FDA Public Hearing on Medication Guide Program Reform

National Association of Chain Drug Stores (NACDS)

John M. Coster, Ph.D., R.Ph
Ronna Hauser, R.Ph.
June 11, 2007

NACDS

- Represents chain-operated retail pharmacies
  - Traditional chain, mass merchandise, supermarket pharmacies
- About 35,000 of 55,000 community pharmacies are chain operated
- Largest provider of pharmacy services in the United States
- Generally provide Consumer Medicine Information (CMI) to patients with prescriptions

Overview

- Pharmacies want to provide useful information to consumers to help them take their prescriptions more appropriately.

- FDA is not implementing MedGuide program consistent with its own regulation.
- MedGuide program is in need of major reforms to be effective for patients.
- Little evidence that distribution of MedGuides actually increases patient understanding of the risks of these medications.
- Overwhelming patients with too much written information may not be useful (CMI, MedGuides, PPIs, etc.)
- Long term solution is to create a single patient-oriented document that combines MedGuides and CMI.

Interaction with FDA on MedGuides

- NACDS and retail pharmacy have had significant and extensive dialogue with FDA to seek changes to MedGuide program that would enhance distribution:
  - Jan. 27, 2005 – teleconference with antidepressant sponsors, FDA and other stakeholders.
  - July 13, 2005 – MedGuide Meeting at Rockwall, Rockville, MD
  - October 17, 2005 - E-MedGuide Meeting with FDA (White Oak)
  - January 12, 2006 – FDA telecon. with NSAID sponsors
  - Sept. 20, 2006 - E-MedGuide Meeting with FDA (Rockwall)
  - December 3, 2006 – Call with FDA on Coumadin MedGuides

FDA Response on E-Printing

Chain pharmacy: give us the ability to print electronically

FDA Response: 19 similar letters to 19 different manufacturers of antidepressant medications

"Although we have no objection to pharmacies printing Medication Guides that meet all the requirements of part 208, we note that the regulation clearly places the burden for producing and distributing Medication Guides on the manufacturer of the product.

"We have notified the sponsors of your offer and our response and recommend that you discuss this issue with the sponsors directly"

– FDA, January 26, 2006

MedGuide Issues

- MedGuides intended to be used for a few drugs per year, not classes of drugs
  - FDA Regulation (1998): *"On average…FDA estimates that no more than 5 to 10 products would be required (to have MedGuides) each year…"*
  - FDA Press Release (2007): *"…it has become more common for Medication Guides to be required for entire classes of drugs (such as NSAIDS.)"*
    - *Just in 2007, FDA added 15 ADHD drugs and 13 sedative drugs – 28 drugs (not counting dosage forms and generics so far in 2007!)*

- Too much paper: inconsistent with FDA's focus on "electronic filings" and "electronic distribution of information"
  - Coumadin MedGuide is 5 pages long- others are up to 20 pages!
  - Consumers also receive CMI from the pharmacy: how much paper is too much?

- Communication of Risk
  - Too much risk information can help reduce compliance
  - Decision should be made at point of prescribing not dispensing.

MedGuide Issues

- Communication from FDA/manufacturer that MedGuide required needs to be substantially improved.
  - No central place to obtain 1-800 numbers
  - Little notice of distribution by manufacturers, especially generic manufacturers

- No consistent rationale for when “class” MedGuides are used
  - Class MedGuide was used with antidepressants, NSAIDs;
  - Class MedGuide was not used with ADHD drugs, sedative/hypnotics
    - Class Medguides are obviously easier to maintain and distribute
    - Should allow one MedGuide for all drugs in class, and for brand and generic versions of the drug.

- No rationale for organized distribution of leaflets
  - Single place needed (1-800#) where all dispensers can obtain all various pads – brand and generics for all drugs
    - FDA should operate this process
  - Impossible to think that all dispensers can track all drugs that need MedGuides and continuously order pads.

- Cost factors
  - Manufacturers should bear cost of distribution and/or printing by pharmacies

Recommendations

- Allow for electronic printing with other pharmacy documents, even if waiver of Part 208 formatting requirements needed
  - Costs should not be absorbed by pharmacies
  - Allow pharmacies to e-mail if patients have capability to receive e-mail.
- Return MedGuide program to original intent: only a few drugs/year
- Class Medguides should be rule if MedGuides are needed
- Dispense on first fill (and then upon request)
- FDA needs to organize this program differently.
  - Guidance needed on distribution practices
  - Consortium needed for class drug MedGuides
  - FDA should organize distribution of all these paper pads (we are NOT advocating paper – but some pharmacies cannot e-print MedGuides)

- <u>Over the Long Term:</u> Move toward single document that combines CMI and MedGuide information – no more than 2 pages – printed by pharmacy systems or distributed by pharmacies.