

# *Overdoses of Painkiller Are Linked to 282 Deaths*

## *Federal Study Details Misuse of OxyContin*

By BARRY MEIER

An extensive federal review of autopsy data has found that the powerful painkiller OxyContin is suspected of playing a role in the overdose deaths of 282 people in the last 19 months, more than twice the number in some previous estimates. The nation's top drug enforcement official recently called the new finding "startling."

The review also found that virtually all the deaths were of people who swallowed the pill whole or crushed into powder, further suggesting that OxyContin misuse may be more difficult to curb. The overdose deaths were previously believed to have been of people who injected or snorted crushed pills, which are quicker and more dangerous forms of drug delivery.

Meanwhile, officials of Purdue Pharma, OxyContin's manufacturer, acknowledged in a recent interview that even after reports that OxyContin had been getting into the wrong hands, the company continued for a while this year to distribute free seven-day supplies of the drug, through doctors, to promote its use.

The federal study on OxyContin, by the Drug Enforcement Administration, is the agency's first to explore links between overdose deaths and a brand name drug. Previous reviews had looked only at drugs' active ingredients, used by many manufacturers. Besides the 282 deaths, which often also involved other drugs and alcohol, federal officials said they found that 500 people had died since the start of 2000 from overdoses involving oxycodone, the active narcotic in OxyContin and other popular painkillers. But federal officials could not say whether the oxycodone linked to those deaths was from OxyContin, a drug for the treatment of severe and chronic pain.

Asa Hutchinson, the administrator of the Drug Enforcement Administration, called the study's results startling and said, "This verifies the

fear and concern that we have had about this drug."

Dr. Paul Goldenheim, the vice president for research and development at Purdue Pharma, said that the Drug Enforcement Agency's data was consistent with the company's own findings. But he emphasized that none of the information implicated OxyContin in any of the reported deaths. "There is no suggestion that the 200 subjects died from oxycodone," Dr. Goldenheim said. The study did not try to determine whether OxyContin alone was responsible for the deaths because the overdose deaths typically involved multiple drugs.

Federal officials have said that abuse of OxyContin has grown faster than abuse of any other prescription drug in decades. Purdue Pharma heavily promoted the drug as safer than other narcotics because its active ingredient was in a time-release mechanism. But abusers quickly learned that crushing the pill disarmed that feature.

Fewer than 10 of the 282 people whose deaths were associated with OxyContin were intravenous drug abusers, and only one showed signs of having snorted the drug.

That finding, federal officials said, suggests that a recent decision by Purdue Pharma to reformulate the time-released painkiller to reduce its abuse by injection or snorting may have limited benefits.

Dr. Goldenheim, the company executive, said that he also believed that more steps would be needed to curb the drug's misuse. "We have been concerned that the reformulation will not solve the bulk of the problem," he said.

Dr. David Gauvin, a pharmacologist at the Drug Enforcement Administration, said medical examiners in 30 states had so far reported about 1,010 overdose deaths involving oxycodone since January 2000.

Based on responses to date, the agency concluded that OxyContin was "directly linked" as a factor in



Associated Press

OxyContin, a potent painkiller, is popular with drug abusers.

110 overdose deaths because tablets were either found in a person's stomach or a prescription for the drug was found on a body. Other confirmation came from reports on interviews with witnesses.

"You may have had a credible witness who said, 'My son took OxyContin, and 20 minutes later he stopped breathing,'" Dr. Gauvin said.

Agency officials classified 172 deaths as "OxyContin possible," cases where autopsy reports showed high blood concentrations of oxycodone without the presence of other compounds like aspirin or acetaminophen. While OxyContin contains only oxycodone, other narcotics, like Percodan and Tylox, use the drug as an active ingredient but also include other compounds.

In 501 cases, the agency did not receive enough information to differentiate between OxyContin and oxycodone, its principal ingredient. And the information in 227 of the 1,010

reports was insufficient to enable the agency to analyze them.

Purdue Pharma executives have defended their decision to distribute free OxyContin pills.

The company's salespeople gave doctors promotional material about OxyContin that contained cards, which doctors would then give to patients along with a OxyContin prescription. A patient would bring the card to a pharmacy for free drugs.

Michael Friedman, the chief operating officer of Purdue Pharma, based in Stamford, Conn., said the sampling program was used to acquaint patients with OxyContin. Mr. Friedman said the company had begun a new card program in July but stopped it a few days later when the Food and Drug Administration placed the highest possible warning on OxyContin's label.

Asked why Purdue continued to offer free supplies in the face of mounting reports of abuse, Mr. Friedman said he believed that people who received the cards from doctors were legitimate patients. He estimated that the company had run four or five similar marketing programs for the drug in recent years and that from 8,000 to 15,000 cards had been distributed each time.

"The fact that we're providing a sample to a patient has no connection to some criminal doctor who was taking money for prescriptions," Mr. Friedman said.

Terry Woodworth, the deputy director of drug agency's division of diversion control, said Purdue Pharma's program did not violate the law. But Mr. Woodworth, who learned about Purdue Pharma's program from a reporter, said he was stunned to hear that the company continued it after reports about abuse. "It's absolutely absurd," Mr. Woodworth said. "Were they meeting the letter of the law? Sure. Were they meeting the intent and spirit? No."

# *At Painkiller Trouble Spot, Signs Seen as Alarming Didn't Alarm Drug's Maker*

By BARRY MEIER

MYRTLE BEACH, S.C. — The line, often 15 to 20 people long, used to spill from a pain management clinic at a strip mall in this beachside city. Other visitors, many from out of town, waited in cars that jammed the mall's parking lot from morning to night.

Some came to the clinic for legitimate treatment. But others came to feed another need, a hunger for narcotics.

The clinic's drug of choice was OxyContin, the powerful painkiller that federal officials say has been a factor in 282 overdose deaths since January 2000 and may have played a role in dozens more. No other drug in the last 20 years has been abused more widely so soon after its introduction, those officials say. Its addicts have broken into pharmacies, clogged treatment centers and sent lawmakers scrambling to find ways to keep the drug from those who use it to get a heroinlike high.

As reports of OxyContin abuse spread early this year, the drug's manufacturer, Purdue Pharma of Stamford, Conn., began a national campaign to convince the public that it was doing everything possible to combat the problem and to make sure that only patients with legitimate needs got the drug.

But while some pharmacists and a law enforcement official in Myrtle Beach, a major trouble spot for OxyContin, said they had warned Purdue Pharma that the clinic was an apparent hotbed of abuse, the company did little, if anything, about it.

In addition, Purdue Pharma's own records, obtained by The New York Times, show that first-quarter sales of OxyContin in a sales territory that includes Myrtle Beach grew by more than \$1 million. During that period, sales in the territory with the next-biggest growth in the country grew by \$700,000. Federal officials say the drug maker should have investigated whether the surge in the territory

here was caused by doctors' overprescribing the drug or by people's misusing it.

"There was total disregard for what was going on over there," said Cheri Crowley, the federal Drug Enforcement Administration agent in charge of the agency's investigation into the clinic, the Comprehensive Care and Pain Management Center. Speaking of prescriptions, she said, "Script after script after script was coming from the clinic."

Comprehensive Care closed in June after the drug agency suspended the narcotics licenses of six doctors who worked there, saying the doctors posed an "immediate danger to public health and safety." Five of the clinic's patients died of drug overdoses, government investigators said. The doctors deny any wrongdoing.

Terry Woodworth, a D.E.A. official in Washington, said the drug maker had a moral obligation to alert state and federal authorities to the warnings its sales representatives had received even though it was not legally required to do so. And Representative James C. Greenwood, a Pennsylvania Republican who presided over a Congressional hearing on OxyContin, said that in general, companies that made narcotics should monitor their sales data and investigate patterns suggesting inappropriate use.

"A company that collects data to see how well its marketing programs are working ought to be able to accept a responsibility to see where relatively obvious instances of abuses are occurring," Mr. Greenwood said.

Purdue Pharma executives declined requests to be interviewed for this article. But in written responses to questions, the company said its officials had acted responsibly in dealings with the clinic. A large number of prescriptions does not necessarily mean that doctors are improperly prescribing a drug, the company added.



Photographs by Wade Spees for The New York Times

Roddy Williams, owner of the Oceanlakes Pharmacy in Surfside Beach, near Myrtle Beach, S.C., is one of the pharmacists who say they complained about overuse of the painkiller OxyContin to drug salesmen.

**PRODUCT LEADERS - OXY CONTIN, OXY-IR, AND OXY FAST  
PRESCRIPTION SALES DIVISION  
FIRST QUATER 2001**

AREA	REPRESENTATTIVES	1ST QTR 2001	
		DOLLAR GROWTH	RANK
01051607	Eric Wilson	1,031,131	1
01080208	Jill Boggs	697,929	2
01110806	Carolyn Young	584,986	3
	McNeal	554,840	4
	Fisher		5

A Purdue Pharma document showed a surge in OxyContin sales in the area listed first, a region that included Myrtle Beach, S.C.

"At Purdue we strongly support local, state and federal law enforcement efforts to combat the abuse and misuse of OxyContin and other pain medications," the company said in a statement. "Everyone committed to the best interest of patients in pain is a victim of prescription drug abuse."

OxyContin, a time-release medication, has proved effective for cancer patients and others suffering from severe, chronic pain. But drug abusers quickly discovered that crushing the pill immediately released its narcotic.

For more than a year, Comprehensive Care was the epicenter of OxyContin abuse in Myrtle Beach, law enforcement officials said. The ease of getting a prescription became so well known that people arrived by the carload from more than 100 miles away, those officials added.

Soon, a pattern of crime and misery, already associated with OxyContin abuse in states like Maine and West Virginia, unfolded. One rehabilitation center in Myrtle Beach has experienced a nearly fourfold increase in the number of OxyContin addicts it has treated in the last 18 months.

"I lived in hell," said Robin Anderson, a former clinic patient who sought treatment twice for her addiction, "and some days I feel like

I'm still in hell." In July, she sued Comprehensive Care and Purdue Pharma in a South Carolina state court, contending that they did not adequately warn about the drug's hazards. They deny those accusations.

Some pharmacists in Myrtle Beach say they told the drug maker of their suspicions about Comprehensive Care months before the clinic closed.

Thomas Ayres, an owner of the Medicine Shoppe in Darlington, S.C., said he had become suspicious when patients from Comprehensive Care began to arrive at his store, 75 miles from the clinic, to fill large OxyContin prescriptions. Mr. Ayres said he had passed on his concerns to a Purdue Pharma salesman around the beginning of this year.

He said the salesman, Maurice Heisig, had appeared to know about the clinic's problems already. "Mo said, 'We are trying to talk with them, but Myrtle Beach is not my area,'" Mr. Ayres said.

Another druggist, Ron Mason, an owner of the Northside Pharmacy in Myrtle Beach, said that he confronted the OxyContin salesman for this area, Eric K. Wilson, around March, not long after his store had been burglarized for OxyContin.

"I told him, 'You know where this



Prescribing patterns at this pain clinic led to a federal inquiry.

is going and that people are abusing this drug, but you are getting your commission on sales,'" Mr. Mason said.

Several druggists said they also complained about the clinic this spring during meetings sponsored by Purdue Pharma. Roddy Williams, owner of the Oceanlakes Pharmacy in Surfside Beach, a town near here, said he had voiced his concern to Mr. Wilson before one meeting. He said Mr. Wilson had responded by telling him that the company was issuing, among other things, prescription pads that could not be duplicated or used for forgeries.

"It was a joke," Mr. Williams said. "People didn't need to copy prescriptions. They were going to doctors who were writing them."

Ms. Crowley, the D.E.A. agent, said she described the havoc that OxyContin was causing in a "heated" telephone conversation with Mr. Wilson in March.

"I told him, Your product is being diverted onto the streets of South Carolina, that it is being sold on the streets of South Carolina and that people are dying from it in South Carolina," Ms. Crowley said.

She said that she did not recall his specific response but that he had said that Purdue Pharma was holding meetings with local pharmacists and doctors about pain management.

Both salesmen, Mr. Wilson and Mr. Heisig, initially referred a reporter's telephone calls to Purdue Pharma headquarters. In written responses to questions, the company acknowledged that both men had been told by "health care professionals" of their "concerns about certain activities at the clinic" — in Mr. Wilson's case, as early as late last year.

Both men, the company added, told their managers about the reports, but Purdue Pharma said the information "did not give the managers reason to take action" other than to tell Mr. Wilson to "continue to stress the proper use" of OxyContin during visits to Comprehensive Care. The company did not elaborate.

Three doctors who worked at the clinic, including Dr. David Michael Woodward, its owner, said they had never been told by any Purdue Pharma official that they were improperly prescribing OxyContin. The doctors also say patients were monitored to make sure that they were not abusing drugs and that those suspected of doing so were reported to state authorities. All the doctors whose licenses were suspended by the D.E.A. are contesting the action.

In a statement, Mr. Wilson said that the situation at the clinic was not "simple or clear" and that many pain patients had received legitimate care there. "If any of the doctors at this clinic have abused their prescribing privileges, then they have exploited all of us," Mr. Wilson said.

Dr. Woodward recently surrendered his state medical license voluntarily. The clinic remains the subject of a criminal investigation, the authorities said. Dr. Woodward denies any wrongdoing.

"Some have suggested that when such suspicions are raised about a particular physician or practice, our sales representatives should stop calling on them," the company said. "That certainly would have been better from a perception standpoint, but if a doctor is intent on prescribing our medication inappropriately, such activity would continue regardless."

As part of its effort to stop the drug's abuse, top Purdue Pharma executives have crisscrossed the country to meet with local officials and offer their help. They have also started programs to help doctors better identify drug abusers. Most recently, the company produced television ads warning teenagers about prescription drug misuse.

Company officials also said that while many prescription drugs were abused, OxyContin had been unfairly singled out, making some doctors afraid to prescribe it for patients who need it. But experts say that OxyContin, while beneficial to many, is extremely powerful: a single tablet can contain up to 16 times the level of the same narcotic found in other painkillers.

In an August interview, two months after Comprehensive Care closed, three top Purdue Pharma executives said the company did not have any prescription data that would have alerted them to problems in Myrtle Beach. But this year's first-quarter sales of OxyContin in Mr. Wilson's territory, which includes Myrtle Beach, showed the highest increase of any sales territory in the country, records show.

During that period, those records show, sales of OxyContin in Mr. Wilson's area increased as much in three months as the sales in some other territories of the country increased during all of last year. A local doctor said in an interview that Mr. Wilson told him that 40 percent of those sales had gone to Comprehensive Care.

The company said in a statement that the sales figures for Mr. Wilson's territory did not suggest anything unusual. "It is not unusual for the volume of prescriptions for OxyContin and other pain medications to change significantly from quarter to quarter in different areas," Purdue Pharma said. The company, which declined to elaborate on the sales documents, added that Myrtle Beach and the surrounding area had growing numbers of older people who used pain medications.

When Mr. Woodworth, the D.E.A. official in Washington, was told about the sales data, he said the company should have investigated.

"It was only one indicator," said Mr. Woodworth, who is the drug agency's deputy director for the division of diversion control. "But it was a hell of an indicator."

# The New York Times

NEW YORK, FRIDAY, DECEMBER 21, 2001

## Few States Track Prescriptions As Way to Prevent Overdoses

By MELODY PETERSEN and BARRY MEIER

In the mountain coal fields of eastern Kentucky, Sheriff Steve Duff of Harlan County recently noticed something curious — people driving to drug stores in neighboring states to fill prescriptions of a potent painkiller called OxyContin.

Their reason, Sheriff Duff believes, was to evade a system in Kentucky that monitors who gets potentially addictive drugs and who prescribes and fills those prescriptions.

That system, the sheriff says, helped him arrest several dozen people last year on OxyContin-related charges. More significantly, it helped police stage Kentucky's biggest ever drug-abuse raid, resulting in the arrest last February of 252 people in a sweep called Operation Oxyfest.

Public health and law enforcement officials have long argued that such monitoring can save lives by quickly identifying problem doctors who over-prescribe narcotics and problem patients who forge prescriptions or con unsuspecting doctors.

But today, just 15 states have such programs because of decades of lobbying by drug companies, doctors, pharmacies and more recently, groups pushing for the greater use of narcotics to control pain. Even in states that monitor prescriptions, some programs are underfinanced, crippling their effectiveness.

Federal drug agents say OxyContin played a likely role in the overdose deaths of at least 296 people since January 2000, in addictions that have overloaded drug treatment centers and in crimes like thefts at pharmacies and on the street. Public officials say OxyContin abuse is also costing taxpayers tens of millions of dollars because so many people who misuse the drug get it through Medicaid, a government-financed health

care program for the poor.

Law enforcement officials say that if more states had good monitoring programs they might have been able to crack down on OxyContin abuse before it claimed so many victims. States with such programs, like New York, have seen little OxyContin abuse, while many without them, including Florida, Maine and West Virginia, have been the hardest hit.

Most of the groups that oppose the monitoring of prescriptions argue that it violates patients' privacy, costs too much or hurts those who really need the drugs by causing doctors to prescribe fewer and less

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potent drugs. But a report by the General Accounting Office in 1992 and a more recent survey by the Justice Department looked at several of those claims and could not substantiate them.

Prescription monitoring has long had some powerful opponents.

"Physicians do not want their activities monitored," said Carmen A. Catizone, executive director of the National Association of Boards of Pharmacy, which supports monitoring. "Drug companies are also a powerful lobby. Once a drug is monitored, sales decrease, and the drug companies don't like that."

OxyContin, made by Purdue Pharma of Stamford, Conn., was originally thought to be less prone to abuse because its narcotic was locked in a time-release formula. But abusers found that they could crush the tablet, then swallow, inhale or inject the powder to give themselves a high as powerful as heroin's.

As a result of OxyContin abuse, there are renewed calls for more prescription monitoring. At least eight states, including Connecticut, New Jersey and Florida, are seriously considering it.

Florida, for example, experienced a 40 percent jump in the number of people who died from drug overdoses in the first six months of this year. OxyContin is cited as a factor in many of those deaths.

"This system will allow us to monitor prescription shopping and doctor shopping and any illicit prescribing by doctors," said Gov. Jeb Bush of Florida, who announced his support for such a system this month.

For years evidence has shown that prescription monitoring works, health officials say. For example, when New York State began tracking prescriptions for certain tranquilizers in the late 1980's — a move opposed by four drug companies and the state medical society — emergency rooms in New York and Buffalo reported 47 percent fewer overdose admissions involving those drugs.

"We saw a vast drying up of those drugs on the streets," said John Eadie, the former director of New York's program who now consults with states on setting up monitoring programs.

But Dr. Russell Portenoy, chairman of pain medicine and palliative care at Beth Israel Medical Center in Manhattan, said there was a downside. Some doctors, he said, prescribed patients tranquilizers that the state did not track, drugs that had greater potential side effects than those that were monitored.

When California sought to add certain tranquilizers to its monitoring program, lobbyists for drug companies and doctors were able to defeat

the move.

The drug industry's main trade group, the Pharmaceutical Research and Manufacturers of America, said it "generally supports" monitoring systems but said that individual drug companies should decide the issue for themselves.

In recent years drug stores and pain specialists have been the most vocal opponents of monitoring.

In North Carolina, a drug tracking system was defeated this year, despite the state's recent problems with OxyContin. That loss frustrated John Womble, manager of the state's controlled substances regulatory agency, who had won the support of the state medical society, only to have the bill opposed by drug stores and some pharmacy chains.

"As long as I'm in state government, we'll continue to try," Mr. Womble said.

In New Mexico last year, the state pharmacy board repealed regulations needed to operate a tracking system after complaints by pharmacists and doctors. The New Mexican system had operated for just two years, said Jerry Montoya, director of the state's pharmacy board.

Pharmacists say they worry about the cost of reporting prescription data. "How much burden do you want to put on pharmacies?" asked R. Dale Tinker, executive director of

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## *Prescription monitoring works in some places.*

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the New Mexico Pharmaceutical Association, which represents pharmacists.

For its part, Purdue Pharma said it was the only drug company that had publicly supported monitoring programs. The company has even offered to help explain the benefits of the systems to physicians.

But Purdue Pharma's support is not unqualified. In West Virginia this year, Purdue Pharma opposed a bill that would have allowed the state to single out a number of narcotics like OxyContin for monitoring.

"If you target just one drug, the illegal trade will just move to the next product that is not watched," said Alan Must, Purdue Pharma's national director of state governmental affairs.

West Virginia's Legislature quickly passed the bill, but it was vetoed by Gov. Bob Wise after doctors and pharmacists wrote him letters contending that the system would violate patients' privacy.

The veto dismayed many people, including William T. Douglass, exec-

utive director of the West Virginia Pharmacy Board. "We have a severe abuse problem in our state, and we have no way to track it," Mr. Douglass said.

Doctors in some states have begun to support tracking.

Lawrence P. Matheis, executive director of the Nevada State Medical Association, said physicians had helped design that state's system, which is often praised by experts as one of the best. By tracking how many doctors a patient visits, it discourages doctor shopping. So if a patient goes to 10 doctors for narcotic prescriptions, the state sends letters to all the doctors.

Keith W. Macdonald, executive secretary of the state's pharmacy board, said the program did not stop doctors from prescribing narcotics to people who needed them.

"A person can get three wheelbarrowfuls of drugs and we don't care," Mr. Macdonald said, "as long as they go to one doctor."

Some states have not started the programs because they believe the costs, which can reach hundreds of thousands of dollars a year, would exceed the programs' benefits. But supporters say the systems save taxpayers money in the long run because of the reduction in fraudulent Medicaid claims and in the cost of prosecuting drug crimes.

In some states, prosecutors are working on so many cases in which OxyContin has been obtained illegally through the Medicaid program that they refer to it as federally financed drug abuse. Medicaid patients can obtain a monthly supply of OxyContin pills for as little as \$1, then sell them on the street for thousands of dollars.

There is no way to know how many fraudulent prescriptions there might be. But public officials say that improper OxyContin prescriptions are costing the public millions of dollars.

Even in Kentucky, a state whose monitoring system is held up as a model, officials say the huge outbreak of OxyContin abuse there has made them realize they are going to have to strengthen the program.

Kentucky's program failed to detect early on that OxyContin was becoming a problem because its staff of three pharmacists were overwhelmed by routine work, said Danna Droz, a public health department official who oversees the monitoring effort.

Kentucky is now adding staff members and changing its operations so that it will better serve as an early warning system, Ms. Droz said. And that will please Kentucky law enforcement officials like Sheriff Duff, who says OxyContin remains a problem in Harlan County.

"The supply is decreasing, and it is harder to come by," Sheriff Duff said of the illegal OxyContin available on the streets. "But it's still coming in."

# The New York Times

NEW YORK, FRIDAY, FEBRUARY 9, 2001

## Cancer Painkillers Pose New Abuse Threat

By FRANCIS X. CLINES  
with BARRY MEIER

LEXINGTON, Ky., Feb. 8 — Harried police detectives in dozens of rural areas in Eastern states are combating what they say is a growing wave of drug abuse involving a potent painkiller prescribed for terminal cancer patients and other people with severe pain.

Illicit dealers have used suffering patients as well as fakers, the authorities report, to "doctor shop" to obtain the drug, OxyContin, for resale. Addicts favor the drug because they have learned to circumvent its slow time-released protection and achieve a sudden, powerful mor-

phine-like high.

OxyContin is often covered under health care plans. Police say that when dealt illicitly on the street it can cost as much as heroin or more. The abuse of the drug, which has been tracked over the last 18 months, has set off a wave of pharmacy break-ins, emergency room visits and arrests of physicians and other health care workers.

In addition to Kentucky, law enforcement officials have cited a troubling number of cases in Maine, Maryland, Ohio, Pennsylvania, Virginia and West Virginia.

"Heck, we already know it's pretty epidemic down here," said Capt. Minor Allen of the Hazard Police Department in southeastern Kentucky,

where federal, state and local police rounded up scores of purported dealers and users this week.

The authorities say dozens of deaths may be laid to OxyContin abuse, but this is strongly disputed by the manufacturer, Purdue Pharmacoel of Norwalk, Conn.

"Abuse of this drug has become unbelievable in the last year, with probably 85 to 90 percent of our field work now related to oxys," Captain Allen said, using street shorthand for the drug.

The drug's active ingredient is oxycodone, a morphine-like substance also found in drugs like Percodan

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and Tylox. But while painkillers like Tylox contain five milligrams of oxycodone and require repeated doses to achieve pain relief, OxyContin contains 40 to 160 milligrams in a time-released formulation that controls pain over a longer period. Chewing or crushing the prescription pill foils its time-release protection, delivering an instant potent euphoria. Once crushed, the drug can be snorted by addicts or dissolved for injection. And this new addiction has occasioned a telltale bit of fresh paraphernalia among teenage abusers, Captain Allen said.

"We find them carrying pill crushers that are sold in drugstores to help elderly people swallow their prescriptions," he noted of a growing drug culture in which the Perry County park has come to called Pillville.

The abuse first drew alarm in Maine 18 months ago in rural eastern areas not previously considered drug problems, Jay P. McCloskey, the United States attorney for Maine, said.

"What is most unusual and disturbing is the number of high school kids and those in the early 20's who got addicted," Mr. McCloskey said.

"We are talking about some of the best students, some of the best athletes," he said, noting that his small state was among the nation's largest consumers of OxyContin per capita.

In Kentucky, the problem became so urgent that Joseph L. Famularo, the United States attorney for the eastern district of the state, directed the roundup of 207 suspects this week

in Operation Oxyfest 2001, a nine-month investigation that produced the biggest drug-abuse raid in state history.

"I personally counted 59 deaths since January of last year that local police attributed to addicts using the drug, and I suspect that's pretty conservative," Mr. Famularo said, noting that cancer patients build a tolerance for the drug while a neophyte abuser may try it and be lethally stricken.

Mr. Famularo's number of deaths was disputed by the drug's maker, with Dr. J. David Haddox, medical director for Purdue Pharma, saying, "I'm concerned about inflammatory statements like that."

Dr. Haddox said that overdose deaths typically involved multiple factors like alcohol and that exaggeration of abuses might cause doctors to deny the drug to suffering patients.

Why so many current abuses seem focused across stretches of Appalachia and other rural areas is an open question. But the authorities note that the prevalence here of retirees and mining workers with health care plans and prescription cards invites exploitation of the elderly and others by illicit brokers.

There have been reports of dealing in New Orleans. But the authorities said there was no evidence of large-scale OxyContin abuse in major drug markets in New York or other urban areas. The authorities said one mark of the new addiction was its rootedness in areas that have had no previous heavy criminal drug traffic to compete against.

Dealers shop for doctors who may be busy, slipshod or quietly coopera-



Photographs by Associated Press

Sal Hernandez, assistant special agent in charge of the F.B.I in Kentucky, at left, announced in Lexington this week a crackdown on a new deadly drug. At right, Scott Hopkins, a Kentucky state police trooper, took into custody one of 200 people arrested on suspicion of dealing the drug.

tive, and then they obtain multiple prescriptions in several areas using the same ailing or not-so-ailing patients, the police say.

For their efforts, dealers realize a tenfold profit over the painkiller's prescription cost. Addicts have been paying about \$1 a milligram for the drug. The top of the line is a powerful 160-milligram tablet intended to work for up to 12 hours.

The authorities expressed little doubt that the abuse of OxyContin was spreading.

Sgt. Kerry Rowland of the Cincinnati police pharmaceutical diversion squad, said: "It's becoming the prescription drug of choice from greater Cincinnati to rural Ohio. It's become rampant because it offers such a pure high with less risk of arrest or overdose, and many times health

care is picking up the cost."

Sergeant Rowland said his squad's average arrests lately included one health care worker a week caught dealing in prescription drugs.

Another concerned area is the region surrounding Roanoke in southwestern Virginia. On Wednesday, 100 local, state and federal law enforcement officials met to discuss mounting overdoses, pharmacy break-ins and other problems associated with OxyContin abuse there, Robert Crouch, the United States attorney in Roanoke, said.

"The graph is spiking," Mr. Crouch said.

Rick Moorer, an investigator with the state medical examiner's office in Roanoke, said that in 1999 there were 16 deaths in southwestern Virginia attributable mainly to OxyCon-

tin in combination with other drugs or alcohol. There was just one such death in 1997, he said.

Federal data shows that while emergency room visits involving oxycodone remained stable from 1990 to 1996, such visits doubled from 3,190 in 1996 to 6,429 in 1999, the period that corresponds with OxyContin's introduction and marketing. That data indicated that deaths attributed to oxycodone products also grew in that period. Drug company officials insisted, however, that they had not been aware of any significant instances of OxyContin abuse until about a year ago when they began hearing the first news reports concerning the drug's abuse.

The new bulletin by the National Drug Intelligence Center warns that abuse of OxyContin appears for now

to be concentrated in the East. But officials said instances of abuse had surfaced as far west as California.

Chuck Miller, a spokesman for the intelligence center, said, "It's showing up elsewhere," and noted that the bulletin warned that continued abuse of OxyContin was likely.

Roy W. Hatfield, the police chief of Harlan, Ky., said: "In the last year, this drug has really shown up around here, pushing out all the old stuff, marijuana, barbiturates. People think it's a legal way to stay high. But now they're discovering how easy it is to get addicted."

Mr. Famularo, the United States attorney here, said his investigation would continue.

"We caught 207," he said. "We didn't catch half of them; that's how pervasive this thing is."

# The New York Times

NEW YORK, MONDAY, MARCH 5, 2001

## Sales of Painkiller Grew Rapidly, But Success Brought a High Cost

By BARRY MEIER  
and MELODY PETERSEN

Dr. Peter Leong recalls the day when he finally snapped at a drug company salesman pressing him to prescribe a powerful narcotic painkiller called OxyContin.

The drug's producer, Purdue Pharma, had already failed to persuade Dr. Leong with repeated offers of free weekend trips to Florida to discuss pain management. But when the salesman suggested that OxyContin — which is as potent as morphine — was safe enough to treat short-term pain, Dr. Leong exploded.

"We threw him out of my office," said Dr. Leong, who runs a pain clinic in Bangor, Me. He thinks OxyContin is potentially too dangerous to use for anything but chronic, severe pain. "OxyContin is a good drug," he said. "But the problem was, they were pushing it for everything."

If Dr. Leong was not a convert, many others were. In a little over four years, OxyContin's sales have hit \$1 billion, more than even Viagra's. Although the drug has helped thousands of people in pain, its success has come at a considerable cost. An official of the Drug Enforcement Administration said no other prescription drug in the last 20 years had been illegally abused by so many people so soon after it appeared.

OxyContin has been a factor in the deaths of at least 120 people, and medical examiners are still counting, according to interviews with law enforcement officials. And doctors like Dr. Leong, pharmacists and law enforcement officials say part of the problem is that Purdue Pharma often oversold OxyContin's benefits without adequately warning of its potential for abuse.

The company also used an often

MEDICINE MERCHANTS  
*Uses and Abuses*

criticized but increasingly common marketing strategy: currying the favor of doctors in private practice with free trips and paid speaking engagements. Purdue Pharma, based in Norwalk, Conn., paid the transportation and hotel costs for hundreds of doctors to attend weekend meetings in spots like Florida to discuss pain management, a company consultant said. Doctors were then recruited and paid fees to speak to other doctors at some of the 7,000 "pain management" seminars that Purdue sponsored around the country. Those meetings stressed the importance of aggressively treating pain with potent, long-acting painkillers like OxyContin.

Purdue also contributed to foundations supporting research on pain, to pharmacy schools and to Internet sites aimed at educating consumers.

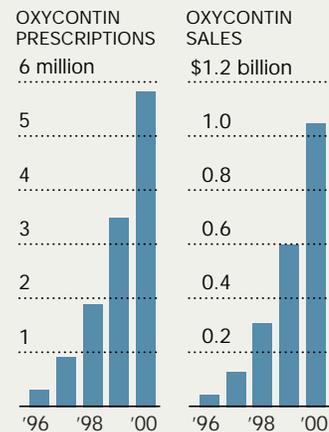
As OxyContin's marketing message spread, the drug caught on with many doctors who medical experts said had little experience in prescribing powerful narcotics. As a result, they often could not spot those who intended to abuse the drug or who did not need it in the first place.

OxyContin, introduced in December 1995, has offered patients something different: a tablet that slowly releases its powerful pain medication, permitting patients, for example, to sleep through the night. "It's a good drug in the right situation," said Dr. Art VanZee, a physician in St. Charles, Va.

Purdue officials say they have promoted the drug responsibly and would have disciplined any sales rep-

### Powerful Pills

The use of the potent painkiller OxyContin has grown substantially since its introduction in 1995.



Source: IMS Health

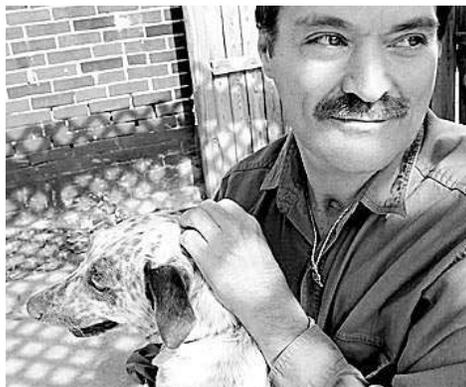
Continued on Page A15

The New York Times

representative who did not. They also said that in informing doctors about the drug, they told them how to spot potential drug abusers, and they have responded quickly to reports of spreading problems.

"We don't have strong medicines that don't have abuse potential," said Dr. J. David Haddox, the company's senior vice president for health policy. "What we have to do is walk the balance between helping the greater good, knowing there are always some people who will divert drugs."

Abuse and addiction involving OxyContin have spread quickly in the last two years, flaring up in at least a dozen states. And while the illegal use of OxyContin took root in rural areas along the East Coast, it has begun moving into cities like Philadelphia. "Nobody is immune from this," said Brantley Bishop, a narcotics investigator in Alabama. "I'm seeing housewives; I'm seeing loggers, nurses, mechanics."



Amber Wendt for The New York Times

'A MIRACLE' Robert E. Mitchell says OxyContin relieved pain so severe he could not walk. "It's like a miracle," he says.

OxyContin was originally thought to be less prone to abuse because its narcotic was locked in a time-release formula. That meant it would not produce the quick spike of euphoria that drug abusers crave. But abusers quickly discovered how to disarm the time-release formula; they simply crushed the tablet, then swallowed, inhaled or injected the powder to give themselves a high as powerful as heroin's.

Getting OxyContin was often easy. A person simply had to find the right doctor, claim great pain and get a prescription. Others just stole prescription pads and wrote their own.

Illegal use of OxyContin mushroomed even though no drug in this country is more tightly regulated. Unlike illegal drugs like cocaine or heroin, OxyContin is monitored by state and federal health officials in its production, marketing and distribution. Now, many of those regulators are trying to figure out how the outbreak occurred and what they might have done to prevent it.

The Food and Drug Administration, for one, is reassessing how it reviews prescrip-

tion narcotics for potential abuse. "We've learned something from this," said Dr. Cynthia McCormick, director of the F.D.A.'s division of anesthetics, critical care and addiction drug products. Dr. McCormick acknowledged that the F.D.A. had failed to research all the ways abusers might tamper with OxyContin, an oversight she said her agency did not want to repeat.

Last Thursday, officials of five states met in Richmond, Va., to discuss ways to halt illegal traffic in OxyContin. In recent months, Purdue has also stepped up its efforts to halt the drug's abuse, including working with law enforcement officials.

### Selling a 'Miracle' Drug

OxyContin came to market amid a sea change in how doctors treated pain. For years, terminally ill patients suffered needlessly because doctors resisted prescribing frequent, potent doses of narcotics, fearing that patients might become addicted.

But with new studies showing that doctors undertreated pain, OxyContin provided a breakthrough opportunity for Purdue Pharma. Until then, the company's biggest drug was MS Contin, which had limited appeal, partly because it contained morphine. OxyContin had broader appeal because it contained a synthetic version of morphine called oxycodone, which, among other things, carried less of a social stigma.

"If Grandma is placed on morphine it's like, 'Oh, my God,'" said Dr. Howard A. Heit, a pain specialist in Fairfax, Va., and a Purdue consultant. "But if Grandma comes home placed on OxyContin — that was O.K."

Although other pain medicine had long contained oxycodone, OxyContin differed in two key respects: it had a time-release formula, and it could be delivered in larger doses because it did not contain the type of nonprescription pain relievers that in larger quantities could cause liver damage.

The F.D.A. approved OxyContin for those with moderate to severe pain lasting more than a few days.

OxyContin is often prescribed for people in chronic pain, like those with back problems or severe arthritis, as well as patients with cancer and other painful diseases.

For Robert E. Mitchell, OxyContin proved nothing short of a wonder drug. A victim of Guillain-Barré syndrome, a rare nerve disorder that can cause paralysis, Mr. Mitchell said his pain had become so severe he could not walk. But with OxyContin, he can now wear shoes and has learned to walk again.

"To me, it's like a miracle," he said.

Seeing great potential in the drug, the company hatched an ambitious marketing plan. To reach consumers, Purdue financed an Internet site called Partners Against Pain, where OxyContin is promoted. It also contributed to groups like the American Pain Foundation, which championed the need for better pain treatment.

Still, most of Purdue's marketing dollars were aimed at doctors. In recent years, Purdue brought in 2,000 to 3,000 doctors to three-day retreats in California, Arizona and Florida, estimated Dr. Heit, the Purdue consultant. At those meetings, doctors were

lectured about treating chronic pain, while being recruited to serve as paid speakers at medical meetings sponsored by Purdue.

Dr. Susan Bertrand, who treats chronic pain in Princeton, W. Va., became a Purdue speaker. She said that for her, recent studies showing the undertreatment of pain had been "almost a religious experience," making her realize how poorly she and others had been trained to deal with the problem.

To help change that, she said, she gave about a dozen paid speeches sponsored by Purdue. The company also helped her start the Appalachian Pain Foundation, an educational group on pain management.

Purdue's marketing campaign quickly began to pay big dividends, with OxyContin sales almost doubling every year, according to IMS Health, a firm that tracks drug sales. OxyContin now earns more in sales than any other narcotic. It also now accounts for 80 percent of Purdue Pharma's revenue, according to court documents filed by Purdue in connection with a patent dispute.

Some doctors and pharmacists said they were put off by the company's sales tactics.

"All companies market," said Dr. Diane Meier, a pain specialist at the Mount Sinai School of Medicine in New York. "But these people were in your face all the time."

Others criticized the way Purdue recruited doctors. "Essentially, they bought the doctors' prescriptions," said Steve Schondelmeyer, a professor of pharmaceutical economics at the University of Minnesota. "It says to consumers that every time you paid for this drug, you sent your doctor to a nice meeting somewhere."

### A Growing Concern

Purdue Pharma's critics agree that doctors must learn how to manage pain better. But Dr. Ted Parran, an associate professor at Case Western Reserve University School of Medicine in Cleveland, says doctors, in their rush to find a remedy, may have been blinded to another problem: addiction.

"Pain medicine docs are on a mission," said Dr. Parran, who teaches doctors how to use narcotics. "In the process, they tend to trivialize addiction."

In this regard, pharmacists play an important backup role for doctors. They provide the last medical defense for preventing addictive drugs from getting into the wrong hands. For instance, they can choose not to fill suspect prescriptions.

Some pharmacists said they, too, found Purdue's safety claims overblown.

John Craig, a co-owner of Hancock's Drug Store in Scottsburg, Ind., remembers a Purdue salesman walking into his pharmacy several years ago with reassurances that OxyContin was safer than other narcotics.

"They were going around to doctors promoting that this was the answer to all abuse," said Mr. Craig, but he already knew that local people were using OxyContin to get high. Since then, the abuse has become worse.

Another pharmacist, Samuel A. Okoronkwo, refused to fill an OxyContin prescription for someone he thought might be an abuser. He said a Purdue salesman sug-

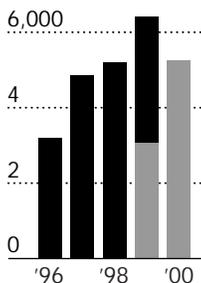
## More Availability, More Abuse

Oxycodone, the active ingredient in the pain medicine OxyContin, is available in different forms. But, since 1995, when OxyContin went on the market, problems involving oxycodone have grown sharply.

### EMERGENCY ROOM VISITS

Visits where oxycodone was mentioned

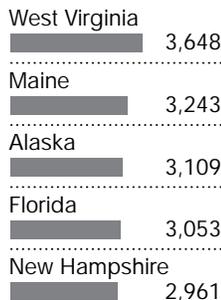
■ FIRST SIX MONTHS



### OXYCONTIN USE, BY STATE

Highest avg. per capita consumption

GRAMS PER 100,000 PEOPLE



Associated Press

Sources: Drug Abuse Warning Network; Drug Enforcement Administration

The New York Times

gested he could get into trouble for arbitrarily not filling prescriptions. "I told him I didn't have to fill a prescription that I didn't feel was medically necessary," he said.

Another druggist, Joseph Yates in Grundy, Va., said simply, "The problem with this drug is the company."

Purdue did not comment when asked about such anecdotes.

Concern about Purdue's marketing prac-

tices has also reached the D.E.A. An agency official said its investigators had recently interviewed doctors and druggists about their dealings with Purdue.

That official said the agency was worried that Purdue was not clearly communicating the drug's serious potential for abuse. "It may take years to repair the damage that this drug has done," said that D.E.A. official, who declined to be identified.

Told of the D.E.A. comment, Purdue responded with a statement that said in part: "In 15 years of marketing narcotic analgesics, Purdue Pharma has never been questioned by the Drug Enforcement Administration regarding our marketing practices."

In May, however, the F.D.A. did question a company advertisement for OxyContin, saying Purdue had improperly implied that OxyContin could be used to treat arthritis patients without first trying milder drugs. A company spokesman said that it disagreed with the F.D.A. but had voluntarily withdrawn the ad.

Dr. VanZee, in St. Charles, Va., has seen the destruction the drug has caused in the valleys and small mining towns of the southwestern part of that state. He said he was treating OxyContin overdoses in youngsters

he had vaccinated as infants.

In the past two years, OxyContin has been a factor in the overdose deaths of 28 people in the area, said an official of the state medical examiner's office. It is difficult to tell the precise cause of an overdose, however, because more than one drug is often involved and OxyContin's active ingredient is in other drugs.

One area clinic, the Life Center of Galax, expected to treat 20 patients in its new methadone program but must now find a way to treat 300, most of them addicted to OxyContin, a clinic official said.

To stem this abuse, Dr. VanZee said, he met last fall with Purdue representatives in a bid to persuade them to cut back on their marketing and to issue a nationwide alert about the drug's hazards. The officials, Dr. VanZee said, appeared sympathetic, but said they viewed the problem as being limited to just a few areas of the country.

"They are either very naive about the extent of the problem," Dr. VanZee said, "or they don't understand what it means to have 300 people in your county addicted — the type of pain that causes in a community and in families."

## Addressing the Problem

Purdue officials said they were as surprised as anyone that OxyContin could be abused. Dr. Haddox of Purdue said he thought the time-release formula would make the pill "less desirable to addicts."

That is not the case now. Last September, the company gathered 20 consultants to look for better ways for doctors to spot potential abusers, said Dr. Heit, the consultant. Four months later, Purdue asked its sales force to remind doctors that drugs like OxyContin "are common targets for both drug abusers and drug addicts."

Purdue said it was now planning to reformulate OxyContin, making it less appealing to abusers. The company is also helping to educate students on the dangers of prescription drugs.

Moves like this have recently earned the company praise from some law enforcement officials.

Some health officials think OxyContin abuse might have been more quickly identified had more states closely tracked the prescribing patterns of narcotics; some 17 states do that now.

Hospitals are addressing the problem in different ways. Mercy Hospital in Portland, Me., gives OxyContin patients urine screens to verify that they are not taking too much, or that they are obtaining the drug but not taking it and then selling it on the street.

A Cincinnati-based hospital chain, the Health Alliance, decided last month to limit OxyContin to just a few types of patients, like those with cancer, after determining that another painkiller was just as effective, cheaper and less prone to abuse.

Purdue Pharma — and some doctors — now worry that media reports on OxyContin abuse are scaring away patients who need the drug. "The publicity, of which you are a part, is causing patients to call us in tears because their physicians are taking them off therapy," said Robin Hogen, a company spokesman. "This is becoming a sad case of patients being abused by drug abusers."

## Three Founders Of Purdue Pharma

Unlike many drug companies that are publicly traded, Purdue Pharma is privately held and part of a network of concerns founded by three brothers, Arthur, Mortimer and Raymond Sackler, all of whom were trained as research psychiatrists and have illustrious ties to the arts and sciences.

A wing of the Smithsonian Institution in Washington bears the name of Dr. Arthur M. Sackler, who died in 1987. He and his brothers also financed a wing at the Metropolitan Museum of Art that houses the Temple of Dendur. In 1995, Dr. Raymond R. Sackler was knighted by Queen Elizabeth in recognition of his contributions to the sciences, arts and astronomy.

The company is now run by the son of Dr. Raymond Sackler, Dr. Richard Sackler, a surgeon who has served as a director of the foundation of the American Medical Association. A Purdue Pharma spokesman declined to make the Sackler family members available for interviews.

## Medicine Merchants

Earlier articles in this series have examined the financing of a blockbuster drug, how lower-costing generic drugs can be kept off the market, alliances between drug companies and patient groups and the production of inexpensive copycat drugs in nations like India.

Articles in this series will remain available at The New York Times on the Web:

<http://www.nytimes.com/drugs>



Bob DeLong/Bangor Daily News

**ILLEGAL USES** OxyContin can be crushed, above, to destroy its time-release function. Abuse has caused overcrowding at a methadone clinic in Virginia, left, where an OxyContin user is treated.



Ted Richardson for The New York Times

# U.S. Asks Painkiller Maker To Help Curb Wide Abuse

By BARRY MEIER

Federal officials have urged the maker of a widely abused narcotic painkiller to limit how it distributes and markets the drug, which has played a role in more than 100 fatal overdoses in several states.

Federal officials have also been in talks about withdrawing or modifying a claim that the painkiller, OxyContin, may be less prone to abuse than similar narcotics.

The moves come as the officials at the Drug Enforcement Administration start what they describe as the agency's first effort to curb misuse of a specific prescription drug. Previously, the agency had sought to reduce abuse of classes of drugs, but officials of the drug enforcement agency said the abuse problem involving OxyContin was so grave that it required unique action.

Terry Woodworth, a top official at the agency, said it was concerned that the promotion and distribution of OxyContin by its manufacturer, Purdue Pharma L.P., to doctors like general practitioners might have led to its wide misuse. The government has said that no prescription drug in the last 20 years has been so widely abused so soon after its release as OxyContin.

Mr. Woodworth said the agency had recently asked Purdue officials to volunteer to limit the drug's distribution to only those specialists who regularly treat patients for chronic or severe pain.

"D.E.A. is extremely concerned that many doctors are prescribing this strong narcotic as an initial treatment for many types of pain and that is a result of how it has been promoted," said Mr. Woodworth, the deputy director of the agency's office of diversion control.

In a statement responding to questions, officials of Purdue, which is based in Stamford, Conn., acknowledged the agency's request but declined to elaborate on how the company would respond.

"We expect to have ongoing, constructive dialogue with the D.E.A. on this subject," the statement said. "We do not think it would be appropriate to go into any specifics at this time."

Separately, Purdue officials have said they have taken voluntary steps

in the past year to combat abuse of OxyContin and are working to reformulate the product.

OxyContin, which was approved by the Food and Drug Administration in late 1995 for treating moderate or severe pain, is the leading narcotic painkiller sold in tablet form in the United States. Last year, its sales in this country exceeded \$1 billion.

Medical authorities and law enforcement officials agree that the drug can be highly effective in treating severe or chronic pain because its time-released form enables its active ingredient to work over many hours. It was first thought that such slowed release would deter illicit use of the drug because abusers prefer the quick euphoric rush that immediately released narcotics provide.

But in just a few years, abuse of OxyContin has become rampant, officials say. The treatment's users quickly discovered that they could defeat the time-released design by crushing or dissolving the tablet. That gave them immediate access to the drug's active ingredient, a synthetic form of morphine called oxycodone, which could then be snorted or injected.

Abusers and others have also been able to obtain OxyContin by going around to doctors and feigning pain. Experts have said that many family doctors and general practitioners have little experience in spotting drug abusers or monitoring how their patients use narcotics.

In recent years, OxyContin has been a factor in more than 120 drug overdose deaths, the authorities report. Communities in Maine, Kentucky and Virginia have been devastated by crime waves involving OxyContin addicts. The treatment has an extremely high street value of a dollar a milligram; a single 40-milligram pill would cost \$40.

Purdue, a privately held company, has aggressively marketed the drug in recent years by paying the hotel and travel expenses of hundreds of doctors who attended weekend "pain management" seminars in vacation spots like Florida.

The company has also held roughly 7,000 seminars around the country for doctors, including many general practitioners, that advocated the use of powerful long-lasting narcotics

like OxyContin in pain treatment.

Purdue officials say they have responsibly marketed and promoted OxyContin. In addition, they say they have moved swiftly to combat misuse of the drug, which they say has brought relief to thousands of patients who otherwise would suffer needlessly.

Also, the company said, in Decem-



Associated Press

Wide abuse of OxyContin has left a trail of death, officials say.

ber it stopped sponsoring trips to seminars for doctors, after the United States attorney's office in Maine, where numerous cases of OxyContin abuse have occurred, asked it to stop doing so.

Mr. Woodworth of the drug enforcement agency said it was still trying to determine what percentage of OxyContin prescriptions were medically necessary. But he emphasized that the agency did not want to prevent those who needed the drug from getting it.

He added, however, that the agency believed the drug had been frequently prescribed by doctors who could have recommended less powerful drugs before turning to OxyContin. He said he believed that part of the reason doctors prescribed OxyContin so readily was their belief that it was less prone to abuse.

"Your family practitioner and pediatrician don't have a speciality in the treatment of chronic and severe pain," Mr. Woodworth said. "When you couple that with the marketing that the drug is less prone to abuse, you have contributed to some of the problems here."

Officials of both Purdue and the F.D.A. declined to comment on any contemplated changes to the product's labeling, citing the confidentiality of discussions between the agency and the companies it regulates.

# *Maker Chose Not to Use A Drug Abuse Safeguard*

## *Company Says It Didn't Anticipate Problems*

By BARRY MEIER

The maker of the widely abused narcotic painkiller OxyContin knew that other companies had used a chemical safeguard to reduce misuse of their products but decided not to take similar steps before marketing the drug, company officials said yesterday.

Officials of the manufacturer, Purdue Pharma, said in statements over the weekend that they had not expected abusers to crush the powerful drug and then inject or snort it so they had not initially considered adding a compound that blocks the drug's narcotic effect when it is taken those ways.

Over the last two years, OxyContin has been cited as a factor in more than 100 overdose deaths nationwide, and people desperate for the drug have been involved in pharmacy robberies and other crimes.

Last week, Purdue Pharma said that it was working to develop a painkiller like OxyContin that would also contain a compound to combat abuse. These narcotic antagonists do not affect a drug if it is taken normally. But if an abuser crushes a drug tablet and injects or snorts the powder an antagonist will block its opiate effect and reduce its appeal.

The company, based in Stamford, Conn., said it would probably take three to five years to develop and test the new drug. Antagonists work by blocking receptors in the brain that are also used by opiates.

"This is very time-consuming research for which there is no road map," Purdue officials stated in response to a series of written questions from The New York Times.

But in interviews last week, some drug-abuse experts were critical of Purdue, saying that the company could have initiated such action earlier and that its projected timetable would do little to immediately address OxyContin abuse.

"This should have dawned on them before," said Terry Woodworth, the deputy director of the division of diversion control at the federal Drug Enforcement Administration.

Purdue officials said they had hoped to avert OxyContin misuse by encapsulating its active narcotic, a

compound called oxycodone, in a time-released formula. The company said it believed that by doing so it would make the drug less appealing to abusers who wanted a quick high.

But even before OxyContin was first sold in 1995, some companies found that some of their products had become popular with drug abusers, and a few manufacturers moved promptly to reformulate those products with antagonists.

In 1983, for instance, Winthrop Laboratories, which was then a subsidiary of Sterling Drugs, added naloxone, an antagonist, to Talwin, one of its pain relievers. Some people were abusing Talwin by crushing the drug, adding an antihistamine and injecting the mixture.

"This seemed to help," said Dr. Sharon Jacobs, the senior medical director at Sanofi-Synthelabo, which acquired Sterling. "It decreased the abuse."

Another manufacturer, Reckitt Benckiser Pharmaceuticals, which makes buprenorphine, another painkiller, also added naloxone when the drug became abused in New Zealand in the 1980's, said Charles O'Keeffe, the president of the company. As with Talwin, abuse of the compound quickly dropped.

A German manufacturer also took similar steps when one of its products was abused, Mr. O'Keeffe said.

Experts said it took about a year or less to reformulate both Talwin and buprenorphine. Mr. Woodworth, the D.E.A. official, said he was troubled by Purdue's timetable.

"The reformulation is a good initiative," said Mr. Woodworth. "But completing it four years out is not helpful in addressing the immediate diversion problems which are rapidly increasing."

Purdue officials said they knew about naloxone's use in drugs like Talwin before the company began selling OxyContin in 1995, but they did not anticipate the ways in which the drug would be abused.

The company officials said naloxone was not a suitable antagonist for oxycodone, the active narcotic in OxyContin, for a variety of technical and medical reasons. It could, for example, produce withdrawal symp-

toms in patients receiving high levels of oxycodone, the officials said. As a result, they said, Purdue has decided to use a different but related substance called naltrexone in a new drug they hope to develop.

They called their timetable "aggressive," given the lack of previous work in combining naltrexone and a narcotic in the same tablet.

"We have been working in an area of basic research for which there is little scientific literature or prior experience," the company said. "We will have to enroll approximately 2,000 pain patients in a series of clinical trials, which will take years to complete."

Naltrexone has a history of use. Over the last two decades it has been used with varying success in different countries as a substitute for methadone in the treatment of drug addicts.

Dr. Joseph R. Volpicelli, the director of the treatment program at the University of Pennsylvania Medical Center in Philadelphia, said the effort failed in this country because heroin addicts preferred methadone to naltrexone. It has had far more success in the treatment of alcohol dependence, Dr. Volpicelli said.

He said that the principal difference between naloxone and naltrexone was that naltrexone was a longer-acting drug. That would appear to make it a better choice for OxyContin, which is a slow-acting, time-released medication.

Some addiction experts said they believed that all narcotics manufacturers should consider adding antagonists to their products, given the drug industry's experiences with Talwin and OxyContin.

"You have drug makers complaining all the time about overregulation," said Dr. Theodore V. Parran Jr., an associate professor at Case Western University School of Medicine. "But gosh, there are some really simple things they can do to decrease diversion."

Dr. Parran, who specializes in training doctors in how to properly dispense narcotics, said corporate profits might be at the root of any resistance to such change.

"People would have lower sales because addicts won't want the drug," he said. "But the sales they would be left with would be real."

Purdue officials said they planned to submit any new painkiller that includes naltrexone to the Food and Drug Administration for approval. The agency has an expedited process of six to ten months under which a manufacturer can seek permission for changes to approved drugs without extensive clinical trials.