BIO International Convention

The Global Event for Biotechnology

June 23–26, 2014
San Diego, CA

Will Government and Payor Policies Encourage Innovation and Create Incentives for the Continued Development of Abuse Deterrent Formulations and Improvements to Existing Technologies?

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I have no financial conflicts of interest to disclose

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Outline

- Goals of Abuse-Deterrent (AD) Formulation development
- Progress in AD Formulation Development
  - Promise of AD formulations
  - Pace of scientific progress
  - Pace of regulatory work
- FDA Work on Remaining Challenges
  - Science of formulations development
  - Science of post-marketing assessment of new formulations

Abuse-Deterrent Opioids Draft Guidance: Goals

- Goals: Two over-arching goals:
  - Encourage the development of successful abuse-deterrent formulations of opioids
  - Assure appropriate development and availability of generic drugs, reflecting their importance in US healthcare
- Accomplishing these goals: incentivize the use of successful abuse-deterrent formulations through Guidance and accurate labeling

Reminder: Much to Learn!

- "The science of abuse deterrence is relatively new, and both the formulation technologies and the analytical, clinical, and statistical methods for evaluating those technologies are rapidly evolving."*
- In particular, the agency encourages additional research on the following topics:
  - Quantitative link between changes in the pharmacokinetics of opioids in different formulations and results of a clinical abuse potential study.
  - How best to analyze a clinical abuse potential study.
  - Quantitative link between the outcomes from a clinical abuse potential study and the impact of formulation on abuse in the community.
  - How best to assess the effects of a new abuse-deterrent formulation on abuse in the community.

* www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm334743.pdf - 189k

Progress in AD Formulation Development

- Pace of Technology—substantial increase in:
  - Numbers of meetings between FDA and industry to discuss AD formulations of opioids
  - Proposals to study novel AD formulations
    - Crush- and extraction-resistant technologies remain important
    - Aversion-based technologies
    - Novel technologies with promise to impact oral abuse in addition to IV and intranasal abuse
- Pace of Scientific and Regulatory Work
  - A priority for FDA
  - Balancing innovator and generics development critical

Focused Work by FDA on AD Formulations

- Continued scientific progress on AD formulations
  - Essential to development of AD generic drugs
  - FDA laboratory working on AD formulation science
  - FDA support of external scientific work on AD formulations
- Continued work to assess impact of AD formulations on actual abuse and misuse of opioids
  - FDA and USG epidemiologists are working to improve the surveillance databases and tools used to assess impact of AD formulations in US market
    - E.g. “DAWN” database replacement, measuring appropriate access to opioids by pain patients

FDA Focus on AD Formulations (cont)

- Refinement of guidance on the AD formulation development in support of both innovator and generics development
  - Importance of providing meaningful, scientific pathway to the development of AD generic drugs
  - Importance of finalizing Guidance for AD Opioids
  - Importance of providing incentives and policy framework that supports iterative improvement in AD technology as science advances
- Work on guidance greatly aided by ongoing scientific work by FDA and others
- Work on guidance aided critically by experience with product development

Big Picture of Work to Address Opioids Abuse

- Work on ADF development is one part of the FDA efforts to confront prescription drug abuse
  - **Improving drugs used to treat pain**
    - Abuse-deterrent formulations of opioids
    - New classes of pain drugs that lack abuse risk
  - **Improving safe use of opioids**
    - Improved education of prescribers and patients to reduce risk of abuse
    - Improved surveillance to understand use of opioids
    - Improved use of packaging and storage of opioids
  - **Improving treatment of opioid abuse**
  - **Improving treatment of opioid overdose**
    - Naloxone autoinjector approval

Conclusions

- Development and broad adoption of successful abuse-deterrent formulation remains an important priority for FDA
- Progress is being made in developing and assessing abuse-deterrent formulations
- FDA guidance seeks to further clarify developmental pathway and incentivize development and use of abuse-deterrent formulations of opioids, as one part of FDA's work addressing opioids abuse