Health Literacy at the Food and Drug Administration: Current Initiatives in Prescription and Nonprescription Drugs

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• The materials presented are available in the public domain.

• I do not have any financial interest or conflict of interest with any pharmaceutical company.
Objectives

- Prescription Drug Initiatives
  - Patient Medication Information (PMI)
  - FDA 907 Action Plan

- Nonprescription Drug Initiatives
  - Nonprescription Safe Use Regulatory Expansion (NSURE)
Patient Medication Information

Goals and Objectives:

- Patients need clear, actionable patient medication information to use prescription medications safely and effectively

- Currently, patients receive several types of information developed by different sources that may be duplicative, incomplete, or difficult to understand (Medication Guides, Patient Package Inserts, and Consumer Medication Information)

- FDA is considering a new regulation to require all prescription drugs to have a single Patient Medication Information (PMI) document standardized in content and format that will provide prescription medication information in an accurate and balanced form delivered in a consistent and easily understood format
  
  - PMI will be provided when a patient receives a prescription medication with the intent that the information be used to take medications properly once the patient has gone home; PMI is not a replacement for patient counseling
  
  - Source of information in PMI would be FDA approved professional labeling
Patient Medication Information
Public Hearing and Workshops

• September 2010: Part 15 Public Hearing held to obtain input on a new framework for development and distribution of PMI

• FDA convened a series of expert meetings and public workshops through a cooperative agreement with the Engelberg Center for Health Care Reform at Brookings to obtain stakeholder input:
  – July 21, 2010: Focused on optimal content and format of a single-page standard patient medication information document
  – October 12, 2010: Public forum to discuss strategies to ensure patient access to effective PMI
  – February 23, 2011: Focused on ideas for designing pilots for distribution of PMI; Effort currently underway to develop a pilot project to evaluate PMI distribution projected to being May 2012
  – July 1, 2014: Explored (1) lessons learned from health literacy researchers engaged in PMI projects and (2) the role of stakeholders who regularly interface with PMI in moving the initiative forward
Next Steps

• Development of the PMI framework is ongoing and will be informed by, among other things, related studies, research, and input that we receive from stakeholders

• Some of the principles we are considering in the development of the PMI framework
  – A surveillance approach that includes reviewing and approving manufacturer-authored PMI
  – All information based on FDA-approved professional labeling
  – Consumer testing for comprehension
  – Updated when certain changes are made to the labeling
FDASIA Section 907 Action Plan

- Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA) Section 907

- FDA Action Plan priorities
  - **Quality**: Improve the completeness and quality of demographic subgroup data collection, reporting and analysis
  - **Participation**: Identify barriers to subgroup enrollment in clinical trials and employ strategies to encourage greater participation
  - **Transparency**: Make demographic subgroup data more available and transparent
FDASIA Section 907 Action Plan
Transparency Actions

• Posting demographic composition and analysis by subgroup in pivotal clinical studies for FDA-approved medical products

• Identifying potential methods to consistently communicate information on demographic subgroups in medical product labeling

• Implementing communication strategies that are sensitive to the language and health literacy needs of underrepresented subpopulations

• Establishing an internal FDA steering committee to oversee and track implementation of the action plan
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OTC Drug Products

OTC drug products generally have these characteristics:

- Can be adequately labeled such that:
  - The consumer can self-diagnose, self-treat, and self-manage the condition being treated
  - No health practitioner is needed for the safe and effective use of the product
- Drug has low potential for misuse and abuse
- Safety margin is such that the benefits of OTC availability outweigh the risks
OTC Consumer Studies

Label Comprehension Study
- Understanding the key label message

Self-Selection Study
- Choosing the right product

Actual Use Study
- Using according to labeled directions

Human Factors Study
- Interacting with the product
Current Limitations of OTC Switch

- Purchasing decision based on information in Drug Facts label and on principal display panel

- Other conditions for marketing are not considered for determining switch

- Rx and OTC not permitted at same time; same indication, population, dose, etc.
Public Health Needs

- Significant undertreatment of common diseases and conditions
- Lack of regular access to medical and pharmacologic care
- Decreased access to health services
Future of Nonprescription Products

• What should the nonprescription drug market look like in 20 years?

• Can the delivery of information for correct self selection and use be improved?

• How can technology impact on self selection and use and expand the availability of certain drug products?

• Can healthcare providers such as pharmacists or technology interventions have a greater role?
Nonprescription Safe Use Regulatory Expansion (NSURE)

- Alleviate the undertreatment of common conditions or diseases by using innovative technologies or other conditions of safe use to expand which drug products can be considered nonprescription
- Explore regulatory approaches that allow for the expansion of the nonprescription drug market
- Communicate the NSURE initiative to interested stakeholders and public started with Public Hearing March 2012
- Explore and further develop a practical regulatory framework for the NSURE concept
## Misconceptions

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<tr>
<th>Misconception</th>
<th>Clarification</th>
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<tbody>
<tr>
<td>New paradigm will reduce or eliminate doctors’ visits.</td>
<td>Intent of the program is to reach those who are not currently seeing a health care provider, not to stop those who do go to the doctor from going.</td>
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<tr>
<td>Consumers will incorrectly select drug products for use.</td>
<td>Conditions of safe use would be tested to ensure that they help patients select products correctly.</td>
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<td>FDA is considering the creation of a third class of drugs.</td>
<td>Drugs will remain either prescription or non-prescription.</td>
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<td>FDA is granting pharmacists prescribing power.</td>
<td>NSURE cannot grant pharmacists prescribing power. Licensing of, and authority over the practice of medicine, pharmacy and other health professionals, including prescriptive authority, is generally granted and controlled by the States.</td>
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<tr>
<td>Every prescription drug product will eventually be OTC.</td>
<td>The approval of a drug product as non-prescription with a condition of safe use will be product-specific and is intended to undergo FDA’s rigorous drug approval process.</td>
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Communication and Outreach

• Expert workshops through a cooperative agreement with the Engelberg Center for Health Care Reform at Brookings
  – Nov 08, 2012 Workshop: *Nonprescription Medications with Conditions of Safe Use as a Novel Solution for Undertreated Diseases or Conditions*
  – May 09, 2013 Workshop: *Innovative Technologies and Nonprescription Medications: Addressing Undertreated Diseases and Conditions through Technology Enabled Self-Care*
  – November 4, 2013 Workshop: *Exploring Implications of the Nonprescription Drug Safe Use Regulatory Expansion (NSURE) Initiative on Reimbursement and Access*

• Presentations and meetings with stakeholders and other Federal Agencies
NSURE Initiative Next Steps

- Continue to engage stakeholders through presentations and expert workshops

- Continue to receive feedback to help policy decision-making

- Explore options for new regulatory development
Questions or Feedback

• Please e-mail any questions concerning PMI or NSURE to the Office of Medical Policy at:
  – CDER-OMP-DMPP@fda.hhs.gov

• Please e-mail any questions or feedback concerning Section 907 to the Section 907 steering committee at:
  – FDASIA907@fda.hhs.gov
Additional Information

• PMI
  – http://www.fda.gov/Drugs/NewsEvents/ucm219716.htm
  – http://www.brookings.edu/about/centers/health/projects/pmi

• Section 907

• NSURE
  – http://www.fda.gov/Drugs/NewsEvents/ucm289290.htm
  – http://www.brookings.edu/events/2012/11/08-nsure-initiative-event
  – http://www.brookings.edu/events/2013/05/09-innovative-technologies-nonprescription-medications

• Understanding OTC Medicines