Labeling Prescription Drugs for Physicians and Consumers (FDA Perspective)

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FDA Strategic Goal

○ Improving Health Through Better Information

- With "better" information, patients and health care providers can make wiser decisions about the relative benefits and risks of medicines

- FDA is facilitating several initiatives aimed at increasing the amount and quality of information available to consumers and health providers

Overview

○ DailyMed

○ Healthy People 2010 Objectives

○ Written Prescription Medicine Information—For Consumers

○ Drug Watch

DailyMed Initiative

- Enhancing patient safety through accessible medication information
  - Collaboration between FDA, NLM and VA
  - FDA sends medication information as Structured Product Labeling (SPL) to NLM
    - SPL is a computer readable format (XML)
  - NLM places SPL into the DailyMed
- SPL to NLM
  - Populate over time
  - Planned to start October 2005

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DailyMed Initiative

- DailyMed is an electronic repository for the SPL
  - Medication information in computer readable form
    - Easy import into information system
  - Comprehensive
    - Includes all US marketed products
  - Reliable
    - Information directly from labeling
  - Up to date
    - New information or changes added daily
  - Free
    - Distributed by National Library of Medicine

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Healthy People 2010

○ **Focus Area 17 - Medical Product Safety**

- 17.1 - Increase HCO monitoring of AEs associated with therapies/devices
  - 84% in 2003 (ASHP study)
- 17.2 - Increase HCO use of EMRs by providers/pharmacists
  - 19% and 33%
- Increase use of prescriber order entry
  - 22% for hospitals >400 beds
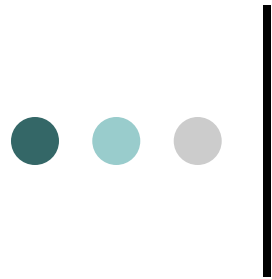
Healthy People 2010 (Cont'd)

- **Focus Area 17 - Medical Product Safety**
  - 17.3 - Increase useful patient information
    - 74% (FDA survey 2001)
  - 17.4 - Increase verbal counseling by prescribers/pharmacists
    - 24% prescribers
    - 12% pharmacists
  - 17.5 - Blood donations

Written Prescription Medicine Information—For Consumers

○ Types of Rx drug information

- FDA-regulated:
  - Medication Guides
  - Patient Package Inserts (PPI)
- Not FDA-regulated:
  - Consumer Medication Information (CMI)
- FDA-prepared
  - Drug Watch

Medication Guides

- FDA-approved patient labeling
- Regulated since 1999 (21 CFR Part 208)
- Required dispensing with each prescription
- Primarily for outpatient Rx products with serious and significant public health concerns
- Regulation specifies format and content
- Generic products must match the Medication Guide requirements of innovator

Medication Guides (Cont'd)

○ Three triggering criteria (at least one criterion must be met):

- Pt labeling could help prevent serious AEs

- Serious risks: could affect pt decision to use

- Pt adherence to directions crucial to effectiveness

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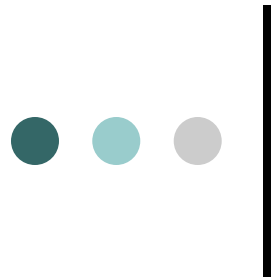
Patient Package Inserts (PPI)

- FDA-approved patient labeling
- Not required to be dispensed with each prescription
  - Exception: oral contraceptives and estrogens (21 CFR 310.501, 310.515)
- Required to be referenced in the PRECAUTIONS section, reprinted at the end of the package insert (21 CFR 201.57(f)(2))

Consumer Medication Information (CMI)

○ Developed by private sector
- Not developed by drug manufacturers
- Typically stapled to outside of pharmacy envelope
- Not FDA-regulated

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CMI – Law & Criteria

- Public Law 104-180
  - Private-sector written CMI must meet certain goals for receipt of useful information: 2000 – 75%; 2006 – 95%
  - If goals not met, restriction on regulation is lifted
- Determining Usefulness of CMI
  - Criteria for usefulness of CMI developed by consensus ("Keystone Action Plan")
  - www.fda.gov/cder/Offices/ODS/keystone.pdf

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Evaluation of CMI Usefulness

- Criteria operationalized in 2001 study by Svarstad and 16-member expert panel
- Study report http://www.fda.gov/cder/reports/prescriptInfo/default.htm
  - Findings: 2000 goals not met: 90% receipt, but 50% useful
  - "Readability" and "Risk Information" scored lowest; "Accuracy" highest

CMI Steps by FDA

○ 2002 Advisory Committee review; encouraged active support by FDA

○ 2002-2004: Meetings with National Council for Patient Information and Education (NCPIE) consortium members

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CMI Steps by FDA (Cont'd)

- 2003 Public meeting to hear private sector plans for achieving 2006 target goals of P.L. 104-180

- 2004/05 Guidance development – anticipate Spring '05 release

- FDA assessment - CY '07

Drug Watch

- The Drug Watch initiative
  - Announced February 15, 2005 by Secretary Leavitt and Acting Commissioner Crawford
  - Intended to provide targeted drug safety information to the public
  - Emerging data/risk information
    - consumer-friendly information sheets written especially for healthcare professionals and patients

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Drug Watch (Cont'd)

○ FDA will seek public input on how to manage concerns associated with disseminating emerging information

○ FDA will seek input from patients and healthcare professionals on how best to make this information available to them

○ Note: Many specifics associated with this initiative are still in development

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