



Association Of State And Territorial Health Officials
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January 17, 2013

Division of Dockets Management (HFA-305)
US Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Comments to Docket No. FDA-2012-N-1154: Framework for Pharmacy Compounding: State and Federal Roles

Ladies and Gentlemen,

On behalf of the Association of State and Territorial Health Officials (ASTHO), I want to thank you for the opportunity to comment on this important matter of improving regulatory oversight of pharmacy compounding operations.

ASTHO is the national non-profit organization representing the public health agencies of the United States, the U.S. Territories, and the District of Columbia, as well as the 110,000 public health professionals these agencies employ. ASTHO members, the chief health officials of these jurisdictions, are dedicated to formulating and influencing sound public health policy and to assuring excellence in state-based public health practice.

ASTHO affirms, as part of the public health mission, the critical importance of protecting all consumers from contaminated and unsafe drugs produced by commercial compounding pharmacies. This fact was clearly demonstrated when state public health, working in partnership with local clinicians and federal counterparts, rapidly and effectively detected, epidemiologically identified, and responded to the Fall 2012 multistate outbreak of fungal meningitis associated with compounded methylprednisolone acetate (MPA), a sterile injectable product produced and distributed by the New England Compounding Center (NECC). ASTHO would also like to commend the US Food and Drug Administration and Congress for its quick actions in assessing the root causes of the outbreak, as it pertains to the lack of legal authorities over, and regulation of large scale commercial compounding pharmacies. To this end, ASTHO supports, in concept, the way forward as proposed by the FDA to create a “risk-based framework” for future regulatory oversight of all compounding pharmacies ranging from those that create a customized medication for an individual patient with an individualized medical need in response to a valid patient-specific prescription to those, like NECC, that produce larger amounts of compounded product, including sterile injectable products, in advance of a prescription or order, and in many cases ships interstate to someone other than the ultimate user.

To this end, ASTHO respectfully submits for consideration our recommendations for the creation of an integrated national pharmacy compounded drug safety system.

A strong, coordinated, and seamless national system should be developed, comprised of relevant federal and state government agencies responsible for pharmacy regulation, healthcare quality and patient safety, and consumer product safety, where applicable. This approach should be based on the principle of shared federal and state responsibility, and reflect a process for multi-agency and multi-jurisdictional coordination and communication, and articulates the respective roles, responsibilities, and authorities of the various agencies involved. This system will improve regulatory oversight of products not only in intrastate commerce but interstate commerce as well.

Additionally, this system must be anchored by having clearly articulated contemporary, not legacy, definitions of the various functional industry processes including pharmacy compounding (possibly with subcategories to address the evolutionary expansion of this industry segment), repackager, “outsourcer”, and drug manufacturer. Brighter lines are needed between these than that which currently exist.

It must also be recognized that compounding pharmacies serve a role in meeting product demands and in reducing the impact of drug shortages. Market forces have made this niche attractive to health care providers, as traditional drug manufacturers have not filled this need. New regulatory programs and controls for compounding pharmacies should be reasonably protective of public health while minimizing, to the fullest extent possible, any negative impacts on the supply chain.

Serious consideration should be given to adopting the key principles and elements of two respected and successful federal/state systems integration efforts having relevance and applicability. They are: 1) The Integrated Food Safety System and, 2) The Centers for Medicare and Medicaid Services’ (CMS) Nursing Home Inspection Program. Key features found in one or both programs that should be considered include:

- Developing a sustainable, better coordinated, prevention-oriented infrastructure premised on full strategic and operational partnerships among all relevant federal, state and local agencies.
- Ensuring that adequate resources are provided to states similar to the FDA state food inspection contract and the CMS nursing home inspection contract programs currently in place with states.
- Advancing enforcement strategies through the adoption and uniform application of science-based national standards including inspection, investigation, emergency response, and product testing protocols; while being respectful of, and preserving the rights of sovereign states and territories to license and regulate compounding pharmacies for the protection of the public’s health.

- Modernizing various communications and information sharing mechanisms, policies and practices including streamlining processes, increasing the issuance and use of FDA commissions and 20.88 confidentiality agreements to allow for critical investigative information to be shared between federal and state partners, and creating a national official establishment inventory list and national risk-based work plan. It is critically important that communication of key information relevant to public health be released to governmental public health officials during emergencies and outbreaks. Lack of information sharing can seriously hamper public health responses (e.g. FDA's inability to release information on possible new cases in MedWatch).
- Enhancing the compounded drug safety workforce by developing core competencies, providing standardized training to new and existing professionals, encouraging standardized credentialing/certification of inspection staff, and recommending appropriate staffing levels for state/territorial compounded drug safety oversight programs commensurate with workload (e.g. as determined by establishment inventories, frequency of inspection, compliance histories, etc.). This will significantly contribute to achieving the desired goal of consistency and equivalency among federal and state programs.
- Creating a culture of continuous quality improvement and program integrity by establishing program audit criteria and performance metrics to ensure that program objectives are met.

ASTHO stands ready to serve as a resource to FDA and to assist in creating and implementing an integrated federal/state system to close existing gaps and improve the regulatory oversight of pharmacy compounding operations.

Sincerely,

Paul E. Jarris, MD

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Executive Director