Senate Health, Education, Labor and Pensions Committee

Hearing on

Pharmacy Compounding: Implications of the 2012 Meningitis Outbreak

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Statement for the Record
Submitted by the

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Good morning and thank you Chairman Harkin, Ranking Member Enzi, and distinguished Members of the Committee, for holding this hearing. My name is Kasey Thompson and I am Vice President of Policy, Planning and Communications for the American Society of Health-System Pharmacists (ASHP). I am here today to provide ASHP's perspective on the recent meningitis outbreak, and to explore potential policy options to help prevent similar events from occurring in the future.

First and foremost, on behalf of ASHP and our more than 40,000 members practicing in hospitals, health systems, and ambulatory clinics, I want to express our sympathy for the victims and their families who were harmed by this tragedy. The patients who relied on these medications deserved much better. Unfortunately, the New England Compounding Center appeared to have been operating in a manner that falls far short of standards for compounding sterile preparations. Further, the scale and scope of NECC's operation more nearly resembles pharmaceutical manufacturing rather than pharmacy compounding.

U.S. hospitals prepare a vast array of compounded sterile preparations every day in order to meet the needs of patients. In fact, the majority of compounded medications hospitals utilize are prepared in-house by pharmacy departments. The compounded medications that hospitalized patients need span 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 and adult medications prepared in concentrations that can be safely administered to babies and children.

However, hospitals also enlist the help of qualified compounding pharmacies for some compounded preparations for several reasons. For example, they may not have necessary equipment or facilities to prepare some high-risk preparations, or they may face medication shortages for commercial products that can only be replicated by a compounding pharmacy.

Hospitals prepare or purchase compounded medications based on specific patient needs and individual medication orders or in anticipation of needs for patients under their direct care. Importantly, medications that are purchased from outside compounding pharmacies are not commercially available from brand or generic manufacturers in the individualized form needed for a specific patient or patients, unless manufacturers cannot supply them.

ASHP has dedicated itself to developing the highest standards for compounding and sterile product preparation in hospitals. Through our peer-reviewed publication, the *American Journal of Health-System Pharmacy*, we began publishing guidelines on sterile and non-sterile compounding in the early 1990s. In 1993 we published the *ASHP Technical Assistance Bulletin on Quality Assurance for Pharmacy-Prepared Sterile Products*. This was revised in 2000, and is currently in the final stages of revision.

These guidelines formed the basis for the three-tier risk assessment structure later incorporated by the United States Pharmacopeia into Chapter 797, its standards for compounding sterile products. In 2010, ASHP published the *ASHP Guidelines on Outsourcing Sterile Compounding Services* to advise pharmacy departments on how to conduct due diligence when selecting outsourcing vendors. In addition, we have developed an assessment tool based on our guidelines that helps pharmacists in hospitals and health systems comprehensively evaluate sterile compounding service providers and use comparative data for their vendor selection process. Our guidelines and assessment tool are and have been available free as a public service to the health care community and others.

Policy Options

We cannot rely solely on the due diligence of purchasers to take the place of proper licensing, inspections and oversight of entities producing compounded medications, especially for those entities that are manufacturing in large quantities and shipping across the country. Pharmacists and other health care providers should not be expected to perform the jobs of regulators by visiting and inspecting pharmacies or manufacturers that they do business with.

The distinction between traditional pharmacy compounding and manufacturing appears to be a regulatory gray area between state boards of pharmacy and FDA. As we have seen, however, the implications of this gray area are serious.

We recognize the regulatory challenges of defining the activities in this gray area, but we firmly believe that specific definitions are essential so that mass production of the scope and scale done by NECC falls within the regulatory jurisdiction of FDA, rather than state boards of pharmacy. To this end, we have developed policy recommendations for the Committee, FDA and other stakeholders to consider as we explore ways to address this gap in oversight.

Previous attempts to define compounding in federal law contained certain elements that should be examined in light of practice changes since 1997. Recent legislative proposals merit further discussion and exploration, since they may reflect those practice changes and allow for the regulatory flexibility among state boards of pharmacy and the FDA that would ensure that hospitals continue to be allowed to obtain compounded medications in anticipation of patient need.

Compounding pharmacies range from small pharmacy operations that compound medications for individual patients directly under their care to large-scale operations that prepare compounded medications in the volumes required to serve the needs of patients

under the care of health systems or physician offices. A number of variables make distinguishing between compounding and manufacturing difficult. Therefore, both functions might be better viewed as a continuum of activites stratified by the potential for risk of patient harm, each requiring defined procedures, equipment, training, and quality controls. At one end of the continuum, oversight of traditional compounding is clearly within the purview of states, as is FDA regulation at the other end of the continuum with pharmaceutical manufacturing. As legislative proposals are considered, it will be important to reaffirm the role of state boards of pharmacy to license and regulate traditional compounding while recognizing that large-scale compounding of sterile products may require oversight by the FDA in cooperation with state boards of pharmacy.

Once compounding activities advance along the continuum to manufacturing and the risk to patient safety and public health increases, there may be a need for a special category of FDA oversight that falls between compounding and manufacturing but does not require a drug approval (e.g., an NDA). For example, if a compounding pharmacy sells to other organizations and not directly to patients, then they may need to be regulated by the FDA. Doing so would allow hospitals, clinics, and physician offices to purchase sufficient quantities of compounded product as is necessary to meet patient needs, while doing so under the assurance that they are making those purchases from appropriately regulated sources.

ASHP recommends stronger communication and collaboration between state boards of pharmacy and the FDA to accomplish this goal. We also believe that state boards of pharmacy should be able to work with FDA to inspect an entity suspected of engaging in large-scale production beyond the scope of pharmacy compounding. Previous court rulings have made FDA's authority to inspect these facilities unclear and subject to legal action.

Finally, we strongly believe that FDA must be provided the resources it needs to perform serious and meaningful regulatory oversight of entities that are potentially engaged in manufacturing. Not to do so now will only hinder the agency in implementing legislation.

Conclusion

To summarize, we are profoundly saddened by what we believe should have been an avoidable tragedy. ASHP remains committed to working with Congress, FDA and other stakeholders to address these regulatory gaps and reduce the likelihood of similar outbreaks from compounded sterile products in the future.