

Janice Dunsavage Remarks
FDA Public Hearing on
CDER Current Risk Management Strategies
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Presentation Time: 15 minutes

- Self introduction and brief bio information.
- ISMP is the nation's only nonprofit organization devoted entirely to medication error prevention and safe medication use. We are known and respected worldwide as the premier resource for impartial, timely, and accurate medication safety information.
- The Institute represents more than 30 years of experience in helping practitioners keep patients safe, and our efforts have been built on a non-punitive approach and systems-based solutions.
- We have a direct connection and trusted relationship with frontline practitioners, which sets us apart from other patient safety organizations
- One cornerstone of ISMP's efforts is a continuous, voluntary, and confidential practitioner error reporting program designed to learn about errors happening across the nation, understand their causes, and share lessons learned with the entire healthcare community.
- The national Medication Errors Reporting Program, operated by the United States Pharmacopeia in conjunction with ISMP, receives error reports from healthcare professionals. ISMP provides independent review of errors submitted, and all information derived from the program is shared with the FDA and the pharmaceutical companies whose products are mentioned in reports.
- Our other many programs and services include print communications with health care professionals--four medication safety newsletters for health care professionals (acute care, nursing, community/ambulatory) and consumers and columns in 16 professional journals and newsletters, which reach more than 3.5 million readers.

- We would be happy to include selected FDA drug safety information in our various information forums. *[Note: total circulation number is combined circ for all ISMP newsletters, journal columns, and ePocrates]*
- To accomplish its ambitious mission of understanding and preventing medication errors, ISMP collaborates on a continuing basis with a wide variety of healthcare practitioners, legislative and regulatory bodies, healthcare institutions, healthcare professional organizations, regulatory and accrediting agencies, employer and insurer groups, and the pharmaceutical industry.
- In regards to risk management, ISMP believes that medication safety needs to become not just a priority in healthcare, but an entrenched value associated with every healthcare priority and linked to every activity. It needs to become an enduring constant that is never compromised.
- Although much has been done to improve medication safety since the last IOM report, all entities involved, especially the FDA, need to take an even more prominent and accountable role in the future.
- ISMP applauds FDA's stated goal of seeking stakeholders for collaboration and implementation of additional risk communication tools, and encourages the agency to work more closely with other organizations such as ISMP to raise awareness among practitioners and the general public about medication errors and adverse drug events.
- The Institute already collaborates with FDA on safe medication use issues—ISMP is a MEDWATCH partner, and regularly communicates with the agency to help prevent medication errors.
- We are also about to embark on an educational campaign with FDA to eliminate the use of error-prone medical abbreviations and dose designations. But more could be done. ISMP is uniquely positioned to provide the FDA with a forum for reaching health care professionals with risk management information.

- For instance, the FDA currently produces only one regular column on safety issues in a healthcare professional publication, *Drug Topics*, which targets pharmacists. In the past, FDA has provided a regular feature article in ISMP's acute care newsletter, and we invite the agency to do so again.
- The biweekly *ISMP Medication Safety Alert! Acute Care* edition is the nation's only publication reaching nearly every U.S. hospital with vital and potentially life-saving information on medication and device errors and adverse drug reactions, as well as practical prevention strategies. FDA information included in the newsletter would reach more than 600,000 healthcare professionals from a wide variety of disciplines.
- ISMP could also assist the agency in posting more current information about medication errors in the Center for Drug Evaluation and Research section of www.fda.gov. Only a limited list of articles is currently offered, and could be expanded considerably.
- The Institute already does something similar with FDA's Center for Devices and Radiological Health. Each month, FDA provides web videos based on information published in the ISMP Medication Safety Alert! Newsletter. We would be happy to have a similar arrangement with CDER, where copies of ISMP drug safety articles or links to our articles are posted on its site.
- ISMP could also post more FDA-generated information on its own web site, www.ismp.org. We currently offer a link to FDA's patient safety videos, and also have a section for FDA drug safety alerts. But additional FDA resources and tools could be added to these locations.
- Another way that ISMP and FDA could work together to improve risk management is by raising greater awareness of reporting methods, including promoting error reporting to the USP-ISMP Medication Errors Reporting Program with the same or greater intensity that error reporting to MedWatch.

- There is precedent for this suggestion--different models of risk management are being developed in other countries where regulatory authorities depend on and promote other reporting programs; for instance, in Canada and Spain, ISMP's affiliate organizations have received funding from the national health ministries to carry out these functions.
- Thank you to FDA for the opportunity to provide input on its risk management communication and how ISMP could further partner with the agency to raise awareness of medication errors and prevention strategies.