

Center for Drug Evaluation and Research

Professional Affairs and Stakeholder Engagement

Safe Use Initiative

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U.S. FDA

Professional Affairs and Stakeholder
Engagement (PASE)

Safe Use Initiative

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

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



The screenshot shows the top portion of the FEDBIZOPPS.GOV website. The header features the text "FEDBIZOPPS.GOV" with a star icon, and "Federal Business Opportunities" to its right. Further right are logos for "IAE", "E-GOV", and "USA.gov". Below the header is a navigation bar with buttons for "Home", "Getting Started", "General Info", "Opportunities" (highlighted in green), "Agencies", and "Privacy". To the right of the navigation bar are links for "Buyers: Login | Register", "Vendors: Login | Register", and an "Accessibility" icon.

FDA Food and Drug Administration Broad Agency Announcement for the Advanced Research and Development of Regulatory Science
Solicitation Number: FDABAA-15-00121
Agency: Department of Health and Human Services
Office: Food and Drug Administration
Location: Office of Acquisitions and Grants Services - Rockville

- 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

Health 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.