Food And Drug Administration Top Officials Call for Sweeping Review of Agency Opioids Policies

In response to the opioid abuse epidemic, today Dr. Robert Califf, the Food and Drug Administration’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.

For more information please see the FDA News Release [here](#).

and the FDA Fact Sheet is found [here](#).