

August 5, 2005

Reference: Docket No. 2005D-0062

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

Dear Sir/Madam:

The National Council on Patient Information and Education (NCPIE) submits the following comments on the Food and Drug Administration's (FDA) *Draft Guidance for Industry on the Food and Drug Administration's "Drug Watch" for Emerging Drug Safety Information* (Federal Register: May 10, 2005, Volume 70, Number 89; Page 24606-24607). These comments do not necessarily reflect those of individual members of the National Council on Patient Information and Education (NCPIE).

NCPIE commends the Agency for its efforts to increase transparency and to get emerging information to health professionals and consumers in a timely manner. Our comments relate primarily to the development of FDA-produced Patient Information Sheets (PIS) to be posted on or linked to the Agency's planned Drug Watch web page, and to Medication Guides, which are required by FDA for certain drug products.

NCPIE wishes to provide both caution and advice to the Agency regarding the messages included in the PIS documents. Since the knowledge base for those drug products targeted for inclusion on the Drug Watch page is incomplete, the message (PIS) needs to be constructed in a way that is informative and helpful, but does not overstate - in an imperative or dictatorial way - what to do, or create undue fear in patients' minds that their medicine's risks are greater than the benefits, which PIS has potential to do.

In the following series of questions, we would ask FDA to clarify or expand on development of the PIS and the PIS vis-à-vis Consumer Medicine Information (CMI) produced in the private sector and FDA-mandated, pharmaceutical company prepared Medication Guides. FDA is also urged to develop and publish for public comment a research agenda to evaluate the impact and effectiveness of written drug information which it requires be developed and disseminated by pharmaceutical manufacturers (Medication Guides) or produces itself (PIS).

What criteria is the Agency using to develop the PIS?

Producers of Consumer Medicine Information (CMI) in the private sector refer to the Action Plan for the Provision of Useful Prescription Medicine Information (Action Plan) for guidance on development of clinical content and design/layout and readability. A consortium of nearly three dozen multidisciplinary stakeholder groups, consumer and patient organizations collaboratively developed the Action Plan criteria in 1996. The Action Plan was subsequently reviewed and accepted by the Secretary of HHS in 1997.

FDA is encouraged to draw on the Action Plan for guidance in producing consumer-friendly, useful PIS.

What is the purpose of PIS?

As reported by FDA in 2002, nearly 90% of prescriptions dispensed by community pharmacies were accompanied by CMI. That percentage is likely closer to 100% today. Does FDA plan to conduct an ongoing national consumer awareness campaign to encourage consumers to visit the “Drug Watch” web page to download and print PIS to coincide with or as an adjunct to CMI they receive with prescription medicines dispensed by community pharmacies? If so, would this be for the purpose of supplementing CMI information or replacing such information?

How will the PIS be promoted and disseminated?

Although access to the Internet continues to expand, significant numbers of consumers do not have such access. Primary reliance on the Internet for access to PIS cannot ensure equal access by consumers to emerging risk and safety information. Encouraging healthcare providers to download and print PIS is problematic given the time and expense of so doing on an ongoing basis. There currently exists a nationwide community pharmacy information delivery system with the capacity to disseminate consumer medicine information with at least 90% of prescriptions dispensed by community pharmacies in the U.S. How can the existing nationwide capacity to deliver information to consumers be enlisted to support communication of emerging drug safety and risk information is a reasonable question to consider.

Why produce a PIS for every drug product?

The following footnote (#5) appears in the draft guidance:

“We also have decided to intensify our current program to provide the public with the most important information for the safe and effective use of drugs in patient friendly language. As part of this continuing effort, we are developing Patient Information Sheets intended to convey critical facets of a product's approved labeling in lay terms. These sheets will include a section for “emerging safety information” in those instances when we determine that there is information on the Drug Watch that a patient should consider. This “emerging safety information” will match the information on the Drug Watch. Information from the Drug Watch that is not in the final labeling of the product will be clearly delineated and segregated along with the following disclaimer: “This information reflects FDA’s preliminary analysis of data concerning this drug. FDA is considering, but has not reached a final conclusion about, this information. FDA intends to update this sheet when additional information or analyses become available.” Our ultimate objective is to develop Patient Information Sheets for all approved drugs, most of which will not have an emerging safety section.”

The last sentence (underlined here for emphasis) conveys FDA's intent to become a drug information publisher -- in addition to its regulatory function and in competition with drug information publishers in the nonprofit and private sectors. Does FDA have resources and expertise to sustain this unique, ongoing function? How will FDA continuously update and distribute the PIS products to consumers? Why is a PIS necessary for every drug product -- and especially for those drugs with a narrow risk or safety profile?

How does the PIS relate to Medication Guides?

FDA currently requires pharmaceutical manufacturers to prepare and disseminate Medication Guides for select drug products that FDA believes pose a serious and significant public health risk in the absence of such labeling information pursuant to 21 CFR 208. Will all drugs for which a Medication Guide is required also have a PIS? Is the PIS intended to serve as an abbreviated Medication Guide? How specifically do PIS and Medication Guides differ, in content and intended use/purpose?

How does FDA plan to evaluate the effectiveness of the PIS and Medication Guides?

In her presentation entitled, *Communicating Risks and Benefits Through Labeling and Leaflets*,* Karen Lechter, J.D., Ph.D. (Division of Surveillance, Research, and Communication Support Office of Drug Safety, FDA), addresses the need for research on Medication Guides (MG's). At the time of her presentation (2002), there were 10 drugs and biologics for which a Medication Guide was required. Currently, there at least twice that number of drugs for which a Medication Guide is required, including two frequently dispensed prescription drug classes (antidepressants and NSAIDs).

Previous FDA research on patient labeling, noted Dr. Lechter, focused on:

- Studies of information patients receive with prescriptions;
- Studies with consumers about preferred formats for patient information;
- Public comment on Medication Guide format.

Areas for future research called for by FDA in Dr. Lechter's (2002) presentation are equally relevant today, and perhaps more so given the expansion in the number of drugs for which a Medication Guide is required and the planned introduction of PIS for every approved drug product. FDA is therefore asked to publish well in advance for comment its planned agenda for research and dissemination of such research related to:

- Are patients receiving MG's and PIS? If not, why not?
- Do patients read MG's and PIS? If not, why not?
- How can we increase reading?

- Do patients understand the information, especially low literate patients? If not, how can we improve the information?
- Will patients heed the information? If not, why not?
- How can we increase compliance?
- Does patient information reduce risks and increase benefits of drugs?
- How can health care providers increase patient receipt and use of MG's and PIS?
- How can healthcare professional involvement be increased?
- How can risks be conveyed without discouraging patients from using a drug that has a favorable benefit vs. risk profile for them?

(* *Communicating Risks and Benefits Through Labeling and Leaflets* is posted on FDA's web site at <http://www.fda.gov/cder/present/DIA62002/risks/sld001.htm>)

Recently, the FDA conducted a national survey to obtain insight of licensed pharmacists' views of the availability and usefulness of drug information tools for communicating drug risks to patients (*A National Survey of Pharmacists to Assess Awareness of Drug Risk Communication Tools*; Parivash Nourjah Ph.D., Lauren Lee Pharm. D., Cindy Kortepeter Pharm.D., and Mark Avigan M.D., C.M. Office of Drug Safety, Food and Drug Administration, Rockville, MD).

FDA's research finds that only 70% of respondent pharmacists were familiar with the term, "Medication Guide." Of these respondents, only 30% stated that Medication Guides were very effective in communicating drug risks. Additionally, only 30% of respondents correctly answered that Medication Guides are required to be dispensed with both new and refill prescriptions. Among pharmacists who have dispensed a medication requiring a Medication Guide, nearly a quarter (23%) reported that patients have complained that a Medication Guide was not understandable. Nearly two-thirds of pharmacists familiar with Medication Guides rated them as somewhat or not effective in communicating drug risks to patients.

Consumer Testing

Findings from this research demonstrate the need for FDA to conduct additional research to re-evaluate the effectiveness and impact of Medication Guides on patients and caregivers. The FDA has the authority to require FDA-approved Medication Guides. According to this draft guidance, FDA's "ultimate objective" is to develop PIS "for all approved drugs." We urge that both of these consumer drug information tools be held to guidelines of the Action Plan for the Provision of Useful Prescription Medicine Information. Further, the FDA should incorporate consumer focus-group testing for both Medication Guides and PIS, and should publish an annual dissemination plan for both hard-copy and electronic distribution.

NCPIE is pleased to have this opportunity to comment.

Sincerely,

William Ray Bullman
Executive Vice President