

OxyContin Manufacturer, Executives Plead Guilty to Drug Misbranding

In-House News:

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Three former and current executives of Purdue Pharma, LP, the maker of OxyContin, pled guilty to misdemeanor charges of drug misbranding on May 10, acknowledging that they deceived consumers about the risks associated with the drug. Michael Friedman, the company's president, Howard Udell, Purdue's principal lawyer, and Paul Goldenheim, the company's former chief medical officer, will pay \$634.5 million in fines for alleging that OxyContin had a lower incidence of abuse and addiction than the drug's competitors, according to United States Attorney John Brownlee.

"With its OxyContin, Purdue unleashed a highly abusable, addictive, and potentially dangerous drug on an unsuspecting and unknowing public. For these misrepresentations and crimes, Purdue and its executives have been brought to justice," Brownlee said.

State and federal agencies began to investigate Purdue Pharma in 2002, even subpoenaing company records.

Brownlee explained, "From these millions of records, they picked out probably 300 to 500 documents and pieced together a case."

The plea deal is yet another juncture in the drug's legal history. Two days prior to the agreement, Purdue Pharma, LP, said it would pay \$19.5 million to resolve allegations that it persuaded physicians to overprescribe OxyContin in 26 states across the United States, as well as the District of Columbia.

The addictive side effects of OxyContin were discovered by the company in 1995 when physicians in focus groups voiced their concerns over the likelihood of drug dependence. However, even after that information was obtained, the company knowingly provided sales representatives with inaccurate data about the drug's addictive nature in comparison with other painkillers, specifically regarding the high potential the drug has for abuse.

Ken Jost from the Justice Department's Office of Consumer Litigation said the case would serve as a deterrent to ward off other pharmaceutical companies who may be tempted to provide false information about their drugs in order to increase their profits. And, more importantly, the case will show that if other companies have misled the public, they too will be prosecuted.

Jost elaborated, "The things that they plot in their boardrooms, the things that they do behind closed doors will not stay behind closed doors. We have the people, we have the resources. We'll take the time, and we'll take the effort to find out what they did and how they did it."

OxyContin's maker acknowledged and assumed responsibility for the wrongdoings of its employees. Purdue Pharma explained in a news release, "During the past six years, we have implemented changes to our internal training, compliance, and monitoring systems that seek to ensure that similar events do not occur again."

According to the FDA, OxyContin, whose active ingredient is oxycodone, is "a narcotic drug approved for the treatment of moderate to severe pain." When properly used, the drug is intended to be consumed whole and subsequently digested over an eight- to 12-hour time span. However, when used improperly, the drug is known to cause a high that is similar to that of heroin. Illegal use of the drug entails individuals crushing OxyContin pills and then swallowing, snorting, or injecting the drug.

According to a United States Drug Enforcement Administration report, between 1996 and 2001, oxycodone-related deaths increased by 500%, which directly corresponded to a significant increase in prescriptions of the drug. In fact, as recently as 2002, OxyContin was either directly or indirectly responsible for 464 deaths, according to the DEA.

The three Purdue Pharma executives, Friedman, Udell, and Goldenheim, are personally responsible for \$34.5 million of the \$634.5 million fine, which will be divided among several federal and state law enforcement agencies, as well as the federal government, among other organizations. Additionally, \$5 million will be used by Purdue Pharma to ensure conformity with the deal.

On the Net

U.S. Food and Drug Administration

www.fda.gov/cder/drug/infopage/oxycontin

Purdue Pharma, LP

www.purduepharma.com

U.S. Drug Enforcement Administration

www.usdoj.gov/dea/index.htm