January 9, 2015

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: FDA-2014-N-1359; Development and Regulation of Abuse-Deterrent Formulations of Opioid Medications; Public Meeting

Dear Sir or Madam:

ASHP is pleased to provide written comments to the Food and Drug Administration (FDA) on the development and regulation of abuse deterrent formulations of opioid medications in addition to our oral comments presented on October 31, 2014. A notice of this public meeting was published on Tuesday, September 23, 2014.[1] ASHP is the national professional organization whose over 40,000 members include pharmacists, pharmacy technicians, and pharmacy students who provide patient care services in acute and ambulatory care settings, including hospitals, health-systems, and clinics. ASHP believes pharmacists have unique knowledge, skills, and responsibilities for assuming an important role in substance abuse prevention, education and assistance, and appreciates and commends the FDA for undertaking work thus far to curb abuse from opioid analgesics. In 2012, ASHP advocated in support of rescheduling hydrocodone-containing combination medications because we believed the resultant increases in safety outweighed the risks to patient access and administrative burden. Emergency department visits attributed to misuse or abuse of narcotic pain relievers increased 153% between 2004 and 2011 to over four hundred and twenty thousand. Oxycodone and hydrocodone containing products account for over half of these visits. [2]

ASHP supports measures such as the formulation and development of abuse deterrent narcotics as one in a collection of strategies to address this national epidemic. However, ASHP cautions the FDA to

1 Federal Register, Volume 79, No. 184. Pages 56810 – 56814

2 Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. (February 22, 2013). The DAWN Report: Highlights of the 2011 Drug Abuse Warning Network (DAWN) Findings on Drug-Related Emergency Department Visits. Rockville, MD.

consider the potential unintended consequences of implementing preferential programs for abuse deterrent formulations and weigh those consequences against the realistic benefit of such formulations. These unintended consequences could include the costs and social stigma to patients that legitimately require higher doses of narcotic analgesics, for example, cancer patients and those with fibromyalgia. In addition, introduction of new formulations to the market would add complexity to therapy. ASHP recognizes that, from a population health perspective, abuse resistant formulations may not reduce the overall level of opioid abuse. Some evidence suggests that for specific agents, abuse, diversion and medication errors decline after introduction of a reformulated product.[2] However, existing data suggest that introduction of an abuse deterrent formulation of a product can cause abusers to switch to alternative agents, such as heroin.[1] ASHP urges the FDA to further investigate the efficacy of abuse-resistant formulations of opioids in preventing drug abuse prior to taking regulatory action to incentivize the marketplace.

ASHP recognizes and advocates for a collaborative and multifaceted solution to the narcotic abuse problem in America. This solution might include other strategies such as a national prescription narcotic monitoring system or better integrating the existing state level prescription drug monitoring programs with one another. ASHP strongly recommends an assessment of current and future research necessary to ensure that the most effective combination of tactics are being used to deter abuse.

ASHP appreciates the opportunity to provide comments. Please contact me by telephone at (301) 664-8806, by email at ctopoleski@ashp.org or Dr. Shekhar Mehta, Director, Clinical Guidelines and Quality Improvement at (301)664-8815, or by email at smehta@ashp.org if you have any questions..

Sincerely,

Christopher J. Topoleski
Director, Federal Regulatory Affairs