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December 21, 2005

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

Re: Docket No. 2005N-0394
Food and Drug Administration's
Communication of Drug Safety Information;
Public Hearing

Dear Sir or Madam:

AstraZeneca is dedicated to the discovery and delivery of innovative pharmaceuticals that help patients lead longer, healthier, and more productive lives. We are also committed to providing accurate, up-to-date risk/benefit information that is comprehensive, understandable, timely and accessible so that patients can have informed conversations with their physicians; and likewise, physicians and healthcare providers can make informed judgments about appropriate therapies for their patients. We are committed, therefore, to working with the Food and Drug Administration (FDA), physicians, patients, healthcare providers and others to improve risk communication tools, and develop additional risk/benefit communication(s) for pharmaceutical products.

AstraZeneca is especially interested in the FDA's ongoing efforts to provide meaningful and authoritative risk/benefit information to consumers, patients and healthcare providers. We recommend that FDA focus on three main areas to achieve this objective:

- Streamline the number of risk communications tools used by FDA and create communications that are clear, concise and in a consistent manner for the intended audience.
- Develop partnerships with external organizations, including the pharmaceutical industry, in order to help ensure that important risk/benefit information is conveyed to the public in an effective and timely manner.
- Re-evaluate the structure of its Internet site in order to enhance its effectiveness and broaden its accessibility.

2005N-0394

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Streamlining FDA's communication tools

We believe risk/benefit information for patients and prescribers alike must be clear, specific, concise, consistent and in context. Currently, the FDA has many different types of communication tools that can address the same subject. Although the information is available, important risk/benefit information may not be effectively conveyed because patients and prescribers are receiving too much information and/or receiving it without proper context.

In addition, we believe that the titles of FDA's risk communication tools —Talk Papers—are not self-explanatory. We suggest using titles that have plain meanings, like Safety Updates and Patient Information. Further, the FDA should explain to patients and healthcare providers what kind of information they should expect to find in a safety update or patient information sheet and any other risk communication vehicle.

Develop Partnerships with External Organizations

AstraZeneca believes the basis of good risk/benefit communication is patient education and outreach. It is an important to unambiguously convey risk/benefit messages to patients and caregivers using Internet and non-Internet based communication vehicles. AstraZeneca strongly encourages the FDA to undertake broadcast and print consumer/patient education campaigns akin to the consumer health campaigns that were undertaken for, among other things, depression and HIV/AIDS. Such consumer/patient education campaigns could remind patients of the necessity of talking to their doctor about the benefits and risks of a particular drug therapy, explain that all drugs have risks and benefits but most risks can be managed when known and understood, and encourage patients to view the FDA's web site for complete, authoritative, up-to-date, and user-friendly information about their medications.

While the FDA should be a primary communicator of safety information, it needs to continue to work with the pharmaceutical industry to facilitate the dissemination of important information in a timelier manner. The pharmaceutical industry has vast experience and a pre-existing infrastructure it can use to further the FDA's effort to provide timely risk/benefit information. Such assistance could ensure prescribers receive updated safety information in a timely manner, and in turn, help facilitate an informed discussion with their patients.

Re-evaluate the structure of FDA's website

Many of today's patients are more knowledgeable and resourceful than ever before. As a result, they are seeking more information and demanding more sophisticated answers about the medicines they take. The FDA has developed a number of Internet based information tools that provide safety risk/benefit information. However, we believe that FDA, with industry and other partners, can improve these on line tools, while also

creating additional non-Internet avenues to disseminate important patient and prescriber information.

The continued development of a web based, “super site” communication vehicle is a step in the right direction. The Drug Safety web page at <http://www.fda.gov/cder/drugsafety.htm> and the Index to Drug Specific Information at http://www.fda.gov/cder/drug/drugsafety/drug_index.htm are good building blocks. We would support streamlining and modernizing the Drug Safety web site using information science and system tools such as web-enabled Document management, meta-tagging, and web-enabled database best practices. The benefit of migrating relevant documents and decommissioning outdated documents is worth the time and resources required. And while the FDA has developed a number of other Internet based information tools that provide risk/benefit information, we believe FDA, with industry and other partners, can improve their current tools, develop new ones, and create additional avenues to disseminate important patient and prescriber information.

We would recommend that user-friendly features be incorporated on FDA’s Internet “super site” geared towards patients and healthcare providers. By simply clicking on or typing in the name of a drug, a patient and/or caregiver, using a drop-down menu, could get all relevant information, *in plain language*, about the drug. These features on a “super site” could also provide patients and caregivers plain language information on any label changes, and the significance/relevance of those changes.

Lastly, we believe the FDA must re-think how it delivers information in a changing communications environment. FDA should consider creating a special trained group within CDER (i.e. Office of Drug Safety) that is comprised of behavioral and information scientists knowledgeable in communication techniques and practices that work with various audiences. We would envision this group conducting ongoing research into new methods of communicating as technology and the public’s demand for safety risk/benefit information increases. If the FDA is to be the first choice for authoritative, safety information, it must proactively engage in education and outreach through a variety of communication channels using a dedicated staff with the specific skills needed to move beyond where we are today.

In considering the specific questions posed by the FDA, AstraZeneca has the following comments:

1. What are the strengths and weaknesses of the communication tools listed (Patient Information Sheets, Healthcare Professional Information Sheets, Talk Papers, Public Health Advisories, Press Releases, Med Watch Safety Updates, Patient Safety News, CDER Educational Campaigns, CDER Internet Site)?

Patient Information Sheets: This communication vehicle is not easy for patients to understand. Although information sheets are purportedly written in simple language, internal feedback from consumers tells us that they are not understood. Additional confusion is created by the different links to Patient Information Sheets on the web site

that lead to different formats of the same document (and perhaps different versions of the same document).

We recommend that the FDA consider improving communication of risk/benefit information to patients by testing the level of understanding and eliminate any potentially confusing language. The FDA should also consider an invitation to patient advocacy groups and communications experts to review such information for patient comprehension prior to full public release.

Press Releases: At times the contents of this form of public communication can be misinterpreted. Critical information concerning safety related matters are not always clear and concise for the intended audiences. Consequently, FDA should have a clarifying mechanism or regular follow-up communications to prevent audience confusion.

FDA Alerts and Public Health Advisories: In order for these tools to be most effective, and for the information communicated to be meaningful, it is recommended that FDA create forums to educate its many audiences as to the objective of these communication vehicles.

The FDA should also consider re-naming various FDA notices to better delineate the more serious of the communications, i.e. "*Safety Alert*" to announce the removal of a drug from the market, from those that are more routine, i.e. "*Label Update Bulletin*" for minor label changes.

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

We believe that FDA's web site is not identifiable as a source of drug information by the public. Many of the communication vehicles under discussion are all posted or linked on the FDA site, but knowledge of the posting is limited. Most of the public becomes aware of the posting through media reports. In order for the FDA to become the primary source for accurate, current and scientifically sound safety risk/benefit information, we recommend that the FDA either proactively publicizes the posting, using the FDA website as a communications as one vehicle, and for wider communications, disseminate the FDA information beyond the web site through alliances with industry or other healthcare information providers.

We suggest that FDA should review new types of communication vehicles (web blogs, e-mails, Internet enabled technology) that are gaining increased credibility and popularity with consumers and healthcare providers. We encourage the FDA to continue to support and be part of various organizations and consortiums seeking new forms of effective electronic communications. Ultimately we see this as a joint effort with industry to help develop new regulatory guidance in this area of drug product communications.

Web site: General feedback from healthcare professionals and patients who have access to the web site indicates that titles of documents don't necessarily convey to consumers

and others what the documents are about. It is also noteworthy that it is difficult to differentiate between different types of communication documents and their relation to one another if they have been issued on the same subject matter.

We find the FDA's glossary of terms at Drugs@FDA <http://www.fda.gov/cder/drugsatfda/glossary.htm> to be helpful and would like to see this glossary expanded with patients as the primary audience. For example, in very basic language, and expanded glossary would explain terms such as label, label change, black box warnings, citizen's petitions, contraindications and drug class. Overall, we suggest that the lessons learned from the Drugs@FDA pilot and launch be used to streamline and modernize the Drug Safety web site using information science and newer system tools. . Specific features could help eliminate difficulties in linking across communication tools and possibly missing essential information, i.e. Patient Information Sheets, Talk Papers, Patient Safety News, and Safety Updates, the FDA currently utilizes.

Another general observation gathered from consumers is that the search function on the web site is difficult to use. A specific problem arises from searching for historic documents, after the initial news links are removed, making these documents more difficult to find. Thus, the inability to effectively obtain the "full picture" on a medication impacts the effectiveness of the current FDA communication about the medication.

We recommend that to help overcome these difficulties, the FDA structure its web site so that each product's materials can be readily identified or easily searched using modern information science and systems technology, processes and standards. We suggest that FDA pool its expertise in information management and information science and systems from key pilots, electronic submissions work, and other cutting-edge experiences from internal and external sources.

3. Do these tools provide the right kind and amount of risk and other information that healthcare 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?

Given the diffuse sources of medical information now available to consumers, it is more vital than ever that the public view FDA as the gold standard for comprehensive, informative, easily accessible and understandable information. As such, it is critical that FDA ensure the information it posts is not preliminary or cursory and is scientifically accurate.

In its communications to the public, the FDA should review the indications of a drug, along with the potential risks and encourage physician and patient discussion so that informed decisions about whether to administer a particular drug can be made.

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

It is AZ's position that the Internet and specifically the FDA web site can be a significant source of information for the public. We feel FDA can significantly improve its Internet based communication capabilities. Areas that should be addressed in crafting an Internet based strategy:

- Communicating effectively with various external audiences about the FDA web site and creating links to high traffic and credible web sites.
- Organizing the information for clarity and ease of use, so that the user can easily find the information they are seeking
- Providing clear and concise high level summaries of important information with reference to more detailed information within another site location
- Ensuring that the information is up to date and continually refreshed to ensure accuracy and continued audience interest in returning for updates.

However, it should be noted that there are many patients who do not have Internet access and require the same important information. We believe that FDA should work with industry and patient advocacy groups to identify other methods of dissemination for those who are non-Internet users or lack access.

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

AstraZeneca's internal research through cultural competency experts has demonstrated that to effectively communicate with this segment of the population verbal messages benefit from reinforcement with visual aides and may require multi-lingual language presentation. In order to promote successful communication, it is helpful to leverage E-based audio technology when available. Further, AZ has found that information grouped into disease categories can be beneficial to this targeted population.

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

We recommend certain vehicles for conveying risk/benefit communication to special populations. They are:

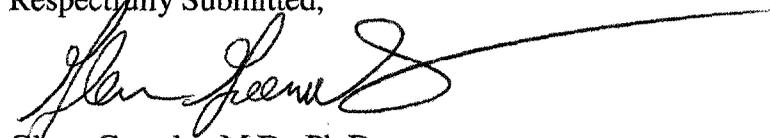
- Develop culturally relevant and organically created communication pieces (e.g. CDER Handbook Spanish Edition).
- Develop dedicated web sites targeted by cultural segment and incorporating relevant disease state information.
- Leverage grassroots advocacy and community groups in efforts to disseminate information and create awareness about risk communication vehicles.
- Establish Regional Drug Safety forums targeted at special populations as another vehicle to communicate reliable sources of drug safety information.

- Work with the pharmaceutical industry to develop Direct Response ads (print, radio, TV) about important drug information (leveraging ethnic media in the process of building trust) and supporting this effort with 1-800 # bi-lingual information access followed up by direct mailing of information.

In summary, there is an opportunity and growing need to improve the way risk and benefit information is communicated by using better methodologies, improving the clarity of content of each communication, recognizing the diversity and broad scope of its intended audience and educating the public.

We are pleased to have had this opportunity to provide our comments and welcome future opportunities for sharing our views and research in this important area.

Respectfully Submitted,

A handwritten signature in black ink, appearing to read "Glenn Gormley", with a long horizontal flourish extending to the right.

Glenn Gormley M.D., Ph.D.
Chief Medical Officer
AstraZeneca