

PinneyAssociates Presents at FDA Public Meeting to Help Facilitate the Development of Abuse Deterrent Opioids

BETHESDA, MD (November 1, 2016) – PinneyAssociates today announced that Dr. [Jack Henningfield](#), Vice President of Research, Health Policy and Abuse Liability, and Dr. [Edward Cone](#), Principal Scientist, Drug Delivery and Abuse Deterrent Drug Products, presented at FDA's Public Meeting on *Pre-Market Evaluation of Abuse-Deterrent Properties of Opioid Drug Products*. The FDA is holding this public meeting on October 31st-November 1st to discuss scientific and technical issues relating to formulation development and pre-market evaluation of opioid drug products with abuse-deterrent properties.

"We have seen the success of abuse-deterrent (AD) products with lower rates of abuse and overdose than expected for comparable non-AD opioids. However, opioid abuse, overdose, and other adverse public health outcomes remain a major public health problem. The efforts of FDA and pharmaceutical developers must be viewed as only one part of the comprehensive approach that is vital to addressing the public health problems resulting from other opioid products, both licit and illicitly manufactured", said Dr. Henningfield. "We must continue to push forward so that those who develop substance use disorders and addiction, can, in the words of former Surgeon General C. Everett Koop, find it as easy to get treatment as it is to get addictive and life threatening drugs."

Dr. Cone added, "I support the efforts of the FDA in their efforts to transition from non-abuse deterrent formulations to AD formulations of opioids. We have seen the promise of these products in reducing abuse rates in the community and in reducing adverse outcomes. However, there remains considerable work to be done. Our proprietary [ALERTT](#)[®] system quantifies the "degree of effort" involved in tampering of drug products, including abuse-deterrent formulations of opioids. Data from the ALERTT system can help sponsors select formulations with the most robust abuse-deterrent properties in early development efforts, which can help to ensure that new drugs coming to market will be of most benefit to public health."

About PinneyAssociates

PinneyAssociates, a pharmaceutical and consumer healthcare consulting company that helps clients to reduce their regulatory risk and enhance the commercial value of their life sciences products. PinneyAssociates consults with pharmaceutical companies that market a wide variety of prescription and over-the-counter medications. PinneyAssociates' experts have extensive

expertise in abuse-deterrent drug formulation evaluation, abuse potential assessment, as well as pharmaceutical risk management, Rx-to-OTC switch, and tobacco harm reduction.

For more information about **Pinney**Associates, please contact us at +1.301.718.8440 or info@pinneyassociates.com, or learn more about our work at www.pinneyassociates.com.