



Highlights of GAO-04-110, a report to congressional requesters

December 2003

## PRESCRIPTION DRUGS

# OxyContin Abuse and Diversion and Efforts to Address the Problem

### Why GAO Did This Study

Amid heightened awareness that many patients with cancer and other chronic diseases suffer from undertreated pain, the Food and Drug Administration (FDA) approved Purdue Pharma's controlled-release pain reliever OxyContin in 1995. Sales grew rapidly, and by 2001 OxyContin had become the most prescribed brand-name narcotic medication for treating moderate-to-severe pain. In early 2000, reports began to surface about abuse and diversion for illicit use of OxyContin, which contains the opioid oxycodone. GAO was asked to examine concerns about these issues. Specifically, GAO reviewed (1) how OxyContin was marketed and promoted, (2) what factors contributed to the abuse and diversion of OxyContin, and (3) what actions have been taken to address OxyContin abuse and diversion.

### What GAO Recommends

To improve efforts to prevent or identify abuse and diversion of controlled substances such as OxyContin, FDA's risk management plan guidance should encourage pharmaceutical manufacturers with new drug applications to submit plans that contain a strategy for identifying potential problems with abuse and diversion. FDA concurred with GAO's recommendation. DEA agreed that such risk management plans are important, and Purdue stated that the report appeared to be fair and balanced.

[www.gao.gov/cgi-bin/getrpt?GAO-04-110](http://www.gao.gov/cgi-bin/getrpt?GAO-04-110).

To view the full product, including the scope and methodology, click on the link above. For more information, contact Marcia Crosse at (202) 512-7119.

### What GAO Found

Purdue conducted an extensive campaign to market and promote OxyContin using an expanded sales force to encourage physicians, including primary care specialists, to prescribe OxyContin not only for cancer pain but also as an initial opioid treatment for moderate-to-severe noncancer pain. OxyContin prescriptions, particularly those for noncancer pain, grew rapidly, and by 2003 nearly half of all OxyContin prescribers were primary care physicians. The Drug Enforcement Administration (DEA) has expressed concern that Purdue's aggressive marketing of OxyContin focused on promoting the drug to treat a wide range of conditions to physicians who may not have been adequately trained in pain management. FDA has taken two actions against Purdue for OxyContin advertising violations. Further, Purdue did not submit an OxyContin promotional video for FDA review upon its initial use in 1998, as required by FDA regulations.

Several factors may have contributed to the abuse and diversion of OxyContin. The active ingredient in OxyContin is twice as potent as morphine, which may have made it an attractive target for misuse. Further, the original label's safety warning advising patients not to crush the tablets because of the possible rapid release of a potentially toxic amount of oxycodone may have inadvertently alerted abusers to methods for abuse. Moreover, the significant increase in OxyContin's availability in the marketplace may have increased opportunities to obtain the drug illicitly in some states. Finally, the history of abuse and diversion of prescription drugs, including opioids, in some states may have predisposed certain areas to problems with OxyContin. However, GAO could not assess the relationship between the increased availability of OxyContin and locations of abuse and diversion because the data on abuse and diversion are not reliable, comprehensive, or timely.

Federal and state agencies and Purdue have taken actions to address the abuse and diversion of OxyContin. FDA approved a stronger safety warning on OxyContin's label. In addition, FDA and Purdue collaborated on a risk management plan to help detect and prevent OxyContin abuse and diversion, an approach that was not used at the time OxyContin was approved. FDA plans to provide guidance to the pharmaceutical industry by September 2004 on risk management plans, which are an optional feature of new drug applications. DEA has established a national action plan to prevent abuse and diversion of OxyContin. State agencies have investigated reports of abuse and diversion. In addition to developing a risk management plan, Purdue has initiated several OxyContin-related educational programs, taken disciplinary action against sales representatives who improperly promoted OxyContin, and referred physicians suspected of improper prescribing practices to the authorities.