American Pharmacists Association
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APhA

April 11, 2003

Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 03N-0017

Dear Sir/Madam:

Thank you for the opportunity to comment on the impact of risk management programs on the practice of pharmacy. The American Pharmacists Association (APhA), founded in 1852 as the American Pharmaceutical Association, represents more than 50,000 practicing pharmacists, pharmaceutical scientists, student pharmacists, and pharmacy technicians.

Risk management activities for prescription drugs are obviously of vital interest to pharmacists, as they are committed to providing their patients with medications that can be used safely and effectively. As the number of drug products found to present a higher-risk has grown significantly over the past several years, pharmacists' focus on, and participation in, risk management programs has increased. The proposed survey on the impact of risk management programs on pharmacy practice, as described in the February 12, 2003 *Federal Register*, is an important step in evaluating the success and workability of risk management programs. Risk management programs can be an effective method of minimizing a drug product's risks, while they impact every part of the health care system in which pharmacists play a crucial role.

APhA supports the Food and Drug Administration's (FDA) proposed survey of 5,000 pharmacists to evaluate pharmacists' knowledge of risk management programs, identify barriers to compliance, and assess the impact of these programs on pharmacy practice. APhA understands that the proposed survey will include 5,000 randomly selected pharmacists, and will include questions designed to help the Agency understand how risk management programs affect the practice of pharmacy and gain insight on practical interventions for future risk management programs.

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APhA is aware of at least eleven prescription drug products that currently make use of a risk management program: alosetron hydrochloride, bosentan, clozapine, dofetilide, fentanyl, fentanyl citrate, isotretinoin, mifepristone, sodium oxybate, thalidomide, and trovafloxacin. Each of these programs was developed by the FDA and/or the product sponsor on a product-by-product basis, and each program has different and sometimes conflicting requirements. For example, under the risk management program for isotretinoin, pharmacists may only dispense the drug after receiving a prescription with a yellow qualification sticker that was written within the past seven days. The pharmacist may only dispense a one month supply per prescription, and must provide the patient with a Medication Guide. In contrast, under the thalidomide risk management program, pharmacists may only dispense the product after registering with the System for Thalidomide Education and Prescribing Safety (S.T.E.P.S.) program, verifying that the prescriber is a registered S.T.E.P.S. participant and that the patient has signed an informed consent. The pharmacist must only provide a four-week supply at one time and must record each prescription.

Although both programs were created with the same goal in mind—to minimize the risk of fetal exposure, the requirements of each program are very different and utilize different risk management tools. Because of the patient populations pharmacists serve, many pharmacists must deal with several of the risk management programs. Imagine the administrative difficulties and confusion that could be generated by trying to keep track of each program's differing requirements. And as the Agency notes in the *Federal Register* announcement of the survey, "many risk management programs require pharmacists to actively intervene and implement actions that deviate from their normal work procedures."[1]

The sheer number and complexity of current risk management programs justifies the proposed FDA survey. An examination of the impact risk management programs have on the practice of pharmacy will be of value both to the Agency and others interested in improving the risk management system. The survey will provide valuable information on pharmacists' familiarity with risk management programs, problems with risk management tools currently in use, and risk management tools that appear to be working well – information crucial to the improvement of existing programs and design of new risk management programs. The survey results will also have practical utility for the FDA's recently announced intention to release draft guidance for industry on the development and evaluation of risk management programs later this year.

For the survey results to be of the most utility to the Agency, APhA offers a few recommendations on the survey administration and content. According to the *Federal Register* announcement, the survey respondents will be randomly selected from lists provided by the State Boards of Pharmacy. While APhA supports a random sampling of pharmacists, we strongly advise the Agency to structure the sample to ensure that it includes pharmacists in all practice settings such as

[1] 68 FR at 7125.

community pharmacies, hospital pharmacies, long-term care facilities, and hospice settings; and to limit the survey to pharmacists in active practice.

Pharmacists in each practice setting have varying opportunities to work with each of the risk management programs mentioned above; and the workability of each program within varying practice settings will differ. For example, the FDA has stated that it is interested in evaluating pharmacists' knowledge of risk management programs and identifying barriers to compliance. A community pharmacist and a hospital pharmacist surveyed about the risk management program for isotretinoin will likely exhibit varying degrees of knowledge of the program and will likely identify different barriers to compliance. The community pharmacist may receive isotretinoin prescriptions more frequently than a hospital pharmacist, and the community pharmacist's primary barrier may be created when a prescription is presented without a yellow qualification sticker or outside of the seven day prescribing window. While the hospital pharmacist may have less exposure to the isotretinoin or other risk management programs, and increased exposure to others, due to the hospital's formulary. A hospital pharmacist presented with a prescription for isotretinoin may also experience a different barrier because most hospitals no longer use paper prescriptions orders, but use computerized order systems. Without a paper prescription for the qualification sticker, the pharmacist does not know if the patient meets the qualification standards. Surveying pharmacists in all practice settings will help the FDA to obtain a more accurate evaluation of the effects of risk management programs on pharmacy practice. Respondents should be asked to identify their practice setting in the survey.

Although the FDA announcement of the proposed survey does not provide specific information on the type of questions respondents will be asked, there are several types of questions we recommend. The survey should include discussion of specific drug products that currently require a risk management program. APhA recommends that the Agency incorporate questions in the survey to assess each respondent's knowledge of, and participation in, each program. Respondents should also be asked how difficult it is to comply with each program's requirements, and to manage the various program tools. It would also be helpful to learn how pharmacists proceed when program requirements are not met. Reponses to these types of questions will provide valuable information to the Agency as it moves forward in the development of a more structured risk management system.

In conclusion, APhA supports the Agency's efforts to examine the impact of risk management programs on the practice of pharmacy. Periodically reviewing the effects of risk management programs will assist the Agency in its efforts to ensure that risk management programs are appropriate for the product, improve health outcomes, and do not create inappropriate or unworkable programs for patients, pharmacists, or prescribers. Again, APhA urges the Agency to include pharmacists in all practice settings in the survey.

Thank you for your consideration of the views of the nation's pharmacists. Please contact Susan C. Winckler, APhA's Vice President of Policy and Communications and Staff Counsel at 202-429-7533 or SWinckler@APhAnet.org, or Susan K. Bishop, Senior Manager, Regulatory Affairs and Political Action at 202-429-7538 or SBishop@APhAnet.org with any questions.

Sincerely,

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Executive Vice President

cc: Susan C. Winckler, RPh, JD, Vice President, Policy & Communications and Staff Counsel
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