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Biography

Robert P Bianchi is currently the President and Chief of Scientific and Technical Affairs at the Prescription Drug Research Center, Bradenton, FL. He is a retired laboratory Director for the Drug Enforcement Administration after 34 years of federal service, where he held increasingly responsible positions as an Analytical Chemist for the FDA and DEA to the Chief of DEA's Laboratory Operations Section. He was also Director of the DEA Special Testing and Research Laboratory where extractability experiments were conducted more than 20 years ago. Since 2005 he has been working with the pharmaceutical industry and FDA on developing *in vitro* protocols to evaluate abuse deterrent formulations and has been actively involved in sharing his experience with the regulatory, treatment, pharmaceutical abuse and law enforcement community. He has provided drug related consultations to more than 30 organizations/companies concerned about OTC and prescription drug abuse and has made numerous presentations to the regulatory, treatment, pharmaceutical, abuse and law enforcement communities.

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Note:

GOVERNMENT AND INDUSTRY RESPONSE TO THE US OPIOID EPIDEMIC

Prescription drug abuse has been declared an epidemic in America by the Centers for Disease Control and Prevention. According to the National Safety Council Prescription Nation 2016, the United States makes up 4.6 percent of the world's populations but consumes 81 percent of the world supply of oxycodone. The FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs while assuring patient access. This is a responsibility shared with the pharmaceutical industry, treatment facilities, educational institutions, and federal, state and local law enforcement agencies. 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 and foods to maintain and improve their health. Toward that end, the FDA issued guidance for industry in April 2015 under the title, abuse-deterrent opioids-evaluation and labeling, which contains the following statement: the goal of the laboratory-based studies, category should be to evaluate the ease with which the potentially abuse-deterrent properties of a formulation can be defeated or compromised. The FDA also issued draft guidance for industry in March 2016 (finalized November 2017) the general principles for evaluating the abuse deterrence of generic solid oral opioid drug products. This presentation will discuss abuse deterrent technology currently approved or in development and the required *in vitro* studies designed to evaluate extractability or tamperability. The FDA position on abuse deterrent delivery systems and the history of abuse deterrent opioid development will also be discussed. Studies on the efficacy of a new formulation to deter abuse will also be discussed.