

Committee on Energy and Commerce
Subcommittee on Health

Hearing on: “Examining Implementation of the
Compounding Quality Act”

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Statement for the Record
Submitted by ASHP



American Society of Health-System Pharmacists

4500 East West Highway, Suite 900

Bethesda, MD 20814

Email: gad@ashp.org

Phone: 301-664-8710

ASHP (American Society of Health-System Pharmacists) is pleased to offer the following statement for the record on pharmaceutical compounding. ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's 45,000 members include pharmacists, student pharmacists, and pharmacy technicians. For more than 75 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety.

In the fall of 2012, the New England Compounding Center (NECC) was behaving more like a manufacturer than a state-licensed pharmacy. That year, as a result of NECC's lack of sterile practices, more than 700 people in 20 states were diagnosed with fungal meningitis and other infections after receiving contaminated medication. Sixty-four patients in 9 states died, making it the deadliest meningitis outbreak in U.S. history.

To help prevent tragedies like the NECC meningitis outbreak, ASHP supports a compounding framework that not only balances safety with patient and clinician access to essential compounded medications, but that also recognizes the different distribution models in hospital and health-system pharmacies. ASHP advocated passage of the Drug Quality and Security Act (DQSA), and we remain committed to ensuring that it is implemented in a manner that protects its goals.

ASHP believes that the current legislative language of the DQSA is sufficient for the FDA to implement an appropriate regulatory structure and that *no additional compounding legislation is needed at this time*.

The use of a prescription for an identified individual patient is a key differentiator between pharmacy compounding and manufacturing. We remain concerned that loosening certain requirements of the DQSA would result in an environment not unlike the one that caused the meningitis outbreak to occur.

To meet the needs of patients, hospitals prepare a vast array of compounded sterile preparations every day, the majority of which are prepared in-house by pharmacy departments. 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, and adult medications prepared in concentrations that can be safely administered to babies and children.

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. It is important to note that in hospitals, no medication — compounded or otherwise prepared — is administered to the patient unless there is a patient-specific medication order.

ASHP believes that the FDA is an important partner in ensuring that pharmacists and the patients they serve can access safe and high-quality compounded medications. We have been working with the agency to ensure that guidances account for hospitals' and health systems' unique care delivery models, which differ significantly from traditional community pharmacy models in a number of ways, including the following:

- **Patient responsibility:** Hospitals and health systems are accountable for patient care outcomes. Thus, for the purposes of both quality and outcomes tracking, it is beneficial for hospitals and health systems to maintain full control over all elements of patient care, including pharmacy access. In-house compounding of medications facilitates tracking of adverse events as well as oversight of care quality. Further, it allows hospitals and health systems to arrange pharmacy operations to provide patients and clinicians with compounded medications when they are needed, without significant wait times.
- **Safety and Quality Regulations:** While all 503A compounding falls under the purview of the state Boards of Pharmacy, compounding in hospitals cannot be disassociated from, and is itself

subject to, other quality and safety standards applicable to hospitals and health systems. These include Centers for Medicare & Medicaid Services (CMS) regulations for reimbursement, Joint Commission (TJC) standards, U.S. Pharmacopeia (USP) chapters <797> and <800>, quality metrics (e.g., for accountable care organizations, patient-centered medical homes, etc.), and state and local department of health regulations. Hospitals and health systems are strongly incentivized to ensure that all facets of a patient's treatment, including medications, are as safe and effective as possible. Strong 503A compounding programs are essential to this effort.

- Limited Compounding: Hospital pharmacists seek to avoid compounding medications when an FDA-approved, commercially available therapeutic alternative is available. Compounding consumes resources and time, and it introduces additional risk into the medication-use process. Further, hospitals and health systems are not incentivized to compound on a large scale. Drugs are often bundled and, therefore, are not reimbursed separately, reducing or eliminating any financial incentive associated with compounding. Thus, in the hospital and health-system context, compounding volume has some built-in limitations that are not applicable in other settings.

These differences underlie FDA's creation of tailored compounding guidances for hospitals and health systems. Such targeted oversight decreases the chances of creating unintended access limitations for hospital and health-system patients, while still allowing FDA and clinicians to protect patient health and safety. Thus far, ASHP has supported FDA's efforts to craft tailored compounding regulation for hospitals and health systems. In particular, we look forward to the forthcoming hospital/health system-specific guidances related to repackaging, mixing, and diluting biologics, and 503B documentation requirements. Regarding published guidance, FDA has promulgated a draft hospital and health-system guidance regarding hospital compounding generally. Although we believe this guidance is a reasonable starting

point, we have asked the agency to revisit and revise certain facets before finalizing it. Specifically, although ASHP agrees that non-patient-specific compounding must be subject to reasonable limitations, we oppose using an arbitrary 1-mile radius in which distribution (not dispensing) of non-patient-specific medications is allowed. Imposing a geographic distance requirement could push compounding out of the pharmacy and back to the bedside, with negative consequences for patients. In order to comply with FDA's proposed hospital and health system guidance, hospitals and health systems would need to reconfigure existing care delivery models — many which have been heavily vetted by various accrediting bodies and regulators, and all of which are designed to maximize patient health and safety. To avoid disruption of functional delivery systems, ASHP supports retaining the requirement that hospitals and health systems distribute compounded medications only to healthcare facilities under common control for use within the four walls of those facilities. We believe removing and replacing the geographic distribution limitation proposed by FDA with a time-based standard is more appropriate and in the best interests of patients.

In place of an arbitrary limitation, ASHP urged the FDA to consider allowing hospitals and health systems to use the USP Chapters <797> and <800> beyond-use date (BUD) time frames for handling of non-hazardous and hazardous sterile compounding. USP Chapter <797> delineates the procedures and requirements for compounding sterile preparations. It focuses on ensuring that compounding pharmacies provide the conditions and institute practices to prevent harm to patients from microbial, chemical, or physical contamination; excessive bacterial endotoxins; variations in product strength; or poor-quality ingredients. Further, in order to meet USP Chapter <797> standards, all personnel involved in sterile compounding must undergo specific training and testing. Similarly, USP Chapter <800> describes the standards for the handling and administration of hazardous drugs with patient safety, worker safety, and environmental protection taken into consideration.

We anticipate that FDA will release a revised version of this guidance with an opportunity to comment.

503B Outsourcing Facilities

FDA suggested that, should the geographic limit create difficulties, 503B outsourcing facilities (hereinafter, “503Bs” or “outsourcing facilities”) can fulfill hospital and health-system needs. ASHP considers 503Bs essential to a strong compounding framework, but we remain concerned that, at present, 503Bs do not have the capacity to meet all system needs. Specifically, the wait times and longer turnaround times that some of our members have encountered when purchasing from 503Bs suggests that they are already straining to meet demand. Outsourcing facilities typically make large batches of compounded drugs and are not equipped to provide tailor-made products to hospitals and health systems. While many of our members rely on 503Bs, they also recognize that these outsourcers are limited in what they can produce. As a result, hospitals and health systems compound products to meet their own unique patient needs and do so in quantities significantly below a 503B’s volume.

CONCLUSION

ASHP thanks the subcommittee for the opportunity to submit this statement. As noted earlier, ASHP believes that the DQSA established a sufficient regulatory framework for the FDA to implement the law and that no further legislation is needed at this time. ASHP remains committed to working with Congress and industry stakeholders to ensure that patients have affordable access to lifesaving and life-sustaining medications.