House Energy and Commerce Committee
Subcommittee on Health

Hearing on

Reforming the Drug Compounding Regulatory Framework

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Oral Statement for the Record
Submitted by the

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Good afternoon and thank you Chairman Pitts and Ranking Member Pallone and distinguished Members of the Subcommittee, for holding this hearing. My name is Kasey Thompson, and I serve as Vice President of Policy, Planning and Communications at the American Society of Health-System Pharmacists (ASHP). I am here today to provide ASHP's perspective as a professional society that represents over 42,000 pharmacists who practice in hospitals, health systems, and ambulatory clinics, and has been a recognized leader for over 20 years in the development of guidelines on compounding and working with compounding outsourcers.

The event caused by the New England Compounding Center resulted in 61 unnecessary deaths and more than 700 meningitis cases. ASHP strongly believes that the authority and accountability between the FDA and state boards of pharmacy needs to be clarified. We applaud the work that Congress has done so far to address this highly complex patient safety and public policy issue, and also commend the National Association of Boards of Pharmacy for its efforts to help states gain better insights into the quality and level of compounding practices throughout the country. We are hopeful that a legislative solution that protects the public and provides assurances to health care professionals that the products they purchase from compounding entities are safe is found before the 1-year anniversary of the NECC tragedy.

We believe that compounding outsourcers that prepare customized sterile preparations that are not commercially available should be held to the highest standards for quality, including relevant Current Good Manufacturing Practices, and should be required to be registered with and routinely inspected by the FDA. Further, we believe that these entities should not copy commercially available products *except* in the case of drug shortages or to make a medically necessary variation that meets patient-specific needs. The drug approval process in the United States is the gold standard, and it should be maintained as such.

However, it is important to recognize that there are many legitimate and medically necessary compounded sterile preparations that simply are not available from a brand or generic manufacturer in the strength or dosage form that the patient needs.

U.S. hospitals prepare a vast array of compounded sterile preparations from FDA-approved products every day in order to meet patient-specific needs. The compounded medications that hospitalized patients need range from simple intravenous admixtures to complex customized medications that are not available off the shelf, such as multi-ingredient cardioplegia solutions for heart surgery, precisely measured combinations of epidural pain medication for women in labor and delivery, concentrated pain medications for cancer patients, and adult medications prepared in concentrations that can be safely administered to babies and children.

Where necessary, hospitals enlist the services of qualified compounding outsourcers for some preparations for several reasons. For example, some hospitals may not have the necessary equipment or facilities to prepare some high-risk sterile preparations, which is sometimes the case in small and rural hospitals with limited resources. Or, they may face medication shortages for commercial products that can only be replicated by outside suppliers that provide customized compounded sterile preparations. They may also enlist the help of outsourcers to provide FDA-approved sterile products in ready-to-administer packages in the strength and dosage forms they need.

The compounding outsourcing industry that has evolved over the last decade provides critical services to hospitals, physician offices, outpatient surgery centers, and other patient-care settings. The vast majority of the products that outsourcers prepare is for anticipatory use, and does not have a prescription at the time of sale. However, it is important to note that in the hospital and health-system setting, all medications have a medication order from an authorized prescriber before the medication is administered to the patient.

The evolution of the compounding outsourcing industry has outpaced the ability of state and federal laws to keep up, creating legal and regulatory gray areas between states and the federal government. Various challenges in the courts to federal authority to regulate pharmacy compounding have also created uncertainty regarding jurisdiction. Unfortunately, it just isn’t as simple as calling these large-scale anticipatory compounding entities that often engage in interstate commerce a pharmacy, repackager, or pharmaceutical manufacturer. They are something in between each of these, but no one category fits them perfectly.

Recent bipartisan Senate legislation (S.959) appears to address the need for clarity in distinguishing between compounding by a pharmacy and the activities of a compounding outsourcer. It assigns responsibility and accountability to the FDA for regulating what S. 959 terms "compounding manufacturers" while preserving the accountability for pharmacy compounding to state boards of pharmacy. It also establishes a user fee program to help ensure that the FDA has the resources it needs to effectively regulate compounding manufacturers.

Because of the potential nationwide scale of these operations, we are concerned that state boards may not be able to provide adequate oversight of these facilities. Many state boards may not have the resources or expertise to evaluate whether a pharmacy has crossed the line and become a manufacturer.

With respect to the regulatory framework proposed in draft legislation by Representative Griffith, ASHP is concerned that the regulatory environment that allowed the New England Compounding Center to operate as a pharmacy would remain intact. In other words, if authority between state boards and FDA is unclear due to a lack of accountability, we would be concerned that neither FDA nor state boards could be held accountable if an entity were licensed as a pharmacy but was also preparing sterile compounded preparations without a prescription and selling across state lines.

In addition, our understanding of the draft legislation is that FDA would only be permitted to inspect a pharmacy that may be operating as a large-scale compounding entity if FDA has received a submission from a state board of pharmacy. This ability for the FDA to have the necessary access to records and inspect a compounding entity would be contingent on state boards being properly equipped with trained personnel to determine if an activity appears to approach manufacturing. We are concerned that FDA may not be fully accountable if the state board does not notify the agency.

Further, this approach would imply that state boards would inspect all prescription records and sales transactions of each licensed pharmacy in their state to identify those entities that may be acting outside the scope of traditional pharmacy and should therefore be referred to FDA. We do

not see that as realistic for many states boards of pharmacy, and therefore believe that these types of compounding outsourcers would be more appropriately regulated by the FDA.

Conclusion

ASHP remains completely committed to working with Congress, the FDA, and other stakeholders in developing a reformed regulatory framework for pharmacy compounding. The end result will give patients and health care professionals the assurance that those entities compounding large-scale, non-patient-specific preparations are properly regulated and are producing safe products.

Thank you again Chairman Pitts and Ranking Member Pallone for holding this hearing on this important public health issue.