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Pfizer settles fraud cases for \$2.3 billion

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BODY:

A landmark \$2.3-billion healthcare fraud settlement by Pfizer Inc. has put the pharmaceutical industry on notice that potentially criminal behavior in promoting drugs for unauthorized uses won't be tolerated by the Obama administration, government officials and legal experts said.

But, they added, some companies will continue to risk prosecution for such questionable practices because the fines and penalties pale in comparison with the extraordinary profits that are being made through the widespread practice of marketing drugs for "off label" uses, or those that have not been approved by the federal government.

The Justice Department described Wednesday's settlement as the largest in its history and said that Pfizer and its subsidiary Pharmacia & Upjohn Co. had agreed to pay the unprecedented civil and criminal penalties to end investigations into their allegedly fraudulent marketing practices and other potentially illegal acts.

The settlement reflects an emphasis by the Obama administration on holding U.S. healthcare corporations accountable for their activities, especially in trying to market drugs to patients and doctors for uses that have not been approved, Justice Department officials and legal experts said. They also noted that several states, and federal prosecutors in various jurisdictions, had been investigating Pfizer for much of the eight years of the Bush administration as well.

"Illegal conduct and fraud by pharmaceutical companies puts the public health at risk, corrupts medical decisions by healthcare providers, and costs the government billions of dollars," Tony West, assistant attorney general for the Civil Division, said at a news conference at Justice Department headquarters.

"We were actually putting patients in danger," said Pfizer employee John Kopchinski, who will get more than \$51 million for bringing his concerns about Pfizer's marketing of the anti-inflammatory drug Bextra to authorities. He is one

of six whistle-blowers who will get payments under the False Claims Act. "We promoted the medicine for uses that were not authorized or FDA approved in order to increase profits. They knew it was wrong."

The settlement resolves criminal and civil liability arising from Pfizer's illegal promotion of certain pharmaceutical products, including Bextra, according to Justice Department documents and officials.

Justice Department officials said Pharmacia & Upjohn agreed to plead guilty to felony violations of the Food, Drug and Cosmetic Act for misbranding Bextra with the intent to defraud or mislead. Pfizer pulled the popular and lucrative drug from the market in 2005, four years after it was approved.

Under provisions of the act, a company must specify the intended uses of a product in its new drug application to FDA. Once approved, the drug may not be marketed or promoted for any other use.

But Pfizer promoted the sale of Bextra for several uses, including for acute pain, and dosages that the FDA had specifically declined to approve because of safety concerns, Justice Department officials said.

The settlement calls for Pfizer to pay a criminal fine of \$1.2 billion, the largest such fine ever imposed in the United States. Pharmacia & Upjohn will also forfeit \$105 million, for a total of \$1.3 billion to resolve the criminal allegations.

Pfizer also admitted to allegations brought by whistle-blowers under the civil False Claims Act that it illegally promoted three other drugs -- Geodon, an anti-psychotic drug; Zyvox, an antibiotic; and Lyrica, an anti-epileptic drug -- and caused false claims to be submitted to government healthcare programs for uses that were not medically accepted and therefore not covered by those programs. It will pay \$1 billion to resolve the civil allegations.

In the civil settlement, Pfizer also admitted that it paid kickbacks to healthcare providers to encourage them to prescribe drugs for off-label uses.

Amy W. Schulman, senior vice president and general counsel of Pfizer, issued a statement saying, "We regret certain actions taken in the past, but are proud of the action we've taken to strengthen our internal controls and pioneer new procedures so that we not only comply with state and federal laws, but also meet the high standards that patients, physicians and the public expect from a leading worldwide company dedicated to healing and better health."

Federal authorities and legal experts, however, said that the fines and penalties levied against Pfizer were so large because it had settled similar charges involving another drug, Neurontin, in 2004, and had promised in the settlement agreement not to engage in such questionable activity.

"This settlement is a good thing both because it sets an example in the pharmaceutical industry that the Obama administration is serious about enforcing healthcare fraud and abuse and because it brings much-needed financial resources to beef up the investigation and prosecution of fraud in the healthcare industry," said Linda Fentiman, a law professor at Pace Law School in New York.

But some legal experts questioned whether the penalty was harsh enough. "The industry for at least 30 years has been doing this. They get a drug approved for one thing and then they do everything they possibly can to promote it illegally for a much larger number of patients," said Dr. Sidney Wolfe, director of the watchdog group Public Citizen's Health Research Group, which has long monitored the issue.

Wolfe and other legal and medical experts said the widespread practice by Pfizer and many other firms undermines the whole federal safety net for drugs and medications, because it encourages -- and in many cases bribes -- doctors to prescribe medications at doses and for uses that have not been proved to be safe.

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GRAPHIC: PHOTO: CIVIL CASE: Pfizer admitted illegally promoting the antibiotic Zyvox. PHOTOGRAPHER:JB
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