OxyContin manufacturer reaches $600 million plea deal over false marketing practices

Naomi Spencer
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On May 10, federal prosecutors announced fines and a plea agreement against OxyContin producer Purdue Pharma for illegally "misbranding" its powerful narcotic painkiller as less addictive than it actually was and deliberately misleading regulators, doctors and patients about the drug's risks. The company was fined $600 million in criminal and civil penalties in conjunction with the felony charge.

OxyContin is a strong narcotic pain relief medication that was introduced to the market in 1996 and prescribed to millions of chronic pain sufferers. In its manufactured pill form, OxyContin releases the powerful and long-used painkiller oxycodone.

With the approval of the federal Food and Drug Administration, Purdue Pharma marketed its pill as less addictive because of its time-release formulation without conclusive evidence. According to a May 10 *New York Times* report by Barry Meier, the FDA allowed the company to publicize that the time release of OxyContin was "believed" to reduce its potential for abuse.

Purdue claimed OxyContin produced "fewer peaks and valleys than with immediate-release oxycodone," and that "delayed absorption as provided by OxyContin Tablets is believed to reduce the abuse liability of the drug." Purdue Pharma dispatched sales representatives who falsely told healthcare providers that the statement was not simply a theory. Company sales officials reinforced the claim by fabricating phony scientific charts.

Documents filed by prosecutors in the Abingdon, Virginia, District Court demonstrated various other tactics Purdue used to mislead the medical community. For example, sales representatives falsely told physicians that OxyContin produced less euphoria and was thus less prone to abuse, and that because of this, the drug could help "weed out" recreational drug users. Doctors were falsely told it was less addictive than opiates, morphine or the notoriously abused painkillers Percocet and Vicodin.

The company also touted a study suggesting that patients taking less than 60 milligrams of OxyContin a day (the standard 12-hour dose pill contains 40 milligrams) could quit with no withdrawal. However, the company suppressed part of the study's results after 11 patients in the study went into withdrawal. Purdue buried this because, the company said, the results would only "add to the negative press."

In addition to the $600 million fine levied against the company, three top executives, who pleaded guilty to misdemeanor charges of being liable for company policy in misleading regulators, the public and doctors about the risk of addiction, were fined a combined total of $35 million.

Purdue Pharma president and chief executive officer Michael Friedman agreed to pay $19 million. Friedman announced his retirement May 11, although the company's spokesperson said the court ruling had nothing to do with the decision.

In addition, Purdue Pharma's top lawyer, Howard Udell, was fined $8 million. Former company medical director Paul Goldenheim agreed to pay $7.5 million. A company statement announcing the guilty pleas declared: "Mr. Friedman, Dr. Goldenheim (while at Purdue) and Mr. Udell neither engaged in nor tolerated the misconduct at issue in this investigation. To the contrary, they took steps to prevent any misstatements in the marketing or promotion of OxyContin and to correct any such misstatements of which they became aware." None face prison time.

While the fines are among the largest ever levied against a pharmaceutical firm, the figure represents less than half of Purdue Pharma's annual OxyContin sales. Between its market debut and 2006, the company grossed more than $10 billion in sales for the medication, which accounts for the overwhelming majority of total company sales. According to *Drug Topics*, a pharmacy publication, OxyContin generated $9.5 billion in US retail sales between 2000 and 2006.

Sidney M. Wolfe, M.D., director of consumer advocacy group Public Citizen's Health Research Group, asked prosecutor John Browlee on the PBS "NewsHour" program May 11, "Why hasn't anyone gone to jail? Even if those three didn't have evidence for going to jail, who are the other people in the company that actually intended to do this?" Wolfe added, "And, secondly, why wasn't the fine much higher? Why was it just a fraction of the profits they made just off of this drug?"

Brownlee answered that investigations were unable to link the misbranding to the decisions of individuals. Instead, he said, prosecutors found "a corporate culture that allowed this product to be misbranded with the intent to defraud and mislead." This rotten culture is by no means unique to Purdue Pharma; to the contrary, deception and data suppression are ubiquitous in the pharmaceutical industry.

The court decision is the latest in a long line of legal rulings on the drug's safety. In 2004, a federal District Court panel of judges in Manhattan found Purdue Pharma guilty of deliberately misleading federal officials in order to retain exclusive patents and prevent cheaper generic versions of OxyContin from hitting the market.

Purdue representatives told the United States Patent Office that OxyContin was unique because 90 percent of patients were relieved of pain by a steady release of 10 to 40 milligrams from the pills, and implied that the company had clinical data to support the claim. However, the medication's inventor admitted in court that such data did not exist, and company documents from as early as 1993 showed that Purdue executives knew this.

The court found Purdue Pharma's "inequitable conduct" and nondisclosure of negative information about the drug invalidated the patent. A year later, a federal appeals court ruled the company deliberately misled the government. At the same time, Purdue Pharma settled a civil case brought by its insurer for $200 million.

Also in 2005, the company defeated a lawsuit brought by a former Purdue sales representative, who had charged she had been fired for refusing to illegally market OxyContin to doctors. She alleged that the company instructed sales representatives to pressure doctors into prescribing high doses of the drug for patients without scientific evidence that it was more effective or safe.

Purdue scuttled scores of other civil suits brought by patients and families of overdose victims, who claimed the company bore responsibility for addictions and deaths. Many of the cases originated in Virginia, West Virginia and Kentucky, where OxyContin was a factor in hundreds of accidents, robberies and fatalities. OxyContin abuse has been linked to hundreds of deaths and thousands of arrests since 2000. In some economically depressed Appalachian counties, crime rates doubled on OxyContin abuse and aggressive police raids.

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Where was the federal government throughout these controversies?

In 2003, the FDA sent a warning letter to Purdue about its illegal marketing campaign. The FDA also accused the company of overstating OxyContin's safety profile by not acknowledging the large number of deaths associated with the drug.

In response to the company's guilty plea last week, associate commissioner for FDA regulatory affairs Margaret Glavin said, "[The] FDA will not tolerate practices that falsely promote drug products and place consumers at health risk," and that the agency "will continue to do all we can to protect the public against drug companies and their representatives who are not truthful and bilk consumers of precious health care dollars."

Considering that the FDA has no authority to impose penalties for violations by pharmaceutical companies, these assurances do not carry much weight. Currently, the agency negotiates with pharmaceuticals over drug marketing tactics, using approval status as leverage. This has little to do with the actual science of medicine development, and how the public is affected by a drug that has federal approval.

The bill most recently passed by Congress, the FDA Revitalization Act, would require that the FDA monitor drugs after they are approved for sale, and would require companies to make many of their internal drug-testing studies public. The Act, if signed into law, would also give the FDA the authority to order—as opposed to request—new studies and label changes. Companies could be required to develop management plans for drugs that have dangerous risks or side effects, and to clearly explain the risks in advertising. Finally, the bill would establish a process by which companies could contest proposed restrictions on drugs, but would give the FDA the final decision.

All of these provisions would ostensibly strengthen the ability of the agency to regulate the drug industry. Whether the agency actually intends to impose regulation on pharmaceuticals, however, is another matter. As Public Citizen's Health Research Group Deputy Director Peter Lurie noted, the Act would also reauthorize a system of user fees established in 1992, whereby drug companies pay the FDA for review of products. The agency is dependent on these fees in lieu of grossly inadequate federal funding.

"The larger problem is that the user fees themselves are an inappropriate way to fund the agency." Lurie told *HealthDay* news service May 10, "We can't have an agency that is dependent for 50 percent of funds for its reviewing functions from the industry it's reviewing. Why it is that we have to put ourselves in this untenable conflict of interest for a function so critical as drug review I just don't understand."

As the Vioxx scandal in 2004 underscored, the dangers posed by conflict of interest to the public are enormous. The FDA knew that Merck's arthritis painkiller drastically increased the risk of heart attacks for years, but could not issue new regulations on the drug and sought to suppress warnings from whistle-blowers within the agency, even after at least 38,000 Vioxx patients had heart attacks.

Besides the conflict of interest inherent in the fees system, pharmaceutical companies will be given federal incentives to comply under the Act, and the maximum fine the FDA could impose for a company's noncompliance would only be $2 million. For companies like Purdue Pharma or Merck, this is a negligible fine that would do little to seriously disrupt a fraudulent marketing campaign.