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Use of Medication Guides to Distribute Drug Risk Information to Patients; Public Hearing

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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 working to stimulate and improve communication of information on appropriate medicine use to consumers and healthcare providers. Please note that my comments do not necessarily reflect those of every member organization of the National Council on Patient Information and Education (NCPIE).

In comments I presented to the Agency in December 2005 at the Public Hearing on Communication of Drug Safety Information, I posed a number of questions for your consideration about Medication Guides. Such questions that call for research and testing of Medication Guides remain relevant and will be reiterated in written comments submitted to this docket by NCPIE.

As noted in December 2005, there exists a nationwide pharmacy information delivery system with the capacity to disseminate written consumer medicine information with every prescription dispensed. How can this nationwide capacity to deliver timely, authoritative information to consumers be engaged, equipped, enabled, and supported by government and the pharmaceutical industry to generate and disseminate emerging drug safety and risk information is a reasonable and productive question for the Agency to consider -- as opposed to an externally developed Medication Guide program can be force fit into such a system after-the-fact.

I would like to address several of the questions posed in the Federal Register announcement of the hearing. Two are directed at consumers and one at pharmacy supply chain stakeholders:

1. What is the best way for consumers to be informed about the serious risks of a drug product or other important prescribing information?

The most effective way for consumers to be initially informed about the serious risks of a drug product or other important prescribing information is through meaningful communication with their healthcare providers. Oral counseling should be reinforced with adjunctive written information that the patient and caregiver can read, understand, and act upon when so advised.

In the U.S. we have in place a vast risk communication network made up of healthcare professionals. It consists of hundreds of thousands of healthcare providers, including prescribers, pharmacists, and nurses.

In theory, when medicines are prescribed in the outpatient setting, patients and their caregivers have several opportunities to be informed about any serious risks of a drug product -- at the time the prescription is written, and when the medicine is dispensed at the pharmacy. This back-stop process (which theoretically provides a safety net for consumers before starting a new medicine) provides opportunity for healthcare providers to counsel and communicate about specific medication benefits and risks, for the exchange of relevant medicine and health information, and question asking and answering.

In practice, FDA's consumer survey research points out as recently as December 2006, that consumers' reported receipt of medication counseling at the doctor's office and at the pharmacy, voluntarily provided, or as the result of question asking, has increased only marginally relative to instructions for use, precautions, and side effects over the past decade.

Currently, consumers routinely receive adjunctive written information at the pharmacy in the form of Consumer Medicine Information (CMI). In 2003, FDA research found that nine of ten new prescriptions were accompanied with such CMI. That figure is likely closer to 100% now. Because counseling does not occur routinely, this information often becomes a consumers' primary source of information.

Is it helpful to produce separate drug risk information to inform consumers about serious risks of a drug product?

As noted, consumers are not regularly receiving risk information orally because there is no infrastructure to deliver such information or because there is a shortage of opportunities for prescribers, pharmacists, or nurses to deliver such information. Rather, consumers are not routinely receiving such risk information because current health practice doesn't recognize or value the time for that critical exchange between healthcare provider and patient.

Prescriptions often are written and provided with little communication about the medicines' risks or benefits, and prescriptions are dispensed with accompanying CMI that is not mediated by the pharmacist to point out, clarify, or reinforce key benefit or risk information. Patients are left with a static information sheet stapled to the pharmacy bag and little or no encouragement from healthcare professionals to ***read and heed*** such information.

Medication counseling guidelines exist for both prescribers and pharmacists, as do countless continuing education offerings to improve oral counseling and communication generally or related to specific diseases or conditions. For example, in 1998, NCPIE collaborated with the American Medical Association, which published, *"Guidelines for Physicians for Counseling Patients about Prescription Medications in the Ambulatory Setting."*

Those guidelines call for an updated **Medication Record** as part of the medical record, and for a **Treatment Plan** – noting that decisions regarding the use of prescription medications are best accomplished out of a collaboration between the physician and the patient. This requires that the patient be aware of relevant information regarding the prescribed medication, as well as available alternatives. Therefore, the physician should discuss with the

patient expectations of treatment and appropriate information regarding risks, benefits and appropriate alternatives of all medications that may be prescribed, prior to deciding on a treatment plan. AMA's counseling guidelines also point out that physicians should counsel patients on their medications, emphasizing what is medically significant.

Part 2 of Question # 1: Do Medication Guides have a unique or important role in educating consumers about these risks compared to other written medication information distributed at the pharmacy? Should the information be combined or simplified into fewer or one communication vehicle(s)?

In May of 2006, NCPIE commissioned IPSOS Public Affairs to conduct two consumer focus groups among daily prescription drug users in Rockville, Maryland. The following is limited to feedback on Medication Guides, as requested in the Federal Register announcement for this meeting:

- No respondents, even in the second group who should be receiving them, were familiar with Medication Guides, or recalled receiving one.

- In both groups, respondents indicated a willingness to read one to two pages of well formatted information in "plain English." Keep it simple and keep it short was by far the respondents' preference for written drug information, including Medication Guides.

- In both NCPIE consumer focus groups, respondents felt that the type of information in the Medication Guides would best be discussed with their doctor before they decide to fill a prescription or take that type of medication. Due to the "warning" nature of the Medication Guide, most respondents felt that Medication Guides should be distributed both in doctor's offices and in pharmacies.

It could also be helpful to consumers who wish to have access to Medication Guides for these documents to be posted in various formats on credible, well-publicized web sites, including Daily Med and MedlInePlus.gov.

Yet to locate a product for which a Medication Guide is required, site visitors on Daily Med must work through multiple clicks and then scroll down past other patient information to reach the product's Medication Guide. Alternatively, a button off the Daily Med home page entitled*,"Medication Guides for Select High Risk Medications,"* could take site visitors to an alphabetic roster of all published Medication Guides, available in various formats, including HTML and PDF for downloading.

The National Library of Medicine's Medline Plus program provides detailed information about prescription and OTC products yet, refers consumers to the FA web site or the manufacturer's web site to obtain the Medication Guide.

Q. 7. What process improvements could be made to ensure that patients receive appropriate drug risk information at the pharmacy?

Between January 2005 and September 2006, NCPIE participated in two teleconferences and helped arrange and participated in three face-to-face meetings with FDA staff and stakeholders to discuss the feasibility / practicality of producing and disseminating Medication Guides electronically in conjunction with the generation of Consumer Medicine Information or CMI at the community pharmacy.

During those meetings, FDA was presented with examples of what was dubbed electronic Medication Guides or *e-MedGuides*. These e-MedGuides, which were generated as separate documents appended to corresponding CMI, were produced on current pharmacy computer systems. Medication Guide content was produced in its entirety, but some layout and formatting stipulated in 21 CFR 208 was lacking with these *e-MedGuides*.

Meeting participants asked FDA to allow for electronic printing of e-MedGuides in conjunction with printing of CMI. FDA was encouraged to provide pharmacies that wish to do so with such waivers as needed to enable them to electronically print Medication Guides. The Agency has continued to stipulate that the onus of disseminating or establishing the means to disseminate Medication Guides falls to the drug sponsors and that pharmacies should take up this issue with the various sponsors.

In addition to concurring with those who have recommended shortening the length of Medication Guides, I would also encourage FDA to collaborate with these same stakeholders in developing and promoting a broad-based medicine risk communication plan that builds on progress that has been made the private and public sectors. Consider what has occurred in relatively short fashion:

- The private sector developed consensus guidelines for what constitutes useful written medicine information (Action Plan).

- The FDA issued its opinion of those Action Plan guidelines -- in the form of a final guidance on CMI -- which signals to the private sector how those guidelines must be operationalized to be deemed "useful" by FDA.

- Drug information publishers have worked diligently to revise CMI clinical content to meet Action Plan criteria.

Consider that there's a convergence of events and timing occurring now that, if exploited aggressively, could make it possible for the U.S. to have in place a comprehensive, workable medicine risk communication program by the end of this decade.

First, the FDA has lead agency status for helping ensure that key drug safety objectives for the U.S. are met. These are delineated in Healthy People 2010, Chapter 17, Medical Product Safety:

17.4: Increase the proportion of patients receiving information that meets guidelines for usefulness when their new prescriptions are dispensed.

17.5: Increase the proportion of patients who receive verbal counseling from prescribers and pharmacists on the appropriate use and potential risks of medications.

Second, just two weeks ago, the FDA announced creation of a new advisory committee to address risk communication. The Risk Communication Advisory Committee will:

- Help FDA better understand the communication needs and priorities of the general public;

- Advise FDA on the development of strategic plans to communicate product risks and benefits; and

- Make recommendations to FDA on what current research suggests about crafting risk and benefit messages, as well as how to most effectively communicate specific product information to vulnerable audiences.

For the short term, i.e., through 2010, and in order to avoid even more unintended consequences wrought by what I've heard some call a "runaway MedGuide program," I would suggest engaging and challenging the critical thinking, academic rigor, and expertise of those who will constitute the new risk communication advisory committee as to the complexities and opportunities brought about by this problem at hand.

Hold their feet to the fire to look and think forward on this particular issue. This will require of them demanding more of technology than appending document A to document B with a hard break separator. They will, as will we all to ensure relevance, have to consider integration and communication of risk information into technology applications like electronic prescribing, personal health and medicine records, and electronic medical records to account for how healthcare providers will communicate among themselves and with patients and caregivers in the not too distant future.

Let's not continue to build from a paper base when momentum, critical thinking, and technology in healthcare is moving forward. Otherwise, as in the situation at hand, the tracks won't connect when we arrive at what we think is our destination.

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