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BY ELECTRONIC MAIL: FDADockets@oc.fda.gov

Division of Dockets Management (HFA-301)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

**Re: FDA's Public Hearing on Communication of Drug Safety Information
[Docket No. 2005N-0394]**

Division of Dockets Management:

The Association of American Medical Colleges (AAMC) is a nonprofit association that seeks to improve the nation's health by enhancing the effectiveness of academic medicine. It represents all 125 U.S. and 17 Canadian accredited allopathic medical schools, nearly 400 major teaching hospitals and health systems, 94 academic societies, and the nation's 67,000 medical students and 104,000 residents. The AAMC is pleased to comment on this important issue, and has listed each question specified in the public hearing announcement and the corresponding comments in the text below. First, however, we emphasize that *all* health care interventions incur risks, and these risks must be weighed against associated benefits.

1. [What are the strengths and weaknesses of the communication tools listed previously in this section of the document \[Patient Information Sheets, Healthcare Professional Information Sheets, Talk Papers, Public Health Advisories, Press Releases, MedWatch Listserv Safety Updates, Patient Safety News, CDER Educational Campaigns, and CDER Internet site.\]?](#)

The strength of the FDA's communication tools is their completeness and thorough coverage of drug safety information. Unfortunately, the weaknesses of the communication tools are so extensive that they almost completely negate their strengths. These weaknesses include poor accessibility, ineffective dissemination, and poor presentation; for prescribers, this means too much superfluous information and not enough stratification, organization, and prioritization of risks and benefits (FDA does not query the physicians about which information they desire and need); for patients, similar problems of presentation result in too much information presented in language filled with unfamiliar medical terminology. Patients also need a clear and prioritized picture of risks versus benefits.

2. What information is available about awareness, use, and perceptions of the effectiveness of these communication tools by health care professionals and by the public in general?

The most telling documentation of the ineffectiveness of the FDA's risk communication tools include the deaths caused by Terfenadine (removed from the market in 1998), Bromfenac (also removed from the market in 1998), and Cisapride (removed from the market in 2000). In each case, information about elevated risks was communicated to physicians, but not in a fashion that prompted prescribers to alter their behavior.

3. Do these tools provide the right kind and amount of risk and other information that health care professionals need to make informed decisions about whether to prescribe drug products, and that the public needs to make informed decisions about whether to use those products?

Information is available for health care professionals and the public to make informed decisions, but, the presentation of the information is cumbersome for physicians and incomprehensible for much of the public.

There are a number of obstacles to effectively communicating risk and safety information to both prescribers and to patients:

Prescribers:

- Physicians have significant time constraints.
- Physicians receive the majority of their information about therapeutics from representatives of pharmaceutical companies rather than from unbiased sources.
- The FDA's own resources are severely constrained.
- Physicians are not well informed about how to report adverse events.

Patients:

- Patients also have significant time constraints.
- Patients have limited familiarity with medical terminology.
- Patients tend to trust the decisions of their physicians and pharmacists and often do not pursue their own independent inquiry about a new prescribed therapeutic.
- Patients are not sufficiently instructed about their important role in reporting adverse events to the FDA.

Some steps that the FDA might consider to help overcome the aforementioned obstacles include:

- The FDA could provide incentives such as partnering with academic and professional organizations to provide CME credits for educating physicians with unbiased sources of drug information.
- The FDA could better utilize communications professionals to revamp, simplify, and improve the effectiveness of agency provided information.
- In the words of some AAMC constituents whom we consulted, the FDA should "simplify, simplify, simplify" information for patients, and "prioritize, prioritize, prioritize" information for physicians. Most patients cannot, and most physicians seem unwilling, to read package inserts. The point at which prescribers prescribe and patients first receive their medication usually represents the *only* opportunity to convey clear and

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simple, limited-length safety alerts and information. This opportunity must be better used with inserts that meet the needs of the readers.

- The FDA should develop practice models where prescribers interact with pharmacists in a team approach, and patients interact with pharmacists more regularly, especially when receiving a *new* medication.
- The FDA should stimulate the improved training of physicians (and other health professionals) in clinical therapeutics, such as by working with the Accreditation Council for Graduate Medical Education (ACGME) or promoting Continuing Medical Education (CME).

4. How easily accessible and understandable are FDA's Internet-based sources of drug information?

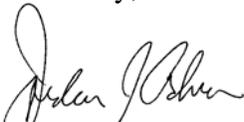
Information is available, but it is not presented in the most effective manner. For example, the process of accessing information from the FDA website is so cumbersome and difficult to navigate that most physicians do not have the time needed to keep up-to-date on newly discovered adverse events. Patients, on the other hand, are not only hampered by time requirements, but also by language that is too often incomprehensible without prior medical training, and by their general inclination to trust their physicians' decisions without independent, personal inquiry. In addition, because searching the FDA website is made more difficult by a lack of common, non-scientific, or non-regulatory keywords, one must know exactly what to look for.

5. To what extent do CDER's patient-focused communication tools provide useful information for people with low health literacy skills? and

6. What mechanisms should CDER consider to convey risk information to special populations (e.g., elderly, non-English speaking)?

The FDA alone does not possess the resources to eradicate the problems presented by non-English speaking and illiterate patients. The agency should create partnerships with entities that have established competence in communication with non-English speaking or illiterate citizens, and experience with broad multicultural issues, to disseminate information on inherent risks and benefits in multiple languages on the Internet or other media.

Sincerely,



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President

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