



January 4, 2006

Division of Dockets Management (HFA-305)
Food and Drug Administration (FDA)
5630 Fishers Lanes, Rm. 1061
Rockville, MD 20852

Re: Docket No. 2005N-0394

Dear Members of the FDA Center for Drug Evaluation and Research (CDER):

The Academy of Medicine of Cleveland/Northern Ohio Medical Association (AMC/NOMA), a physician organization representing over 4,300 physicians in Northern Ohio, would like to respectfully submit our public comments regarding the FDA's Communication of Drug Safety Information.

Recently, our board of directors agreed to adopt as our policy the American Medical Association (AMA) recommendations regarding postmarketing drug safety issues. Our organization completely agrees with the AMA that the FDA should address these recommendations. Our board adopted the AMA policy with some slight changes to the language. These recommendations are as follows:

1. Urge the Food and Drug Administration (FDA) to issue a final rule, as soon as possible, implementing modifications to the format and content of the prescription drug package insert with the goal of making the information more useful and user-friendly to physicians;
2. Urge the FDA to collaborate with physician organizations to develop better risk communication vehicles and approaches;
3. Urge the FDA to apply new tools to gather data after drugs are approved for marketing, including a broader use if targeted post-approval studies, institution of active and sentinel event surveillance, and data mining of available drug utilization databases;
4. Monitor the design and implementation of any independent drug safety board that may be instituted within the FDA, or external to the agency, and respond as appropriate;
5. Support adequate funding to implement an improved FDA postmarketing prescription drug surveillance program.

We agree with the AMA that there is a need to look at the benefits versus the risks involved in drug therapy and any way that we can improve the safe use of prescription drug products post marketing is a laudable goal and one that should be pursued by the FDA.

The FDA has requested comments on the risk communications items developed by the FDA and posted on the FDA web site. Several AMC/NOMA board members have reviewed the web site and are of the opinion that while the site does provide a plethora of information about risks of drug products, accessing that data from the FDA site is a time-consuming task. Our physician members would concur with the AMA that other relevant communication tools must be developed in order to keep physicians apprised of the rapid changes that can occur relative to drug safety issues.

For example, as noted by the AMA, “Dear Doctor” letters are not always read in a timely manner. Therefore, in addition to hard-copy mail these letters should be disseminated through other formats – such as publication in medical journals, medical society web sites, as well as through communications to physicians via blast fax, blast email, and direct downloads to personal digital assistants. In this age of information technology, usage of electronic means of communication, inclusive of e-prescribing systems, would be the most efficient way to notify physicians of drug safety issues. If the hard-copy letters continue to be sent out to physicians, we would agree that the format of the “Dear Doctor” letters must be altered to alert the physician of the need for action. The first part of the letter should clearly outline the possible severe outcomes to patients that could occur from a new adverse event, that the adverse event could be preventable if the drug is used correctly, and what steps the physician should consider to prescribe the drug appropriately.

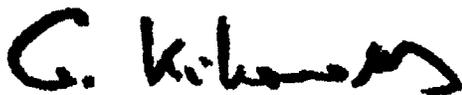
We also agree with the AMA that pharmaceutical representatives should be trained to educate physicians on risk information about their products. These representatives gain access to our offices everyday to promote the benefits of their companies’ products and these same representatives should be able to provide information to physicians about safety problems.

The AMC/NOMA believes that in order to better address patient concerns physicians would strongly recommend that the FDA provide physicians and other healthcare providers with major announcements on drug or device side effects through the above referenced communication routes, prior to their release to the general public. We realize that the FDA is prohibited from providing this early release of information to physicians due to regulations, but we believe that it would be helpful if physicians and healthcare providers were provided with this information prior to public release so that we could be prepared to address these matters with our patients.

With regard to our patients, your consumers, the FDA has sought comments whether or not the FDA Internet-based sources of drug information are easily accessible and understandable. We are of the opinion that anyone trying to access information on the FDA site may experience problems in accessing the information. It is our opinion that the information is not presented in a concise manner and this warrants further evaluation by the FDA. The web site should be evaluated for ease of usage as well as whether or not elderly consumers would be able to access the information on the site (Internet access, understanding of the data presented, etc.) Elderly patients often take multiple medications and drug-drug interactions and over and under dosing related to confusion or sight impairment is a real concern. Personal medication records should be encouraged if at all possible.

The physician members of the AMC/NOMA would be pleased to provide additional input relative to this issue in the future. Physicians are on the front line everyday prescribing medications to our patients and we must have drug safety issues brought to our attention as soon as possible. We stand ready to assist the FDA and other physician organizations in the future on this important issue.

Sincerely,



George E. Kikano, M.D.
President
The Academy of Medicine of Cleveland/Northern Ohio Medical Association (AMC/NOMA)