



**CLAAD**

Center for Lawful Access  
and Abuse Deterrence

**FOR IMMEDIATE RELEASE**

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## **Same Abuse, Different Drug Highlights Need for FDA Action**

*Bureaucracy Frustrates Industry, Law Enforcement Responses to Rx Abuse*

April 11, 2011 – Washington, DC – *The Courier-Journal* of Louisville, KY, recently [reported](#) on a surge in the illegal use of oxymorphone, a powerful opioid pain reliever. At the end of last year, the often-abused opioid OxyContin OC was removed voluntarily from the U.S. market and replaced with OxyContin OP, a new formulation designed to be less susceptible to certain forms of abuse. Since then, law enforcement and public health officials have witnessed an increase in the abuse of a similarly potent prescription pain medication, oxymorphone.

A national alliance of families, medical professionals, law enforcement, and drug abuse prevention advocates responded to the news of the surge in oxymorphone overdoses, calling for the Food and Drug Administration (FDA) to fulfill its responsibility to address the abuse of prescription medications.

According to the not-for-profit Center for Lawful Access and Abuse Deterrence (CLAAD), the FDA's policies prevent the widespread use of new medications designed to be more resistant to tampering for purposes of abuse. As a result, law enforcement and public health officials must continually fight the same battles over different drugs.

Extended-release opioids contain significant amounts of active ingredients that, when crushed, chewed or ground, produce an intense "high."<sup>i</sup> Abuse harms millions of Americans and is estimated to cost billions of dollars in workplace, health care, and criminal justice expenditures.<sup>ii</sup>

There is a bright side to the news coming from Kentucky, according to Michael Barnes, a CLAAD spokesman: "Reports that the new OxyContin is less attractive to abusers suggest that new medication technologies can play an important role in the nationwide effort to address prescription drug abuse."

Presently, the FDA does not permit drug companies to describe new products as "abuse-deterrent" even if human clinical trial data supports the assertion. As a result, many prescribers do not know that several new pain relievers in addition to OxyContin OP have been designed to resist certain types of tampering. FDA requires what

amounts to years of post-marketing epidemiologic studies for “abuse-deterrent” labeling.<sup>iii</sup>

Given that companies may not describe the abuse-deterrent features of new medications, health care providers continue to prescribe widely abused traditional opioids, such as oxycodone, and epidemiologic studies of new formulations are nearly impossible.

“The FDA is unwittingly perpetuating a vicious cycle of abuse,” Barnes said.

According to CLAAD, FDA should permit claims that medications “may” deter abuse if human abuse liability studies support the notion. In doing so, the FDA would enable professionals to learn of new drug technologies and create a more realistic environment for epidemiological data collection.

“The FDA has to understand that health care practitioners must be able to learn about these new technologies before they can begin prescribing them,” Barnes said.

In 2010, the Office of National Drug Control Policy (ONDCP), Substance Abuse and Mental Health Services Administration (SAMHSA) and the Drug Enforcement Administration (DEA) released a new study showing a 400 percent increase in substance abuse treatment admissions for prescription pain relievers.<sup>iv</sup> The July 2010 report follows a June 2010 report from the Centers for Disease Control and Prevention (CDC) which also found that prescription drug abuse is a leading cause of unintentional death in the United States.<sup>v</sup>

CLAAD’s *National Prescription Drug Abuse Prevention Strategy* details recommendations as to how the FDA can address the challenge of ensuring the availability of prescription medications while preventing their abuse. Among them are the following:

- Incentivize the development of medications formulated to minimize abuse.
- Allow pharmaceutical companies to illustrate the abuse-deterrent qualities of new medications supported by human abuse liability data.
- Mandate that medication labels and medication guides contain information on proper medication storage and disposal.

The *2010 National Prescription Drug Abuse Prevention Strategy* may be found online at <http://www.claad.org/>.

## **About the Center for Lawful Access and Abuse Deterrence**

The primary objective of the Center for Lawful Access and Abuse Deterrence (CLAAD) is to coordinate a comprehensive national effort to prevent the diversion, misuse, and abuse of prescription medications while ensuring adequate medical care for patients in need. CLAAD enables health professionals, law enforcement, businesses, and government, among many other entities, to share resources and work together to prevent the diversion, misuse, and abuse of medications.

**Website:** <http://www.claad.org/>

**Reporters:** CLAAD can connect you with health care professionals in the fields of pain care and addiction medicine, as well as families that have suffered from prescription drug abuse.

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<sup>i</sup> <http://www.gao.gov/new.items/d04110.pdf>

<sup>ii</sup> Strassels SA. Economic burden of prescription opioid misuse and abuse. *J Manag Care Pharm.* 2009 Sep;15(7):556-62.

<sup>iii</sup> <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM198650.pdf>

<sup>iv</sup> <http://www.oas.samhsa.gov/2k10/230/230PainRelvr2k10Web.pdf>

<sup>v</sup> <http://www.samhsa.gov/newsroom/advisories/1007140544.aspx>