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My name is Ray Bullman. I am the Executive Vice President of the National Council on Patient Information and Education (NCPiE), a non-profit coalition of over 100 organizations representing healthcare professionals, voluntary health groups, consumer and patient organizations, businesses, and government agencies. I have worked for the NCPiE for 21 years in various positions, most currently as chief staff executive since January 1995. Please note that my comments do not necessarily reflect those of individual members of the National Council on Patient Information and Education (NCPiE).

I would like to first thank FDA for convening this meeting and for allowing NCPiE the opportunity to comment today. The agency is to be commended for its efforts to increase transparency and to get emerging information to health professionals and consumers in a timely manner.

My comments relate primarily to the development of FDA-produced *Patient Information Sheets* (PIS) that, for some approved drug products, are currently posted on or linked to the Agency's Drug Watch web page. Additionally, since there is a relationship to FDA's Patient Information Sheets and FDA-required *Medication Guides*, which are required for certain drug products, I also have a few comments in that regard.

Regarding the agency's Patient Information Sheets (PIS), I would provide both caution and advice to the Agency regarding the messages included in those consumer-directed documents. Since the knowledge base for those drug products targeted for inclusion on the Drug Watch page is incomplete and emerging, the message to consumers via a Patient Information Sheet or other such vehicles needs to be constructed in a way that is informative and helpful, but does not overstate what to do, or create undue fear in patients' minds that their medicine's risks are greater than the benefits, to the extent that patients will not take the medication -- which the Patient Information Sheets have potential to do.

I would ask FDA to clarify the development and utility of the Patient Information Sheet, including its relationship to other written information consumers routinely receive with prescription medicines at community pharmacies. Additionally, since the agency continues to expand the list of medicines for which a Medication Guide is required to be dispensed with the medication at community pharmacies along with the aforementioned written consumer medicine information, FDA is also urged to develop and publish for public comment a research agenda to evaluate the impact and effectiveness -- including possible unintended consequences of both Patient Information Sheets and Medication Guides.

I would also ask what criteria the Agency is using to develop its Patient Information Sheets. Producers of useful written drug information for consumers in the private sector are mandated by federal law (P.L. 104-180) to use criteria for usefulness contained in 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 of its written information. A consortium of nearly three dozen multidisciplinary stakeholder groups, consumer, and patient organizations developed this Action Plan criteria in 1996.

The *Action Plan* was subsequently reviewed and accepted by the Secretary of HHS in 1997. FDA is therefore encouraged to draw on the *Action Plan* for guidance in producing consumer-friendly, balanced (with respect to risk and benefit/quality of life information), and useful Patient Information Sheets.

I would also ask what is the purpose of Patient Information Sheets. As reported by FDA in July 2002, nearly 90% of prescriptions dispensed by community pharmacies were accompanied by written consumer medicine information. That percentage is likely closer to 100% today. Does FDA plan to develop and conduct an ongoing, national consumer awareness campaign to encourage consumers to visit the FDA web site and to then download and print Patient Information Sheets to supplement (or perhaps serve as an alternative to) the written drug information that is routinely disseminated with new and refill prescription medicines dispensed by community pharmacies? Are Patient Information Sheets intended to supplement, or replace such existing information?, and how does a PIS relate to a Medication Guide?

I would also ask how will Patient Information Sheets be promoted and disseminated. Although access to the Internet continues to expand, significant numbers of consumers, and particularly older adults, do not have such access. Primary reliance on the Internet for access to Patient Information Sheets cannot ensure equal access by consumers to emerging risk and safety information. Encouraging healthcare providers to download and print Patient Information Sheets is problematic given the time and expense of so doing on an ongoing basis.

There currently exists a nationwide pharmacy information delivery system with the capacity to disseminate written consumer medicine information with every prescription dispensed by community pharmacies in the U.S. How this existing nationwide capacity to deliver timely, authoritative information to consumers can be enlisted, equipped, and enabled to support communication of emerging drug safety and risk information is a more reasonable question to consider than how FDA can compete with such a system.

I would also ask, why produce a Patient Information Sheet for every drug product. As stated in footnote # 5 of FDA's recent draft guidance on its drug safety initiative, "...*Our ultimate objective is to develop Patient Information Sheets for all approved drugs, most of which will not have an emerging safety section.*"

This implies that FDA will become a drug information publisher -- in addition to its regulatory functions and in competition with drug information publishers in the nonprofit and private sectors. It raises questions such as: does FDA have resources and expertise to sustain this unique, ongoing function?

How will FDA continuously update and distribute Patient Information Sheets to consumers with every prescription dispensed? And lastly, why would a Patient Information Sheet be necessary for every drug product -- and especially for those drugs without a narrow therapeutic index (i.e., "safer" drugs)?

I would also ask how the Patient Information Sheet relates to or differs from 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. Since a Patient Information Sheet is going to be prepared for every drug product, that would include those drugs for which a Medication Guide is required. Is the Patient Information Sheet duplicative of a Medication Guide? Is it intended as an abbreviated Medication Guide (Medication Guide "Light")? Another question this raises is, how specifically do Patient Information Sheets and Medication Guides differ, not just in content, but in intended use and purpose?

I would also ask how FDA plans to evaluate the effectiveness of Patient Information Sheets (singularly, and in relation to their impact relative to existing written consumer medicine information and Medication Guides. In a 2002 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. At the time of that presentation, there were 10 drugs and biologics for which a Medication Guide was required. Currently, there is many times that number of drugs for which a Medication Guide is required, including two frequently dispensed prescription drug classes (antidepressants and NSAIDs / Cox -2 drugs).

Areas for research on Medication Guides (and I would now add Patient Information Sheets) called for by FDA in Dr. Lechter's presentation are perhaps more relevant today than in 2002 given the expansion of the number of drugs for which a Medication Guide is required and the planned introduction of a Patient Information Sheet for every approved drug product.

FDA is therefore encouraged to publish well in advance for comment its planned agenda for research and dissemination of such research related to:

- Are patients receiving Medication Guides and Patient Information Sheets? If not, why not?
- Do patients read Medication Guides and Patient Information Sheets? If not, why not?
- Do patients understand the information, especially low literate patients? If not, how can the information be improved?
- Will patients heed the information? If not, why not?
- Do Medication Guides and Patient Information Sheets reduce risks and increase benefits of drugs? If so, which combination works best, and why?
- 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 at: <http://www.fda.gov/cder/present/DIA62002/risks/sld001.htm>)

Earlier this year, 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 found that only 70% of respondent pharmacists were familiar with the term, "Medication Guide." This after Medication Guides have been required for some medications since 1999. 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. Given these findings by FDA, and the added complexities of introducing a Patient Information Sheet for every drug product that would work synergistically with the drug information already being provided to consumers – FDA should reconsider its policy on Patient Information Sheets and focus such time and resources on creating awareness about Medication Guides and encouraging healthcare providers to mediate such information with patients at the point of prescribing and dispensing.

Very limited time remains for FDA to ensure that drug information publishers' efforts to produce balanced, useful, written consumer medicine information is conveyed with new and refill prescription by the end of 2006, pursuant to the Action Plan.

One way that this national effort to develop and deliver useful information to consumers could be advanced is by FDA actively reviewing and commenting on the content of information produced by private sector publishers to ensure that it meets FDA's threshold for risk and safety information, for example. The agency could be providing ongoing guidance on the development of content of drug information in the marketplace.

Instead, the agency, as recently as October of this year, notified major drug information publishers, through NCPIE, that it will not assist publishers in this manner, noting that *"... there is ample information available to data vendors and pharmacies to help guide them toward producing and distributing information to consumers that meets the criteria set forth in the Action Plan. With the 2002 evaluation, our recent draft guidance, and the Action Plan, all parties should be poised to meet the target established by Congress."*

I would suggest that in this instance, collaboration, rather than competition, can best ensure delivery of balanced risk / benefit information to consumers.

Thank you very much for your consideration.