



Sarah Zarbock, PA-C, is the editor in chief of JAAPA.

On the OxyContin scandal: Don't abandon patients in pain

Purdue Pharma recently announced a resolution to a 4-year investigation by the United States Attorney's Office in the Western District of Virginia involving the promotion of OxyContin (oxycodone HCl controlled-release) tablets.¹ As part of the settlement, five of its top executives pleaded guilty in federal court to criminal charges that the company had misled doctors and patients when it claimed the drug was less likely to be abused than traditional narcotics.² The company agreed to pay more than \$600 million in criminal penalties. Three executives who pleaded guilty to a single strict liability misdemeanor for "misbranding" were spared jail sentences but must pay a combined \$24.5 million in fines.³

Obscured in the legalese of the Purdue Pharma public statements is the concept of *misbranding*, the legal term for making false representations through labeling, advertising, or statements by company officials.³ From 1996 to 2001, Purdue made statements about OxyContin that went beyond the FDA-approved prescribing information for the product. According to court papers, Purdue promoted the synthetic morphine substitute as a low-risk painkiller, contending that OxyContin's time-release formulation posed less of a threat of abuse and addiction than more traditional narcotic pain relievers.³

OxyContin, introduced in 1995, is a controlled-release oral formulation of oxycodone HCl, a semisynthetic opioid, and is indicated for the management of moderate to severe pain when an around-the-clock analgesic is needed for an extended period of time.⁴ Drug abusers soon learned, however, that they could bypass or "short-circuit" the time-release mechanism by chewing, crushing, or dissolving the pills and ingesting, injecting, or inhaling them or absorbing them rectally. In so doing, users can experience intoxication as powerful as that obtained from heroin—a reaction that does not occur when the drug is taken as prescribed.⁵ The abuse numbers are chilling—OxyContin addiction has been increasing dramatically over the past 10 years, by 300% in the United States alone.⁶

Based on the headlines, the OxyContin story seems to be more about greed and turning innocent pain patients into addicts than about good patient care. The revenue generated in 2000 by Purdue Pharma was \$600 million.³ According to court papers, the company grossed at least \$10.2 billion in OxyContin sales from 1995 to 2006.³

Overzealous marketing of this narcotic analgesic has two very disturbing outcomes. One is the astonishing increase in OxyContin abuse, and the other is how Purdue Pharma

deceived the public about the benefits of its medication over those of other prescription analgesics.

Pain management is something that patients, families, and health care providers wrestle with all the time, in part because of the fear of addiction. Kathy Foley, MD, a leading pain expert, remarked in a press release from the Soros Foundation Open Society Institute that more than 50 million people in the United States with legitimate chronic pain forego effective treatment with prescription medications because of misconceptions and fear of becoming addicted.⁷ This fear has been fed by sensationalized media reports documenting the illegal abuse of OxyContin and other drugs that would otherwise treat pain safely. Purdue Pharma capitalized on this fear by stating that their medication carried a lower risk of addiction.

Given current events, legitimate users of OxyContin will understandably question whether they should be taking the drug. "By highlighting OxyContin's illegal use," Dr. Foley remarked, "we fail to educate the public about the role such analgesic drugs play in providing relief for millions of patients suffering from severe pain."⁷

PA's must be strong advocates for their patients in pain. Those treated with OxyContin need our counsel and support. PAs should review the treatment of patients who are legitimate users, perhaps even contacting them individually. We must also be knowledgeable about how to treat pain effectively,⁸ clarify misunderstandings, and be proactive and caring. Our patients deserve nothing less. **JAAPA**

REFERENCES

1. Statement of Purdue Pharma regarding resolution of the federal investigation in the Western District of Virginia. Purdue Pharma Web site. http://www.purduepharma.com/pressroom/news/wdvaresolution/Purdue_statement_on_WDVA_resolution.pdf. Accessed June 6, 2007.
2. Meier B. Narcotic maker guilty of deceit over marketing. May 11, 2007. New York Times Web site. <http://www.nytimes.com/2007/05/11/business/11drug.html?ex=1180065600&en=f388818f2c0f0db5&ei=5070>. Accessed June 6, 2007.
3. Hammack L. \$630 million fine for drugmaker. May 11, 2007. The Roanoke Times Web site. <http://www.roanoke.com/news/roanoke/wb/xp-116470>. Accessed June 6, 2007.
4. Oxycodone addiction. AddictionSearch.com Web site. http://www.addictionsearch.com/treatment_articles/article/oxycodone-addiction_14.html. Updated February 8, 2007. Accessed June 6, 2007.
5. Hanson GR. Hearing before the Health, Education, Labor, and Pensions Committee United States Senate - "OxyContin: Balancing Risks and Benefits." Statement for the Record. National Institute on Drug Abuse Web site. <http://www.nida.nih.gov/Testimony/2-12-02Testimony.html>. Accessed June 6, 2007.
6. Benderman D. Oxycontin addiction. Alcoholism Treatment Web site. <http://www.1st-alcoholism-treatment.com/Oxycontin-Addiction.html>. Accessed June 6, 2007.
7. Distorted fear of addiction to prescription drugs seen as major barrier to effective pain treatment. October 22, 2002. Project Death in America. Soros Foundation Open Society Institute Web site. http://www.soros.org/initiatives/pdia/news/fearaddiction_20021022. Accessed June 6, 2007.
8. American Academy of Physician Assistants. Profession. 2006-2007 Policy Manual. HP-3200.3.4. AAPA Web site. <http://www.aapa.org/manual/profession.pdf>. Accessed June 8, 2007.