

Fact Sheet – FDA Opioids Action Plan

The FDA is deeply concerned about the growing epidemic of opioid abuse, dependence and overdose in the United States. In response to this crisis, the agency has developed a comprehensive action plan to take concrete steps toward reducing the impact of opioid abuse on American families and communities. As part of this plan, the agency is committing to work more closely with its advisory committees before making critical product and labeling decisions; enhancing safety labeling; requiring new data; and seeking to improve treatment of both addiction and pain. At the same time, the FDA will fundamentally re-examine the risk-benefit paradigm for opioids and ensure that the agency considers the wider public health effects. The FDA is committed to taking all of these steps transparently and in close cooperation with its sister agencies and stakeholders.

The FDA's actions include:

- **Expand use of advisory committees.** Starting today, the FDA will convene an expert advisory committee before approving any new drug application for an opioid that does not have abuse-deterrent properties. And the Pediatric Advisory Committee will make recommendations regarding a framework for pediatric opioid labeling before any new labeling is approved. The FDA will consult an advisory committee on abuse-deterrent formulation (ADF) opioids when they raise novel issues. **Outcome:** Review and advice from external experts with opportunity for public input before approval of any new opioid that does not have abuse-deterrent properties and expert advice on pediatric opioid labeling.
- **Develop warnings and safety information for immediate-release (IR) opioid labeling.** The FDA is developing changes to IR opioid labeling, including additional warnings and safety information that incorporate elements similar to the extended-release/long-acting (ER/LA) opioid analgesics labeling update that occurred in 2013. **Outcome:** Better information for doctors about the risks and how to prescribe safely.
- **Strengthen postmarket requirements.** Because the evidence base to guide the use of opioid medications, particularly in the setting of long-term use, is substantially lacking, the FDA is strengthening the requirements for drug companies to generate postmarket data on the long-term impact of using ER/LA opioids. **Outcome:** Better evidence on the serious risks of misuse and abuse associated with long-term use of opioids, predictors of opioid addiction and other important issues.
- **Update Risk Evaluation and Mitigation Strategy (REMS) Program.** ER/LA opioids are currently subject to a REMS program that requires sponsors to fund continuing medical education (CME) providers to offer, at low or no cost, CME courses on the appropriate use of these products. The FDA will update the REMS program requirements

for opioids after considering advisory committee recommendations and review of existing requirements. **Outcome:** Increase the number of prescribers who receive training on pain management and safe prescribing of opioid drugs in order to decrease inappropriate opioid prescribing.

- **Expand access to abuse-deterrent formulations (ADFs) to discourage abuse.** The pharmaceutical industry has shown significant interest in developing ADFs and the technology is progressing rapidly. ADFs hold promise as their abuse-deterrent qualities continue to improve and as they become more widely available. The FDA will issue draft guidance with its recommendations for the approval standards for generic abuse-deterrent formulations. Release of this guidance is a high priority, since the availability of less costly generic products should accelerate prescribers' uptake of ADFs. **Outcome:** Spur innovation and generic ADF product development.
- **Support better treatment.** The FDA is reviewing options, including over-the-counter availability, to make naloxone more accessible to treat opioid overdose, building on the agency's recent approval of intranasal naloxone. The agency actively supports the Centers for Disease Control and Prevention guidelines for prescribing opioids for the treatment of pain and will facilitate the development of evidence and improved treatments. **Outcome:** Broader access to overdose treatment, safer prescribing and use of opioids, and ultimately, new classes of pain medicines without the same risks as opioids.
- **Reassess the risk-benefit approval framework for opioid use.** The FDA will seek advice from the agency's Science Board in March 2016 and is already engaging the National Academy of Medicine on how to take into account our evolving understanding of the risks of opioids, not only to the patient but also the risks of misuse by other persons who obtain them. These reports will be publicly available. **Outcome:** Formal incorporation of the broader public health impact of opioid abuse in approval decisions.