



NATIONAL ASSOCIATION OF  
CHAIN DRUG STORES

Statement  
of  
The National Association of Chain Drug Stores  
for the  
United States House of Representatives  
Committee on Energy and Commerce  
Subcommittee on Health

Hearing on:

“Examining Implementation of  
the Compounding Quality Act”

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2123 Rayburn House Office Building

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The National Association of Chain Drug Stores (NACDS) thanks Chairman Burgess, Ranking Member Green, and Members of the Energy and Commerce Committee Subcommittee on Health for the opportunity to submit a statement for the hearing on “Examining Implementation of the Compounding Quality Act.”

NACDS and the chain pharmacy industry are committed to partnering with Congress, the Food and Drug Administration (FDA), state boards of pharmacy, and others in the pharmacy community on policies that support the delivery of high quality, affordable healthcare services that meet the diverse healthcare needs of patients across the country. NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS’ nearly 100 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 152,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 20 countries. Please visit [www.NACDS.org](http://www.NACDS.org).

As the face of neighborhood health care, chain pharmacies and pharmacists work on a daily basis to provide the best possible care to patients and to meet their medication needs. Where some patients require medicines that are not otherwise available as commercially-manufactured preparations, chain pharmacists perform prescription drug compounding to ensure that patients have access to medications necessary to treat their

medical conditions. These types of pharmacist compounding services have been offered by pharmacies since the early days of the pharmacy profession. Over the years, these services have remained a valuable and important component of our nation’s healthcare system.

When Congress enacted the Drug Quality and Security Act (“DQSA), lawmakers recognized the importance of allowing pharmacists in retail community pharmacies to continue to provide traditional compounding services and maintained pharmacists’ ability to do so under Section 503A of the Food, Drug, and Cosmetic Act. The chain pharmacy community supports the implementation of the DQSA in a manner that is consistent with the intent of Congress to maintain access to compounding services historically provided by retail community pharmacies.

Among its various actions to implement the DQSA, FDA published a draft memorandum of understanding (MOU) in 2015 outlining the responsibilities of FDA and individual state boards of pharmacy with respect to investigation and response to complaints related to interstate distribution of compounded drugs, and interstate distribution of inordinate amounts of compounded drugs. Like other pharmacy stakeholders, the chain pharmacy community is concerned that certain provisions in the draft MOU – if finalized and implemented – could impede retail community pharmacists’ and pharmacies’ ability to provide traditional compounding services that are permitted under Section 503A of the Food, Drug & Cosmetic Act.

Notably, Section 503A of the Food, Drug & Cosmetic Act clearly distinguishes the act of dispensing as separate from the act of distribution.<sup>1</sup> However, the language of the draft MOU defines the term “distribute” to include the act of “dispensing.” In doing so, the draft MOU fails to maintain the important distinction between compounded products that are distributed versus compounded products that are dispensed.

Before finalizing the MOU, it is imperative that FDA remedy the inconsistency between the language of law and the MOU. Given that Section 503A establishes that the scope of the MOU is to “address the *distribution* [emphasis added] of inordinate amounts of compounded drug products,” the language of the MOU should address distribution only.<sup>2</sup> Otherwise, the MOU may impede retail community pharmacies’ ability to dispense compounded medications to their patients pursuant to a prescription.

Additionally, we are concerned that the draft MOU imposes an arbitrary cap on what constitutes an “inordinate amount” of compounded product distributed interstate.

Imposing this arbitrary limitation is problematic for a number of reasons. It fails to take into consideration regional and geographic issues, individual pharmacy volume, and other factors that may necessitate higher rates of interstate distribution in certain circumstances. Furthermore, it is concerning that the cap on interstate distribution would be calculated using both compounded drug products that are distributed and *dispensed* [emphasis added] in and out of state. As we discussed above, the law establishes that the scope of

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<sup>1</sup> 21 U.S.C. §353a(3)(B)(ii)

<sup>2</sup> 21 U.S.C. §353a(3)(B)(i)

the MOU is limited to distribution only. Including compounded drug products that are dispensed would be inconsistent with the language of the law.

Overall, the limitations established in the draft MOU regarding what constitutes an “inordinate amount” of compounded product may impede patient access to compounded products by restricting the supply of compounded products that may be distributed out of state. We believe that defaulting to any arbitrary cap is contrary to the overall goal of the MOU, which is to facilitate communication among the states and FDA on how to best trigger investigation of a compounding pharmacy where appropriate. For these reasons, the language establishing these specific limits should be eliminated from the MOU entirely.

We note that the 2018 Compounding Policy Priorities Plan published by FDA earlier this month acknowledges that because of the many stakeholder concerns with the draft MOU, FDA plans to substantially revise the MOU to address many of the concerns raised. We are hopeful that the concerns we highlighted in our comments above will be among the issues that FDA addresses before finalizing the MOU, as these are central to maintaining patient access to the important pharmacist compounding services provided in retail community pharmacies across the nation.

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