



## **Purdue Pharma L.P.'s Agreement with the Government**

The terms of the agreement announced today include:

- Purdue Pharma L.P. will pay \$470 million to government agencies and \$130 million to resolve private civil liabilities related to OxyContin® (oxycodone HCl controlled-release) Tablets. Purdue already has either paid, or agreed with claimants to pay, the full \$130 million designated for civil claims. The Company also will enter into a non-prosecution agreement and civil settlement calling for it to maintain a compliance program and to engage an Independent Review Organization (IRO) with respect to Purdue Pharma products for a 60-month period.
- The Purdue Frederick Company, Inc. will enter a guilty plea to a single felony violation of "misbranding" related to the marketing of OxyContin prior to July 2001. Misbranding does not mean that the FDA-approved prescribing information for OxyContin was incorrect. Under this plea, misbranding refers to statements some employees made, or told other employees to make, that went beyond the FDA-approved prescribing information for the product in promoting OxyContin to some healthcare professionals.

As part of the Company's agreement with the government and based upon their senior positions at the Company, Michael Friedman, President and CEO; Howard R. Udell, Executive Vice President and Chief Legal Officer; and Paul Goldenheim, M.D., formerly Executive Vice President, Chief Scientific Officer and head of research and development, will each make a payment and plead guilty to a single "strict liability" misdemeanor for misbranding.

"Strict liability" is a legal doctrine under which an individual, such as an executive officer of a company, may be held accountable for the acts of others at the Company by reason of holding a position of responsibility and authority. As the government has agreed: "...[A]n individual could be held criminally liable for a misdemeanor violation...without having knowledge of, or intent to cause, the misbranding if that individual was a responsible corporate officer at the time of the misbranding."

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.

Dr. Goldenheim is currently active in advising and developing businesses in the healthcare/biotechnology field.

Purdue Pharma L.P. is a research-based pharmaceutical company known for its pioneering work on persistent pain. Headquartered in Stamford, CT, Purdue is engaged in the research, development, production, and distribution of both prescription and over-the-counter medicines and hospital products. For years, Purdue has established innovative and effective programs to help physicians, pharmacists and law enforcement combat prescription drug abuse and diversion. Additional information about Purdue can be found at [www.purduepharma.com](http://www.purduepharma.com). Program information is available at [http://www.purduepharma.com/pressroom/app/news\\_announc/ss\\_10ptPlan.asp](http://www.purduepharma.com/pressroom/app/news_announc/ss_10ptPlan.asp)

The professional product labeling for OxyContin<sup>®</sup> Tablets contains the following **boxed warning**:

**WARNING:**

**OxyContin is an opioid agonist and a Schedule II controlled substance with an abuse liability similar to morphine.**

Oxycodone can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing OxyContin in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse, or diversion.

**OxyContin Tablets are a controlled-release oral formulation of oxycodone hydrochloride indicated for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time.**

**OxyContin Tablets are NOT intended for use as a prn analgesic.**

**OxyContin 60 mg, 80 mg, and 160 mg Tablets, or a single dose greater than 40 mg, ARE FOR USE IN OPIOID-TOLERANT PATIENTS ONLY. A single dose greater than 40 mg, or total daily doses greater than 80 mg, may cause fatal respiratory depression when administered to patients who are not tolerant to the respiratory depressant effects of opioids.**

**OxyContin TABLETS ARE TO BE SWALLOWED WHOLE AND ARE NOT TO BE BROKEN, CHEWED, OR CRUSHED. TAKING BROKEN, CHEWED, OR CRUSHED OxyContin TABLETS LEADS TO RAPID RELEASE AND ABSORPTION OF A POTENTIALLY FATAL DOSE OF OXYCODONE.**

Full prescribing information for OxyContin is available at <http://www.purduepharma.com/PI/Prescription/Oxycontin.pdf>.

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