Prescription Drug Monitoring Program Initiatives at the FDA

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Disclaimer

This presentation reflects the views of the author and should not be construed to represent FDA’s views or policies.
Objectives

• Discuss the FDA Opioid Action Plan and the Safe Use Initiative

• Learn about FDA initiatives and projects leveraging PDMP data to engage high-risk prescribing practices and improve patient safety

• Explore the different mechanisms to engage and collaborate with the Center for Drug Evaluation and Research and the FDA
Opioid Epidemic

• On an average day in the US...
  – More than 650,000 opioids are dispensed
  – 3,900 people initiate nonmedical use of a prescription opioid
  – 78 people die from an opioid related overdose
Opioid Epidemic in Maryland

• In 2015, 1259 overdose deaths state wide
• In first 9 months of 2016, 1468 overdose deaths
• Comparing the first 9 months of 2016 to 2015, overdose deaths increased 62%

What is FDA doing about Opioids?

• FDA has taken numerous actions to address risks associated with opioid use, misuse, and abuse.

• Actions include labeling changes, warning letters regarding misleading ads, scientific workshops, public hearings, advisory committee meetings, approval of abuse-deterrent formulations, and requiring postmarket safety studies.

• Opioid safety is not a new area for FDA – FDA’s actions regarding opioid risks date back at least 15 years.

http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm338566.htm
Recent FDA Actions


“In response to the opioid abuse epidemic, today Dr. Robert Califf, the FDA’s Deputy Commissioner for Medical Products and Tobacco, along with other FDA leaders, called for a far-reaching action plan to reassess the agency’s approach to opioid medications. The plan will focus on policies aimed at reversing the epidemic, while still providing patients in pain access to effective relief.”

http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm
FDA Opioids Action Plan

To reverse the epidemic while still providing patients with access to effective relief

- Advisory Committees
- IR Labeling
- Post-market
- REMS
- Abuse Deterrent
- Supporting Treatment
- Risk-Benefit
FDA Opioids Action Plan

To reverse the epidemic while still providing patients with access to effective relief

- **Advisory Committees**
  - Expand the use and advice from external experts

- **IR Labeling**
  - Develop warnings and safety information

- **Post-market**
  - Better evidence on the serious risks of misuse and abuse with long-term use

- **REMS**
  - Update and increase number of prescribers who receive training on pain management and safe prescribing

- **Abuse Deterrent**
  - Spur innovation and generic abuse-deterrent formulations and product development

- **Supporting Treatment**
  - Access to overdose treatment, safer prescribing, new classes of pain medicine

- **Risk-Benefit**
  - Reassess risk-benefit framework and incorporate broader public health impact
FDA and PDMPs

FDA has supported the Prescription Drug Monitoring Program Center of Excellence at Brandeis University.

• Working to improve prescriber utilization of state Prescription Drug Monitoring Programs (PDMPs)
• Examining the impact of strategies to reduce misuse and abuse of opioid medicines.

Current Approaches

CDER’s Professional Affairs and Stakeholder Engagement Staff are continuing efforts to work with PDMP’s:

– Outreach effort to understand the details of each state’s PDMP (Shawn Brooks/Hank Hoang) and data sharing between various PDMPs.

– Working with the National Association of Boards of Pharmacy (NABP) to understand their efforts to facilitate information sharing between PBNPs.
Current Approaches

FDA’s efforts with engaging PDMP’s focuses on understanding:

• The various approaches to gathering information and the goals of each state PDMP

• Any interventions made on a state level to modify prescribing behavior

• Whether these interventions have been successful
Challenges of PDMP Data

• Communication barriers (legal and IT)
• Various approaches and solutions have been employed
• Data differs from state to state
• Need a platform to share best practices
• FDA supports efforts to reduce preventable harm but has a limited role, as PDMPs are state programs
Safe Use Initiative

• **Goal:** Reduce preventable harm by developing, implementing, and evaluating cross sector interventions with partners committed to safe and appropriate medication use.
Conceptual Framework for Non-Preventable Harm

- Indications
- Identified Risks
- Potential Risks
- Missing Information

Unavoidable subset of Identified Risks

Gaps in Current Knowledge
Conceptual Framework for Preventable Harm

- Indications
- Identified Risks
- Potential Risks
- Missing Information

Inappropriate Use

Not incorporating current knowledge when drug is selected

Not taking actions to address the avoidable subset of Identified Risks

Unintended Exposures

Intentional misuse
Safe Use Partners

• Federal agencies

• Healthcare professionals and professional societies

• Pharmacies, hospitals, and other health care entities

• Patients, caregivers, consumers, and their representative organizations
Extramural Research

Safe Use funds projects that “develop innovative methods to create, facilitate, and encourage research in the area of safe medication use that seeks to reduce preventable harm from drugs.”

This is accomplished via the Broad Agency Announcement (BAA), an open and continuous announcement to solicit research proposals.

Details on the BAA can be found at FedBizOpps.gov
https://www.fbo.gov/index?s=opportunity&mode=form&id=9c48c509b0bfb19144d50ffc667f9550&tab=core&cview=1
Current Safe Use Opioid Projects

• Opioid Patient-Prescriber Agreement Development and Pilot

• Nurse Pain Educator Pilot Program

• Analysis of NY State PDMP Data Assessing Impact of State Intervention on High Risk Prescribers of Opioids and Combo Opioids/Benzodiazepines

• Reducing the Use of Opioid Therapy Following Orthopedic Surgery
State Intervention on High Risk Prescribers

- Data for the New York PDMP will be used to identify “high-risk” prescribers.
- “High-risk” is based on patients receiving a high daily dose of an opioid or co-prescribing of an opioid and a benzodiazepine.
High Risk Prescribers

• Providers identified as high risk will receive an educational intervention.
• Intent of the intervention is to facilitate safer prescribing practices to improve patient safety.
• Intent is not to be punitive, but to promote thoughtful and informed prescribing
Assessment of Intervention

Will the intervention have an effect on...

• Number of controlled substance prescriptions?
• Prescribing patterns?
• Mean daily dose per patient?
• Morbidity? (overdoses, prenatal exposures)
• Mortality?

http://www.fda.gov/Drugs/DrugSafety/SafeUseInitiative/ucm188762.htm#opioidssafe
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Questions?