

**Statement on
RISK MANAGEMENT OF PRESCRIPTION DRUGS**

**From the
American Society of Consultant Pharmacists**

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Mr. Chairman, members of the Committee. My name is Tom Clark, Director of Professional Affairs for the American Society of Consultant Pharmacists. ASCP is an association of 7,000 members who provide medications and pharmaceutical care services to older adults, both home and community-based as well as those who reside in nursing homes and assisted living settings. Our comments today will include a focus on risk management issues as they relate to older adults and long-term care.

Thank you today for this opportunity to present testimony on the important issue of risk management for prescription drugs. The FDA is to be commended for devoting attention to this issue and seeking ways to improve the current structure and systems for managing risk associated with prescription medications.

Older adults are especially vulnerable to the risks of medication use. They take more medications than other persons and are more likely to have diminished ability to metabolize drugs due to declining kidney and liver function. Adverse drug reactions are observed two to three times more frequently in geriatric patients than in adult patients younger than 30 years. It is also estimated that adverse drug effects are responsible for up to 10% of hospital admissions in older patients.¹

Risk communication

In the past 30 years, the number of medications available for use by physicians and other prescribers has grown substantially. In earlier years, physicians could learn a few key medications in each therapeutic category and gain experience and knowledge with those medications. Today, the average prescriber confronts dozens of drug formularies from the various health plans used by their patients.

As a result, prescribers today must be able to use virtually all of the available drugs to treat the types of conditions or patients being managed.

At the same time, the amount of information available today is exploding. Prescribers receive information by mail, FAX, e-mail, web sites, personal contact, and other methods. Information comes from medical journals, pharmaceutical companies, government agencies, and many other sources.

One question on which FDA has requested input is: How can communication with health care professionals be more effective? How can the FDA cut through the information overload and background noise to ensure that health professionals are not only aware of, but also apply important information about risks of medications in their patient interactions?

ASCP Suggestion on Risk Communication

In response to this question, we offer an idea for consideration. The idea is based on a strategy that FDA currently uses when issuing notices about recall of medications. A Class I recall is a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death. A Class II recall is a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. A Class III recall is a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

This system of prioritizing medication recalls enables health care professionals to quickly identify situations where urgent action is needed to avoid loss of life. The class of the recall provides guidance to the practitioner on the urgency and importance of the issue.

Perhaps the FDA should consider developing a similar prioritized system for issuing "Medication Safety Alerts". A Class I Medication Safety Alert would involve a situation where patient lives may be lost or serious adverse health consequences may occur if certain precautions or actions are not taken with use of the designated medication. The information about the need for liver monitoring with the use of troglitazone, for example, might have fit into a Class I Medication Safety Alert category. The drug recall framework might also be used to establish guidelines for Class II and Class III Medication Safety Alerts.

Existing tools for risk management

In recent years, a number of medications have been identified which present significant risk of harm if not used appropriately. The safeguards inherent with the use of prescription medications in the United States have been found to be inadequate for safe use of these particular medications. In some cases, medications have been withdrawn from the market. In other cases, special risk management programs have been established in an effort to better manage the risks from the medication.

Withdrawal from the market

When useful medications are withdrawn from the market, patients who could benefit from them are deprived of the benefits. The withdrawal of cisapride heightened ASCP's interest in the medication risk management issue. Cisapride was a medication used to increase motility of the upper gastrointestinal tract, and of value in managing a common complication of diabetes called diabetic gastroparesis. Without cisapride, therapeutic options are now more limited.

Metoclopramide can be used, but in older adults, metoclopramide frequently causes movement disorders including extrapyramidal symptoms and tardive dyskinesia. These symptoms are similar in appearance to Parkinson's disease and are sometimes irreversible even when the medication is discontinued.

One recent study found that prescribers frequently confuse the drug-induced side effects of metoclopramide with the onset of true Parkinson's disease. In fact, older adults who take metoclopramide are three times more likely to be placed on a medication for Parkinson's disease.² As a result, these patients are exposed to the risks of unneeded drug therapy.

Erythromycin is another treatment approach.³ It does increase upper gastrointestinal motility and is used for this purpose. But erythromycin is an antibiotic. In this era of increasing concern about antibiotic resistance, the fact that clinicians are using this approach is a clear indication of the need for additional therapeutic options.

Cisapride is a prime example of a medication that was lost to clinicians because of the weaknesses in the current system for safe use of medications. It could be brought back onto the market with appropriate safeguards to provide an additional therapeutic option where few are now available.

Multiple risk management programs are confusing

The various medication risk management programs currently used have each been developed individually and separately. Each program is administered separately, with different telephone numbers to call and requirements for participation. The logistical challenges in obtaining the needed information and authorization to prescribe, dispense or use these medications present a significant barrier to access for these medications in patients who could benefit from them.

Restricting the source of supply for the drug product

Some of the tools and strategies used in existing risk management programs have serious limitations and drawbacks. When patients are required to obtain

the restricted medication from only an exclusive pharmacy provider, this segregates that particular medication from the patient's usual source of supply for other needed medications. As a result, any drug interactions involving the restricted medication will be difficult to detect. The designated provider for the high risk medication may attempt to collect information about other drugs in use by the patient, but if the patient later needs a new medication, the usual pharmacy provider may not detect the interaction with the restricted medication.

Removing the local pharmacist from the loop with the restricted medication also keeps the pharmacist from being able to assist the patient with identification of possible adverse effects from the restricted medication, or additive side effects with other medications the patient may be taking.

Residents of nursing homes and assisted living facilities are usually served by specialized long-term care pharmacies that provide needed services such as specialized packaging, drug delivery, 24-hour emergency service, and others. When special distribution programs exclude these pharmacies from participation, these needed services, especially the special packaging, are usually not available from the exclusive pharmacy distributors. This creates significant logistical problems for the long-term care facilities and increases the risk of medication errors.

Prescriber restrictions

Restricting a medication to use only by physician specialists also presents significant problems. In some cases, patients may have to wait for weeks or months to get an appointment with the specialist to begin drug therapy. The specialist may also be geographically distant from the patient, requiring substantial time and effort to make the trip to the specialist. Finally, one assumption with this approach is that the specialist will be knowledgeable about the designated medication and strategies to minimize risk. Although this

assumption may generally be valid, this represents a potential hole in the safety net.

Requiring prescribers to complete educational programs before prescribing the medication may impose a significant burden on the physician. If physicians choose not to prescribe the drug, this reduces access to the medication by the patient, and forces the patient to go to a different prescriber just for this specific medication.

Prescription stickers

The strategy of having the prescriber place a special sticker on the prescription to show that certain risk-management steps have been taken has a number of problems. In the long-term care setting, traditional prescription forms are seldom used. Prescribers may write prescription orders in the medical record at the nursing facility, or telephone orders from their office. Nursing homes have about 1.6 million residents, and an additional 1-2 million persons reside in assisted living or board and care homes. Any risk management approach must consider the unique needs and requirements of these long-term care settings. ASCP would be pleased to offer assistance to FDA in developing or revising risk-management strategies to consider the special needs of patients in these long-term care settings.

New Risk Management Tools: Involving the Pharmacist

The existing menu of options used in risk management of medications has failed to employ a key resource: the community pharmacist. In some cases, the community pharmacy is bypassed altogether through exclusive distribution arrangements with a single mail order pharmacy or a highly restricted distribution network.

Involving the pharmacist as a key player in medication risk management is highly desirable for several reasons. Pharmacists have, in fact, always had an important role in managing risk of medications. Evaluation of the appropriateness of the prescription by the pharmacist is the last safety check before the medication reaches the patient. If the pharmacist believes the medication dose may be too high or the medication may interact with another drug the patient is already taking, the prescriber will be alerted to ensure that the patient is not inadvertently harmed.

Why not strengthen this structure and provide the pharmacist with tools and resources to assist with managing risk of designated medications? Existing risk management programs focus heavily on prescribers. The United States has about 676,000 practicing physicians, plus many more mid-level prescribers such as nurse practitioners and physician assistants. Does it make more sense to focus resources and attention on the nearly 1,000,000 prescribers or the 55,000 pharmacies where the medications are obtained?

ASCP suggests that a voluntary network of participating pharmacies could form the basis for a comprehensive medication risk management system. This network would include any pharmacy willing to meet the program guidelines. The pharmacist who dispenses the medication to the patient would be responsible for ensuring that specific risk management strategies are implemented. Education would be provided to the pharmacist and documented to ensure adequate knowledge and skills for performing the tasks.

Pharmacy-based risk management strategies could include:

- Confirmation that drug interactions and contraindications to the medication do not exist. This would be conducted using standardized checklists and forms developed by a group of stakeholders, including the FDA, pharmaceutical manufacturer, prescribers, pharmacists, and other relevant parties.
- Patient education, counseling, and/or training

- Verification that needed laboratory tests have been conducted on schedule
- Monitoring of the patient and reporting of adverse drug reactions to the prescriber, FDA and manufacturer

Long-term care pharmacies must be included in any pharmacy-based risk management approach to ensure that the 3 to 4 million residents of long-term care facilities have access to these medications when needed.

Pharmacy-based risk management is not the total answer to the issue, but can be an important tool in a comprehensive risk management program. Pharmacy-based risk management strategies may be adequate for some medications. In other cases, additional strategies may be needed.

The advantages of the pharmacy-based approach are:

- Prescriber restrictions can be eliminated or minimized, reducing the burden on prescribers
- Consumers will have better access to the medication
- The pharmacist, who has regular contact with the patient anyway, is enrolled in the effort to minimize risk from the targeted medications
- A voluntary, but closed, network of pharmacies permits better oversight and accountability for use of high-risk medications
- Allows concentration of limited resources on a smaller “target”, since the number of pharmacies is relatively small compared to the number of prescribers
- A pharmacy-based risk management network can provide an infrastructure and starting point for management of high-risk medications. A common telephone number and web site could be developed for access to information about all the designated medications, reducing confusion and barriers to access to these medications.

The American Society of Consultant Pharmacists is pleased to have this opportunity to provide input on medication risk management. We welcome the

opportunity to continue to discuss these issues with the FDA and collaborate in the development or refinement of medication risk management strategies.

Thank you.

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