

Purdue, OxyContin Maker, Races Rivals to Deter Abuse

By Catherine Larkin April 28 (*Bloomberg*)

Purdue Pharma LP, the maker of the painkiller OxyContin, is racing smaller drug companies to introduce tamper-resistant pills that addicts can't abuse.

Closely held Purdue agreed last year to pay \$634.5 million to settle claims that promotions from 1996 to 2001 misled doctors about the risks of OxyContin, its best-selling product with more than \$1 billion in sales last year. A generic version was among the medicines taken by actor Heath Ledger in his fatal overdose in February.

The Stamford, Connecticut-based drugmaker will ask a joint panel of U.S. advisers next week to back a new OxyContin formula that may prevent abusers from crushing the pill or dissolving it in alcohol to release several hours of narcotics at once. Pain Therapeutics Inc., Alpharma Inc. and Elite Pharmaceuticals Inc. predict a \$1 billion market for alternatives they're developing even if Purdue beats them to pharmacies.

"This is clearly a defensive move by Purdue recognizing that their OxyContin franchise is in danger," said E. Russell McAllister, an analyst who covers Pain Therapeutics at Merriman Curhan Ford & Co. in Portland, Oregon, in a phone interview. "All the drugs coming down the pipeline are better than what's on the market, and presumably the new OxyContin formula."

Pain Therapeutics was unchanged at \$6.95 in Nasdaq Stock Market composite trading at 4 p.m. New York time and has lost 12 percent in the past 12 months. Alpharma rose 19 cents to \$25.79 on the New York Stock Exchange, capping a 5.2 percent increase in the past 12 months. Elite gained 11 cents, or 17 percent, to 76 cents on the American Stock Exchange and has fallen 68 percent in the past 12 months.

\$6.37 Billion Sales

U.S. sales of prescription opioids -- drugs including OxyContin derived from the opium poppy -- surged to \$6.37 billion last year, a 52 percent gain from 2002, according to IMS Health Inc., a Norwalk, Connecticut research firm. Also in the group are fentanyl drugs including Cephalon Inc.'s Fentora and Actiq, hydrocodone drugs including Abbott Laboratories' Vicodin, morphine and codeine.

Doctors considered sustained release, high-dose painkillers a major breakthrough for cancer and chronic pain when introduced in the mid-1990s, though the drugs were easy to manipulate. As many as 4 percent of high school students and 3 percent of young adults say they've used OxyContin in the past year, according to a Monitoring the Future study released last year by the National Institute on Drug Abuse.

About 10 billion doses of these drugs are now dispensed yearly in the U.S., and use may rise after the new formulas are introduced, said Nathaniel Katz, head of the Program on Opioid Risk Management at Tufts University in Boston and a consultant to companies developing abuse-resistant painkillers.

'Untapped Market'

"Eventually these drugs will replace the existing drugs and there will be liabilities for doctors who don't make the switch," Katz said in a phone interview. "There's plenty of room in this essentially untapped market."

Outside advisers to the Food and Drug Administration will consider Purdue's new formula May 5 in Gaithersburg, Maryland. Pain Therapeutics, Alpharma and Elite fell as much as 10 percent in New York trading after the meeting was announced and say they plan to attend to get a better sense of the competition.

Purdue hasn't disclosed how its new OxyContin technology works or how effective it has been in studies. A review of pending patents suggests the pill has "rubbery characteristics" to prevent tampering and may release no more than a quarter of its active ingredient when dissolved in ethanol, said Corey Davis, a Natixis Bleichroeder analyst, in a March 31 note to clients.

The new OxyContin formula may be approved by July, at least six months ahead of any competitors, Davis said.

Targets for Abuse

While opioids are an important tool in managing pain, they are "targets for illegal trafficking and abuse," said Purdue spokesman James Heins in an e-mailed message.

"As long as they are equally safe and effective for patients, having new tamper-resistant formulations in the marketplace could have a significant public health benefit," Heins said.

A taffy-like version of oxycodone, the active ingredient in OxyContin, is being developed by Pain Therapeutics, of San Mateo, California, and partner King Pharmaceuticals Inc., of Bristol, Tennessee. The gummy texture of the capsule, Remoxy, is difficult for abusers to convert into a form that can be injected or snorted and resists dissolving in alcohol and water.

The companies plan to submit Remoxy this quarter for FDA approval.

"Up until about a year ago, a bunch of investors were really still pooh-poohing it," said Remi Barbier, chief executive officer of Pain Therapeutics, in a phone interview. "People have shifted from 'Who needs it?' to 'Who's going to win the billion-dollar market?'"

Using a Chemical

Alpharma and Elite are counting on the chemical naltrexone, which can counteract most of the euphoria gained from opioids. Their painkillers include naltrexone encased in a protective coating that allows the chemical to pass through the digestive tract unabsorbed when the drug is taken as directed.

When the pill is crushed, chewed or cut open, the naltrexone is released along with the narcotic, preventing it from causing a high.

Embeda, an extended-release morphine pill being developed by Alpharma, has a kernel of naltrexone at its center. The Bridgewater, New Jersey-based drugmaker submitted Embeda to the FDA in February and then retracted its request for approval April 21 to revise undisclosed technical issues. Alpharma said it plans to resubmit the application as soon as possible.

ELI-216, a once-a-day capsule made by Elite of Northvale, New Jersey, contains tiny pellets of naltrexone and oxycodone. Elite said it plans to start the final stage of testing ELI-216 in people soon.

King is also testing a painkiller called Acurox that combines oxycodone with the chemical niacin, which causes facial flushing if taken in excess.