

VIA Electronic Submission to <http://www.regulations.gov>

November 25, 2009

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2009-N-0295 Providing Effective Information to Consumers about Prescription Drug Risks and Benefits; Public Workshop

Dear Sir or Madam:

Thank you for the opportunity to submit our comments as a follow up to the Food and Drug Administration Public Workshop, “*Providing Effective Information to Consumers about Prescription Drug Risks and Benefits*,” held on September 24 and 25, 2009. As the Food and Drug Administration (FDA) considers issues pertinent to approaches that will result in written prescription drug information for consumers that is comprehensible, accurate, and easy to access, the National Community Pharmacists Association (NCPA) appreciates the opportunity to share our perspectives. NCPA represents America’s community pharmacists, including the owners of more than 22,700 independent community pharmacies, pharmacy franchises, and chains. Together they represent an \$88 billion health-care marketplace, employ over 65,000 pharmacists, and dispense over 40% of all retail prescriptions.

NCPA is a strong advocate for a “one document” solution

NCPA has appreciated the opportunity over the years to work with the FDA to address the issues surrounding written prescription drug information. In the recent past, NCPA has addressed our support for the creation and use of a single, FDA-approved plain language document to replace existing written information distributed by pharmacies with the Agency in a variety of ways. NCPA presented on February 26, 2009, to the FDA Risk Communication Advisory Committee and submitted written comments to the Agency (*FDA 2008-S-0627- Expert and Consumer Evaluation of Consumer Medication Information – 2008*) on June 1, 2009, stating our belief that it is most worthwhile to address CMI in the context of our support for the creation and use of such plain language document.

NCPA continues to maintain this position and reiterates our support for the citizen’s petition we and other pharmacy and patient care partners filed in 2008 urging the FDA to issue guidance permitting pharmacies to distribute such a document, hereinafter referred to as the “one document” solution.

NCPA commends FDA for holding a public workshop on written drug information

NCPA would like to commend the FDA for holding this workshop and for Dr. Janet Woodcock's and the Agency's recognition of a one-document solution, long advocated by NCPA, as the most logical proposal to address the multitude of written information currently disseminated with prescription drugs.

We fully support the conclusions listed in the FDA Issues Paper prepared for the public meeting and reiterated by the FDA at the workshop. Patients do need access to written drug information that is accurate, balanced, and delivered in a consistent format and that information should be available electronically and should be based on user-testing. This collaborative effort is going to need to encompass a variety of stakeholders and NCPA is appreciative of FDA's invitation to play an integral role in the development of new prescription drug patient materials and for the opportunity to share the independent-pharmacy perspective during a panel discussion held at the public workshop.

Workshop discussions on distribution & access of information to pharmacies

Flexibility in distribution

Allowing for flexibility in how prescription drug information is distributed was a key point reiterated multiple times at the workshop. As noted in the workshop summary posted on the FDA's website, patients prefer to receive information at the prescriber level that is followed up with information at the pharmacy level. This permits the patient to discuss questions with the doctor/nurse and enables the patient to prepare more informed questions for the pharmacist.

There is not a one-size-fits-all approach to distributing prescription drug information, and patients should be able to retrieve FDA-approved information from their physician, pharmacist, via email, or on a website, to name a few options. In addition, benefit information must be added to written prescription drug information that is delivered to patients. Current information is too risk-heavy and can thwart well intentioned efforts by pharmacists to ensure patients are adherent to their medication regimens.

Regarding technology that can allow pharmacies to print the one document solution, it was noted at the workshop that some pharmacies do not operate laser printers, so any efforts to include requirements that the document be in color or contain high-resolution graphics could not be met by pharmacies, nor should pharmacies have to incur additional costs to print such a document.

Pharmacy workflow is critical to day-to-day operations and therefore NCPA urges FDA to support a one document solution that can be easily integrated into current practice. Independent pharmacies must be allowed to work with their pharmacy management system vendors to access the document and print on demand with every prescription.

Presentation of information

FDA will need to take into account evolving technologies when providing guidelines for how information contained in the one document solution should be presented. Consideration should


be given to the various formats in which the information may be provided and the length of such information should be carefully tested by end-users. NCPA will continue to advocate that the one document should not be more than one page in length, except in special circumstances that the FDA clearly defines. The one document will most likely be presented in a printed format for the near future, but the FDA should account for instances when making the document available only electronically to patients may make the most sense.

Conclusion and Recommendations

In conclusion, NCPA supports the FDA's efforts to enhance written prescription drug information that is distributed to patients. NCPA advocates for a FDA-approved document, written by the sponsor and validated by user testing, that could be printed at the pharmacy level using technologies that exist in pharmacies today. The template for the document that FDA approves would be no more than one page in length, except in special circumstances clarified by the Agency, and would include embedded access to more detailed information if the patient so chooses, such as 1-800 numbers or links to websites. Pharmacies should be able to work with their pharmacy management system vendors to access the one document and print on demand with every prescription dispensed, thus eliminating the need for disparate pieces of paper that may or may not be read by the patient. The document should be a useful tool for the pharmacist to use when educating their patients about medications.

NCPA appreciates the opportunity to comment on *Docket No. FDA-2009-N-0295: Providing Effective Information to Consumers about Prescription Drug Risks and Benefits; Public Workshop*. If you have any questions, please contact me at (703) 683-8200 or john.coster@ncpanet.org.

Sincerely,



John M. Coster, Ph.D., R.Ph.
Senior Vice President, Government Affairs
National Community Pharmacists Association