FDA confronts opioid addiction and overdose deaths

By Bryant Furlow

Faced with a growing nationwide epidemic of opioid drug addiction and overdose deaths, the Food and Drug Administration (FDA) has announced a comprehensive review of the agency's opioids policies. The US saw more than 28,000 opioid overdose deaths in 2014 (the most recent year for which complete data is available) according to a January, 2016, Centers for Disease Control [CDC] analysis.

“We're going to fundamentally re-examine the risk-benefit paradigm for opioids and ensure that we consider their wider public health effects”, said Robert Califf (FDA, Silver Spring, MD, USA) at a press conference on February 4. The agency's plan includes improved transparency in the drug approval process for opioids, convening of expert panels, commissioning of clinical and observational studies, and an emphasis on abuse deterrent formulations. Califf also pledged improved communication with physicians, starting with improved safety labeling for prescription opioids. The agency will also work to improve access to naloxone, a drug that treats opioid overdose, he said.

“There has been a huge escalation of overdose deaths, both for prescription drugs and heroin”, noted Roger D. Weiss (McLean Hospital, Belmont, MA, USA). “It is a major priority for the Government—the CDC—in addition to the FDA. The White House is stressing prescription opioid deaths and the issue is being addressed at the state level as well. There's no one answer to this crisis. Attacking it on multiple fronts is important”.

The White House has sought US$1·1 billion from Congress to help address the crisis. States are seeking to increase access to local treatment services to improve education efforts—particularly among high-school students—and to better control prescribing of pain drugs, Weiss and others report.

According to public health officials, many people who ultimately die of heroin overdoses first become addicted to prescription opioids. Heroin overdose rates have sometimes increased after efforts to restrict opioid prescribing.

“Overdoses from prescription opioid pain relievers are a driving factor in the 15-year increase in opioid overdose deaths, whereas the sharp increase in opioid overdose deaths since 2010 is attributable in large part to overdoses from illicit opioids, especially heroin”, noted the lead author of the CDC analysis, Rose Rudd (US Centers for Disease Control and Prevention, Atlanta, GA, USA).