

PinneyAssociates and DrugScan Collaborate to Offer *In Vitro* Tamper Testing of Abuse-Deterrent Drugs

Bethesda, MD, April 21, 2014 -- PinneyAssociates and DrugScan announce a collaboration to provide *in vitro* laboratory tamper testing of abuse-deterrent drug products and formulations to pharmaceutical companies developing opioids and other drugs that act on the central nervous system.

In January 2013, the Food and Drug Administration (FDA) published Draft Guidance to Sponsors on Abuse-Deterrent Opioids – Evaluation and Labeling, which provided a framework for the types of *in vitro* manipulation and extraction studies required for consideration of labeling related to physicochemical barriers to abuse. These guidelines provide incentives to industry to make drugs safer and less abusable.

“PinneyAssociates and DrugScan have joined forces to provide pharmaceutical companies with a team of scientists experienced in tamper testing together with a trusted, innovative, state-of-the-art toxicology laboratory,” said Edward Cone, Ph.D., Principal Scientist, Drug Delivery and Abuse Deterrent Drug Products, PinneyAssociates.

Dr. Edward Cone leads PinneyAssociates’ effort on abuse-deterrent drugs. His 2006 seminal paper in the journal, *Drug and Alcohol Dependence*, on pharmaceutical tampering illustrates the real-world impact that formulations can have on the abuse risk of medications. Dr. Cone is lead author of a 2013 published laboratory model in *Drug and Alcohol Dependence*, describing the practical implementation of assessing the abuse deterrence and tamper resistance of drug formulations.

“Pharmaceutical companies developing abuse-deterrent formulations require well-designed, scientifically sound tamper testing of their drug products to inform labeling and scheduling decisions. Furthermore, such studies have implications for potential human abuse potential study designs as well,” commented Jack Henningfield, Ph.D., Vice President, Research, Health Policy, & Abuse Liability, PinneyAssociates.

“Through rigorous scientific implementation of required FDA laboratory tests today, we support patient safety in the future,” said Anthony Costantino, Ph.D., President and Chief Executive Officer of DrugScan.

As part of the collaboration, PinneyAssociates transferred proprietary technology and provided training to DrugScan related to the assessment of the smoking potential of abuse-deterrent formulations and the assessment of the physical strengths and weaknesses of a drug formulation when subjected to manipulation attempts.

PinneyAssociates’ scientists include internationally respected leaders in the evolving science of *in vitro* assessment of abuse-deterrent drugs and formulations (commonly

referred to as “tamper testing”) and drug abuse liability assessment. Through our collaborations, we offer comprehensive *in vitro* assessment on abuse deterrence and tamper resistance of drug formulations and actives as well as animal and human abuse liability assessment related services. For more about **Pinney**Associates, please visit <http://www.pinneyassociates.com>

DrugScan is a leader in clinical and forensic toxicology, medication monitoring, and drug detection laboratory services. DrugScan has been certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) since 1989 and is accredited by the College of American Pathologists (CAP), ensuring consistently high levels of service, compliance with regulations, and achievement of the highest standards of accuracy, professionalism and responsiveness. For more about DrugScan, please visit <http://www.drugscan.com/>