



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
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STATEMENT

OF

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FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

UNITED STATES SENTENCING COMMISSION

“Public Hearing on Proposed 2015 Amendments to the Federal Sentencing Guidelines”

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Introduction

Chair Saris, Vice Chair Breyer and distinguished Commissioners, I am Dr. Sharon Hertz, Acting Director of the Division of Anesthesia, Analgesia, and Addiction Products, Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). Thank you for the opportunity to be here today to discuss the relative potencies of hydrocodone and oxycodone.

FDA's Role

FDA is responsible for protecting the public health by assuring the safety, efficacy and security of, among other products, human and veterinary drugs, including opioids. FDA is also responsible for advancing the public health by helping to speed innovations that make medicines more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medicines to maintain and improve their health.

With respect to opioids, we play a critical role in the development, review, and approval of opioid-based analgesic products. FDA reviews applications for opioid medical products, requires accurate drug prescribing information, and monitors how these products are used once they go to market. In so doing, a balance must be struck between their benefit in treating patients and the risks associated with the use, misuse, abuse, and addiction to patients and to others.

Combating opioid misuse, abuse, and addiction has long been a priority for the Agency, and FDA has taken many steps to address this problem over the last few decades. We have taken

action to build upon existing initiatives and develop new ones, including establishing an internal task force to focus on this critical issue. FDA is also an active participant in working groups established by HHS and the Office of National Drug Control Policy.

Recent Agency actions include implementation of a Risk Evaluation and Mitigation Strategy, or REMS, for all extended-release and long-acting opioid analgesics, the goal of which is to encourage training for prescribers of these drugs in order to ensure their safe and appropriate use. In 2013, the Agency issued a draft guidance document to assist industry in developing new formulations of opioid drugs with abuse-deterrent properties.

Over the last decade or so, FDA has worked to pursue a targeted, science-based, multi-pronged approach that addresses misuse, abuse, and addiction at critical points in the development of an opioid product and in its use throughout the health care system. Pertinent to the present discussion, in 2013 the FDA held a two-day meeting to discuss the issues surrounding the use and abuse of drugs containing hydrocodone, including discussions about the relative effects of hydrocodone and other opioids¹.

Comparison between hydrocodone and oxycodone products

Hydrocodone and oxycodone analgesic products have a number of similarities:

- Both belong to the opioid analgesic class of drugs;

¹ Available at: <http://www.fda.gov/advisorycommittees/calendar/ucm332857.htm>

- Both are available as immediate-release formulations in combination with other drugs (usually acetaminophen) and extended-release formulations;
- Both drugs are in schedule II of the Controlled Substances Act (CSA); and
- Both hydrocodone and oxycodone products have a long marketing history and large market share.

Comparison of hydrocodone and oxycodone potency

Potency refers to the dose of a drug required to produce a given effect. Opioids are indicated for the treatment of pain, generally in the moderate to severe range. While the data about relative potency of different opioids are limited, the data we *do* have from a variety of sources suggest that hydrocodone and oxycodone have similar potency when used as an analgesic for pain management.

Additional information regarding the comparative subjective effects of opioid medications is based on the euphoric effects (and drug “liking”), produced by these drugs. Euphoric effects contribute to their potential for abuse. CDER’s Controlled Substances Staff (CSS) has reviewed six studies published between 2003 and 2010 related to the abuse potential for hydrocodone. These studies were conducted in subjects who abuse drugs and they were asked to provide subjective assessments on whether the drug under study made them high, whether they like the feeling the drug gives them, and whether they would choose to abuse the drug again. CSS staff concluded that, based on these studies, hydrocodone single-entity and combination products produce similar euphoric effects to morphine and oxycodone in a dose-dependent manner.

I am happy to answer any questions you may have.