

**Stakeholder Meeting on REMS**  
**March 8, 2013, 9:30 AM – 11:00 AM**  
**FDA White Oak Campus, Silver Spring, MD**  
**Building 1, Room**

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**Purpose**

To provide an update on FDA’s REMS Integration Initiative and progress toward fulfilling PDUFA V commitments in the areas of REMS policy, standardization, and evaluation

**Participants**

FDA

Wayne Amchin	CDER	Mwango Kashoki	CDER, presenter
Randi Clark	CDER	Adam Kroetsch	CDER, presenter
Sharon Coleman	CDER	Elaine Lippmann	CDER
Mary Dempsey	CDER	Claudia Manzo	CDER
Nancy Dickinson	CDER	Megan Moncur	CDER
Kristen Everett	CDER	Marilyn Pitts	CDER
Elizabeth Everhart	CDER	Kevin Prohaska	CDER
Michie Hunt	CDER	Gary Slatko	CDER, presenter
Georgiann Ienzi	CDER	Douglas Throckmorton	CDER
Jessica Jacobs	CDER	Theresa Toigo	CDER, presenter
Susan Jenney	CDER	James Valentine	OC
Julia Ju	CDER	Wendyann Zanders	CDER

Stakeholders

Marcie Bough	American Pharmacists Association
Marc Boutin	National Health Council
Paul Brown	National Research Center for Women & Families
Mary Jo Carden	Academy of Managed Care Pharmacy
Justine Coffey	American Society of Health System Pharmacists
Anita Ducca	Healthcare Distribution Management Association
Andrew Emmett	Biotechnology Industry Organization
Amanda Grimm	American Academy of Dermatology Association
Ronna Hauser	National Community Pharmacists Association
Angela Jeansonne	American Osteopathic Association
Nik Johnson	Academy of Managed Care Pharmacy
Michael Maroni	Alliance for Aging Research
Stacie Maass	American Pharmacists Association
Kevin Nicholson	National Association of Chain Drug Stores
Angela Ostrom	Epilepsy Foundation

Kate Ryan	National Women’s Health Network
Brenda Sarokhan	Janssen Biotech
Roslyne Schulman	American Hospital Association
Rebecca Snead	National Alliance of State Pharmacy Associations
Allison Tuszynski	Healthcare Distribution Management Association

**Background Material:**

**REMS Update Presentation**

- Introduction to the FDA REMS Integration Initiative, Theresa Toigo
- REMS Policy Work Group, Mwango Kashoki
- REMS Design and Standardization Work Group, Adam Kroetsch
- REMS Evaluation Work Group, Gary Slatko

**1. Presentation**

- A. Terry Toigo welcomed the stakeholders to FDA. Following introductions, Ms. Toigo and her colleagues made presentations to update the audience on the REMS Integration Initiative and progress FDA has made toward REMS-related goals established by PDUFA V. (The presentation and presenters are shown above.)
- B. Ms. Toigo thanked the group for their input and stressed that FDA is seeking stakeholder feedback through a variety of outreach efforts. She invited the group to participate in future public meetings and to send their additional comments on REMS to [REMSIntegrationInitiative@fda.hhs.gov](mailto:REMSIntegrationInitiative@fda.hhs.gov).

**2. Stakeholder Comments.** Following the presentation, the stakeholders made the following comments.

- A. **Standardization of Information.** It would be useful for pharmacists to have standardized information about the components of a given REMS and the required actions for prescribers, pharmacists, and others who will be responsible for implementing the REMS. This could be provided in a format similar to the highlights section in professional product labeling. (Marcie Bough, APhA)
- B. **Education and Awareness.** It would be helpful for FDA to build on their existing tools and materials promote greater understanding of REMS among health care professionals, including medical and pharmacy students. For example, FDA could use a Web page to provide “REMS 101” training, and send out reminders to health care providers that REMS materials are located on FDA’s Web Page. (Marcie Bough, American Pharmacists Association)

- C. **Enhanced FDA Understanding of Practice Settings.** It is desirable for FDA to understand the controls that are already in place in different practice settings, in order to avoid adding redundant REMS tools. FDA responded that when appropriate there are different REMS requirements for pharmacy in outpatient retail and inpatient practice settings, but welcomes feedback from stakeholders about how well REMS have worked for them in each type of setting. (Roslyne Schulman, American Hospital Association)
- D. **Standardization of REMS for Specific Types of Risk.** It could be helpful for FDA to standardize the REMS tools for specific types of risk that have common elements, such as when and what type of pregnancy test is required for REMS associated with teratogens. Doing so would make these REMS less onerous and complicated for the women who must comply with them and more predictable for the health care professionals who must implement them. (Kate Ryan, National Women’s Health Network)
- E. **Balanced Messaging About REMS to Patients.** Some women have stated that they appreciate the protection a REMS provides against teratogenic risk. Other patients may perceive REMS as an annoying step they must go through to obtain a drug. Health care professionals should encourage patients to understand that a REMS is actually the mechanism enabling their access to a drug that otherwise would not have been approved. (Kate Ryan, National Women’s Health Network)
- F. **Broader Research Support for REMS.** REMS represent an attempt to transfer abstract knowledge into practice settings to effect behavioral change. Historically, the health care system has been unsuccessful at making this transfer. We know too little about which strategies work to effect the desired changes, although research performed by AHRQ and others has been helpful. Stakeholders should encourage third parties to perform or fund research to determine which strategies succeed at effecting behavioral change. (Marc Boutin, National Health Council)
- G. **Reducing REMS’ Burden:** It is difficult to define what is meant by “unduly burdensome” or know how to find the right balance between burden and safety. It would be useful to know whether health care professionals and patients perceive shared system REMS as less burdensome than single product REMS. FDA has approved several shared system REMS and welcomes stakeholder feedback on how well these REMS have worked for them. (Paul Brown, National Research Center for Women and Families, and Kate Ryan)
- H. **Early Consultation about Potential REMS for New Products.** Drug sponsors consider it desirable to have risk management discussions early in the NDA or BLA review process. FDA responded that the agency has structured the 21<sup>st</sup> Century Review process to ensure that early discussions occur, and has put in place project management to ensure that all staff involved in the NDA or BLA

review are aware of emerging safety issues that might require a REMS. FDA also believes that greater standardization of approaches to managing specific types of risk will result in clearer expectations of the types of intervention that might be required for a drug under review. (Andrew Emmett, BIO)

### 3. Stakeholder Comments Submitted Prior to the Meeting

- A. **Patient focused drug development (PFDD) and benefit-risk framework.** Information gleaned from these new tools, both of which are designed to solicit patients' views on benefits and risks, could be incorporated into FDA's decision-making processes in their application of REMS for a newly approved products or to evaluate existing REMS. Stakeholders can help FDA better understand how patients make tradeoffs between benefit and risk at different points of the drug's life cycle, and also from the perspectives of patients at different stages of a given disease or condition. FDA has not anticipated that REMS would be a specific topic in PFDD meetings, we do expect that for decisions regarding new REMS, the patient perspectives about disease and treatments would be part of the overall benefit-risk assessment that would inform whether or not a REMS is needed. (Eric Gascho, National Health Council)
  
- B. **Stakeholder engagement during REMS development.** It is important for FDA to engage stakeholders, including physicians, early in the process of REMS design and development. A REMS can have a major impact on clinical practice flow. REMS implementation will occur more smoothly and successfully if FDA consults physicians when the REMS is being designed. (Amanda Grimm, American Academy of Dermatology Association)
  
- C. **Transparency.** Data collected through REMS should be publicly available and analyzed at regular intervals to determine whether the REMS is meeting its goals, which should be stated explicitly at the outset. The agency should continually evaluate data on REMS program to determine their effectiveness, efficiency, and the burden they place on patient access (including uninvolved patient cohorts), physicians, pharmacists and other stakeholders. (Amanda Grimm, American Academy of Dermatology Association)