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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% of the world's populations but consumes 81% 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. 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 1, 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 The FDA also issued draft guidance for industry in March 2016 the "General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products".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.

Biography

Robert P Bianchi is the President and Chief of Scientific and Technical Affairs at the Prescription Drug Research Center in Bradenton, Florida. Previously, he has spent 34 years in federal service as a Chemist at the FDA and DEA, including as Chief of the DEA's Laboratory Operations Section, and the Director of the DEA Special Testing and Research Laboratory, where *in-vitro* studies were done more than 20 years ago. For the last decade, he has participated dozens of category 1 studies on abuse-deterrent opioid formulations, appeared as a panelist and presenter at abuse deterrent formulation and prescription drug abuse professional meetings. He has provided drug related consultations to more than thirty organizations/companies concerned about OTC and prescription drug abuse and has made numerous presentations to the treatment, pharmaceutical and law enforcement communities.

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