CDER Topics and Questions for March 1, 2016 Science Board Meeting

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. This meeting of the Science Board is one part of the broader set of initiatives outlined in the Action Plan by the FDA to confront prescription opioid abuse. The discussion has several general goals:

1. To discuss the role of opioids in pain management and the scientific challenges facing FDA in supporting the development of new drugs to treat pain that have reduced risks of being abused. This could include non-opioid pain drugs that lack abuse potential or opioid drugs that are formulated to be resistant to abuse.
2. To discuss the scientific challenges the FDA faces in seeking to understand the real-world use of opioids to treat pain, including the impact of opioids with potentially less risk for abuse.
3. To discuss the role that the FDA plays as a part of a larger Federal, State and local response to the challenges of providing appropriate pain treatment while reducing prescription opioid drug abuse.

Questions for the Committee will be of a general, non-voting nature and include the following:

1. What additional steps should the FDA consider to encourage the development of new pain medicines with reduced risks for abuse?
2. What additional actions should the FDA take to improve our understanding of the use, misuse and abuse of drugs used to treat pain?
3. FDA has formed extensive partnerships with other Federal and non-Federal partners. Are there other similar activities FDA should seek out with a goal of improving the management of pain in the United States while reducing prescription opioid abuse?
4. As announced in our Action Plan, FDA is engaged in a comprehensive set of activities to incorporate our evolving understanding of the risks of opioids into our regulatory actions. How does the discussion today advance the understanding of risk (both to the patient and to family members and others who may obtain opioids without a prescription), and are there other actions that FDA should take within its regulatory authorities to address the public health impact of opioid abuse?