Overview

- Lessons to be learned from PhRMA assessment on electronic distribution of PIs
- Translating these lessons to the distribution of ePMI
Lessons learned from PhRMA assessment on paperless labeling
PhRMA Paperless Labeling Initiative

- Pharmaceutical Research and Manufacturers of America (PhRMA) has long supported the systematic approach to reduce the use of paper prescribing information at dispensing sites.
- Electronic distribution of prescribing information will enhance patient safety by having the most recent prescribing information available.
PhRMA Paperless Labeling Initiative

- Since 1998, PhRMA has collaborated with external stakeholders from the pharmacy and healthcare provider communities to ensure that the perspectives of dispensers were considered.
  - 2 Field Trials conducted [2002, 2004]
  - Pharmacy Technology Assessment conducted [2008]
PhRMA proposes that NLM’s DailyMed be the singular database of current labeling:
  - FDA approved labeling pushed to NLM daily
  - Ensures that all are accessing the same current electronic labeling for each product.
PhRMA Paperless Labeling Initiative

- **Subsequent Enhancements to DailyMed:**
  - Searchability of DailyMed by NDC code.
  - Link the DailyMed database to standard bar code technology (UPC) using the product’s NDC number.

- **Still Desired:**
  - Develop additional SPL stylesheet to enable the prescribing information to be printed in a smaller, but readable, font size directly from the DailyMed website, where needed.
Features of the Desired System

- Cost neutral to dispensing sites
- Available at all dispensing sites
- Readily accessible
- Timely (information current, updates pushed)
- Comprehensive (complete PI)
- Standardized format
- Printable (where needed to be printed)
- Text cannot be edited by dispenser
- Virus protected
- Exploit bar coding technologies for rapid access
- Provided via existing pharmacy systems (minimize interference to existing workflow)
PhRMA Paperless Labeling – Revision

- Project Revised based on 11/16/10 Stakeholder Meeting with PhRMA member companies, GPHA, NLM, Vanderbilt University, FDA (Randi Levin), Pharmacy Organizations (APHA, NCPA, NCPDP):
  - Paperless labeling pilot using DailyMed will not be conducted with pharmacies as originally planned.
  - An assessment of the state of readiness for a paperless labeling pilot among a nationally representative sample of pharmacies including chain and independent retail pharmacies, hospitals, and other dispensing sites (both urban and rural) will be conducted instead.
  - Issues will be identified and feasibility of potential solutions will be explored.
  - The project will be conducted by Vanderbilt University with Dr. Kevin Johnson as Principal Investigator.
PhRMA Paperless Labeling Initiative

- **Identify Opportunities to Collaborate:**
  - Educate stakeholders to increase awareness of DailyMed (e.g., Physicians, Pharmacists).
  - Ensure labeling is available for all prescription drug and therapeutic biological products approved for use in the United States.
  - Phased-in Approach
## Assessment Timeline

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<tr>
<th>Milestone</th>
<th>Jan</th>
<th>Feb</th>
<th>March</th>
<th>April</th>
<th>May</th>
<th>June</th>
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Translating these lessons to the distribution of e-PMI
ePML

- Understand the variety of intended audiences (many cohorts)
- Define very specific objectives for delivery of ePML (e.g., increase access, readership, verified readership, comprehension, compliance, etc.)
- Carefully consider the current state of technology, how it is used by intended audiences, and where it is trending
Thank You!