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August 27, 2013

The Honorable Joseph R. Pitts  
Chairman, Subcommittee on Health  
2125 Rayburn House Office Building  
Washington, D.C. 20515

Dear Chairman Pitts,

Thank you for the opportunity to appear before the Subcommittee on Health on Tuesday, July 16, 2013 to testify at the hearing entitled "Reforming the Drug Compounding Regulatory Framework." During the hearing, Congressman John D. Dingell asked ASHP to provide additional information for the record in the form of three questions. The answers to those questions are provided below.

Again, thank you for the opportunity to provide ASHP's perspective on pharmaceutical compounding and offer potential solutions. We greatly appreciate your leadership on this issue as we work to prevent another tragedy such as the meningitis outbreak of 2012.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kasey K. Thompson', is written over a horizontal line.

Kasey K. Thompson, Pharm.D., M.S.  
Vice President, Policy, Planning and Communication

Cc: The Honorable Frank Pallone, Jr.  
Ranking Member, Subcommittee on Health

**TOGETHER WE MAKE A GREAT TEAM**

The Honorable John D. Dingell, questions for the record:

1. Do you believe that it is important to have clear lines of division between FDA and State boards of pharmacy when it comes to regulating compounding pharmacies? Please elaborate.
2. In your testimony, you mention that your members also use compounded sterile preparations which are not available in an appropriate form from a manufacturer. Is this correct? Would you please submit a list of examples of these kinds of products?
3. Does Section 503(a), as currently drafted and interpreted, recognize the existence of these compounding outsourceurs and our reliance on them? Please elaborate.

Answers:

- 1) Yes, ASHP believes that it is important to have clear lines of regulation between FDA and state boards of pharmacy in order to establish which has authority and accountability for the various entities engaged in compounding. The company responsible for the meningitis outbreak in 2012, the New England Compounding Center (NECC), was licensed by the Massachusetts Board of Registration in Pharmacy as a pharmacy. However, the company was behaving more like a drug manufacturer by preparing sterile medications based on market demand, rather than individual prescriptions and offering them for sale, many times to a customer located in another state. This led to significant confusion among state and federal regulators about who had jurisdiction over NECC, and the manner in which the entity should be regulated (state-required United States Pharmacopeia standards versus FDA-required Current Good Manufacturing Practices). ASHP recognizes that the lines between a traditional pharmacy compounder and an entity operating like a manufacturer may not be clear in all cases, however, we believe that in those questionable or borderline cases, collaboration between state boards of pharmacy and the FDA is necessary to best determine whether or not an entity is no longer operating within the scope of traditional pharmacy compounding. In order to do this the law must be clear that FDA has the authority to make this determination in certain circumstances and to regulate compounding practices that go beyond traditional compounding.
- 2) Our members use compounded sterile medications that are not available in the appropriate form from the manufacturer. Note: Some examples are of sterile injectables prepared according to the manufacturer's instructions, which falls under the USP 797 definition of compounded sterile preparations. However, FDA's current definition excludes this activity from its definition of compounding. The following examples include those not available in commonly used combinations, those requiring further preparation to administer, not available in ready to administer form, and not available at all.

Not available in commonly used combinations

- Preservative free combinations of opioid pain medications with local anesthetics infused with a pump controlled by the patient Intravenous feeding solutions of protein, sugar, electrolytes, vitamins, and minerals
- Mixtures that stop the heart and protect it during cardiac surgery [cardioplegia]

Requires further preparation to administer to patient

- Drugs prepared for administration with specific devices, e.g. intravenous or subcutaneous patient-controlled analgesia pumps, syringe pumps, devices that deliver drugs to the brain [Ommaya reservoir ] e.g. pain or anti-spasticity drugs, chemotherapy
- Injectables that are in powder or lyophilized form that require reconstitution or dilution for administration, e.g. common antibiotics, pressor drugs that must be infused slowly, e.g. norepinephrine

Available but not in ready to administer form

- Drugs used in surgery, emergency care, and special procedural areas e.g., interventional radiology and endoscopy not available in pre-filled syringes or ready-to-use infusions, e.g. anesthetics and sedatives
- Drugs not available in the most commonly used dose, e.g. multidose vials of anti-nauseants, pain medications, anesthetics

Not available at all

- Adult drugs used in pediatrics that are too concentrated or need to be preservative-, dye-, alcohol-, or additive-free
- Ophthalmic injections of drugs not labeled for ophthalmic use, but well-studied and reported as safe and effective, e.g. antibiotics, oncologics, and anesthetics.
- Preservative-free versions of drugs for pain, inflammation, and other indications that are injected into the spine or brain

3) ASHP believes that it does not. The marketplace has evolved in such a manner that a new type of pharmaceutical entity has emerged that is neither a drug manufacturer nor a pharmacy. These entities either offer outsourced compounding services or prepare sterile compounded medications without a prescription and offer them for sale to customers, in some cases customers located out of state. Unique preparations and dosage forms for specific patient populations such as pediatrics, efforts to reduce waste of expensive resources, and accreditation requirements have continued to fuel demand for supplies of ready-to-use sterile preparations. Furthermore, current law has been inconsistently interpreted across circuit court jurisdictions. We believe this added to the confusion that occurred over whether states boards of pharmacy or the FDA had authority to regulate the NECC. In short, ASHP believes that current law needs to be updated to reflect this new marketplace, and that Section 503 A does not provide for appropriate regulation of these entities. Because of the lack of clarity in the law, entities such as the NECC were licensed as pharmacies but behaved more like a drug manufacturer. We remained concerned that if this is not addressed events like the fungal meningitis outbreak of 2012 will occur again.