



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

Statement
Of
The National Association of Chain Drug Stores

For:

U.S. House of Representatives
Committee on Energy and Commerce
Subcommittee on Health

Hearing on:

“Reforming the Drug Compounding
Regulatory Framework”

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2123 Rayburn House Office Building

National Association of Chain Drug Stores (NACDS)
1776 Wilson Blvd., Suite 200
Arlington, VA 22209
703-549-3001
www.nacds.org

The National Association of Chain Drug Stores (NACDS) thanks Chairman Pitts, Ranking Member Pallone, and Members of the Subcommittee on Health for consideration of our statement for the hearing “Reforming the Drug Compounding Regulatory Framework.” We commend the Committee for its ongoing efforts to adequately evaluate and, where necessary, address issues related to the compounding of prescription drugs. NACDS welcomes the opportunity to work with you on this important task to ensure that policies are in place that facilitate access to safe and effective compounded prescription drugs.

NACDS represents traditional drug stores, supermarkets, and mass merchants with pharmacies – from regional chains with four stores to national companies. Chains operate more than 41,000 pharmacies and employ more than 3.8 million employees, including 132,000 pharmacists. They fill over 2.7 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 over \$1 trillion 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 \$1.81 trillion, equal to 12 percent of GDP. For more information about NACDS, visit www.NACDS.org.

Introduction

As we conveyed in a previously submitted statement to the Committee in May 2013, NACDS supports the mission and work of FDA in ensuring that Americans receive only safe and effective prescription drugs. Safeguarding the health and welfare of our patients remains our highest priority. Pharmacist compounding services are the only source of critical medications for millions of patients who each have their own unique health care needs. For these patients, there are no commercially-manufactured preparations available. Accordingly, we agree with FDA that prescription drug compounding services are a valuable and important part of our nation’s healthcare system.

Background on Compounding

Since the early days of the pharmacy profession, prescription drug compounding has been a traditional function of the practice of pharmacy. Throughout the years, pharmacists have continued this core practice, compounding medications based on prescription orders for individual patients whose needs cannot otherwise be met with commercially available products. Prescription drug compounding addresses critical medical needs for many such patients.

State boards of pharmacy regulate both practicing pharmacists who engage in compounding and the pharmacy facilities wherein they practice. State boards of pharmacy require that pharmacists be properly trained to prepare compounded medications and test pharmacists on this competency. Additionally, state boards of pharmacy license pharmacies after ensuring that, among other things, they have the proper tools and equipment to compound prescription drug medications.

The state pharmacy practice acts enforced by boards of pharmacy consistently define the activities that constitute “compounding.” Generally, the practice involves the mixing of two or more drug substances together to deliver to the patient a product that is not commercially available. Most retail pharmacies engage in the compounding of skin creams, lotions, ointments, liquids, or suppositories to meet the needs of individual patients who require medications that are not otherwise commercially available.

Some chain pharmacies may have a local or regional central compounding facility that they use to compound frequently-ordered products that are not commercially available, which are then distributed to individual retail stores in the chain. These compounded products are made in anticipation of prescriptions for these products based on the prescribing patterns of physicians.

NACDS Supports Regulating the Practice of Compounding in a Manner that Preserves State Board Authority and Promotes State and Federal Collaboration

NACDS believes that state boards of pharmacy should retain sole jurisdiction over traditional prescription drug compounding. State boards of pharmacy have the experience and expertise to

continue to regulate this integral function of pharmacy practice. Although it is appropriate for FDA to regulate the manufacturing of prescription drugs, FDA should not be granted authority over traditional pharmacy functions. FDA would not have the resources, ability or expertise to regulate pharmacies and the practice of pharmacy. Moreover, concurrent state and federal jurisdiction over pharmacies would cause unnecessary confusion for FDA, state boards of pharmacy, and pharmacies. All would be unsure as to where federal authority ends and state authority begins. Thus, we support legislative initiatives to maintain the authority of state boards of pharmacy to oversee and regulate traditional compounding practices while appropriately focusing FDA's authority on manufacturing.

NACDS recognizes the importance of collaboration between FDA and the state boards of pharmacy to investigate any questionable practices so that prescription drug compounding is regulated in the best interests of patients. Despite best efforts, there still may be entities that seek to circumvent patient safety measures as well as federal and state regulation. To prevent future tragedies, closer collaboration between FDA and state pharmacy regulators would serve to root out rogue entities that seek to use a state pharmacy license as a shield from federal oversight. To this end, we support legislative initiatives to establish a reporting tool for state boards of pharmacy to identify compounding pharmacies that may be in violation of accepted compounding practices and/or are operating as a manufacturer. This would provide FDA with targeted information that would prompt the agency to focus their inspection activities where they are most needed.

Important to Maintain Pharmacists' Ability to Provide Traditional Prescription Drug Compounding Services

Prescription drug compounding practices enable pharmacists to meet the medication needs of their patients that cannot be met with commercially available products. There are numerous circumstances in which it is both appropriate and necessary for pharmacists to compound medications. For example, chain pharmacists helped to meet the need for liquid Tamiflu during the 2009 H1N1 flu outbreak through their ability to compound the liquid product from Tamiflu capsules – and at the request of FDA. In other cases, a pharmacist may be called on to

compound a liquid form of a medication for a patient battling cancer, when that patient is not able to swallow the pill form of the medication. So that patients have access to the important compounding services provided by pharmacists, we support legislative initiatives that recognize and maintain the ability of pharmacists to provide these types of traditional prescription drug compounding services. This includes compounding of commercially available products where the prescriber determines the variation will have a clinical difference for a particular patient; and compounding of commercially available products that are in shortage as identified on a public or private national or regional shortage list. Legislative initiatives must ensure that pharmacists are allowed to continue to provide compounded prescription drug medications in these circumstances to meet critical patient needs.

Conclusion

NACDS thanks the Committee for consideration of our comments. We look forward to continuing to work with policy makers and stakeholders on these important issues.