U.S. FOOD & DRUG ADMINISTRATION

Center for Drug Evaluation and Research
Professional Affairs and Stakeholder Engagement
Safe Use Initiative

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Professional Affairs and Stakeholder Engagement (PASE)
Safe Use Initiative
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Topic	Speaker
Introduction to FDA PASE Safe Use Initiative	Mary Ghods, RPh, FDA
Evaluation of a medication label health literacy tool focused on prescription and OTC NSAIDs	Amy Barton Pai, PharmD, University of Michigan, Department of Clinical Pharmacy
Discovery study of the optimal labeling and dosing of OTC pediatric cough and cold medications	Shonna Yin, MD, New York University, School of Medicine / Bellevue Hospital Center

Organizational Goal

- Reduce preventable harm by identifying specific, preventable medication risks and developing, implementing and evaluating cross-sector interventions with partners who are committed to safe medication use

- Stakeholders include but are not limited to patients, patient advocacy groups, healthcare professionals, professional societies, healthcare delivery systems, payers, and state or other federal regulatory or public health bodies

Expanding the Evidence Base

- Safe Use aims to develop and evaluate new options that allow FDA and the broader healthcare community to enhance safe and appropriate medication use

Current FDA/SUI Research

- Opioid Patient-Prescriber Agreement Pilot
- Nurse Pain Educator Pilot Program
- National Standardization of Intravenous (IV) and Oral Liquid Medications
- Educational Resource for the Effective Communication Between HCPs and Patients About Impairing Risks of Prescribed Medication in Relation to Driving

http://www.fda.gov/Drugs/DrugSafety/SafeUseInitiative/ucm277720.htm

Heath Literacy Informs Regulatory Decision Making

- FDA regulation requires that over-the-counter medication labels be written at a level easy to be read and understood by the ordinary individual, including individuals of low comprehension.
  http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

- Label comprehension studies inform FDA whether a medication can be used safely and effectively without professional oversight.
  - Drug manufacturers are responsible for producing labels that comply with this requirement.
  - Academia and research organizations also conduct label comprehension studies when preventable harm from medications due to a lack of health literacy is suspected.