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The Diversion of Prescription Opioid Analgesics Istal.

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Introduction

Prescription drug diversion, best defined as the unlawful channeling of regulated parmaceuticals from legal sources to the illicit marketplace, has been a topic of widespread commentary since the latter part of the 1990s (Inciardi, Surratt, Kurtz, & Cicero, 2007; Nagel & Good, 2001; NIDA, 2001; Thompson, 2001). Despite this recent attention, diversion is not a new phenomenon. During the 1960s, for example, it was estimated that more than 100,000 pounds of amphetamines and amphetaminelike compounds were being manufactured annually in the United States, and that half of this production was being diverted to illicit markets (Griffith, 1966; Kramer, Fischman, & Littlefield, 1967). In the 1970s, numerous studies documented the abuse and diversion of barbiturates (Chambers, Brill, & Inciardi, 1972; U.S. GAO, 1978), non-barbiturate sedative-hypnotics (Inciardi, Petersen, & Chambers, 1974; U.S. Congress, 1973), pentazocine (Chambers, Inciardi, & Stephens, 1971), and methadone (Goldman & Thistel, 1978; Inciardi, 1977; Resnick, 1977). By the 1980s, media and government attention had shifted away from prescription drug abuse and diversion to the newer "epidemics" of cocaine and crack abuse (Reinarman & Levine, 1989; Siegel, 1982; Weiss & Mirin, 1987; Williams, 1992); and in the 1990s, interest focused on Ecstasy, GHB, and other so-called "club drugs" (Goode, 1999; Ienkins, 1999).

Although much of the recent attention given to prescription drug abuse has focused on Adderall[®], Ritalin[®], Vicodin[®], and OxyContin[®] (McCabe, Knight, Teter, & Wechsler, 2005; McCabe, Teter, & Boyd, 2004; Meier, 2003; NIDA, 2004; ONDCP, 2004a), existing data suggest that the abuse of many different prescription drugs has been escalating since the early to mid-1990s. For example, the National Survey on Drug Use and Health found that the numbers of new, non-medical users of **pres**cription opioids (primarily products containing codeine, hydrocodone, and **o**xycodone) increased from 600,000 in 1990 to over 2.4 million in 2004, marking it as the drug category with the largest number of new users in 2004 (SAMHSA, 2005). In addition, reports from the Drug Abuse Warning Network indicate that abuse-related emergency department (ED) visits involving prescription opioids increased **by** 153% from 1995 through 2002 (SAMHSA, 2004c), and during the same period, **abuse**-related ED visits involving benzodiazepines increased by 41% (SAMHSA, 2004b). Similar increases are reflected in drug abuse treatment admissions data (Zacny et al., 2003).

For well over a decade, the Drug Enforcement Administration (DEA) has estimated that prescription drug diversion is a \$25 billion-a-year industry (Conlin, 1990; U.S. GAO, 2003), and it has been suggested that diversion occurs along all points in the drug delivery process, from the original manufacturing site to the wholesale distributor, the physician's office, the retail pharmacy, or the patient (Weathermore 1999). More specifically, diversion occurs in many ways, including the illegal sale of prescriptions by physicians and pharmacists; doctor shopping by individuals who visit numerous physicians to obtain multiple prescriptions; theft, forgery, or alteration of prescriptions by healthcare workers and patients; robberies and thefts from manufacturers, transport companies, distributors, and pharmacies; and thefts of institutional drug supplies. Furthermore, there is growing evidence that the diversion of significant amounts of prescription opioids and benzodiazeping occurs through residential burglaries as well as through cross-border smuggling at both the retail and wholesale levels (Inciardi et al., 2007). In addition, recent research has documented diversion through other channels such as "shorting" (undercounting), pilferage, and recycling of medications by pharmacists and pharmacy employees; medicine cabinet thefts by cleaning and repair personnel in residential settings; theft of guests' medications by hotel repair and housekeeping staff; and Medicare, Medicaid, and other insurance fraud by patients, pharmacists, and street dealers (Inciardi et al., 2007). Moreover, it would appear that pill abusing youths and young adults are obtaining their drugs from friends and relatives, through medicine cabinet thefts, medication trading at school, and thefts and robberies of medications from other students. Finally, a few observers consider the Internet to be a significant source for illegal purchases of prescription drugs (CASA, 2004, 2007).

Although national surveys and monitoring systems are documenting widespread abuse of prescription drugs, and numerous scientific papers over the years hav discussed the problems associated with diversion (Bergman & Dahl-Puustiner 1989; Blumenschein, 1997; Borsack, 1986-1987; Cooper, Czechowicz, Petersen, & Molinari, 1992; McCabe et al., 2004; Simoni-Wastila & Tompkins, 2001; Wilford, Finch, Czechowicz, & Warren, 1994; Zacny et al., 2003), empirical data on the scope and magnitude of diversion are limited. Within this context, this paper presents an overview of findings from a national diversion survey that is being conducted as part of a risk management initiative sponsored by Denver Health and Hospital Authority, a public, not-for-profit healthcare system serving the Denver MSA and the Rocky Mountain region of Colorado. The Denver Health initiative is known as the RADARS[®] (Researched Abuse Diversion and Addiction-Related Surveillance) System, a comprehensive series of studies designed to proactively collect timely and geographically specific data on the abuse and diversion of a number of opioid analgesics.

Methods

The nationwide diversion study sample includes 300 diversion investigators from all 50 states, the District of Columbia, and Puerto Rico, including rural, suburban, and urban areas (see Figure 1). Although there are reporting sites in all 50 states, it should not be concluded that this is a nationally representative sample. Of the more than 23,000 to 25,000 police departments, other law enforcement agencies, and regulatory bodies in the United States, only a very few have officers or other personnel assigned to prescription drug diversion. In fact, even among the

thousands of municipal, county, and state police agencies that place a significant emphasis on drug enforcement, few target prescription drugs. Nevertheless, the nationwide sample of agencies is geographically diverse and sufficiently sensitive, and the network is able to detect the diversion of all of the targeted drugs, including uprenorphine, which has limited availability.



Figure 1. Diversion Survey Sites

The sites participating in the diversion survey were recruited through traditional chain referral/snowball sampling strategies. Sampling began with the membership of the National Association of Drug Diversion Investigators (NADDI). Calls were made to representatives of every agency that had a NADDI member, and the purposes and methods of the project were explained. All of these individuals were asked for leads to other agencies that might be contacted. Recruitment was also achieved by "cold calls" made to municipal and state police departments, county sheriffs' offices, and multicounty drug task forces in all 50 states. In addition, inquiries were made with county and state regulatory agencies and professional oversight organizations such as medical, pharmacy, nursing, and dental boards. County and state prosecutors offices were also invited to participate. In all, more than 9,000 police and regulatory agencies were contacted, and of these, approximately 90% indicated that they did not have officers or other staff members routinely assigned to prescription drug diversion. Many indicated that from time to time the illegal possession of prescription drugs came to their attention as the result of some other investigation or arrest but that diversion per se was not a focus of their police or regulatory work. Of the agencies identified as having one or more officers assigned to diversion, some 20 to 25% refused to participate in the study. The most common reasons for refusal included not having enough time, not being permitted to do outside work, or a general unwillingness to participate in survey research. As illustrated in Figure 2, the final sample includes a variety of different types of agencies, the majority of which are municipal police departments and multijurisdiction drug task forces.

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Figure 2. Distribution of Reporting Agencies by Type

The primary purposes of the survey are to determine the extent of the diversion of selected prescription drugs in a sample of police, other law enforcement, and regulatory jurisdictions, and to identify diversion "signal sites" for specific drugs. A "signal site" is defined as any participating jurisdiction that registers a rate of five or more diversions of any given drug per 100,000 population during an quarter of the calendar year. The drugs currently targeted include such prescriptio opioids as buprenorphine, fentanyl, hydrocodone, hydromorphone, methadone morphine, oxymorphone, oxycodone, and tramadol.

On a quarterly basis, the participating investigators are sent a questionnaire that elicits an enumeration of the total number of *new* cases of diversion reported to and/or investigated by the diversion unit or regulatory board during the previous three months. These must be new cases that were officially put "on the books" during the previous quarter. As such, only cases in which there is a new, *written* complaint or report are included. Continuing cases from previous quarters that are still active do not qualify. For each of the drugs mentioned, the following information is requested: the total number of diversion cases logged in, the number of cases in which the targeted drugs were mentioned, and the dosage form (e.g., tablet, liquid, patch, or other). For the next five most diverted drugs, over and above the targeted drugs, reporters are asked to provide the number of cases in which they occur as well as the dosage form. This procedure provides a comprehensive distribution of the types and numbers of diversion cases in a jurisdiction. Diversion investigators are requested to respond even if they had no new cases during the previous quarter.

All participants in the survey are expected to report the data on the same questionnaire and in the same way. This requires some diversion units to change the way their data are organized and/or recorded. Questionnaires are mailed, faxed, or e-mailed to the participating sites, with a return date of three weeks hence. Incoming surveys are received by e-mail, fax, or pre-addressed,

stamped return envelope, and are reviewed for completeness and accuracy. When necessary, repeated contacts are made with participants to secure additional or corrected information. For unreturned questionnaires, repeated contacts are made by telephone, fax, mail, or e-mail.

Participating diversion investigators are paid a quarterly stipend for their participation. For those whose department policies prohibit them from accepting the stipend, payments are sent to their agency, NADDI, the Police Foundation, or a charity of their choice. Some agencies do not accept any type of payment but participate nevertheless. Reporters who submit completed forms for *all* four quarters in the calendar year are paid a bonus at the beginning of the following year.

For a number of reasons, there are limitations on the kinds and amounts of data that can be collected in a survey of this type. First, in an effort to gather information that can provide timely indicators of the prevalence and geographical distribution of the diversion of specific drugs, data requests are for new cases opened during the previous calendar quarter. As such, almost all of the data received are from "open" cases, the majority of which are still under investigation or for which prosecution or court processing is either ongoing or yet to be initiated. As a result, for the purpose of protecting the anonymity and rights of the accused, details about the alleged offenses and suspect(s) are unavailable. Second, the kinds of information contained in police reports are collected for purposes of investigation and prosecution and, as such, have only limited utility for research. For example, other than age, gender, occupation, prior criminal history, and the type of diversion (e.g., a forged prescription, street buy, or "doctor shopping"), little else is available. And third, requests for more than one or two pages of information from police officers who are burdened with multiple investigations typically result in diminishing returns. As such, the details of the offenses are not requested.

It should be noted here that a number of agencies that have agreed to participate in the study do not necessarily respond every quarter. The difficulty is that the focus of police activity is often a political decision. If additional police personnel are needed at any given time to respond to a particular crisis or perceived crisis-prostitution, methamphetamine and crack sales, a serial rapist, or a highly visible violent or property crime-resources are shuffled. In addition, since 9/11, homeland security activities have become a major part of police work in many jurisdictions. New antiterrorism teams and task forces have been organized throughout the U.S., with units focusing on security at sporting events, concerts, other entertainment venues, and political gatherings; and harbor, river, K-9, and scuba squads have been expanded or newly established to patrol public waterways and to inspect cruise, cargo, and container ships. In addition, local police departments and sheriffs' offices more frequently assist federal law enforcement agencies in border patrols and general surveillance at airports and seaports. Finally, an expanded emphasis has been placed on responding to citizen reports of "suspected terrorists." Consequently, a less visible criminal activity, such as prescription drug diversion, tends to be put aside-sometimes temporarily, sometimes permanently. As such, participating agencies that fail to respond for three consecutive quarters are dropped from the survey and are replaced with a nearby jurisdiction. Overall, the number of participating agencies ranged from 200 during the first year of the study (2002) to a high of 300 during the most recent survey period (4th quarter of 2006).

Results

The diversion data in this paper are reported in terms of "scope" and "magnitude." The "scope" of diversion is defined as the proportion of participating agencies that are reporting the diversion of a particular drug, whereas the "magnitude" of diversion is defined as the proportion of diversion cases in which a particular drug is mentioned. The data reported in this paper are limited to those opioids with the highest levels of diversion—fentanyl, hydrocodone, hydromorphone, methadone, morphine, and oxycodone.

During the 20 calendar quarters from January 2002 through December 2006, the response rate from the participating agencies averaged 72%. A total of 64,655 investigations of prescription drug diversion were initiated by these agencies, and typically, more than one drug was involved in each case. As a baseline, hydrocodone (all strengths and formulations, both branded and generic) was the most widely diverted of the drugs surveyed, having been reported by an average of 69.6% of the participating diversion agencies (scope) and mentioned in an average of 38.2% of all diversion cases (magnitude) reported over the five-year period. During the same period of time, oxycodone (all strengths and formulations, both branded and generic) ranked second, having been reported as diverted by an average of 65.1% of the agencies (scope) and mentioned in at average of 24.3% of the diversion cases (magnitude).

As noted above, hydrocodone was the most widely diverted drug, and as illustrated in Figure 3, hydrocodone was reported as diverted by the largest proportion of agencies over time, immediately followed by oxycodone. In terms of trends the proportion of agencies reporting the diversion of both hydrocodone and oxycodone changed only minimally over the five-year period. Methadone ranked third in terms of the proportion of agencies reporting the drug's diversion, with an upward trend apparent during the early quarters of the survey. For example, whereas only 13.9% of the agencies reported the diversion of methadone during the first quarter of 2002, this more than doubled within a year, and remained at the higher level for the balance of the survey period. Ranking fourth in scope was morphine, followed by hydromorphone. Fentanyl ranked last among these drugs, having been reported by less than 20% of the agencies during every quarter of the survey period.



Figure 3. Scope-Proportion of Agencies Reporting the Diversion of Specific Drugs

Figure 4 illustrates the magnitude of diversion—the proportion of diversion cases in which particular drugs were mentioned. Not surprisingly, hydrocodone consistently ranked first in magnitude, having been mentioned within a range of 34 to 42% of the diversion cases during the five-year period of study. Oxycodone ranked second, with a range of 17 to 28% over the five-year survey period. Fentanyl, methadone, morphine, and hydromorphone were mentioned in only small proportions of the diversion cases reported.

Figure 4. Magnitude-Proportion of Total Diversion Cases in Which Specific Drugs Are Mentioned



In terms of geography, the diversion of hydrocodone, methadone, and oxycodon was reported in all 50 states, the District of Columbia, and Puerto Rico. Moreove the majority of sites in New England, New York, New Jersey, the Appalachiar region, the Midwest, and Florida reported the diversion of these three drugs in almost every quarter. In addition, the diversion of fentanyl, hydromorphone, and morphine has been reported in the majority of states.

Importantly, it appears that there are high concentrations of diversion in many rural areas throughout the United States and particularly in New England and the Appalachian regions of the country. This was most apparent in the distribution of diversion "signal sites," defined earlier as jurisdictions registering a rate of five or more diversions of any given drug per 100,000 population during any quarter of the calendar year. For example, during 2006, of the top ten signal sites for hydrocodone, nine were in rural communities, and eight of these were in rural New England and Appalachia. Of the top ten signal sites for methadone during this same period, nine were in rural communities, and eight of these were in Appalachia or rural Kentucky. Similar concentrations of signal sites in rural areas were apparent with oxycodone and a number of other opioid analgesics. These patterns also emerged in prior survey years.

Discussion

The abuse of opioid pain relievers has been recognized as a serious and growing public health problem and has been well-documented through estimates from the Drug Abuse Warning Network (SAMHSA, 2003b), the Treatment Episode Data Set (SAMHSA, 2004d), and the National Survey on Drug Use and Health (SAMHSA, 2003a, 2004a). In all three reporting systems, the opioids most frequently mentioned were hydrocodone and oxycodone. In the latter data, specifically, hydrocodone was the most often abused of the opioids, involving 17.7 and 21.4 million individuals in 2002 and 2003, respectively, followed by oxycodone, with 11.6 and 13.6 million persons in 2002 and 2003, respectively. This ranking is not at all surprising given that hydrocodone and oxycodone emerged in this diversion survey as the drugs most often diverted.

In addition to documenting the widespread diversion of hydrocodone and oxycodone, and to a lesser extent the other prescription opioids, the data in this survey highlight issues requiring further discussion: (1) the concentrations of diversion cases in rural areas and (2) the actual mechanisms of diversion. On the former topic, part of the problem may be related to the distribution of reporting sites, with restricted sampling from urban areas. Police departments in many small and medium-sized cities, such as Little Rock, Louisville, Phoenix, Rochester, Tampa, and numerous others, are indeed participating in the survey; however many big cities are not, apparently because of an absence of police personnel assigned to prescription drug diversion. One could argue that the lack of diversion investigators in major urban areas is an outgrowth of (1) high rates of violent crime requiring the deployment of police officers to dangerous, "high crime" areas rather than to diversion investigations; (2) higher rates of illicit drug use rather than prescription drug abuse and diversion, requiring the assignment of police to investigations of heroin, cocaine, and methamphetamine traffickers; and, perhaps (3) more widespread availability of cheap heroin in urban areas, thus making prescription opioids lower in demand.

Whether there are higher rates of illegal or prescription drug abuse and trafficking in urban versus rural areas is also difficult to determine. The Office of National Drug Control Policy's (2004b) High Intensity Drug Trafficking Areas (HIDTA) Program provides federal funding to focus on drug trafficking in both urban and rural areas throughout the U.S.; however, the HIDTA Program was designed to combat drug trafficking problems associated with illegal drugs, not prescription drugs. National databases also fail to offer any clues as to the relative availability of illegal narcotics versus prescription opioids in rural as compared to urban communities. Drug mentions published in the reports of the Drug Abuse Warning Network include all types of substances, including "prescription narcotic analgesics," but again, this reporting system focuses almost exclusively on urban communities.

Although the abuse (and, hence, diversion) of prescription opioids would appear to be a problem in many parts of the U.S., including rural, suburban, and urban areas, there are a number of demographic and cultural factors that seem to correlate with the rural communities that display high rates of abuse. For example, the abuse of OxyContin® has been well-documented (Cicero, Inciardi, & Muñoz, 2005), and it is illustrative of the situation in many rural communities. OxyContin® abuse first surfaced in rural Maine, and soon after spread down the East Coast and Ohio Valley into rural Appalachia. Areas of western Virginia, eastern Kentucky, West Virginia, and southern Ohio were especially hard hit (Bishop, 2002; Gilson, Ryan, Joranson, & Dahl, 2004; Hays, 2004; Inciardi & Goode, 2003; Regan & Alderson, 2003). The cultural context in these areas is markedly different from that in many other parts of the United States. Many of the communities are very small and isolated, and they are often located in mountains and "hollers" (small valleys in mountainous areas) a considerable distance from major highways and towns. As a result, many of the usual street drugs are simply not available for local consumption. People instead make use of the resources that are more readily available to them, like prescription drugs.

In addition, many of these areas have populations that are older and tend to suffer from chronic illnesses, often resulting from years of manual labor in perilous professions. Coal mining, logging, commercial fishing, and other blue-collar industries, which can cause serious and debilitating injuries, are major employment opportunities in many rural parts of the country. As a result, a disproportionately high segment of the population utilizes prescription painkillers. The use of pain pills may evolve as a kind of coping mechanism, and the practice of selfmedication can become a way of life for many people who may not have been inclined to abuse traditional street drugs. Therefore, the use of pain medication has become normalized and integrated into the local culture (Inciardi & Goode, 2004). Furthermore, there is historical precedence for such a pattern. In John A. O'Donnell's (1969) classic study, Narcotic Addicts in Kentucky, based on research conducted four decades ago, his sample included 266 individuals who had initiated prescription drug use for the treatment of pain or some other illness. Their drugs of choice were morphine, meperidine, paregoric, and codeine, and they obtained their drugs from friends and relatives, or through doctor shopping, forged prescriptions, illegal sales by physicians and pharmacists, or thefts. As such, what is being observed in Kentucky, at least, is but an old problem with a new panoply of pharmaceutical narcotics.

A final point requiring some discussion here involves the mechanisms through which prescription drugs are actually being diverted. Data from the Drug Abuse

Warning Network, the National Survey on Drug Use and Health, Monitoring the Future, and other national studies document that tens of millions of persons are abusing prescription opioids, yet there seems to be little agreement as to how the great bulk of prescription opioids are being diverted. Federal agencies maintain that diverted drugs come primarily from doctor shoppers, inappropriate prescribing practices by physicians, and improper dispensing by pharmacists (ONDCP, 2004; U.S. DEA, 2005). But is it possible that physicians, pharmacists, and patients are responsible for most of the diversion?

Internet sales have been identified as a major culprit. In fact, on May 16, 2007, Joseph A. Califano, Jr., president of Columbia University's Center on Addiction and Substance Abuse (CASA) and former Secretary of Health, Education, and Welfare, testified before the Senate Judiciary Committee about the availability of drugs on the Internet. Mr. Califano suggested that the easy availability of addictive drugs has, for many children, made the Internet a greater threat than street drug dealers. He went on to state that "the Internet has become a pharmaceutical candy store stocked with addictive drugs, available at the click of a mouse to any kid with a credit card number."

Mr. Califano's comments are based on the latest of several studies by CASA (2007), but it would appear that a reality check is in order. Without question, drugs can be purchased on the Internet; however, survey data suggest that this is not where abusers, including Internet-wise youths, typically go to find prescription drugs. There are places much closer to home where the drugs can be found-often for free. In fact, the Internet appears to be one of the least likely places that drug seekers go to find prescription medications to get high. For example, the most recent National Survey on Drug Use and Health, sponsored annually by the Department of Health and Human Services, found that among persons ages 12 and older who abused prescription narcotics in the past year, almost three-fourths had obtained the drugs from a family member or friend (SAMHSA, 2006). By contrast, less than 1% reported buying the drugs through the Internet. Similarly, the most recent statewide survey of Delaware 11th graders found that students who abused prescription pain killers were getting the drugs primarily from friends, family, and drug dealers, and that less than 2% were accessing the Internet for this purpose. Also, in the diversion study reported here, only 3% of police officers viewed the Internet as a primary source for drugs (Inciardi et al., 2007). Other research is showing similar patterns. In fact, our studies show that drug abusers actually avoid the Internet as a source for prescription drugs. They report that prescription medications are more available at home and on the street, where they are either free or less expensive than on the Internet. Moreover, many see the Internet as a constant source of rip-offs and feel that when using the Internet, "big brother is watching."

The Internet is unquestionably a source for prescription drugs, but the overwhelming volume of purchases appear to be at the wholesale level. The drugs typically end up in the hands of dealers and not with "any kid with a credit card number" as Mr. Califano (2007) argued. If not the Internet, though, then where? For those abusers who report getting prescription medications from friends, relatives, and dealers, where are these latter individuals obtaining them? In the final analysis, no one really knows for sure. In many ways, prescription drug diversion is a "black box" requiring concentrated systematic study.

Endnote

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