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Narcotic Maker Guilty of Deceit Over Marketing

By [BARRY MEIER](#)

ABINGDON, Va., May 10 — The company that makes the painkiller [OxyContin](#) and three of its current and former executives pleaded guilty Thursday in federal court here to criminal charges that it had misled doctors and patients when it claimed the drug was less likely to be abused than traditional narcotics.

The company, Purdue Pharma, agreed to pay \$600 million in fines and other payments to resolve the criminal charge of “misbranding” the product, one of the largest amounts ever paid by a drug company in such a case.

The three executives, including its president and its top lawyer, also pleaded guilty to misdemeanor charges of misbranding the drug. Together, they agreed to pay \$34.5 million in fines.

The guilty plea — by Purdue Frederick, an affiliate of Purdue Pharma — is the latest of a number of cases brought by the Justice Department against pharmaceutical makers that accuse them of misbranding, a broad statute that makes it a crime to put false or misleading information about a drug on its label or in ads, or to promote it for unapproved use.

Another company, [Bristol-Myers Squibb](#), pleaded guilty Thursday to making false statements to the government involving its anti-clotting medicine Plavix. [Page C3.]

The Purdue plea underscores the growing pressure on the drug industry over its marketing. On Wednesday, the Senate passed a bill to give the [Food and Drug Administration](#) power to oversee drug advertising and labels, and to restrict the distribution of risky medicines.

OxyContin is a powerful, long-acting narcotic that provides relief of serious pain for up to 12 hours. Initially, Purdue Pharma contended that OxyContin, because of its time-release formulation, posed a lower threat of abuse and addiction to patients than traditional, faster-acting painkillers like Percocet or Vicodin.

That claim became the linchpin of an aggressive marketing campaign that helped the company sell over \$1 billion worth of OxyContin a year.

Purdue Pharma, based in Stamford, Conn., heavily promoted OxyContin to doctors like general practitioners, who often had little training in treating serious pain or in recognizing signs of drug abuse.

But experienced drug abusers and novices, including teenagers, soon discovered that chewing an OxyContin tablet — or crushing one and then snorting the powder, or injecting it with a needle — produced a high as powerful as heroin. OxyContin is a pure, high-strength version of a long-used narcotic, oxycodone.

By 2000, parts of the United States, particularly rural areas, began to see soaring rates of addiction and crime related to use of the drug.

At a news conference Thursday in Roanoke, Va., John L. Brownlee, the United States attorney for the Western District of Virginia, said the impact of Purdue’s marketing of OxyContin had resulted in rising crime rates, teenage drug addiction, deaths and other problems.

“The results of Purdue’s crimes were staggering,” he said.

In a statement, the company said the three executives were not aware of the wrongdoing by other company employees. Misdemeanor charges of “misbranding” can be brought against corporate executives even if they are unaware of such crimes.

The three men — Michael Friedman, the president; Howard R. Udell, its top lawyer; and Dr. Paul D. Goldenheim, its former medical director — led Purdue at the time of the crimes.

The developments marked a sharp reversal for Purdue Pharma, a privately held company. Its executives had defeated hundreds of lawsuits from patients claiming that they became addicted to OxyContin. They also rebuffed critics, including some in Congress, who said that the company’s aggressive marketing of OxyContin may have spurred its abuse.

The company’s defenders included the former New York mayor, [Rudolph W. Giuliani](#), whose firm was hired in 2002 by Purdue Pharma as part of a crisis management strategy and to improve security at its manufacturing plant.

More recently, Mr. Giuliani, acting as a lawyer for Purdue, took part in several meetings last year between Justice Department officials and defense

lawyers for the company and individual executives.

Melanie Hillis, a spokeswoman for the Bracewell & Giuliani law firm, which is based in Houston, said that Purdue Pharma was a client of the firm. She said Mr. Giuliani had not been involved in representing the company for several months.

The company and the three executives pleaded guilty at a small courthouse in this small city at the edge of Appalachia, a region where OxyContin abuse became so widespread that the drug was dubbed “hillbilly heroin.” Mr. Brownlee and other prosecutors decided to investigate Purdue Pharma after bringing cases against drug addicts as well as local doctors accused of illegally prescribing the drug.

“I think we had a responsibility to bring cases against everyone who was making money,” Mr. Brownlee said.

The crimes to which the company and its executives pleaded guilty took place between late 1995, when the federal Food and Drug Administration approved OxyContin for sale, and mid-2001, when Purdue Pharma, facing public criticism and regulatory scrutiny, dropped all “reduced-risk” claims related to the drug.

During that period, OxyContin produced \$2.8 billion in revenue for Purdue Pharma.

Federal officials said that internal Purdue Pharma documents showed that company officers recognized that, even before the drug was marketed, they would face stiff resistance from doctors concerned about the potential of a narcotic like OxyContin to be abused by patients.

As a result, prosecutors charged, the company effectively started a fraudulent and deceptive marketing campaign aimed at convincing doctors that OxyContin, because of its time-release formula, was less prone to abuse, and that it was less likely to cause addiction or to produce other narcotic side effects than competing drugs. In its plea agreement, the company acknowledged doing so.

“We accept responsibility for those past misstatements and regret they were made,” the company said.

According to prosecutors, some Purdue Pharma supervisors and employees used fraudulent techniques to promote OxyContin to doctors.

For instance, when the painkiller was first approved, F.D.A. officials allowed Purdue Pharma to state the time-released nature of a narcotic like OxyContin “is believed to reduce” its potential to be abused.

But some Purdue sales representatives falsely told doctors that the statement meant that OxyContin was less likely to lead to addiction or abuse than traditional, fast-acting painkillers like Percocet.

In addition, some company sales officials gave doctors misleading scientific charts to support such fraudulent claims. Also, Purdue Pharma trained its sales representatives on how to overcome concerns by doctors that OxyContin could be easily abused, according to the transcript of a training tape made for Purdue Pharma sales official that was released by Mr. Brownlee.

Purdue Pharma also knew, prosecutors charged, that large quantities of oxycodone could be easily extracted from OxyContin so the drug could be intravenously injected by drug addicts.

Of the \$600 million in payments, Purdue Frederick will pay \$470 million in fines and payments to a variety of federal and state agencies.

It also agreed to pay at least \$130 million to resolve civil lawsuits brought by pain patients who claimed they became addicted as a result of having OxyContin prescribed to them. A lawyer for one company executive said that much, if not all, those funds have been paid out in the process of settling lawsuits. There are still claims against the company by private plaintiffs.

This week, Purdue agreed to pay \$19.5 million to 26 states and the District of Columbia to settle complaints that it encouraged physicians to overprescribe OxyContin.

Some drug industry critics said Thursday that while the fines sent an important message, the amounts were far too low, given the vast profits from OxyContin sales and the problems caused by the drug.

“The damage to the public from these white-collared drug pushers surely exceeds the collective damage done by traditional street drug pushers,” Dr. Sidney Wolfe, the director of the health research group at [Public Citizen](#), an advocacy group in Washington, said.

Mr. Friedman, Purdue’s president, agreed to pay \$19 million in fines; Mr. Udell, its lawyer, \$8 million; and Dr. Goldenheim, \$7.5 million. A Purdue Pharma spokesman said that Mr. Friedman planned to leave the company this year but that his departure was not related to his guilty plea.