

Profits Over Patient Care

MISLEADING CLAIMS ABOUT PAINKILLER OXYCONTIN RESULT IN HUNDREDS OF DEATHS, \$634 MILLION FINE.

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The manufacturer of the popular painkiller OxyContin and its top three current and former executives recently pleaded guilty to misleading the public about the drug's addiction risks. The U.S. Attorney in the Western District of Virginia filed charges based on the drugmaker's claims that the drug was less addictive and less susceptible to abuse than other pain medications. Purdue Pharma, LP, which markets the drug, agreed to pay \$634.5 million in fines, one of the largest sums ever paid by a drug company in this type of case.

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

OxyContin, an opium derivative, is a highly addictive painkiller designed to be ingested in tablet form and digested over a 12-hour period. Purdue initiated a fraudulent marketing campaign presenting the drug as a treatment with less danger of abuse and addiction than fast-acting painkillers such as Vicodin and Percocet because of its 12-hour time-release formula. After OxyContin's release in 1995, drug abusers and teenagers quickly learned to crush the tablets and swallow, snort or inject the powder for a heroin-like high. Unlike Percocet and other painkillers which contain the narcotic oxycodone and other ingredients, OxyContin is pure oxycodone.

Evidence suggests that even before marketing OxyContin, Purdue knew about the potential abuse of the drug and gave false information about its addiction potential to sales representatives. Recognizing that the drug would face severe resistance by doctors, internal company documents show company officials elected to focus on the time-release aspect of the drug. Although the Food and Drug Administration (FDA) permitted Purdue to state that OxyContin's time-release feature "is believed to reduce" its addictive potential, Purdue sales representatives stated this theory as fact. Purdue extensively promoted OxyContin to doctors, many of whom had little training in identifying the signs of patient drug abuse.

The FDA approved OxyContin for sale in 1995. In 2002, the U.S. Drug Enforcement Administration reported that the drug had caused 146 deaths and contributed to an additional 318 fatalities. By that time, Purdue had made untold millions off the drug.

Purdue's CEO, general counsel and chief medical officer made the uncommon move of pleading guilty to a misdemeanor count of misbranding the drug. The three, in their individual capacities, were charged with paying \$34.5 million of the total fine. In their defense, Purdue asserted that it "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." The fines will be divided among the individuals who sued the company, a Virginia prescription monitoring program, the federal government, and federal and state Medicaid programs, with the majority going to state and federal law enforcement agencies (\$470 million).

In a statement, Purdue said, "Nearly six years and longer ago, some employees made, or told other employees to make, certain statements about OxyContin to some health care professionals that were inconsistent with the FDA-approved prescribing information for OxyContin and the express warnings it contained about risks associated with the medicine. The statements also violated written company policies requiring adherence to the prescribing information...We accept responsibility for those past misstatements and regret that they were made...During the past six years, we have implemented changes to our internal training, compliance and monitoring systems that seek to assure that similar events do not occur again."

According to Ken Jost of the Justice Department's Office of Consumer Litigation, this case serves to put pharmaceutical companies on notice of the consequences of breaking the law to make a profit. The lesson is clear:

When drugmakers put profits before patient care, everyone suffers. Of course, this should come as no surprise to the chiropractic profession, which has touted the benefits of drug-free chiropractic care for years, while warning consumers about the dangerous side effects of medications.

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