Califf, FDA top officials call for sweeping review of agency opioids policies

In response to the opioid abuse epidemic, today Dr. Robert Califf, the FDA’s Deputy Commissioner for Medical Products and Tobacco, along with other FDA leaders, called for a far-reaching action plan to reassess the agency’s approach to opioid medications. The plan will focus on policies aimed at reversing the epidemic, while still providing patients in pain access to effective relief.

The FDA will:

- Re-examine the risk-benefit paradigm for opioids and ensure that the agency considers their wider public health effects;
- Convene an expert advisory committee before approving any new drug application for an opioid that does not have abuse-deterrent properties;
- Assemble and consult with the Pediatric Advisory Committee regarding a framework for pediatric opioid labeling before any new labeling is approved;
- Develop changes to immediate-release opioid labeling, including additional warnings and safety information that incorporate elements similar to the extended-release/long-acting (ER/LA) opioid analgesics labeling that is currently required;
- Update Risk Evaluation and Mitigation Strategy requirements for opioids after considering advisory committee recommendations and review of existing requirements;
- Expand access to, and encourage the development of, abuse-deterrent formulations of opioid products;
- Improve access to naloxone and medication-assisted treatment options for patients with opioid use disorders; and
- Support better pain management options, including alternative treatments.

As one of the cornerstones of this plan, the FDA will seek guidance from outside experts in the fields of pain management and drug abuse. For example, the FDA has already asked the National Academy of Medicine to help develop a framework for opioid review, approval and monitoring that balances individual need for pain control with considerations of the broader public health consequences of opioid misuse and abuse.

“We are determined to help defeat this epidemic through a science-based and continuously evolving approach,” said Califf. “This plan contains real measures this agency can take to make a difference in the lives of so many people who are struggling under the weight of this terrible crisis.”
In addition, the FDA will convene independent advisory committees made up of physicians and other experts when considering for approval any new opioid drugs that do not contain abuse-deterrent properties. The FDA will also convene a meeting of its standing Pediatric Advisory Committee to make recommendations regarding a framework for pediatric opioid labeling and use of opioid pain medications in the pediatric population.

The FDA is also strengthening the requirements for drug companies to generate postmarket data on the long-term impact of using ER/LA opioids. The agency expects this to result in the most comprehensive data ever collected in the field of pain medicine and treatments for opioid use disorder. The data will further the understanding of the known serious risks of opioid misuse, abuse, overdose and death.

Opioids are a class of drugs that include prescription medications such as oxycodone, hydrocodone, and morphine, as well as the illicit drug heroin.

Drug overdose deaths, driven largely by overdose from prescription opioids and illicit drugs like heroin and illegally-made fentanyl, are now the leading cause of injury death in the United States – surpassing motor vehicle crashes.

“Agencies from across the Department of Health and Human Services and throughout the federal government are united in aggressively addressing this public health crisis,” said U.S. Health and Human Services (HHS) Secretary Sylvia M. Burwell. “The FDA is a vital component to combating this epidemic, and the innovation and modernization they have committed to undertaking is an important part of the overall efforts at HHS.”

This renewed effort falls within the context of a broad national campaign that includes a major initiative led by HHS. Secretary Burwell has made addressing opioid abuse, dependence, and overdose a priority, and work is underway within HHS on this important issue. The evidence-based initiative focuses on three promising areas: informing opioid prescribing practices; increasing the use of naloxone, building on the FDA’s recent approvals of injectable and intranasal naloxone; and using medication-assisted treatment to move people out of opioid addiction. The FDA’s call to action is also supportive of the Centers for Disease Control and Prevention’s current work on guidelines for prescribing of opioids for the treatment of chronic pain outside of end of life care.

“Things are getting worse, not better, with the epidemic of opioid misuse, abuse and dependence,” added Califf. “It’s time we all took a step back to look at what is working and what we need to change to impact this crisis.”

The agency will provide updates on progress with the goal of sharing timely, transparent information on a regular basis.

For more information:

Fact Sheet – FDA Opioids Action Plan
Opioid Medications
The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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