

OxyContin and Prescription Drug Abuse

James A. Inciardi & Jennifer L. Goode

If anything has been learned about the drug problem in the United States, it is that patterns of drug abuse are continually shifting and changing. Fads and fashions in the drugs of abuse seem to come and go; drugs of choice emerge and then disappear from the American drug scene; and still others are reconstituted, repackaged, recycled, and become permanent parts of the drug-taking and drug-seeking landscape. And as new drugs become visible, there are the concomitant media and political feeding frenzies, followed by calls for a strengthening of the "war on drugs." It happened with heroin in the 1950s, with marijuana and LSD in the 1960s, with Quaalude and PCP in the 1970s, and with methamphetamine, "ice," ecstasy, crack and other forms of cocaine in the 1980s and 1990s. The most recent entry to the drug scene to receive this focused attention is OxyContin—a narcotic painkiller several times more potent than morphine.

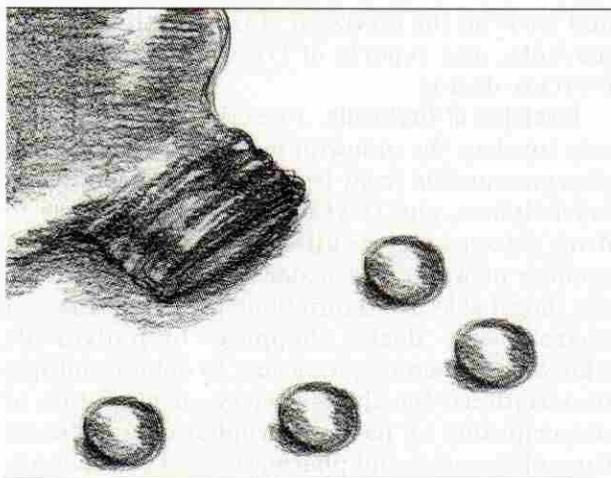
Since OxyContin was first introduced to the market in early 1996, it has been hailed as a breakthrough in pain management. The medication is unique in that its time-release formula allows patients to enjoy continuous, long-term relief from moderate to severe pain. For many patients who had suffered for years from chronic pain, it gave them relief from suffering. But during the past three years OxyContin has received a substantial amount of negative attention—not for its medicinal effects, but for its addiction liability and abuse potential.

OxyContin and Oxycodone. The active ingredient in OxyContin is "oxycodone," a drug that has been used for the treatment of pain for almost 100 years. Oxycodone is a semi-synthetic narcotic analgesic most often prescribed for moderate to severe pain, chronic pain syndromes, and terminal cancers. When used correctly under a physician's supervision, oxycodone can be highly effective in the management of pain, and there

are scores of oxycodone products on the market—in various strengths and forms. Popular brands include Percocet and Percodan; Roxicet and Roxicodone; and Endocet, OxyIR, and Tylox, to name but a few. However, no oxycodone product has generated as much attention as OxyContin.

Produced by the Stamford, Connecticut-based pharmaceutical company, Purdue Pharma L.P., OxyContin is unique because unlike other oxycodone products that typically contain aspirin or acetaminophen to increase or lengthen their potency, OxyContin is a single entity product that can provide up to 12 hours of continuous pain relief. Tablets are available in 10-, 20-, 40-, and 80-milligram doses. The company also introduced a 160-milligram dose in July 2000 for its opioid-tolerant patients, only later to withdraw it from the market amidst controversy over its alleged abuse.

When the clinical trials for OxyContin were reviewed by the Food and Drug Administration, the drug was demonstrated to be an effective analgesic in individuals with chronic, moderate-to-severe pain. Yet it was also judged by the FDA to carry a substantial risk of abuse because of its properties as a narcotic. As a result, OxyContin was approved by the FDA but placed in Schedule II of the Controlled Substances Act (CSA), which is the tightest level of control that can be placed on an approved drug for medical purposes. The placement of OxyContin in Schedule II warned physicians and patients that the drug carried a high potential for abuse and that it needed to be



Dr. Inciardi is the Director of the Center for Drug and Alcohol Studies and a Professor in the Department of Sociology and Criminal Justice at the University of Delaware. Ms. Goode is a research specialist at the Center for Drug and Alcohol Studies.

carefully managed, particularly among those at risk for substance abuse. In addition, in the Physicians' Desk Reference and on the drug's package insert, OxyContin carries a boxed warning—more commonly known as the infamous “black box.”

Importantly, this “black box,” voluntarily inserted in the packaging information by Purdue Pharma in 2001, alerts potential users that taking broken, chewed, or crushed OxyContin tablets leads to rapid release and absorption of a potentially fatal dose of the drug. But even before the insertion of the “black box,” drug abusers had figured out how to compromise OxyContin's controlled-release formula and set off on a powerful high by injecting or snorting dissolved tablets or by crushing and ingesting them.

Despite the numerous controls and warnings required by the FDA, OxyContin has been a major economic success for Purdue Pharma, accounting for some 80% of the company's total business. Prescriptions have risen steadily since the drug's introduction, as the number of prescriptions dispensed increased 20-fold from 1996 through 2000. More than 7.2 million prescriptions were dispensed in 2001 and retail sales totaled more than \$1.45 billion, representing a 41%

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increase in sales between 2000 and 2001 alone. Retail sales increased again in 2002, topping \$1.59 billion. In terms of dollar amount, OxyContin now ranks the highest in retail sales of all brand-name controlled substances. Federal regulators, however, are put off by these numbers, and focus on the diversion of OxyContin to illegal markets, and reports of OxyContin abuse and overdose deaths.

Diversion of OxyContin. Prescription drug diversion involves the unlawful movement of regulated pharmaceuticals from legal sources to the illegal marketplace, and OxyContin's attractiveness to drug abusers has resulted in its diversion in a number of ways. The major mechanisms include the illegal sale of prescriptions by physicians and pharmacists; “doctor shopping” by individuals who visit numerous physicians to obtain multiple prescriptions; the theft, forgery, or alteration of prescriptions by patients; robberies and thefts from pharmacies and pharmaceutical warehouses;

and thefts of samples from physicians' offices as well as thefts of institutional drug supplies by health-care workers. In all likelihood, OxyContin has been diverted through all of these routes.

Diversion has also occurred by means of fraud, particularly through the abuse of medical insurance programs, a phenomenon observed and investigated most often in a number of rural communities. Medicaid fraud, for example, presents an inexpensive mechanism for abusing drugs and oftentimes an easy route to a lucrative enterprise. For example, a Medicaid patient may pay only \$3 for a bottle of a hundred 80-milligram OxyContin tablets. In areas where employment and money are scarce resources, the temptation to sell some of the pills for the going “street price” of \$1 per milligram provides an opportunity to earn money. In this example, the \$3 bottle from the pharmacy can net the patient up to \$8,000 on the illegal market.

Just one corrupt physician, pharmacist, health-care worker, or other employee in the health-care field can have a significant impact on the availability of the product as well. For example, before he was arrested in 2002, a Pennsylvania pharmacist had illegally sold hundreds of thousands of painkillers, including OxyContin, over a three-year period. He made \$900,000 on his transactions (only to lose it all in the stock market). Although he operated an independent neighborhood pharmacy, he was reportedly the state's third-largest purchaser of OxyContin. Similarly, a number of physicians in Eastern Kentucky were arrested in 2003 for a variety of diversion schemes. One saw as many as 150 patients each day, writing narcotic prescriptions for them after a visit of less than three minutes each. Another traded painkillers for sex with female patients whom he had addicted to narcotics. A third opened an office in a shopping mall where he generated prescriptions—one after another—almost as quickly as he could write them.

How much diversion of OxyContin actually occurs is impossible to calculate, because there is not a single national reporting system on pharmaceutical diversion. Nevertheless, some data are available which at least suggest the extent of OxyContin diversion, relative to other drugs of abuse, including narcotic painkillers. In a 2001 survey of 34 police agencies with pharmaceutical diversion units, for example, a total of 5,802 cases of diversion (of any drug) were reported during the calendar year. The reporting agencies were asked to indicate which drugs were most commonly diverted, and in how many cases each was investigated. The most commonly diverted pharmaceutical drug was hydrocodone (Vicodin, Lortab, and similar narcotic analgesics), noted in 31% of the

total cases. This was followed by oxycodone in 12% of the cases, and alprazolam (Xanax) in 6% of the cases. Of the 701 cases involving an oxycodone product, 416 were OxyContin. Overall, OxyContin was represented in only 7% of the drug diversions, a rather small proportion given the attention the drug has received. In addition, the data documented that the diversion of OxyContin was part of a much broader pattern of prescription-drug diversion. That is, in the great majority of cases in which OxyContin had been diverted, a wide spectrum of other drugs were being diverted at the same time.

OxyContin Abuse: Do the Figures Add Up? Although there are several sources of national data on drug abuse that have been operating for decades, the collection of specific data on OxyContin abuse is quite recent. In the Monitoring the Future Survey, a government-sponsored study of drug abuse among high school students and young adults that has been conducted annually since 1975, the collection of information on OxyContin began only in 2002—and this was initiated at the request of Purdue Pharma. The 2002 survey found that 4% of 12th graders, 3% of 10th graders, and 1.3% of 8th graders had used OxyContin at least once during the past year. Interestingly, the use of Vicodin (a brand of hydrocodone) in the past year was at least double that of OxyContin—9.6% for 12th graders, 6.9% for 10th graders, and 2.5% for 8th graders. In the 2001 National Household Survey on Drug Abuse, another government survey conducted annually, only “lifetime use” (at least once in a person’s lifetime “to get high”) data were collected for OxyContin. For persons ages 12 and over, less than one-half of 1% reported ever using OxyContin to get high.

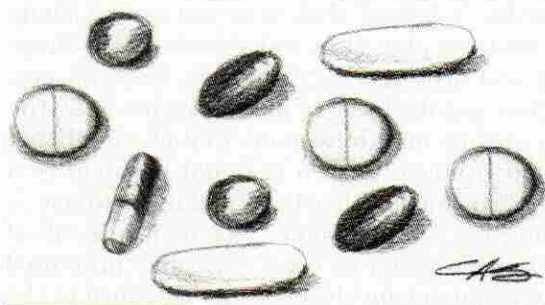
The Drug Enforcement Administration started actively collecting and analyzing data from medical examiners in an attempt to establish the extent of the OxyContin problem. Medical examiner reports from 2000-2001 from 32 states reflected that 949 deaths were associated with oxycodone, of which almost half (49%) were “likely” related to OxyContin. Because there are

a multitude of oxycodone products on the market, it is impossible to determine the specific brand of drug found in a cadaver. Nevertheless, out of the 949 deaths, DEA reported that 146 were “OxyContin verified,” while another 318 were “OxyContin likely.” To make things even more complicated, the majority of the toxicological analyses reported multiple-drug use, suggesting that the death may have been the result of an overdose induced by a combination of substances, not just oxycodone by itself. When taking all of these factors into consideration, it is very difficult to establish a direct link between OxyContin and cause of death.

An Emerging National Epidemic? OxyContin abuse first surfaced in rural Maine during the late 1990s, and soon after spread down the east coast and Ohio Valley, and then into rural Appalachia. Communities in western Virginia, eastern Kentucky, West Virginia, and southern Ohio were especially hard hit, and a number of factors characteristic of these areas seem to correlate with their apparent high rates of abuse. In northern Maine and rural Appalachia, for example, there are aspects of the culture that are markedly different from those in other parts of the country. Many of the communities are quite small and isolated, often situated in the mountains and “hollers” a considerable distance from major towns and highways. As a result, many of the usual street drugs are simply not available. Instead, locals make do with resources already on hand, like prescription drugs. In addition, isolation impacts heavily on options for amenities and entertainment. Many substance-abuse treatment clients in these rural areas have told their counselors that they started using drugs because of boredom.

Many adults in these rural areas tend to suffer from chronic illnesses and pain syndromes, born out of hard lives of manual labor in perilous professions—coal mining, logging, fishing, and other blue-collar industries which often result in serious and debilitating injuries. As a result, a disproportionately high segment of the population lives on strong painkillers. The use of pain pills evolves into a kind of coping mechanism, and the practice of self-medication becomes a way for life for many. As such, the use of narcotic analgesics has become normalized and integrated into the local culture.

Data suggest that the abuse of OxyContin may be escalating in certain areas. For example, the number of patients in Kentucky seeking treatment for oxycodone addiction increased 163% from 1998 to 2000. While OxyContin is not necessarily always the cause, officials there say that it is one of the most widely abused oxycodone products. Crime statistics seem to support the claim,



as Kentucky is one of the leading states for OxyContin-related crimes. Between January 2000 and June 2001 alone, 69 of the state's 1,000 pharmacies reported OxyContin-related break-ins.

Drug treatment admissions from several states may also offer evidence to support a growing trend in OxyContin abuse. Programs in Pennsylvania, Kentucky, and Virginia have reported that 50% to 90% of newly admitted patients identified OxyContin as their drug of choice. Figures obtained by DEA from the American Methadone Treatment Association also suggest an increase in the number of patients admitted for OxyContin abuse. Moreover, according to the Maine Office of Substance Abuse, the number of narcotics-related treatment admissions (excluding heroin) increased from 73 in 1995 to 762 in 2001. While OxyContin cannot take all of the blame, officials say it is nonetheless a major contributor and also point out that opiate-based prescription drugs in general outpaced the percentage increases for all other types of drugs in the state. Treatment admissions for these drugs increased 78% from 1998 to 1999 (199 to 355) and another 47% from 1999 through September 2000 (355 to 521), which suggests a possible increase in OxyContin use.

A separate study conducted by Maine's Substance Abuse Services Commission and the Maine Office of Substance Abuse found that treatment admissions for narcotic abuse increased 500% since 1995, and that opiate-related arrests constituted more than 40% of the Maine Drug Enforcement Agency's caseload. The study, commissioned because of the publicity the state received for being one of the first to identify OxyContin abuse, analyzed several aspects of prescription opiate abuse. The study linked the use of narcotics with increased rates of crime, emergency medical treatment, and outbreaks of hepatitis C. While OxyContin was not the only opiate abused in the state at the time, it constituted the centerpiece of the study results published in *Alcoholism & Drug Abuse Weekly*.

Based on these and similar reports in a few other states, it has been suggested in numerous media outlets that the abuse of OxyContin is on the rise, and that its popularity is rapidly spreading beyond the rural East Coast to other parts of the United States. At the same time, however, there is also concern that the media have played an integral role in boosting the drug's popularity.

The Media Frenzy. Media outlets in Maine began reporting on OxyContin abuse in early 2000. The *Bangor Daily News*, for example, ran several features which included information not only about the properties of the drug, but also about how to compromise its time-release mechanism, the tac-

tics of diversion that people were using to obtain the drug (including Medicaid fraud), and the concerns of the medical profession about the potential for abusing the drug. In addition, numerous examples of alleged OxyContin-related crimes were described in detail.

Media coverage changed dramatically after Kentucky's sensational "Operation OxyFest 2001," when more than 100 law enforcement offi-

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cers from numerous jurisdictions worked together to arrest 207 OxyContin users and dealers throughout the state. A blitz of national media coverage followed. The Associated Press, *Time*, *Newsweek*, the *New York Times*, and other media giants, as well as local newspapers across the nation, all ran alarming stories about the potentially lethal and dangerous new drug. Much of the initial coverage of OxyContin seemed to follow a similar formula: It started off with the personal tale of a chronically ill patient for whom OxyContin had suddenly made life worth living, followed by a contrasting tale of a lowly, depraved junkie who had become a slave to the drug, all the while littering the piece with both information and misinformation about the drug. Headlines screamed about OxyContin-related crimes, including pharmacy break-ins and terrifying accounts of elderly patients' homes being invaded and raided for the drug. Some stories of robberies appeared in local media outlets, only to be followed by a string of copycat attempts. There were numerous stories of physicians who ran "pill mills" to feed the addiction of their clients, and contrasting stories of other doctors who had been scared off from prescribing the drug. There were numerous reports of pharmacies that had stopped stocking the drug for fear of inviting crime.


It would appear that, although the abuse of OxyContin is indeed real, it is just one of many drugs that are abused by individuals whose drug-taking and drug-seeking behaviors focus on prescription painkillers. It also appears that the media stories may have contributed to shifting OxyContin abuse from a regional problem to a national problem. Clearly, OxyContin abuse is anything but an "epidemic." Nevertheless, all of the attention given to OxyContin has prompted U.S. government involvement. In response to the

heightened awareness of OxyContin abuse and diversion, the DEA launched its own comprehensive plan to prevent the illegal distribution of the product. Its broad goals include enforcement and intelligence; regulatory and administrative authority; industry cooperation; and awareness, education and outreach initiatives. Industry cooperation is an integral part of the plan, including encouraging Purdue to adopt a balanced marketing plan. As recently as January 2003, the FDA sent Purdue a letter contending that the company improperly disclosed information on OxyContin's risks, including a "particularly disturbing" ad that ran in the November issue of *JAMA* (the Journal of the American Medical Association). In response, Purdue has pledged that all future advertisements will balance information about the benefits and risks of the product, as required by the federal Food, Drug and Cosmetic Act.

There have also been calls to reformulate the drug, to make it more difficult for abusers to compromise its time-release mechanism. Purdue has pursued alternative formulas, but success has been elusive thus far. Clinical trials found that when naloxone, a narcotic blocker, was added to OxyContin, it sometimes blocked pain relief for patients who ingested the tablets correctly. The company is pursuing an alternate approach by

shifting from a tablet to a capsule that contains similar beads of the oxycodone combined with naltrexone, another narcotic blocker. If taken correctly, only the OxyContin beads would dissolve in the system, but if an abuser were to crush the pill, he would crush and activate the naltrexone, therefore masking the drug's effects. The company said complete testing could take as long as five years. Even if this is accomplished, drug abusers are clever people, and will likely compromise the new formulation in due course.

In the meantime, Purdue has launched its own public relations offensive. Among the initiatives, it has created educational and outreach materials, including a series of print and television ads and "Painfully Obvious," a program that provides resources to educate parents, teachers, and students about the dangers of prescription drug abuse.

Despite the bad press and pressure from the government, the success of OxyContin has not faltered. Only time will tell if the success will be short-lived or if the negative attention will slowly start to chip away at product confidence. In the meantime, those who use it correctly will continue to enjoy consistent pain relief, while those who abuse it will surely continue to inflict pain on the company, law enforcement, the community, and themselves. 

Spam ...

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slowly, and law enforcement generally has other priorities than spam. That means enforcement might not be there to back up any new stiff anti-spam penalties. And if spammers don't have to worry about getting caught, the penalties likely won't act as much of a deterrent.

Ban It. The most straightforward solution is an outright ban on junk e-mail. Under such a plan, sending unsolicited e-mail would be illegal, punishable by fines. Consumers who receive unwanted mail also could file in small claims court. Congress has already been down this road. In the late 1980s, when fax machines were the new communications technology, marketers had similarly realized how cheap and easy it was to advertise by blast-faxing large numbers of fax machines. The problem was, as with spam, that senders had to bear little of the cost of their advertising campaign. The sender just had to print up one copy of his ad. Fax owners, meanwhile, found that their fax machines were continually clogged with unwanted junk faxes, which ate up paper and toner supplies as well.

In the early 1990s, Congress passed a law that

banned the practice of sending commercial faxes to anyone who hadn't specifically requested them. The result was that the problem pretty much disappeared. This spring, the U.S. Court of Appeals for the Eighth Circuit ruled that the law was constitutional, saying it didn't violate advertisers' First Amendment rights. The court made an interesting observation, which is relevant to the current spam debate: "It was not unreasonable for Congress to choose a system that protects those who would otherwise be forced to bear unwanted burdens over those who wish to send and receive unsolicited fax advertising."

The problem with an outright ban, like the weaknesses of other solutions, is that while it would effectively eliminate most legitimate forms of spam, it would likely have little impact on those spammers already breaking the law by using phony return addresses or other fraudulent means to get recipients to open up the message.

In the end, some combination of all these approaches may be needed. With the growth of spam, e-mail itself, which has been an incredibly valuable communications tool, is becoming more of a headache than a help. Left unchecked, spam could make cell phones and pagers equally aggravating. 