King of Pain: FDA Plans to Reevaluate Its Opioid Policies

Alan G. Minsk

The Food and Drug Administration (FDA) announced recently that it intends to reevaluate its policies on opioid medications, designed "at reversing the epidemic, while still providing patients in pain access to effective relief."[1] The agency said that drug overdose deaths are now the leading cause of injury death in the United States. While FDA is not trying to steal Sting's title as the King of Pain (see The Police's 1983 song by the same name), it is trying to demonstrate its plan to play a major role in combatting opioid abuse and misuse.

Among its proposed actions, FDA intends to take the following steps:

- Expand use of advisory committees:
  - FDA will convene an independent, expert advisory committee before approving any new drug application for an opioid that does not have abuse-deterrent properties;
  - the Pediatric Advisory Committee will make recommendations regarding a framework for pediatric opioid labeling before any new labeling is approved;
  - FDA will consult an advisory committee on Abuse-Deterrent Formulation (ADF) opioids when they raise novel issues.
- Develop warnings and safety information of immediate-release (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, which occurred in 2013.
- Strengthen postmarket requirements to generate postmarket data on the long-term impact of using ER/LA opioids.
- Update Risk Evaluation and Mitigation Strategy (REMS) Program for opioids after considering advisory committee recommendations and review of existing requirements.
- Expand access to ADFs to discourage abuse:
  - FDA will issue draft guidance with its recommendations for the approval standards for generic abuse-deterrent formulations; this is a high priority for the agency.
- Support better treatment by reviewing options, including over-the-counter availability, to make naloxone more accessible to treat opioid overdose:
  - the agency wants broader access to overdose treatment, safer prescribing and use of opioids, and new classes of pain medicines and alternative treatments without the same risks as opioids.
- Reassess the risk-benefit approval framework for opioid use
  - FDA will seek counsel from the agency's Science Board in March 2016 on how to evaluate the risks of opioids.

1 www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm.

Authors and Contributors

Alan G. Minsk
Partner, Atlanta Office
404.873.8690
alan.minsk@agg.com

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Atlanta Office
171 17th Street, NW
Suite 2100
Atlanta, GA 30363

Washington, DC Office
1775 Pennsylvania Avenue, NW
Suite 1000
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