



# NCPA<sup>®</sup>

*the* NATIONAL COMMUNITY  
PHARMACISTS ASSOCIATION

THE VOICE OF COMMUNITY PHARMACY

**NCPA's Perspective on  
CMI, MedGuides and PPI  
February 26, 2009  
before the Public Advisory Committee, FDA**

Tony Lee, Esq.  
Director of Public Policy

[Tony.Lee@ncpanet.org](mailto:Tony.Lee@ncpanet.org)

(703) 683-8200

[www.ncpanet.org](http://www.ncpanet.org)

# What do patients want to know?

- What the drug is/does
- How to take the drug
- The potential side effects
- 1-800 number for questions

# The Problem

- Medication Guides, Patient Package Inserts, and Consumer Medication Information are all too technical, long and not user friendly. They do not effectively present patients with the information that they are seeking.

# CMI

- Information is often too lengthy to fit on the CMI, which is often stapled onto or put into the patient's pharmacy bag with the prescription
- The information is too technical

## **The most important basic information is lost among other information included because of liability concerns**

- . . . CMI evaluated in 2008 had lower adherence to “directions about how to use, monitor and get the most benefit” than in 2001, due to increased emphasis in 2008 on information about how to monitor medications for safety and effectiveness. Importantly, there were lower levels of adherence in 2008 to the formatting criterion “information is readily comprehensible and legible”, a criterion which evaluates how information is formatted and how difficult the CMI leaflets are to read and understand.
- *Expert and Consumer Evaluation of Consumer Medication Information 2008, at*
- [http://www.fda.gov/cder/news/CMI/final\\_report.pdf](http://www.fda.gov/cder/news/CMI/final_report.pdf)

## CMI Info is not patient-friendly

- “Most CMI accompanying nonsolid medication samples is written at a reading level that exceeds that of many consumers and does not meet recommended standards for readability and comprehensibility of patient education material.”
- *Do Medication Samples Jeopardize Patient Safety?*, Andrea S Franks, Shaunta’ M Ray, Lorraine S Wallace, Amy J Keenum, and Barry D Weiss, *The Annals of Pharmacotherapy*, at <http://www.theannals.com/cgi/reprint/43/1/51>

## Practical barriers - CMI

- 2 main physical practice barriers to pharmacies being able to print out complete CMI:
  - Pharmacy information software template formats -- programmed to print only one page of information, regardless of actual document length
  - Pharmacy having necessary equipment to print out additional pages of medication information
- In order to print complete information from CMI vendor, the template to be printed in the pharmacy has to be set up to accommodate all of the information, the printer has to be able to print any information overage on a separate sheet of paper, or a combination of both.

# Medication Guides

- Are also supposed to contain specific information on the safe and effective use of a medicine.
- Instead, they read as clinical, highly technical descriptions of the chemical content of the medications.
- As FDA has heard, stakeholders are concerned that this is duplicative with the CMI.
- NCPA supports patient education, but this has become a legal document for manufacturers.

# PPIs also not effective

- PPIs (Patient Package Inserts) can be just as cumbersome as Medication Guides
- Drug companies write them for oral contraceptives and estrogen-containing products
- They're often issued in small font, are lengthy, and have a lot of information that is not user-friendly

# The Solution

- FDA should move quickly to approve the pharmacy provider groups' "One document" citizen's petition, which calls for the voluntary use of one standardized document in lieu of other drug information documents.
- The format could be, among other possibilities, one double-sided piece of paper, in 3 columns, for most drugs. Some prescriptions might require additional information.

# “Clear and Less” is more

- What the patient wants to -- and should -- know, should be stated in non-technical, concise terms:
- What the drug is/does
- How to take the drug
- The potential side effects
- 1-800 number for questions

# Need a Global Solution

- Even significantly improving Med Guides, PPIs and CMI is not the answer. The information will inevitably be duplicative and confusing to the patient. A clear, concise statement is much more preferable than multiple, comprehensive legal documents.

# “Too Much Information”

- The issue is not discreetness, but rather redundancy, which can distort what the patient needs to know. An example is receiving info from not only all three mediums, but also from other messages from drug manufacturers that is included in the packaging. Such inappropriate over emphasis about, say, the suicide risk of taking anti-depressants, is detrimental to the patient.
- CMI and Medication Guides have become longer, and are sometimes both duplicative and have conflicting information.

# Alternative

- NCPA does NOT recommend an alternative, as past FDA attempts to address these sorts of drug information materials (such as simplifying warning labels in 2001 and changing PPIs in 2006), and future similar attempts, cannot change the fundamental problem that these documents will be both conflicting and redundant, and not provide the concise information that patients need.
- That being said, at the very least, the CMI should adopt a clear, concise format.