

**United States House of
Representatives
Committee on Energy
and Commerce
Subcommittee on Health Hearing on
“Examining Drug Compounding”
Thursday, May 23, 2013 - 10:00am**

Chairman Pitts, Vice-Chairman Burgess, Ranking Member Pallone and Members of the Subcommittee, my name is Joe Harmison and I am a pharmacist, owner of DFW Prescriptions and past president of the National Community Pharmacists Association (NCPA). NCPA appreciates the opportunity to share the community pharmacy perspective regarding issues relating to drug compounding. NCPA represents the interests of America’s community pharmacists, including the owners of more than 23,000 independent community pharmacies. According to a NCPA member survey, almost 86% of independent community pharmacies compound medications. Our members perform a wide variety of compounding services including hormone replacement medications, making suspensions palatable for pediatric patients, different dosage forms for patients suffering from intractable nausea and vomiting, and medications for cystic fibrosis patients, to name a few. Specific to my practice, I compound medications primarily used in the treatment of pain that help patients and their physicians treat their conditions. We are compliant with U.S. Pharmacopeial Convention (USP) <797> Pharmaceutical Compounding—Sterile Preparations standards.

Our hearts go out to the families who have suffered from the tragic event surrounding the New England Compounding Center (NECC), and NCPA is committed to working with Congress on the issue of practices that exceed state regulated compounding. NCPA commends the Committee for taking a closer look at what actions and inactions led to the tragic NECC event. We believe the Committee is taking the proper steps to address this tragedy by focusing on investigations into what steps should have been taken and oversight to ensure that the appropriate regulatory bodies are exercising their full authority.

Importance of access to compounded medications

Compounding is a backbone of pharmacy practice and for many decades independent community pharmacists have provided millions of adults, children, and animals with access to safe, effective and affordable medications through compounding services. When manufactured drugs aren't an option, independent community pharmacists provide traditional pharmacy compounding to prepare customized medications for patients in accordance with a prescription based on the patient's individual needs. Compounding services can help bridge the gaps during times of prescription drug shortages. Drug shortages have nearly tripled, according to the FDA, and their impact can be devastating. Patients must be assured that they are not forced to go without needed medications or treatments because their medication is unavailable and compounding of that medication is prohibited or tied up in bureaucracy.

It is important to reiterate that pharmacist compounding is an integral part of the pharmacy profession and meets patients' needs in hospitals, long-term care and assisted living facilities, home infusion settings, and many community settings.

State Board of Pharmacy oversight of pharmacy compounding is critical

NCPA has always and will continue to advocate that pharmacy compounding is best regulated by the state Boards of Pharmacy while manufacturing is overseen by the FDA. Pharmacy compounding of medications is an important part of medical care that allows for the dispensing of custom-made medications and should continue to be regulated by state Boards of Pharmacy, as all other medical licensed professional practices are. These state Boards of Pharmacy currently oversee all aspects of a pharmacy from licensure, oversight of pharmacists and technicians, the process of filling prescriptions, records, documents, and compliance with the state's laws and regulations. If the FDA has a concern about an appropriately-licensed pharmacy, then the FDA currently has the authority to ask the state Board of Pharmacy to work with them to address the issue. If it is found that an entity acting under the guise of a pharmacy has exceeded their state-regulated authority, then the state Boards of Pharmacy should suspend the license of the pharmacy until it complies with state laws and regulations governing compounding or meets FDA standards for manufacturing and registers with the FDA. All parties involved must make certain that the state Boards of Pharmacy are adequately staffed, trained, and funded to effectively regulate compounding.

NCPA encourages state Boards of Pharmacy to require uniform compliance with USP 797 in order to provide more uniform production standards. As such, every state will be assured that resident and non-resident pharmacies alike are all in compliance with these USP standards.

Compounds are prepared based on prescriptions or on anticipation of demand

In most cases, compounded medications must originate from a prescription for a specific patient from a health care professional and are made specifically for an individual patient's needs. In other instances, pharmacists participate in anticipatory compounding where they anticipate a demand that a physician might have for a compounded drug based on historical prescribing patterns. In order to preserve access to these vital compounded medications, pharmacies should not be hindered in their ability to engage in anticipatory compounding as long as it is reasonable and based on a historical pattern of prescriptions received by that pharmacy or for specific patients served by that pharmacy.

Compounding should not be defined by the quantity of medications produced or to where the medications are shipped. Compounding should be defined as the preparation of medications upon receipt of a prescription, or, where in reasonable quantities, in anticipation of need for a medication based upon historical patterns.

To the contrary, compounding should not be defined by nuances such as type of product (i.e. sterile and non-sterile) as risk and complexity of compounding is not solely dependent upon product type; quantity of product made as a pharmacy can produce a significant number of compounded medications and not be a manufacturer as long as the pharmacy is making these medications based on individual prescriptions or in anticipation of need based on historical patterns; or interstate commerce as a pharmacy may legitimately ship to more than one state as long as the pharmacy makes the medications being shipped based on individual prescriptions or in anticipation of need based on historical patterns.

Clear lines of communication between the FDA and State Boards of Pharmacy are needed

The FDA should share all inspection data in a timely fashion with state Boards of Pharmacy. Furthermore, FDA should communicate to state Boards of Pharmacy whether the response from the entity inspected addresses all concerns and is sufficient without necessary further action or whether further action is needed to address these concerns. The FDA should strengthen the communication between its regional offices and the states. In addition, FDA should utilize all existing authority and resources in developing and sharing data with states. In order to address the failure in communication in the past, FDA must utilize, and strengthen if necessary, all existing portals and resources in order to produce the needed data sharing to increase communication between the states and FDA.

In conclusion

While discussing what new regulations should be undertaken to prevent this tragedy in the future, before expanding federal authority it is imperative that Congress look at whether current laws and regulations are being properly enforced. NCPA urges the Committee to preserve the authority of state Boards of Pharmacy over compounding by defining any new category with FDA oversight in a very limited and narrowly targeted manner. In addition, any legislation must not be used to facilitate a broad expansion of FDA power over the historically state-regulated practice of pharmaceutical compounding.

NCPA is committed to working with Members of Congress in order to make certain that a tragedy such as the New England Compounding Center does not occur in the future while also preserving patients' access to customized and safe compounded medications. Thank you for inviting me to testify and to share the viewpoints of independent community pharmacy.