Arch Chem Res 2019, Volume 3
DOI: 10.21767/2572-4657-C2-018

Government and industry response to the US opioid epidemic

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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. 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 The FDA also issued draft guidance for industry in March 2016 (finalized November 2017) the "General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products".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.