



NATIONAL ASSOCIATION OF  
CHAIN DRUG STORES

**Statement on**  
**RISK MANAGEMENT OF PRESCRIPTION DRUGS**

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Mr. Chairman and members of the Committee, my name is Gary Wirth, Director of Pharmacy Professional Services for Giant Food and Pharmacy. I am appearing today as a representative of the National Association of Chain Drug Stores (NACDS), of which Giant is a member. Giant operates 155 pharmacies in five states. NACDS membership includes more than 200 chain companies that operate 33,000 community retail pharmacies. Chain pharmacy is the single largest segment of pharmacy practice employing approximately 100,000 pharmacists. Chain community pharmacies fill about 70 percent of the 3 billion prescriptions provided to patients each year.

We very much appreciate the opportunity to appear today to contribute our perspectives on the development of an effective prescription drug risk management strategy. Chain community pharmacies are the primary point of distribution for outpatient prescription drugs in the United States. In addition, pharmacists provide an easily accessible point of contact for patients. As medication experts, pharmacists help ensure the safe and effective use of high-risk medications by their patients. For that reason, it is important that any risk management system developed will integrate the systems and procedures already in place at community pharmacies for the safe use of prescription drugs. It is also important to ensure that any program represents a collaborative effort of the entire health-care team, including manufacturers, physicians, pharmacists, and the Food and Drug Administration (FDA) patients.

### **All Drugs have Benefits and Risks**

Prescription medications allow individuals to lead healthier lives. Needless to say, drug products are not 100 percent safe, and we know that there are certain acceptable risks associated with prescription drug use. If the (FDA) approves a drug, we assume that the benefits of taking the drug outweigh the risks, and that the drug is safe for widespread consumption. Still, after extensive evaluation through the approval process, no one fully understands all of the risks associated with the product.

In reality, some of the most serious adverse drug events may not be known at the time of approval, but only after the drug has been used in a broader population in real-world conditions.

As a broad principle, NACDS supports the concept that, once a high risk drug is approved for marketing by the FDA, the drug should be available through any community pharmacy outlet that chooses to stock the product and help ensure its appropriate use through educational programs, counseling, and other appropriate interventions. The reason is simple. It is important for the pharmacist that already has an established relationship with the patient, and who knows the patient's medical condition, to coordinate and integrate the "risk-managed" drug into the patient's existing prescription medication regimen. That is, if the patient is already taking multiple medications, it is important for the patient's regular pharmacy provider to help assure that the new "risk managed" drug does not present any potential interaction problems for the patient.

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### **Current Risk Management Activities**

Acknowledging that there are risks from inappropriate use of any prescription drug, community pharmacies try to help patients understand how to make the most effective use of their medications. For many years, pharmacies have used computerized systems to check for potential drug-drug, drug-food, and now drug-nutritional interactions; drug overdoses; and, duplicative drug therapy. In addition, community pharmacists provide quality written information to consumers with their prescription medications to help reinforce the face-to-face counseling they receive.

Pharmacists also follow-up with patients through phone calls and other professional contacts after the prescription is filled to improve adherence with the prescribed therapy. Follow-up monitoring is important because, often times, adverse effects of medications are only detected when prescriptions are refilled. Moreover, some community pharmacists are certified experts in the pharmaceutical management of certain disease states, such as diabetes.

These pharmacists provide more intense personal education and counseling to assist patients in managing the disease. In fact, Giant operates several pharmacies, which are certified by ADA to provide diabetes self-management and training to Medicare beneficiaries.

It is clear that, for some drug products, more intense monitoring, education, and management is needed to ensure that the risk is managed appropriately. For example, over the past few years, several drugs have been approved by the FDA with certain restrictions on how the drug could be sold or distributed to limit potential risk to the patient. In other cases, drugs have been removed from the market because of inappropriate use. Some of these drugs might have remained on the market if certain professional or patient safety programs were put in place. Lotronex may be a good example. In other cases, already-marketed drugs were required to develop new professional and patient safety programs. A good example is Accutane.

### **Program Development**

We commend the agency for initiating this dialogue about risk management approaches. We also understand that, if the agency believes a new or existing drug needs a risk management program, then the agency will ask the manufacturer/sponsor to develop a program, and then negotiate with the sponsor to develop a program that meets the agency's requirements.

Because pharmacies, physicians and patients will be the key participants in the risk management program, it is imperative that our input is considered during the development process of risk management programs. NACDS believes that program development should seek to avoid impractical situations once the program is implemented. For example, the Accutane sticker program, which has been implemented and running just over a month, seems to be a workable program. Fortunately, the program is feasible as a stand-alone program, but more importantly, it works in conjunction with other day-to-day pharmacy operations.

There are other risk management programs that have not worked so well, and there is the potential for more programs that will not work in the real world. If pharmacy is involved in the developmental stages of the program, many of these problems can be avoided.

### **Goal Should be Standardization, Not Fragmentation**

While we recognize that each drug product is unique, a different risk management approach has been developed for each current "risk-managed" drug. This fragmented risk management approach can create confusion for professionals and patients, potentially defeating the goal of creating less potential for risk. We need a standardized, seamless, computer-based system that can be easily accessed by practitioners to deliver risk management services to patients.

We believe that a fragmented assortment of individual risk management programs is counterproductive to minimizing risk. Currently, it is even possible for two separate risk management programs to evolve for brand and generic versions of the very same drug. It is almost impossible to maneuver all of the different risk management programs available.

The current risk management system is analogous to the situation that has developed with the use of multiple various PBM drug formularies. There are literally thousands of formularies, and each formulary is different. Physicians, pharmacies, and even patients themselves are often unaware of which drugs are covered. This whole process is time consuming, resulting in delays and confusion for patients, pharmacists and physicians. We should seek to avoid these formulary fragmentation hassles in current and future risk management programs.

Having said this, I would now like to turn to some of the issues that the agency and others should consider for an effective standardized risk management strategy for certain prescription drugs.

- **Assumption of Liability and Payment for Risk Management Services:** A fundamental question that will have to be answered as pharmacies consider participation in these programs is the nature of the risk and liability that pharmacies will be asked to assume, and how pharmacies will be compensated for taking on this additional liability.

While pharmacies are willing to participate in risk management programs, many are concerned about additional liability that they might incur by participating. In one scenario, the pharmacy may actually be asked to bear some of the additional liability that may result from providing a drug that has a higher than normal risk. In other cases, the manufacturer may assume the additional liability that is involved, shielding the pharmacy from any liability. These factors must be clearly articulated for pharmacies as they consider participation. Payment to pharmacies must be commensurate with the liability that the pharmacy will be asked to assume.

Regardless of the level of liability assumed, providing additional risk management services to patients results in additional costs to providers. FDA traditionally has not become involved in economic issues relating to the financing of prescription drugs. However, if the agency is going to require that health professionals perform certain additional activities relating to the management of a drug product, then it is logical to assume that pharmacists will be compensated for these services. The manufacturer should bear the financial burden of providing these services. We ask the agency to explore these issues, because providing these services could come at a much higher cost.

- **Education and Training:** NACDS believes that educating and training health professionals on the proper use of medications that have high risk programs is an important component of a manufacturer's risk management strategy. We encourage manufacturers to develop these educational programs in conjunction with pharmacists, and create an important feedback and evaluation component back to the FDA and the manufacturer from the community retail pharmacy community.

- **Access and Distribution:** As we have already stated, for patient care and patient safety reasons, we are opposed to limiting distribution of outpatient drugs to a restricted network of pharmacies, and total circumvention of community pharmacy practice. Patients should be able to obtain high-risk drugs from the same health professionals that they currently use to obtain their other medications and health care services. Patients rely on their community pharmacist for the latest health information. As a medication expert, the pharmacist can act as a safety-net in the patient's medication therapy.

However, we recognize that not all pharmacies may choose to participate in a particular risk management program. FDA should provide any community pharmacy the opportunity to participate in a risk management program, provided that they meet the eligibility requirements of that program. We also support the notion of allowing pharmacies to access these products through the traditional channels of wholesale distribution.

- **Registries and Patient Eligibility:** Professional or patient registries identify the patients that can take, the physicians that may prescribe, or pharmacists that may dispense certain high-risk drugs. We understand the interest in these registries, but want to express our concern with the potential for multiple registries using multiple databases. There is value to developing a central registry or database that can be used by any manufacturer with a risk management program that can identify those patients, physicians, and pharmacists, that are eligible to participate in the program.

Each drug's risk management program could have its own identifiers so that pharmacies could only access information for patients that are seeking prescriptions for their own particular high-risk drug. Current pharmacy technology and electronic transaction standards can readily support such a system.

This system would also indicate the quantity of medication that could be dispensed, whether or not refills are allowed, any monitoring or follow-up the pharmacy is required to do, as well as whether the patient has met all the qualifications and requirements for receiving the drug. We are concerned with the potential for the use of “multiple colored” prescription “stickers” that indicate whether the patient has met these requirements. We believe that a real-time system is more accurate and reliable than relying on this paper trail. Indeed, with electronic prescribing becoming a reality, paper-based sticker programs may quickly become outdated.

- **Generic Versions:** NACDS is concerned about generic versions of brand name products that have risk management programs. That is, when a generic becomes available, does the generic have the same risk management program as the brand? We believe that to minimize confusion for the patient and the pharmacist, that the program should be the same. We also do not believe that risk management programs should be developed with the goal of potentially making it more difficult for generics to come to market, nor do we think that FDA should approve generic versions with different risk management programs from the brand.
- **Communications:** NACDS believes that effective, timely, and consistent communications with professionals and patients is an important part of any risk management program. There are two components to these communications. First, materials have to be developed to help educate physicians and pharmacists and help the professionals to communicate with patients. Second, the FDA and the manufacturer should seek consistent feedback from health professionals about the actual use of the drug in patients, and share this information – in a non-identifiable manner – with health professionals that are participating in the drug’s risk management program. This process requires the use of a single portal for collection of information, and consistent evaluation of documented events. Additionally, pharmacies have access to “real-time” information systems that allow easy communication with patients, physicians, third-party payers, the FDA and manufacturers.

NACDS shares the goal of improving safe medication use and ensuring that patients have access to life sustaining and improving medications—including those medications which have a higher risk of adverse effects when not used appropriately. In summary, NACDS supports a risk management system that:

- (1) allows adequate access to valuable prescription medications that might otherwise be considered "higher than normal risk" and become unavailable;
- (2) provides the broadest possible participation of patients' community pharmacists;
- (3) uses standardized programs, processes, and technology;
- (4) recognizes the critical role of the pharmacist in the health care team; and
- (5) provide appropriate reimbursement for expenses incurred through participation in the risk management program.

In addition to input of a product manufacturer and the FDA, an effective system will include the participation and input of pharmacists, prescribers, and patients. We thank you for the opportunity to comment on this important public health issue.

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