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May 7, 2012

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NACDS Expresses Cautious Optimism with FDA's Proposed "New Paradigm" for Third Class of Drugs

Emphasizes that collaboration among healthcare professionals benefits patients

Alexandria, Va. – The National Association of Chain Drug Stores (NACDS) today submitted [comments](#) to the Food and Drug Administration (FDA) regarding its position on the “new paradigm” for a third class of drugs. The comments were submitted to FDA today in conjunction with the agency’s hearing titled, “Using Innovative Technologies and Other Conditions of Safe Use to Expand Which Drug Products Can Be Considered Nonprescription.”

In its comments, NACDS emphasized the value of community pharmacies as high-quality and accessible health and wellness centers. NACDS also emphasized the importance of current and future collaboration among healthcare professionals for the ultimate benefit of patient care and to reduce healthcare costs.

“In recent years retail community pharmacies have played an increasingly important role in providing patient care. Activities such as the increased number of health screenings provided by pharmacists help educate patients and give them a better understanding of their health status and potential needs. Pharmacists also provide vital patient care through their participating in collaborative practice agreements and their expanding role in providing immunizations. Pharmacists are uniquely positioned and qualified to take on these expanded roles.” NACDS stated in its comments.

NACDS noted that arrangements already exist in 34 states that allow pharmacists to engage in collaborative practice agreements with physicians. Such written agreements foster collaboration between a pharmacist or pharmacy and a physician or group of physicians to manage patients’ drug therapy. Under this type of arrangement, pharmacists serve as physician extenders and help to monitor and carry out physicians’ drug therapy plans for their patients.

Overall, NACDS also cited cautious optimism regarding the creation of a “new paradigm,” and is eager to work with FDA to prevent unintended consequences of a “new paradigm” of third class drugs.

“Structured properly, this new paradigm has the potential to increase access, improve patient compliance, and reduce health care costs. However, a flawed structure could result in a group of drugs with limited access, reduced compliance, and lacking in a clear compensation policy for pharmacies, despite the additional clinical and administrative responsibilities that it would impose,” NACDS stated.

One of the most critical unintended consequences is the impact on consumers – and their wallets – regarding what may occur when prescription-only medications become over-the-counter medications, and potentially may not be covered by insurance or other third-party payers.

“Costs for some of their medications that were previously covered by their third party payer might no longer be covered if dispensed under this new paradigm and would therefore be an out of pocket cost to them. This may be viewed as a positive for decreasing costs to healthcare system, but if the patient no longer can afford the product and adherence decreases, the costs associated with poor outcomes and increased hospitalizations and emergency room visits could increase,” NACDS stated in its comments.

NACDS also expressed the importance of clear guidance on what types of drugs would qualify for this new status, so as not to disrupt medication regimens for patients, as well as medication management counseling between pharmacists and patients for these regimens.

“Consistency and predictability are needed to train pharmacists and other pharmacy staff, determine formulary placement and reimbursement policy, and ensure uninterrupted availability for patients. Consequently, NACDS advocates that this new paradigm should be a permanent class for drugs that require special counseling, monitoring, screening, lab testing, or other clinical intervention,” NACDS stated in its comments.

NACDS will continue to work with FDA to address these issues and challenges so as to ensure that patients benefit from community pharmacy’s care and services to help improve their health and reduce healthcare costs across the board.

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The National Association of Chain Drug Stores (NACDS) represents traditional drug stores, supermarkets, and mass merchants with pharmacies – from regional chains with four stores to national companies. Chains operate more than 40,000 pharmacies and employ more than 3.5 million employees, including 130,000 pharmacists. They fill over 2.6 billion prescriptions annually, which is more than 72 percent of annual prescriptions in the United States. The total economic impact of all retail stores with pharmacies transcends their \$900 billion in annual sales. Every \$1 spent in these stores creates a ripple effect of \$1.81 in other industries, for a total economic impact of \$1.76 trillion, equal to 12 percent of GDP. For more information about NACDS, visit www.NACDS.org.

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