



February 19, 2015

Oregon Pharmacy and Therapeutics Committee

Re: Class Update with New Drug Evaluation: Long-Acting Opioids - Draft

Dear Committee Members,

Pfizer welcomes the opportunity to comment on the OSU/OHA draft review of the long-acting opioids drug class dated March 2015.

The 4 research questions addressed by this drug review are focused upon the clinical efficacy and safety of long acting opioids, but do not address the major public health issue concerning abuse of prescription opioid medications. In 2013, an estimated 11.1 million Americans ≥ 12 years of age, or approximately 4% of the US population, used prescription pain relievers for nonmedical purposes¹, with Oregon having the highest rate in the nation in 2012².

We ask the Committee to consider the potential for abuse as a critical consideration in determining opioid product preference, and for the available data for abuse deterrent formulation opioids to be included in this drug class review.

In consideration of the opioid abuse epidemic, Pfizer suggests incorporation of an additional research question such as: "Is there evidence that the drug has abuse deterrent properties that would be expected to reduce abuse by any route of administration?"

Prescription opioid abuse is a major public health concern in Oregon and nationally:

- In Oregon, according to a 2011-2012 SAMHSA survey, more than 185,000 Oregonians, ages 12 and over, were estimated to have abused painkillers in the previous year².
- The percentage of prescription pain reliever use in Oregon in 2012 by people 12 or older was 6.4 percent, the highest of any state and above the national rate of 4.6³.
- Oregon has the 21st highest drug overdose mortality rate among all states—a majority of which are from prescription drugs⁴.
- The main source of prescription pain relievers for the majority (67.6%) of opioid abusers was from friends or relatives; approximately 53% of these medications were obtained for free, and 15% were purchased or taken without asking from friends or relatives. Furthermore, 83.8% indicated that their friend or relative who provided them these drugs for free had obtained the drugs from only one doctor⁵.

The FDA has recognized that the development of opioids containing abuse-deterrent properties is an important step towards the goal of creating safer opioid analgesics⁶. In fact, FDA deputy director for regulatory programs, Douglas Throckmorton, M.D., stated that the, "development of abuse-deterrent opioid analgesics is a public health priority for the FDA"⁷. Similarly, the White House included expediting the "development of abuse-deterrent formulations (ADFs)" in its action steps for responding to the prescription drug epidemic⁸. In January 2013 the FDA issued draft guidance to Industry on the evaluation and labeling of abuse deterrent opioids⁶.

Abuse-deterrent opioids contain the same pain relieving ingredient as opioids currently on the market; however, they also contain technologies designed to deter manipulation of the medication by drug abusers and reduce the “high.” Abuse deterrent opioids provide the needed pain relief to patients, but deter those who are crushing and swallowing; snorting; smoking; or injecting from using these important medications inappropriately.

Since the FDA released its draft guidance to Industry, it has approved abuse-deterrent labeling for four opioid medications. Based on data from in vitro laboratory studies and clinical studies including abuse potential studies in recreational opioid abusers, the FDA included in the product labeling language describing that these four opioid medications are expected to result in a meaningful reduction in abuse.

Reformulated extended release oxycodone was the first abuse deterrent opioid to become available. Abuse of extended release oxycodone decreased by approximately 50% among a group of opioid abusers after its reformulation⁹. Economic modeling suggests that such reductions in abuse on a national level would lead to a decrease in annual healthcare costs by an estimated \$430 million¹⁰.

Pfizer appreciates the opportunity to comment on the draft drug class review for long-acting opioids and requests, in view of the serious public health concern in Oregon of prescription opioid abuse, that the Committee consider including drugs that have demonstrated a potential to decrease abuse as part of the Oregon PDL.

Sincerely,



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¹ US Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Results from the 2013 NSDUH: Detailed Tables. Available at: <http://www.samhsa.gov/data/NSDUH/2013SummNatFindDetTables/DetTabs/NSDUH-DetTabsSect1peTabs1to46-2013.htm#tab1.1a>. Accessed December 12, 2014.

² SAMHSA: <http://www.samhsa.gov/data/sites/default/files/NSDUHStateEst2011-2012/CountTabs/Web/NSDUHsaeCountTabs2012.htm>. Last accessed Feb 18, 2015.

³ KATU: <http://www.katu.com/news/local/Oregon-works-to-dull-pain-of-prescription-drug-abuse-228051231.html>. Last accessed Feb 18, 2015.

⁴ Trust for America's Health: <http://healthyamericans.org/reports/drugabuse2013/release.php?stateid=OR>. Last accessed Feb 18, 2015.

⁵ Substance Abuse and Mental Health Services Administration. Results from the 2013 National Survey on Drug Use and Health: Summary of National Findings, NSDUH Series H-48, HHS Publication No. (SMA) 14-4863. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2014.

⁶ Guidance for Industry Abuse-deterrent Opioids -- Evaluation and Labeling. *Draft Guidance January 2013* <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM334743.pdf>. Last accessed Feb 18, 2015

⁷ FDA. *FDA approves abuse-deterrent labeling for reformulated OxyContin*. FDA News Press Release. April 16, 2013. Available at: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm348252.htm>. Last accessed November 4, 2014.

⁸ The White House. *The Administration's Response to the Prescription Drug Epidemic: Action Items*. Available at: http://www.whitehouse.gov/sites/default/files/ondcp/issues-content/action_items_response_to_the_prescription_drug_epidemic.pdf. Last accessed November 4, 2014.

⁹ Butler SF, Cassidy TA, Chilcoat H, et al. Abuse rates and routes of administration of reformulated extended-release oxycodone: initial findings from a sentinel surveillance sample of individuals assessed for substance abuse treatment. *J Pain*. 2013;14(4):351-358.

¹⁰ Rossiter LF, Kirson NY, Shei A, et al. Medical cost savings associated with an extended-release opioid with abuse-deterrent technology in the US. *J Med Econ*. 2014;17(4):279-287