Comments Submitted to FDA 2008-S-0627

Expert and Consumer Evaluation of Consumer Medication Information - 2008

June 1, 2009

The National Community Pharmacists Association (NCPA) presents the following comments on the 2008 study “Expert and Consumer Evaluation of Consumer Medication Information”.¹ The report identifies and discusses several issues regarding the content and format of Consumer Medication Information (CMI).

Rather than concentrate on the content and formatting issues, we believe that it is most worthwhile to address CMI in the context of NCPA’s support for the creation and use of a single, FDA-approved plain language document to replace existing written information distributed by pharmacies. NCPA has joined our pharmacy and patient care partners on a citizen’s petition urging the FDA to issue guidance permitting pharmacies to distribute such document, hereinafter referred to as the “one document” solution.

Any FDA effort to make CMI more useful for the patient should be accompanied by a broader assessment of the usefulness and purpose of other information leaflets the pharmacist may be required to provide. While we recognize that the FDA has worked hard to try and improve these medication documents, the problem needs to be addressed in a fundamentally different way that combines useful written information with the personal relationships between pharmacists and their patients.

CMI is but one piece of prescription drug information that a patient might receive with their prescription. Other items could include Medication Guides, Patient Package Inserts, and advertising materials from manufacturers. These documents are often reviewed under the context of trying to thoroughly meet what can be given to the consumer to address all liability concerns.

Instead, the question that should be asked is, “what do patients need (and want) to know, and what is the most succinct, clear way to present that information to the patient?” The answer can be simply stated as: 1) What the drug is/does; 2) How to take the drug; 3) What are the potential side effects; and 4) Encouraging patients to obtain further information and assistance from their pharmacist or physician, or possibly a government or manufacturer source.

The overriding problem is that Medication Guides, Patient Package Inserts, and Consumer Medication Information are technical, long, redundant, oftentimes conflicting, and not user friendly documents. They do not effectively present patients with the information they are seeking.

¹ The National Community Pharmacists Association (NCPA) represents the interests of pharmacist owners, managers, and employees of more than 23,000 independent community pharmacies. These independents employ nearly 60,000 licensed pharmacists and over 300,000 additional employees across the United States.
Consumer Medication Information (CMI)

Prescription information is often too technical and lengthy to properly fit on the CMI printout, which is normally stapled onto or put into the patient’s pharmacy bag with the prescription. Unfortunately, CMI is often discarded by patients even before they leave the pharmacy.

As the FDA appears to recognize, the fundamental problem is that 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.2

In addition, 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.”3

Medication Guides and Patient Package Inserts (PPIs)

FDA requires pharmacists to provide Medication Guides for an increasing number of medications that have a particular “risk” which must be highlighted for the patient. In many cases, information provided in these Medication Guides, which can be anywhere from 1 to 20-plus pages in length, is duplicative of information in the CMI; are difficult for the pharmacist to obtain from the manufacturers and not easy to print; and are often not read by the patient because of their considerable length. NCPA supports patient education, but Medication Guides have tended to move away from their original purpose.

PPIs can oftentimes be just as cumbersome as Medication Guides. Drug companies write them for oral contraceptives and estrogen-containing products, among others. They’re often issued in small font, are lengthy, and contain information that is not user-friendly.


The solution

Even significantly improving Medication 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 tedious documents.

FDA should move quickly to address the “one document” solution 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 sheet of paper, in 3 columns, for most drugs. Some prescriptions might require additional information.

Previous FDA attempts to address written prescription drug information materials 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. NCPA looks forward to working with the FDA to address the “one document” solution, the general concept of which the Risk Advisory Committee endorsed in late February.

Contact NCPA Government Affairs, 703-683-8200