the power to impose criminal penalties for certain drug-related offenses. It gives a state agency (usually the Justice Department but at times, as in Missouri, the Health Department) the authority to suspend or revoke a registration to manufacture, distribute or dispense controlled substances. Some of the criteria used to determine if a license will be suspended or revoked are whether the applicant:

(1) has furnished full information on his registration application;

(2) has been convicted of a felony under any federal or state law relating to controlled substances; or

(3) has had his federal registration suspended or revoked.

Some laws permit the state authority to limit the revocation or suspension to all controlled substances or to a particular controlled substance. Unlike federal legislation, state laws will normally specify which practitioners can prescribe controlled substances (e.g., physicians, dentists, podiatrists and veterinarians in California.)

Other state statutes which affect the prescription drug abuse and diversion problem are:

° Laws which provide immunity from lawsuit to individuals who in good faith report to state licensing authorities possible violations by practitioners of controlled substances laws.

° Laws which prohibit Medicaid and health care financing fraud and abuse.

° Laws which set up centralized controlled substances boards to analyze information, coordinate the actions of licensing boards and law enforcement agencies, and work with the concerned professional societies and pharmaceutical manufacturers.

° Laws which allow practitioners to be diverted to educational programs before their registration is revoked or suspended.

° Laws which institute multiple prescription programs. Some authorities claim that these systems help identify physicians whose prescribing practices are questionable and allow them to take action more quickly. Others say that they are not cost effective and that there are systems now available which adequately supply the same information. The usefulness of multiple prescription systems should be reviewed.

The above is not intended to be an exhaustive list of all the provisions which affect the prescribing and dispensing of controlled substances. Additions would be welcomed.

III. Problems With Existing Legislation

The legislation described above has as its main objectives the assurance of quality health care and the protection of the public health. Towards these ends, state legislators have given particular attention to the problems of the diversion and abuse of prescription drugs and have provided state authorities power to take action against problem practitioners. Nevertheless, prescription drug abuse remains widespread. Evidently, there remain gaps in existing legislation and regulation that legislatures should fill. In addition to problems with existing legislation, all parties should work towards improving communication among state officials, professional societies and manufacturers.

Each state has laws which allow enforcement agencies to proceed against doctors and pharmacists who are knowingly diverting controlled substances. It is however difficult to obtain convictions against these individuals owing to problems of proof, their standing in the community and other factors. Likewise, while professional practice statutes are on the books, at times they are not adequately enforced due to a lack of investigators and other resources. For a variety of reasons, state agencies often do not actively seek the assistance of professional societies and manufacturers of prescription drugs, all of whom have a specific interest and responsibility in preventing the abuse of controlled substances.

Existing state legislation is almost always patterned after the Federal Controlled Substances Act. This act is structured primarily to control the drugs themselves and not towards identifying and dealing with the retail level diverter. State law, therefore, often does not allow the authorities to deal with practitioners in a flexible and rapid manner.

° Most states do not require the concerned agencies to analyze available information such as ARCOS, DAWN and MMIS which will help identify possible points of diversion.

° Some states only permit the revocation or suspension of a license and do not allow the placing of restrictions on prescribing or dispensing controlled substances.

° Most do not provide for the "voluntary" education of problem practitioners.

° The criteria for revoking a license is sometimes too vague or too narrowly drawn.

° There is no encouragement for the concerned agencies, professional societies and manufacturers to work together to address the issue.

° Too often the state professional licensing authority does not have adequate resources to investigate, prosecute and discipline licensees.

° Immunity statutes are too weak and people are concerned about lawsuits when considering reporting possible cases of prescription drug diversion.

° Neither federal nor state (except Wisconsin) statutes define the term "diversion," indicating that there has been no real focus on this problem.

° Existing legislation has forced states to take drug specific actions, such as limitations on Medicaid reimbursement for certain drugs, since they were easier to implement than measures which would deal with the real problem, the diverter at the physician/pharmacist level.

IV. Elements of Effective State Legislation

A. Health Professions Practice Act

There is evident need for a strong health professions practice act covering all those who can prescribe or dispense controlled substances. In the mid 1970s, DEA sponsored the drafting of a "Comprehensive Final Report on State Regulatory Agencies and Professional Associations" and a "Model Health Professions Practice Act and State Regulatory Policy." State authorities should review the model act, in particular, to determine whether its provisions would improve their ability to take effective action against problem practitioners. A copy of the model act is attached. Suggestions on how that act could be improved and how states could be encouraged to adopt similar provisions would be useful.

B. State Controlled Substances Act

A similar review should be taken of the Uniform Controlled Substances Acts. Under these laws, state authorities should be directed to use existing information to locate diverters and be given some flexibility in dealing with them either by limiting their ability to prescribe controlled substances or in mandating educational programs to help ensure proper prescribing. These laws (or regulations written under them) should require the authorities to monitor these practitioners after state intervention. Likewise, legislators should mandate that state agencies report to them on the most heavily prescribed and dispensed controlled substances in the state. This would be particularly useful for Schedule II drugs and narcotics in Schedule III which are covered by the ARCOS system.

C. Adequate Resources

A key element in any successful diversion prevention program is the availability of adequate resources to allow agencies to undertake investigations and take disciplinary measures if necessary. A state could have the perfect controlled substances act and the perfect health professions act and still have a substantial diversion problem without the concerned agencies having enough funding and manpower to take action. Therefore, state legislation should specifically deal with this budgetary issue and provide sufficient support to the regulatory agencies.

D. Immunity Statutes

There must be a strong immunity statute which protects people who identify possible diverters. Most states have provisions which deal with this issue. A model immunity provision should be drafted and adopted.

E. Centralized Controlled Substances Boards

David Joranson from the Wisconsin Office of Alcohol and Other Drug Abuse has identified the following state agencies and organizations as having a role in preventing prescription drug diversion and abuse: State Council, Commission, or Task Force on Drug Abuse; Single State Agency on Drug Abuse; State Police, Attorney General or Department of Justice; Department of Regulation, Registration and Licensing of Health Professions; Medical Licensing Authority; Dentistry Licensing Authority; Veterinary Licensing Authority; Pharmacy Licensing Authority; Nursing Licensing Authority; State Medical Assistance Agency; State Medicaid Fraud and Abuse Units; State and Local Professional Societies or Associations (medical, dental, veterinary, pharmacy, nursing, etc.); local law enforcement agencies; Diversion Investigative Units; legislators and legislative committees having health responsibilities; manufacturers of controlled substances.

This listing alone demonstrates that there is a need for interagency coordinating and cooperation among the many

agencies involved with drug diversion, each in only a partial way. Without central coordinating and problem identification, the diversion problem would likely not be a priority for any of these agencies and their potential contributions to the solution would be largely unrealized.

In 1971 the Wisconsin legislature set up the Controlled Substances Board. The Board is responsible for administering the provisions of the Wisconsin Uniformed Controlled Substances Act. Its membership consists of the Attorney General, the Secretary of the Department of Health and Social Services, the Chairman of the Pharmacy Examining Board, the Secretary of the Department of Agriculture, Trade and Consumer Protection, a pharmacologist and a psychiatrist. They are appointed to three year terms by the governor.

In 1980, the Controlled Substances Board, the Pharmacy Examining Board, the Medical Examining Board, the Dentistry Examining Board, the Veterinary Examining Board and the Drug Enforcement Administration signed a Memorandum of Cooperation aimed at coordinating the efforts of these agencies to prevent diversion of controlled substances to non-medical use. Attached is an analysis prepared by the American Medical Association on "The Wisconsin Program for Controlling Diversion of Controlled Substances." This describes in detail the role of the various agencies and notes the 1981 legislation which requires the Controlled Substances Board

to regularly prepare and make available to the concerned agencies reports on diversion patterns within the state.

Several states have drug abuse advisory boards and interagency task forces to deal with drug problems including prescription drug abuse. It appears, however, that Wisconsin is unique in having a statutorily mandated Board such as the one described above. It should be noted, however, that this Board has no power of itself to move against diverters. Rather, it synthesizes available information and provides it to the various boards and law enforcement agencies who can then take action. The Board also forms a focal point for exchange of data between the state and the various professional societies and, on occasion, pharmaceutical manufacturers. Wisconsin is one of the few states which has made a conscious effort to involve manufacturers in dealing with and preventing prescription drug abuse within the state. This practice should be encouraged. Manufacturers have an active interest in ensuring that their products are used correctly. The wiser companies -- and this is the vast majority -- are eager to work with the state authorities to halt diversion.

The Wisconsin Controlled Substances Board experience is described in detail since it appears to be the first effort of its kind in the nation. Other states are considering similar mechanisms. One proposal would give the Controlled Substances Board actual power to issue controlled substances

licenses, conduct investigations and take disciplinary actions. Another state is considering setting up a board which will administer a two-tiered process for dealing with the problem. The first, more informal, level would consist of the concerned agencies, professional societies and manufacturers discussing diversion problems in relatively broad terms. The second level would be a review by the governmental agencies of particular problem prescribers and dispensers. That group would be able to recommend action. The aim is to approach the problem quickly and in a cooperative manner.

In all probability other states have set up coordinating bodies to deal with the problem of prescription drug abuse. These should be identified and recommendations made on adopting similar measures in other states.

F. Other Statutory Initiatives

Other statutory initiatives which should be reviewed are:

° The question of access to investigative records by professional peer review groups.

° The monitoring of the effects of intervention (criminal justice, licensure, educational, etc).

° The setting up of a central source to receive records of disciplinary actions and to provide them to licensing authorities in other jurisdictions.

° Questions relating to ensuring confidentiality of information.

V. Conclusion

State legislation by itself cannot reduce prescription drug abuse and diversion. It can however provide the framework and give the impetus needed to the concerned parties, both in and out of the government, to deal with the issue in an effective manner. More and more people are recognizing that to do this greater attention has to be paid to diversion at the practitioner level rather than just placing stricter controls on a particular substance.

The subcommittee on legislation should discuss means of identifying other approaches and mechanisms which will allow and encourage public and private groups to work together to reduce prescription drug abuse.

VI. Attachments

1. Model Health Professions Practice Act and State Regulatory Policy.

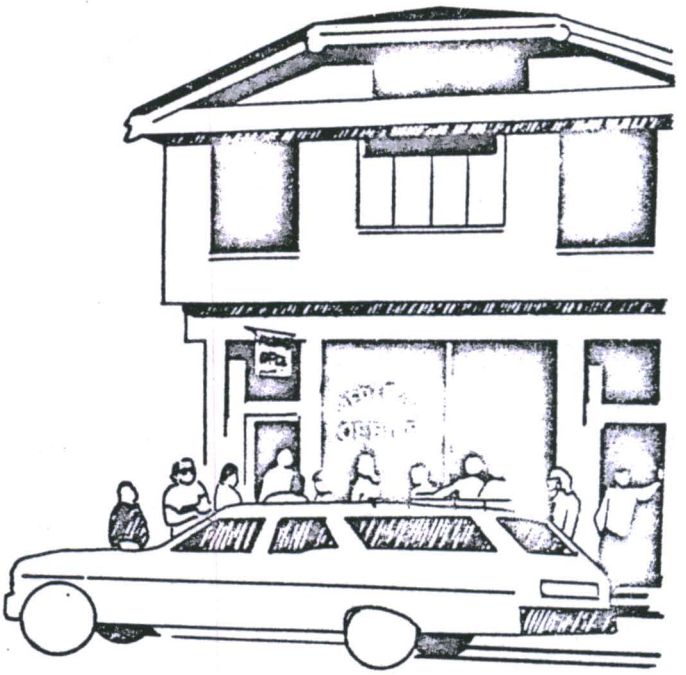
2. The Wisconsin Program for Controlling Diversion of Controlled Substances.

PLEASE FORWARD COMMENTS TO:

Robert T. Angarola
Hyman & Phelps, P.C.
1120 G Street, N.W.
Suite 1040
Washington, D.C. 20005

The Investigation and Prosecution of Professional Practice Cases Under the Controlled Substances Act

Introduction to Professional Practice Case Law and Investigations



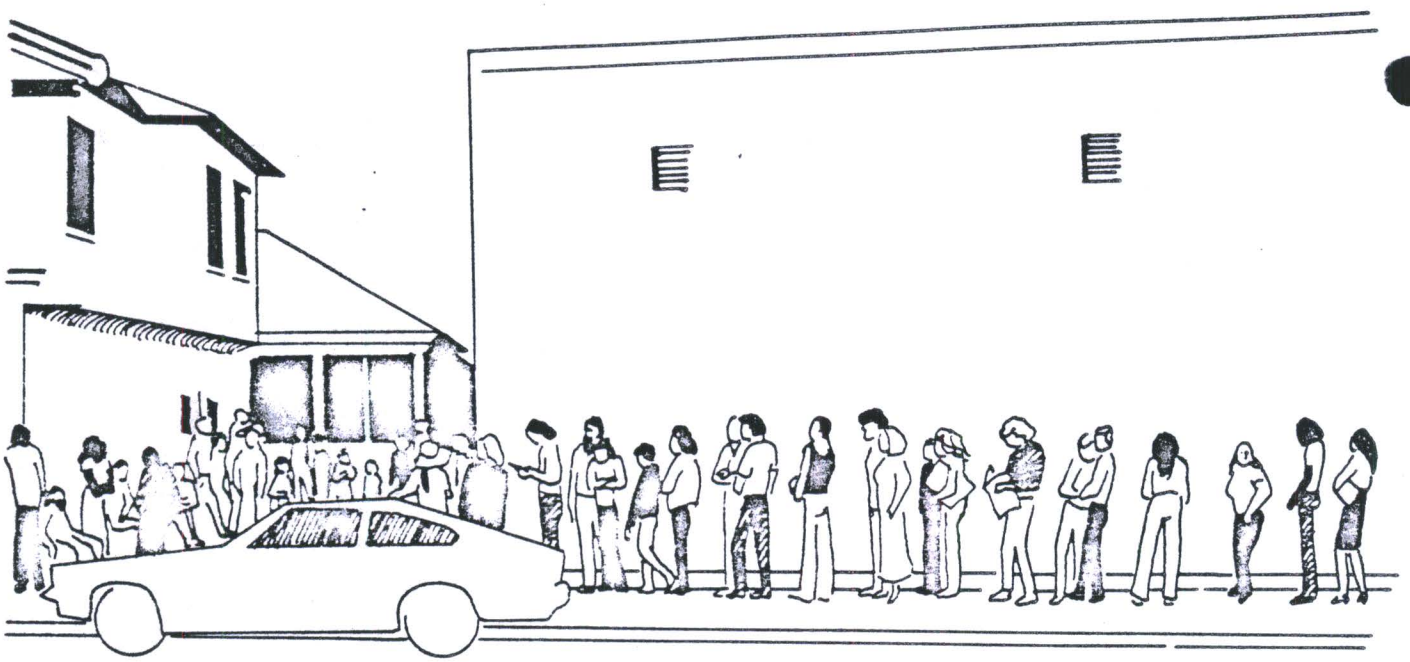
Stephen E. Stone
Associate Chief Counsel
Drug Enforcement Administration

In its most recent study on the subject of prescription drug abuse, the U.S. General Accounting Office (GAO) noted that prescription drugs are abused or misused by more Americans than cocaine, hallucinogens or heroin.[1] Moreover, GAO reported, these prescription drugs were identified in drug-related emergency room admissions and deaths more often than all illegal drugs combined. The "prescription drugs" to which the GAO was referring were legitimately manufactured medicinal controlled substances, including narcotics, stimulants, depressants and tranquilizers. In 1980, prescription drugs accounted for 15 of the 20 controlled substances most frequently reported by hospital emergency rooms.

Each year DEA-registered manufacturers produce an estimated 20 billion dosage units of controlled substances. Of these, an estimated 200 to 250 million dosage units are diverted into the illicit marketplace and therefore into the hands of abusers. Some of these drugs are stolen from manufacturers and distributors, some are stolen from common carriers while in transit between legitimate handlers, and some are taken in the course of armed robberies and burglaries of pharmacies and other registrant locations. Diversion by theft is, without doubt, a significant source of diverted controlled substances. However, while there is presently no accurate method of quantifying the various sources of diversion, experience has taught that a great proportion is willfully and intentionally diverted at the retail level of the distribution chain by licensed and registered physicians, pharmacists and other health professionals.

This article is not intended to be an indictment of the various health professions. The vast majority of the more than 650,000 retail-level registrants[2] handle controlled substances in a responsible and lawful manner. The various professional organizations share DEA's concern and are themselves pursuing solutions to the problem. Nevertheless, the potential damage which can done by a few members of a lawless minority is staggering. A few examples serve to illustrate this point:

- **On January 11, 1982, Dr. E. Gordon Dickie was convicted of numerous controlled substance felony violations in U.S. District Court in Honolulu. Dr. Dickie, a gynecologist, supplemented his practice by writing prescriptions for Quaalude (methaqualone) tablets. He wrote 15,267 such prescriptions for a total of over 461,000 tablets in the four years from 1977 through 1980. That amounted to 58 percent of all of the methaqualone prescribed by Hawaii's 1900 registered physicians.**
- **On September 21, 1982, Nobel Adjin Lartey, a New York City pharmacist, was convicted in the U.S. District Court for the Southern District of New York. Mr. Lartey was convicted of possessing controlled substances with intent to distribute them and conspiring to unlawfully distribute controlled substances. Mr. Lartey owned three pharmacies, two of which he used to funnel drugs into the third, which in turn was little more than a front for a large-scale diversion operation. In a relatively short period of time, Mr. Lartey diverted over 1.2 million dosage units of controlled substances.**
- **On May 25, 1978, pharmacist Timothy Hayes[3] of**



Houston, Texas, was convicted of one count of conspiracy to distribute controlled substances and 35 counts of unlawful distribution of Schedule II controlled substances. The underlying DEA-Texas Department of Public Safety investigation revealed that in one four-and-a-half-month period, Mr. Hayes had filled no fewer than 2,492 prescriptions, reflecting the dispensing of 181,680 tablets of Dilaudid, a Schedule II narcotic. Further analysis showed that 72 percent of these prescriptions were written by one physician.

The problem of retail-level diversion of narcotics and other dangerous drugs is by no means a recent development. The earliest cases were prosecuted under the Harrison Narcotic Drug Act. In *United States* v. *Doremus*, decided on March 3, 1919, the United States Supreme Court affirmed the conviction of a physician who had dispensed 500 one-sixth grain heroin tablets to a person whom the Court described as a "dope fiend."[4] The same day, the Supreme Court affirmed the convictions of a physician named Webb and a pharmacist named Goldbaum. Dr. Webb routinely furnished morphine prescriptions to known addicts and Mr. Goldbaum routinely filled those prescriptions. So heavy was their volume that within an eleven-month period Goldbaum purchased from Memphis-area wholesalers thirty times as much morphine as was bought by the average retail druggist doing a much larger general business.[5] A year or so later, the Court upheld the conviction of a Pittsburgh-area physician named Jin Fuey Moy. This doctor, the Court wrote, prescribed morphine in large quantities, "8 to 15 drams at a time," to professed morphine users. In some cases he performed a superficial medical examination—in others, none at all. Furthermore, Dr. Moy charged his patients according to the amount of morphine prescribed, invariably one dollar per dram.[6] These cases clearly established that registered physicians were permitted to prescribe and dispense narcotic drugs strictly within the bounds of their professional practice and that prescriptions issued outside the appropriate limits of one's professional practice protected neither the physician who issued them nor the pharmacist who accepted and filled them. They set the course for practitioner investigations and prosecutions for years to come.

As years passed, drugs other than narcotics found favor with addicts and abusers and, as before, a few unscrupulous physicians and pharmacists proved to be a ready source of supply. Amphetamines and barbiturates became the subject of heavy abuse and federal laws aimed at those drugs were enacted. By 1970, faced with a variety of federal laws, each attempting to control a different type of drug, each requiring a different enforcement approach, and each imposing disparate sentences, Congress enacted this country's first comprehensive federal drug statute, the Comprehensive Drug Abuse Prevention and Control Act of 1970[7], Title II of which is the Controlled Substances Act, establishing five schedules of controlled substances, regulating their lawful use in medicine, science and industry, and criminalizing their unlawful use, possession and distribution. With the enactment of the Controlled Substances Act, a new era of practitioner investigations and prosecutions began.

The seminal Supreme Court case relating to the prosecution of practitioners subsequent to the enactment of the Controlled Substances Act was *United States* v. *Moore*[8], decided in 1975. Dr. Moore, a Washington, D.C. physician, had been convicted in U.S. District Court of illegally prescribing huge quantities of narcotics. As Jin Fuey Moy had done some fifty years earlier, Dr. Moore charged not for the medical services he rendered but for the number of pills he prescribed. A divided panel of the U.S. Court of Appeals for the District of Columbia Circuit concluded that

Dr. Moore had been improperly charged with illegal distribution of controlled substances and it reversed his conviction. The appellate decision was in direct conflict with decisions in other circuits and, thus, the first practitioner case under the Controlled Substances Act reached the U.S. Supreme Court. There the conviction was reinstated. The unanimous court observed that physicians who strayed beyond the bounds of professional practice could be prosecuted under the Harrison Narcotic Act of 1914. They further observed that Congress was aware that registrants—who had the greatest access to controlled substances and the greatest opportunity for diversion—were responsible for a large part of the illicit drug traffic. Since Congress had intended that the new law strengthen federal drug law enforcement, and not weaken it, it was inconceivable that Congress could have meant to carve out a vast new exemption for practitioners, giving them leave to divert drugs in any amount with impunity.

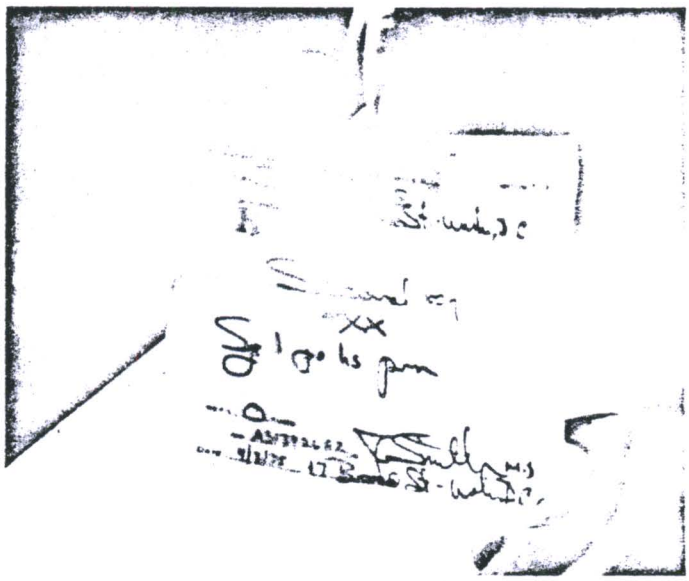
Accordingly, the Supreme Court held that only the lawful acts of registrants were exempted from the general prohibitions of the new law and that implicit in the registration of a physician is the understanding that he is authorized to act only "as a physician." A practitioner is registered to distribute, dispense, administer and conduct research with respect to controlled substances in the course of professional practice only.

Since 1970 hundreds of practitioner cases involving physicians, pharmacists, dentists and veterinarians, as well as many additional non-professional abettors and co-conspirators, have been tried in federal and state courts[9] and convicted of diverting controlled substances. For all of this experience, the successful prosecution of a professional practice case remains one of the most challenging, and at times frustrating, assignments for investigators and prosecutors alike. Health professionals often enjoy a high degree of public esteem and confidence. "Script writing" and other forms of diversion can be extremely lucrative activities, enabling the perpetrators to engage first-rate criminal defense counsel. In order to properly present a professional practice case in a manner likely to overcome the built-in hurdles, an unusual degree of investigative and prosecutorial preparation is required. Nevertheless, the large number of federal and state professional practice cases which have been successfully prosecuted over the years attest to the soundness of the legal theories which have been developed and to the dedication and professionalism of the investigators and prosecutors who were responsible for them.

The term "in the course of professional practice" defines the boundaries of practitioner investigations and prosecutions. Acts of prescribing or dispensing of controlled substances which are done within the course of the registrant's professional practice are, for purposes of the Controlled Substances Act, lawful. It matters not that such

acts might constitute terrible medicine or malpractice. They may reflect the grossest form of medical misconduct or negligence. They are nevertheless legal. On the other hand, any act of prescribing, dispensing or distributing of a controlled substance other than in the course of the registrant's professional practice is an illegal distribution of that controlled substance, subject to the same penalties as if the drug were sold by the lowest pusher on the street. In fact, the Supreme Court, in describing Dr. Moore's conduct, stated that he had acted "as a large-scale pusher—not a physician." Accordingly, the task which confronts the investigator in a professional practice case is gathering sufficient evidence to show, beyond any reasonable doubt, that the defendant doctor or pharmacist is acting outside the course of his professional practice.

Initial information tending to indicate diversion on the part of a practitioner may come from any one or more of a number of sources. In the case of pharmacies and dispensing physicians, excessive purchase reports and periodic summaries of drug transactions provided to DEA by pharmaceutical manufacturers and distributors are often the first indication of irregularity. State pharmacy board inspectors may notice unusual patterns of ordering and dispensing in the course of routine inspections. Information concerning suspicious prescribing by a practitioner can come from many sources. Frequently, a concerned parent, spouse or other relative will notify either federal or state authorities that someone has been getting prescriptions of unusual type or quantity from a particular physician. Pharmacists may become concerned when they observe unusual prescribing by a physician for "patients" who do not appear to be truly in need of the kind of drugs they are receiving. Local police departments frequently find prescription vials in the possession of persons arrested for a variety of offenses. It goes without saying that there may be a perfectly innocent reason lying behind any of these indicia. On the



other hand, receipt of any information of this type may indicate a serious criminal diversion problem and should not be ignored.

Investigations of pharmacists and medical practitioners are quite different, due primarily to the fact that a pharmacist's legitimate activity is limited to the dispensing of drugs pursuant to physicians' orders (prescriptions) and must be thoroughly documented, whereas a physician is permitted to prescribe, dispense and administer controlled substances, subject only to the requirement that such be done within the scope of his professional practice and subject to very little in the way of required documentation. Accordingly, except when a physician and pharmacist are jointly under investigation as in a conspiracy case, the investigations will be handled quite differently.

Subsequent to receipt of initial information tending to call a physician's prescribing or dispensing practice into question, the investigator should query other law enforcement organizations, such as state, county or local police or sheriff's departments, and medical board investigators, to determine whether any of these agencies have additional intelligence or parallel investigations under way. In many cases, a joint federal/state investigation can be mounted, bringing to bear the peculiar expertise and specialties of the various agencies. Known drug offenders with whom local departments are most familiar can often provide unique insight into the violative registrant's office practice. Both DEA diversion investigators and state pharmacy board personnel are adept at performing pharmacy surveys which will reveal the type of drugs being prescribed, the indications and instructions found on the prescriptions, and an estimate of the size of the physician's violative practice. In many cases, such preliminary investigation can lead to the finding of a totally innocent explanation for the unusual activity so as to make further investigation unnecessary. Assuming that all of the preliminaries have cumulatively increased the likelihood of illicit conduct, the next step is to conduct a surveillance of the medical office. Obviously, some offices are located in large buildings or under other circumstances which would make direct observation impossible. However, wherever possible, direct surveillance is very useful in practitioner cases. The surveillance can assist in the determination of whether the practitioner's practice is large enough to support the number of prescriptions observed during the pharmacy survey; it can lead to the identification of "patients" who are known offenders; and it can assist the undercover agents in preparing themselves for the next step in the investigation. Finally, the surveillance team can clock the amount of time any given patient remains within the confines of the office. While this is not, in and of itself, evidence of wrongdoing, it may be a useful adjunct to observations later made in the office itself.

While every practitioner case is different, most lend themselves to an undercover approach in which agent, posing as a typical client, attempts to obtain drugs or prescriptions under circumstances showing lack of a physician-patient relationship. In order for a practitioner to prescribe or dispense in the course of his professional practice, there must exist between the doctor and the "patient" a valid physician-patient relationship. To establish this relationship, the patient must come to the physician seeking treatment for some kind of physical or psychological condition or symptomology. The physician must then obtain from the patient enough of a medical history, either through interview or by written form, to assist him in making a diagnosis of the complaint and the patient's general physical condition. Moreover, the physician must conduct an examination or other medically recognized procedure sufficient to make a diagnosis. Finally, there must be a logical connection, or nexus, between the drug ultimately prescribed and the physical or psychological condition diagnosed.

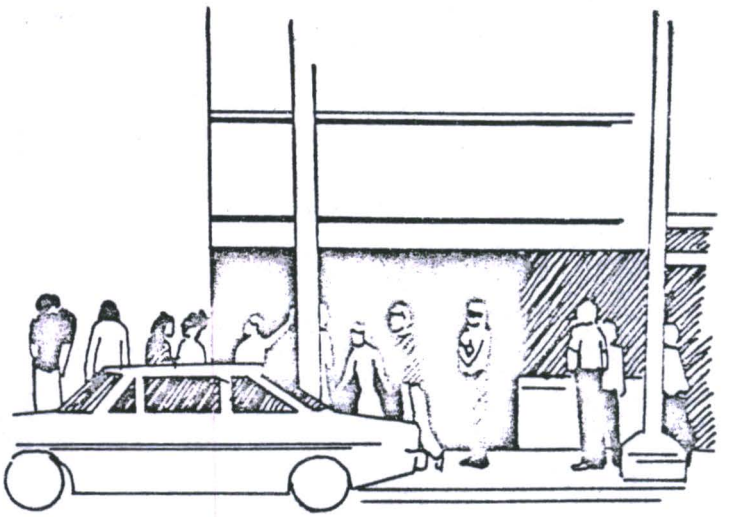
Patients of violative physicians typically do not present medical complaints. They come to the office seeking drugs, usually one or more specific drugs, or prescriptions for such drugs. Thus, undercover personnel should present themselves as persons seeking drugs and should never give a legitimate medical complaint. Once a degree of familiarity between the agent and the doctor has developed, the agent should become more and more forthcoming with information which must lead any reasonable physician to conclude that his "patient" is selling the medication, sharing it with one or more others, or using it at parties or other recreational activities. Over the years, undercover ruses used to obtain drugs and prescriptions have been limited only by the imagination and skill of the agents involved. Nonmedical reasons which have traditionally been successful include the following: students working one or more jobs at night and needing amphetamines to keep them going; interstate truckers who want to complete a long run without stopping for sleep; pimps who give pills to their working

girls to enable them to put in a fuller night, and many more. One clever agent was able to convince the defendant physician that he played better trombone while taking speed. The agent, in addition to being a professional musician, was also a consummate actor. Another agent, having previously received narcotics from a dentist, sent his false teeth in with his partner and obtained another prescription when the partner showed the dentist which of the porcelain bicuspids was aching. These investigative techniques, when used by experienced and well-briefed undercover personnel, give the practitioner every opportunity to dismiss the agent as a drug abuser or to prescribe controlled substances notwithstanding that knowledge. The undercover techniques used in these cases have withstood challenges on the basis of entrapment and have met with the approval of the courts.[10]

Pharmacy investigations can emerge directly from one involving a physician, and vice versa. In many instances, the violative physician will direct his "patients" to one or more pharmacies with whom he has developed an understanding. Use of these pharmacies lessens the chances that the physician's prescribing practices will be questioned. The U.S. Court of Appeals for the Fourth Circuit described such a physician-pharmacist relationship in its opinion in *United States* v. *Coward.*[11]. The Court wrote:

> As a physician, Dr. Shingleton could authorize controlled drugs for his patients but could not actually provide them., Provision of the drugs required the services of a pharmacist who would not be alarmed at the prospect of serving customers large quantities of either stimulants or depressants or both. The doctor found two such pharmacists: appellant Coward, the proprietor of Landis Drug Company in Landis, and one Robert Dixon Coffey, who did business in a neighboring town.
>
> In time Dr. Shingleton established a mutually profitable relationship with each pharmacist; he prescribed and the pharmacists vended. The Shingleton-Coward venture included such features as Dr. Shingleton's giving discount coupons for Landis Drug and establishing direct telephone lines between the doctor's office and Coward's pharmacy. Shingleton also furnished Coward with presigned blank prescription pads to facilitate prescription-by-telephone service.

The Controlled Substances Act. 21 U.S.C. §829. permits pharmacists to dispense controlled substances only pursuant to prescriptions issued in writing, or orally communicated to them, by registered physicians and other practitioners.[12] For a prescription to be effective, it must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. While the responsibility for proper prescribing rests on the prescriber, a corresponding responsibility rests

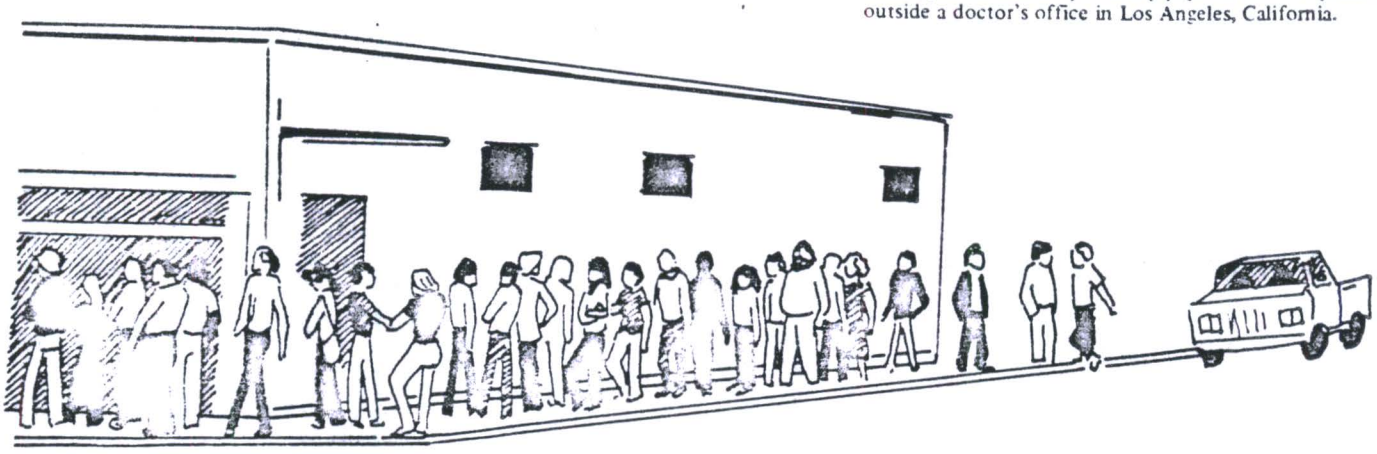


upon the pharmacist who fills the prescription. An order which is not written for a legitimate medical purpose is not considered to be a "prescription" within the meaning of the law and protects neither the practitioner who issued it nor the pharmacist who knowingly filled it.[13] Commenting on this corresponding liability, an appellate court in California, upholding the license revocations of a Los Angeles pharmacy and several individual pharmacists, said:

> The statutory scheme clearly calls upon pharmacists to use their common sense and professiona! judgment. Failure to do so mocks the controls inherent in the prescription process. Society cannot tolerate the presence within these professions of persons who abdicate their professional responsibility and permit themselves to be used as a conduit by which controlled substances reach the illicit market.[14]

The California court found that during a 45-day period the pharmacy had filled over 10,000 prescriptions written by a small group of doctors for four heavily abused controlled substances. Some of the "patients" for whom the doctors had prescribed included "Henry Ford." "English Ford." "Esther Williams," "Terry Tune," "Wells Fargo" and "Pearl Harbor."

Undercover investigations of violative pharmacists may utilize various approaches. In some instances, sales of controlled substances are transacted "under the counter" without prescriptions. These cases are probably the easiest to prosecute since there is no attempt to cloak the drug distribution in the mantle of legitimacy. In other investigations, questionable prescriptions obtained from nearby "script" doctors are presented to pharmacists under circumstances plainly designed to alert the pharmacist to the character of the prescriptions. Where the legitimate professional would refuse to fill the prescriptions—many would also feel compelled to notify the appropriate authorities—



Artist's sketch of a sequence of surveillance photographs showing, here and on preceding pages, a line of "patients" outside a doctor's office in Los Angeles, California.

the violative one will accept them without question and will probably charge a premium for the drugs so dispensed.

Not all practitioner cases, pharmacist or physician, lend themselves to undercover investigations. Many cases can be handled by more traditional investigative methods. In the case of physicians, analysis of prescriptions, manually and with the aid of computers, can be used to produce a series of profiles by patient, drugs and dates. These profiles are examined by pharmacologists and other experts who can later testify concerning the legitimacy of the defendant's prescribing practices. The same analyses can be used to identify the persons who obtained the prescriptions and had them filled. While many of these people are drug abusers or traffickers and may be reluctant to assist in the prosecution of their source of supply, many others come to realize that their tragic conditions were perpetuated and exacerbated by the activities of a pusher in a white coat. Such individuals often have vivid recall of the circumstances under which they obtained their prescriptions, the dates, the names they used, the drugs they requested, the office procedures involved, prices paid and pharmacies used. While their testimony may not be quite as good as that of a trained undercover investigator backed up by his or her taped conversations with the doctor, they are able to speak from long experience, are seen as victims and make effective witnesses.

Since pharmacies must by law maintain records, normally in the form of prescriptions, for the controlled substances they dispense, as well as inventories, order forms and other receiving records, criminal investigations are frequently conducted through the use of record examinations and accountability audits. Shortages of large quantities of controlled substances without valid explanation, when accompanied by a pattern of ordering which exceeds the pharmacy's legitimate needs, a lack of prescriptions for these drugs or an unusual number of forged or otherwise fraudulent prescriptions on file, is evidence that the missing drugs were unlawfully distributed. In investigating this type of case, a thorough investigation requires that all pharmacy personnel be interviewed with respect to the pharmacy's ordering and dispensing procedures; records, including order forms and prescriptions, should be carefully examined and, if necessary, subjected to handwriting analysis; and suppliers should be questioned with respect to the pharmacy's ordering procedures and modes of payment. An in-depth investigation will assist in pinpointing the individual, or individuals, responsible for the diversion, an absolute necessity for obtaining appropriate criminal sanctions as opposed to administrative or civil remedies.

Editor's Note: *This is the first part of a two-part article. Part two will deal with indictments, the use of expert witnesses, prescription surveys, and the seizure and use of medical records.*

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1. Report to the Congress. "Comprehensive Approach Needed to Help Control Prescription Drug Abuse." Report No. GAO/GGD-83-2 (October 29, 1982).
2. As of mid-October 1982, the Drug Enforcement had 663,591 current registrants, about 654,000 of which were at the retail level.
3. *United States* v. *Hayes*, 595 F.2d 258 (5th Cir., 1978).
4. *United States* v. *Doremus*, 39 S. Ct. 217 (1919).
5. *Webb* v. *United States*, 39 S. Ct. 217 (1919).
6. *Jin Fuey Moy* v. *United States*, 41 S. Ct. 98 (1920).
7. Public Law 91-513 (October 27, 1970).
8. *United States* v. *Moore*, 96 S. Ct. 335, 423 U.S. 122 (1975).
9. The majority of states and U.S. territories have adopted, in some fashion, the Uniform Controlled Substances Act modeled after the Federal statute.
10. See, for example, *United States* v. *Jobe*, 487 F.2d 268 (10th Cir., 1973) and *United States* v. *Rosen*, 448 F. Supp. 926 (E.D. Louisiana, 1977), affirmed, 582 F.2d 1032 (5th Cir., 1978).
11. *United States* v. *Coward*, 669 F.2d 180 (4th Cir., 1982).
12. 21 CFR §1306.04(a).
13. See, for example, *United States* v. *Kershman*, 555 F.2d 198 (8th Cir., 1977); *United States* v. *Hayes*, 595 F.2d 258 (5th Cir., 1979); and *United States* v. *Lawson*, 682 F.2d 480 (4th Cir., 1982).
14. *Vermont & 110th Medical Arts Pharmacy, et. al.* v. *Board of Pharmacy of the State of California*, 125 Cal.App.3d 19 (1981).