

Senate Committee on Health, Education, Labor and
Pensions

Hearing on

Pharmacy Compounding: Proposed Legislative Solution

May 9, 2013

Oral Statement for the Record
Submitted by the



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Good morning and thank you Chairman Harkin, Ranking Member Alexander, and distinguished Members of the Committee, 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 on the Committee's draft proposal on pharmaceutical compounding.

As stated in previous testimony, in the interest of patient safety, ASHP supports closing the regulatory gaps for a category of commercial compounding outsourcers that we now refer to as "compounding manufacturers," and we applaud the Committee's effort to accomplish closing these gaps.

We believe this proposed legislation addresses the regulatory uncertainties that were caused through the various challenges to Section 503A of the Food and Drug Administration Modernization Act of 1997. Importantly, the Committee's proposal leaves traditional compounding as a core component of the practice of pharmacy under the sole purview of state boards of pharmacy.

ASHP strongly supports the creation of a category known as "compounding manufacturer," which would fall completely within the purview of FDA. We further agree that not allowing a compounding manufacturer to register as a pharmacy in any state establishes a clear boundary between FDA jurisdiction and the jurisdiction of state boards of pharmacy. Being under the purview of the FDA gives the public the certainty of knowing exactly which regulatory body is

accountable, and will help prevent an entity like the New England Compounding Center from inappropriately operating as a pharmacy ever again.

Simply put, we believe the Committee got it right with this proposed legislation. The proposed legislation assures hospital and health-system pharmacists, physicians, and other purchasers of compounded products that compounding manufacturers that prepare sterile products have taken the necessary steps to ensure their facilities meet the most rigorous Current Good Manufacturing Practices, have been inspected by the FDA, and most importantly, do not pose a threat to our patients due to inadequate regulatory oversight.

Under the proposal, health care providers will have the assurance that if they purchase an outsourced sterile product from a compounding manufacturer, wherever it is located throughout the country, that the product they purchase has come from an FDA-inspected and -approved facility. We also agree that a compounded drug sold to a health care entity by a compounding manufacturer should be labeled “not for resale.”

ASHP agrees that commercially available products should not be compounded except to meet specific medical needs or if they are placed by the FDA on its drug shortage list. Furthermore, there should not be any loopholes in the law that would enable an entity to circumvent the drug approval process. We believe that the current approval processes for new and generic drugs should be preserved as the gold standard, and in no way minimized or circumvented.

ASHP supports the provision that exempts health systems from being designated as compounding manufacturers. We believe it is critical to make the distinction between health systems--which are fully accountable for the comprehensive care of the patient--and a compounding manufacturer that prepares and sells its products across state lines without a prescription or knowledge of the patient to a third party for administration.

In a hospital or health system, the same entity that compounds the medication is also responsible for the care of the patient. No medication, compounded or otherwise prepared, is administered to the patient unless there is a patient-specific medication order. Compounded medications prepared by pharmacy departments and all other medications used in hospitals and health systems are prescribed or ordered based on established relationships with the medical staff and other prescribers, all of whom are formally credentialed and privileged by the hospital or health system. Further, hospitals and health systems are not engaged in the retail sale of compounded products to other entities, but instead prepare and purchase compounded preparations for use on the patients being cared for in their hospital, health system, and clinics.

Hospitals also have Pharmacy and Therapeutics Committees comprised of medical, administrative, and pharmacy staff that only allow safe and effective products to be placed on their approved drug formularies. They also have well-established quality improvement, infection control, and risk management committees as well as adverse event monitoring and reporting systems. Another distinguishing factor for health systems is that they must comply with CMS Hospital Conditions of Participation, and are accredited by quality improvement organizations such as The Joint Commission and DNV Healthcare, both of whom have deemed status with

Medicare. These are just a few examples of how health systems function differently than other care settings and are therefore appropriately excluded from the class of compounding manufacturers in the draft legislation in the draft legislation.

We support the definition of “health system” in the provision in the bill that defines traditional compounder. However, it may need to be revised to reflect contemporary health systems that include ambulatory clinics and infusion centers under their common control. We have submitted comments to the Committee that raise this point and look forward to working with other hospital organizations and Committee staff to resolve this need for language that reflects the various components of today’s health systems.

ASHP supports the provisions in the draft legislation that grant FDA the authority to designate a list of drugs that should not be compounded. There are complex medications with mechanisms of action or delivery systems that should not ever be compounded. In addition, we agree that the FDA should identify bulk substances that should not be used in compounding.

We agree with the draft language requiring compounding manufacturers to report adverse drug events to the FDA MedWatch program and to have a licensed pharmacist directly supervising the compounding operations.

Finally, we support the establishment of user fees for compounding manufacturers in order to provide the FDA with adequate resources to regulate their activities. We also ask that Congress

continue to consider increasing FDA's budget appropriation so that it can fulfill its vast global public health mission.

In closing, I want to again thank you Chairman Harkin and Ranking Member Alexander for the bipartisan leadership you have demonstrated in the interest of protecting the public health, and for holding this hearing and putting forth a thoughtful and well-developed legislative proposal. ASHP believes this proposal provides the proper pathway forward to protect patients and ensure that a harmful event like the meningitis outbreak of 2012 will never happen again. We are completely committed to working with you to help get this important legislation passed into law.

Thank you.