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FDA Unveils Action Plan to Combat Opioid Abuse

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The ***U.S. Food and Drug Administration ("FDA")*** recently announced a "far-reaching action plan" to evaluate and improve the agency's prescription opioid policies. The announcement came amidst public criticism and mounting political pressure on the FDA to address the country's "opioid abuse epidemic," including a hold placed by Senate Democrat Edward J. Markey on President Obama's nominee to lead the FDA, Dr. Robert M. Califf. In a December 21, 2015 letter to ***U.S. Department of Health & Human Services ("HHS")*** Secretary Sylvia M. Burwell, Senator Markey warned that he would block a vote on Califf's nomination to be FDA commissioner until the FDA commits to rescinding pediatric OxyContin approval, empaneling advisory committees on any future opioid-approval questions, and immediately ensuring that issues of addiction, abuse, and dependence are considered by the FDA when making a final decision about the approval or indication(s) for an opioid drug.

The FDA's plan provides agency responses to eight issues relating to opioid abuse:

1. **Managing pain in children**: An FDA Pediatric Advisory Committee will convene to address the use of opioid medications in children, including through the development of an evidence-based guide for treatment, and provide input on policies for adding new pediatric opioid labeling.

2. **Addressing the lack of non-opioid alternatives for pain management**: The FDA will work with members of industry and the National Institutes of Health to develop alternative pain medications that pose a comparatively lower risk of addiction; these will include non-pharmacologic approaches to chronic pain treatment.

3. **Reviewing labeling and post-marketing surveillance requirements**: The FDA will reexamine how opioids should be labeled and will require drug companies to generate post-marketing data on the health impact of long-term use of extended-release/long-acting

("ER/LA") opioids. The last change to opioid labelling occurred in September 2013, when the FDA required ER/LA opioid analgesics to contain more extensive safety labeling and directed opioid makers to conduct four post-marketing observational studies and one clinical trial.

4. **Balancing individual need for pain care and societal risk**: The FDA will seek guidance from "outside experts" in the fields of pain management and drug abuse, including the National Academies of Sciences, Engineering, and Medicine, to help develop a framework for opioid review, approval, and monitoring that balances patients' need for pain control with broader public health consequences of the misuse and abuse of painkillers.

5. **Meeting the need for timely action**: The FDA Science Board, which advises the agency regarding specific, complex scientific and technical issues, will advise on the role of pharmaceuticals in pain management, development of alternative pain relievers, and more comprehensive post-marketing surveillance activities.

6. **Prioritizing abuse-deterrent formulations and overdose treatments**: The FDA will encourage the development of more effective abuse-deterrent features and prioritize the issuance of guidance on generic opioid products in abuse-deterrent formulations. The agency will also support the development, marketing, and availability of countermeasures to opioid overdose, such as the opioid antagonist naloxone.

7. **Creating clear guidelines for opioid use**: The agency is supporting the Centers for Disease Control and Prevention's ("CDC") Draft Guideline for Prescribing Opioids for Chronic Pain —intended for use by health care providers in determining when to initiate or continue opioid therapy for chronic pain—as well as the Surgeon General's recommendations for curbing inappropriate opioid prescribing practices.

8. **Developing a better evidence base**: HHS agencies and the FDA program for mandatory, industry-funded studies are developing a coordinated plan for conducting research that will provide an evidence-based guide for opioid use and consider new and alternative approaches to pain therapy and prevention.

The primary objective of the FDA's multi-prong plan is largely information gathering. This likely will mean more extensive post-marketing testing and reporting requirements for pharmaceutical manufacturers, including additional studies and analyses of the health risks and benefits associated with long-term use of ER/LA opioids previously approved for sale by the FDA and opioid alternatives. Providers, meanwhile, may be subject to new CDC and Surgeon General guidelines for opioid prescribing for chronic pain outside of end of life care. Additional, more immediate changes may ensue, as the FDA's plan came under criticism within hours of its unveiling last week. Senator Markey, for example, complained that the above proposals "fall short of what is needed" and indicated that he would continue to block Dr. Califf's candidacy until the FDA commits to holding advisory committees of outside experts for all opioid approval decisions.

How the FDA proceeds remains to be seen. Foley will closely monitor and report on any proposed agency action.

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