NACDS
NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

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Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Subject: Risk Management Programs and Planning Concept Papers

The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to submit additional comments on the development of an effective prescription drug risk management strategy. We support the Food and Drug Administration's (FDA) efforts to help assure the safe use of prescription drugs, including those that may present certain risk management challenges.

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.

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Community pharmacies are the primary point of distribution for outpatient prescription drugs in the United States. In addition, pharmacies provide an easily accessible point of contact for patients. As medication experts, pharmacists can help ensure the safe and effective use of high-risk medications by their patients. For that reason, it is important that any risk management programs that are developed 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, patients, and the Food and Drug Administration (FDA).

As a broad principle, NACDS supports the concept that, once a drug with a specific risk management program is approved for marketing by the FDA, the drug should be available through any community pharmacy outlet that chooses to stock the product. Pharmacy can help assure that patients use the drug appropriately through educational programs, counseling, and other appropriate interventions.

Risk Management Program Classification

All prescription drugs have some level of manageable risk. However, certain drugs have special or unique risks associated with their use that might require certain types of educational or interventional programs beyond traditional physician and pharmacist education of the patient. However, we do not support classifying all prescription drugs into "risk management" categories. Only those drugs that have been identified as having certain preventable risks that require enhanced effort than the traditional patient educational efforts undertaken by health care professionals should be subject to the four-levels of proposed risk management categorization. FDA-approved risk management programs should be the exception rather than the rule. Moreover, these programs should not create a pretext for the regulation of the practice of medicine or pharmacy by the FDA.

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Because pharmacists, physicians and patients will be the key participants in the risk management program, it is imperative that their input be considered during the development process of risk management programs. NACDS believes that a goal of the program development phase should seek to avoid impractical situations once the program is implemented. For example, programs that require stickers be placed on "risk-managed" prescriptions can be workable. However, if there are several risk-managed drugs, each with its own color sticker and different information on the sticker, it can create confusion for physicians and pharmacists. If pharmacists are involved in the developmental stages of the program, many of these problems can be avoided. In other words, these programs cannot be developed in isolation of other programs that already exist in the market.

Risk Management Program Standardization

While we recognize that each drug product is unique, different risk management approaches are being developed for each current "risk-managed" drug. Future risk management programs could use other approaches, creating further fragmentation. This fragmented risk management approach can create confusion for professionals and patients, potentially defeating the goal of creating less potential risk. For that reason, we believe that creating standard categories of risk management program levels make sense. However, standardizing and integrating the systems that are used to operationalize these programs is important as well. We need a standardized, seamless, computer-based system integrated into current pharmacy prescription processing systems that can be easily accessed by practitioners to deliver risk management services to patients. All data collection, documentation, and reporting should be conducted in the same manner for all risk-managed drugs. Patient privacy should be protected in developing these systems.

Moreover, it is even possible for two separate risk management programs to evolve for brand and generic versions of the very same drug. We encourage the agency to assure that the risk management programs for generic versions be the same as their brand name version, and that the agency address this issue in its final risk management guidance.

Usefulness of Package Inserts and "Dear Health Care Professional" Letters

Professional package inserts and letters to health care professionals are incorporated into "Level 1" risk management programs. While a useful source of information, these approaches have some limitations. The package insert serves as a good source of drug information. However, the usefulness of information contained in the package insert may not include additional risks that are identified after the product is introduced. We recognize that efforts are underway to implement an electronic paperless labeling system that would allow more frequent updating.

While acknowledging that such an electronic system can provide more useful and timely information, there are several operational and cost issues associated with such a system that would have to be addressed before it can be implemented in retail pharmacies. NACDS is working with the FDA and other stakeholders to ascertain the best method of disseminating information contained in electronic format to pharmacies.

With respect to letters to health care professionals, because several pharmacists may staff a pharmacy in different shifts, it is possible that the information will not reach every pharmacist. Additionally, if the pharmacist is not required to put the process into practice immediately, or on a frequent basis, random letters may be filed away and not readily retrievable when needed. We urge that these letters be sent to chain corporate offices as well, who often have their own means for consistent communication with individual chain stores.

Payment for Risk Management Services

NACDS is still concerned with the nature of the risk and liability that pharmacists will assume, and the method of compensation for participating in a risk management program. Payment to pharmacies must be commensurate with the liability and the scope and nature of activities that the pharmacy will be asked to assume.

Regardless of the level of liability assumed, providing additional risk management service 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.

It would also seem logical that payment to pharmacies for these services may have to be borne both by the product's manufacturer and health plan sponsors. In cases where individuals do not have health insurance, then the responsibility will likely fall to the manufacturer. In any case, the agency must address the economics of these risk management programs because their success depends upon consistent funding to pay health professionals for the additional services that are required.

Risk Management Program Evaluation

Pharmacists can and should have an important role in risk management program evaluation. It is clear that if the program cannot be operationalized – or not done so in an efficient manner – then the goals and objectives of the program cannot be met. Thus, FDA and manufacturers should have both a clinical evaluation component, as well as an operational evaluation component to their risk management programs.

Because these programs have to be incorporated into the general workflow of a physician's office or a pharmacy practice setting, the agency should also recognize that not all pharmacy practice settings are the same, and assure that any evaluations are made from a wide range of these settings.

The use of qualitative measures in program evaluation is as important as quantitative measures. Pharmacy chain corporate staff should be included in helping to plan, assess, and evaluate these programs, as should pharmacists providing direct care to patients. Pharmacies can also provide feedback to manufacturers on how physicians are implementing the risk management program or other trends with the use of other medications or specific situations that might be related to the use of risk-managed drugs.

Conclusion

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

NACDS supports a risk management system that:
(1) allows adequate access to valuable prescription medications that are considered "higher than normal risk";
(2) provides the broadest possible participation of community pharmacists;
(3) uses standardized programs, processes, and technology;
(4) recognizes the critical role of the pharmacist in the health care team; and
(5) provides appropriate reimbursement for expenses incurred through participation in the risk management program.

We thank you for the opportunity to comment on this important public health issue.

Sincerely,

S. Lawrence Kocot
Senior Vice President and General Counsel