The United States Attorney's Office

Western District of Virginia

NEWS RELEASE
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WESTERN DISTRICT OF VIRGINIA

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May 10, 2007

THE PURDUE FREDERICK COMPANY, INC. AND TOP EXECUTIVES PLEAD GUILTY TO MISBRANDING OXYCONTIN; WILL PAY OVER $600 MILLION

John L. Brownlee, United States Attorney for the Western District of Virginia, and Virginia Attorney General Bob McDonnell announced today that The Purdue Frederick Company, Inc., along with its President, Chief Legal Officer, and former Chief Medical Officer have pleaded guilty to charges of misbranding Purdue's addictive and highly abusable drug OxyContin. Purdue and the three executives will pay a total of $634,515,475. OxyContin is a Schedule II prescription pain relief medication, classified as having the highest potential for abuse of legally available drugs. The Purdue Frederick Company, Inc., and the three executives have admitted that Purdue fraudulently marketed OxyContin by falsely claiming that OxyContin was less addictive, less subject to abuse, and less likely to cause withdrawal symptoms than other pain medications when there was no medical research to support these claims and without Food and Drug Administration approval of these claims.

"Even in the face of warnings from health care professionals, the media, and members of its own sales force that OxyContin was being widely abused and causing harm to our citizens, Purdue, under the leadership of its top executives, continued to push a fraudulent marketing campaign that promoted Oxycontin as less addictive, less subject to abuse, and less likely to cause withdrawal, " said United States Attorney John Brownlee. "In the process, scores died as a result of OxyContin abuse and an even greater number of people became addicted to OxyContin; a drug that Purdue led many to believe was safer, less abusable, and less addictive than other pain medications on the market. Today's convictions are a testament to the outstanding work of the prosecutors and agents who spent years investigating this important case."

The Purdue Frederick Company, Inc. and Purdue Pharma, L.P. are part of a worldwide group of related and associated entities engaged in the pharmaceutical business. These entities manufacture, market, and distribute OxyContin, an extended-release form of oxycodone.

"Purdue put its desire to sell OxyContin above the interests of the public," said Assistant Attorney General Peter D. Keisler. "Purdue abused the drug approval process which relies on drug manufacturers to be forthright in reporting clinical data and, instead, misled physicians

about the addiction and withdrawal issues involved with Oxycontin."

"The criminal behavior exhibited in this case damages the reputation of a critically important industry. Pharmaceutical companies have an obligation to patients, physicians, and those in the industry they serve to market prescription drugs in accordance with the law and FDA regulations." said Virginia Attorney General Bob McDonnell, " I applaud John Brownlee and his team for their leadership, as well as the Virginia Medicaid Fraud Control Unit, FDA and all of the other state and federal law enforcement agencies that worked so hard over the past four years to investigate this complex criminal scheme and bring the wrongdoers to justice."

"FDA will not tolerate practices that falsely promote drug products and place consumers at health risk," said Margaret O.K. Glavin, Associate Commissioner for Regulatory Affairs, FDA. "We 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."

The Purdue Frederick Company, Inc., pleaded guilty to felony misbranding OxyContin with the intent to defraud and mislead. President and Chief Operating Officer Michael Friedman, Executive Vice President and Chief Legal Officer Howard Udell, and former Executive Vice President of Worldwide Medical Affairs Paul D. Goldenheim, pleaded guilty to a misdemeanor charge of misbranding OxyContin. All the pleas were entered in United States District Court in Abingdon this morning.

"Purdue's illegal sales and marketing practices concealed information from patients and many health care providers regarding the potency and abuse potential of OxyContin for corporate profit," said Daniel R. Levinson, Inspector General for the U.S. Department of Health and Human Services. "We commend the highly qualified team of prosecutors and investigators from a variety of Federal and State agencies for developing a global resolution that addresses the criminal violations of the past, ensures strict compliance in the future, and serves as a strong warning to others who may consider illegally marketing pharmaceuticals."

"The falsification of drug product information is a very serious breach of the public's trust. IRS Criminal Investigation will continue to concentrate its resources on the tax and money laundering aspects of these types of investigations in cooperation with the United States Attorney's Office and other federal, state, and local authorities," said Charles R. Pine, Special Agent in Charge.

"Today's guilty pleas mark a significant milestone in the fight against corruption by company officials who seek to illegally enrich corporate profits at taxpayers' expense," stated Gordon S. Heddell, Inspector General, U.S. Department of Labor. "These convictions demonstrate our steadfast resolve to investigate any individuals who would defraud Labor programs, such as the Office of Workers' Compensation Programs, by overcharging them. My office remains committed to working with other law enforcement agencies and the U.S. Attorney to fight this type of corruption."

Pursuant to written plea agreements, Purdue and the executives will pay a total of $634,515,475.00. Purdue's payments will include:

$276.1 million forfeited to the United States

$160 million paid to federal and state government agencies to resolve liability for false claims made to Medicaid and other government healthcare programs

$130 million set aside to resolve private civil claims (monies remaining after 36 months will be paid to the United States)

$5.3 million paid to the Virginia Attorney General's Medicaid Fraud Control Unit to fund future health care fraud investigations

$20 million paid to fund the Virginia Prescription Monitoring Program for the foreseeable future

In addition, Purdue will pay the maximum statutory criminal fine of $500,000.

Purdue's top executives will pay the following amounts to the Virginia Attorney General's Medicaid Fraud Control Unit:

$19 million paid by Michael Friedman

$8 million paid by Howard R. Udell

$7.5 million paid by Dr. Paul D. Goldenheim

Each executive will also pay a $5,000 criminal fine.

The Director of the Defense Criminal Investigative Service, Mr. Chuck Beardall, stated, "It is unthinkable that purely for greed, addictive drugs were fraudulently marketed to the public, and in so doing threatened the health and safety of our citizens. Among those endangered were soldiers, sailors, airmen, marines, and their families, all of whom avail themselves of the military health system. At a time when our military personnel and their loved ones are sacrificing so much, something like this is incomprehensible and grossly reprehensible."

According to the Statement of Facts filed with the Court, beginning in January 1996 and continuing through June 30, 2001, Purdue's market research found that "[t]he biggest negative of [OxyContin] was the abuse potential." Despite this finding, Purdue's supervisors and employees falsely and misleadingly marketed OxyContin as less addictive, less subject to abuse, and less likely to cause withdrawal than other pain medications. Purdue misbranded OxyContin in three specific ways:

1. Purdue sales representatives falsely told some health care providers that OxyContin had less euphoric effect and less abuse potential than short-acting opioids. This message was presented to some health care providers through the use of graphs that exaggerated the differences between blood plasma levels achieved by OxyContin compared to the levels of other pain relief medications.

A. Purdue supervisors and employees participated in the misbranding in the following ways. Purdue supervisors and employees sponsored training that used graphs that exaggerated the differences between the blood plasma levels of OxyContin as compared to immediate-release opioids. These graphs were used to falsely teach Purdue sales supervisors that OxyContin had fewer "peak and trough" blood level effects than immediate-release opioids and that would result in less euphoria and less potential for abuse than short-acting opioids.

B. Purdue supervisors and employees permitted new Purdue sales representatives to use similar exaggerated graphical depictions during role-play training at Purdue's headquarters in Stamford, Connecticut.

2. Purdue supervisors and employees drafted an article about a study of the use

2. Purdue supervisors and employees drafted an article about a study of the use of OxyContin in osteoarthritis patients that was published in a medical journal on March 27, 2000. On June 26, 2000, each sales representative was provided a copy of the article together with a "marketing tip" that stated that the article was available for use in achieving sales success. Sales representatives distributed copies of the article to health care providers to falsely or misleadingly represent that patients taking OxyContin at doses below 60 milligrams per day can always be discontinued abruptly without withdrawal symptoms. The article also indicated that patients on such doses would not develop tolerance. The marketing tip that accompanied the article stated that one of the twelve key points was, "There were 2 reports of withdrawal symptoms after patients abruptly stopped taking CR [controlled release] oxycodone at doses of 60 or 70 mg/d. Withdrawal syndrome was not reported as an adverse event during scheduled respites indicating that CR oxycodone at doses below 60 mg/d [milligrams per day] can be discontinued without tapering the dose if the patient condition so warrants." These marketing claims were made even though Purdue representatives were well aware of the following information:

A. The year before the article was published and distributed to sales representatives, Purdue received an analysis of the osteoarthritis study and a second study from a United Kingdom company affiliated with Purdue that listed eight patients in the osteoarthritis study "who had symptoms recorded that may possibly have been related to opioid withdrawal," and stated that "[a]s expected, some patients did become physically dependent on OxyContin tablets but this is not expected to be a clinical problem so long as abrupt withdrawal of drug is avoided."

B. In May of 2000, Purdue received a report of a patient who said he or she was unable to stop taking OxyContin 10 mg every 12 hours without experiencing withdrawal symptoms. Executives also learned that "this type of question, patients not being able to stop OxyContin without withdrawal symptoms ha[d] come up quite a bit . . . in Medical Services lately (at least 3 calls in the last 2 days)."

C. In February 2001, Purdue received a review of the accuracy of the withdrawal data in the osteoarthritis study that listed eleven study patients who reported adverse experience due to possible withdrawal symptoms during the study's respite periods and stated "[u]pon a review of all comments for all enrolled patients, it was noted that multiple had comments which directly stated or implied that an adverse experience was due to possible withdrawal symptoms;" Even after receiving this information, on March 28, 2001, supervisors and employees decided not to write up the findings because of a concern that it might "add to the current negative press."

D. Supervisors and employees stated that while they were well aware of the incorrect view held by many physicians that oxycodone was weaker than morphine, they did not want to do anything "to make physicians think that oxycodone was stronger to or equal to morphine" or to "take any steps in the form of promotional materials, symposia, clinicals, publications, conventions, or communications with the field force that would affect the unique position that OxyContin ha[d] in many physicians[']mind[s]."

3. Purdue sales representatives, while promoting and marketing OxyContin, falsely told health care providers that the statement in the OxyContin package insert that "[d]elayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug," meant that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to "weed out" addicts and drug seekers.

The statement was later amended to read, "[d]elayed absorption, as provided by OxyContin tablets, when used properly for the management of pain, is believed to reduce the abuse liability of a drug." Nevertheless, Purdue continued to market OxyContin in the same manner as described above.

Purdue supervisors and employees took part in the misbranding in the following ways:

A. Supervisors instructed Purdue sales representatives to use the reduced abuse liability statement and the amended statement to market and promote OxyContin.

B. Supervisors told Purdue sales representatives they could tell health care providers that OxyContin potentially creates less chances for addiction than immediate-release opioids.

C. Supervisors trained Purdue sales representatives and told some health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of intravenous abuse, although Purdue's own study showed that a drug abuser could extract approximately 68% of the oxycodone from a single 10 mg OxyContin tablet merely by crushing the tablet, stirring it in water, and drawing the solution through cotton into a syringe.

D. By March 2000, Purdue had received reports of OxyContin abuse and diversion occurring in different communities but allowed sales staff to continue promoting and marketing OxyContin in this manner.

The case was investigated by the Virginia Attorney General's Medicaid Fraud Control Unit; Food and Drug Administration, Office of Criminal Investigations; Internal Revenue Service Criminal Investigation; the Department of Health and Human Services Office of Inspector General; Department of Labor, Office of Inspector General; Defense Criminal Investigative Service; Virginia State Police; and West Virginia State Police. The case was prosecuted by Assistant United States Attorneys Rick Mountcastle, Randy Ramseyer and Sharon Burnham and U.S. Department of Justice, Office of Consumer Litigation, Trial Attorneys Barbara Wells and Elizabeth Stein.