



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

Statement
Of
The National Association of Chain Drug Stores
For
U.S. Senate
Committee on Health, Education,
Labor, and Pensions
Hearing on:
Pharmaceutical Compounding: Proposed
Legislative Solution
May 9, 2013
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430 Dirksen Senate Office Building

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The National Association of Chain Drug Stores (NACDS) thanks Chairman Harkin, Ranking Member Alexander, and Members of the Senate Committee on Health, Education, Labor, and Pensions for consideration of our statement for the hearing “Pharmaceutical Compounding: Proposed Legislative Solution.” We look forward to our continued work with you on ensuring that Americans receive safe and effective compounded prescription medications.

NACDS commends the Committee for your efforts to better regulate the compounding of prescription medications. We thank the Committee for the opportunity to provide our views on your proposed legislation to better regulate the compounding of prescription medications. 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

NACDS supports the mission and work of FDA in ensuring that Americans receive only safe and effective prescription medications. 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 pharmacist compounding services are a valuable and important part of our nation’s healthcare system.

Background on Compounding

Prescription compounding has been a traditional function of the practice of pharmacy ever since the beginning of the profession. Compounding is an important component of patient care because many patients need prescription products that are not made commercially by drug manufacturers. Compounding by pharmacists is the only way to meet these patients' needs. Traditional compounding is based on individual prescription orders for individual patients for products that are not commercially available. Because of these patient needs compounding continues to be an integral function of pharmacy practice.

Pharmacists are trained to prepare compounded medications and are tested on this competency. State boards of pharmacy license pharmacies after ensuring, among other things, that they have the proper tools and equipment to compound prescription products.

The definition of what constitutes “compounding” is consistent from state to state. Generally, it 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. 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.

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.

Preserving State Board Authority

NACDS supports the Committee's draft proposal for maintaining state board of pharmacy jurisdiction over traditional compounders. This is a proper role for state pharmacy boards. Traditional pharmacy compounding has been an integral function of the practice of pharmacy since the early days of the profession. State boards of pharmacy have the experience and expertise to continue to regulate this integral function. We urge the Committee to continue to maintain this policy as your draft legislation evolves. We believe that state boards of pharmacy should continue to regulate functions that are the practice of pharmacy, while FDA should 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.

Similarly, we thank the Committee for not unnecessarily expanding FDA authority over the records of pharmacies. NACDS would have serious concerns with any proposal to expand FDA authority in this manner. FDA already possesses sufficient inspection authority over pharmacies in order to determine whether a pharmacy is potentially acting in violation of the Federal Food, Drug, and Cosmetic Act.

We thank the Committee for adopting our recommendation in your draft legislation to better define the differences between manufacturing and traditional compounding. We agree with the Committee's use of a three-pronged test requiring all factors be met in order for an entity to be considered a manufacturer that falls under FDA authority.

State and Federal Collaboration

We support the provision in the Committee's draft legislation that FDA and the state boards of pharmacy work together to investigate any questionable practices so that compounding is regulated in the best interests of patients. To prevent future tragedies, there must be a close

collaboration among FDA and the boards of pharmacy. Despite best efforts, there still may be entities that seek to circumvent patient safety measures as well as federal and state regulation. We support state and federal joint efforts to root out rogue entities that seek to use a state pharmacy license as a shield from federal oversight.

Concerns with Proposed Legislation

Although we support the concepts of the Committee's draft legislation, we have a concern that the definition of "compounding manufacturer" may inadvertently include the traditional pharmacy compounding of sterile products pursuant to a prescription order, as some pharmacies do "pool" sterile drugs for patients pursuant to a prescription order. This may negatively impact the ability of pharmacies to continue to provide sterile compounded products to patients.

As provided above, we support the Committee's proposed three-pronged test for determining whether an entity is a manufacturer that falls under FDA authority. However, the Committee's proposal would also deem as manufacturers those pharmacies that repackage a drug using sterile preservative-free single-dose vials or by pooling sterile drugs. Pharmacies that perform these types of functions, such as for Total Parenteral Nutrition (TPN) for home-infusion purposes, would lose their status as pharmacies and would no longer be able to provide these critical services to many of the sickest patients. We urge the Committee to further review this language, as it appears to be over-broad and would hinder patient access to critical sterile compounded medications. We welcome the opportunity to work with the Committee to amend the language so that it addresses the Committee's concerns without having negative impacts on patient access.

Conclusion

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