



August 21, 2013

The Honorable Joseph R. Pitts  
Chairman  
Subcommittee on Health  
420 Cannon House Office Building  
Washington, DC 20515

The Honorable Frank Pallone, Jr.  
Ranking Member  
Subcommittee on Health  
237 Cannon House Office Building  
Washington, DC 20515

Dear Chairman Pitts and Ranking Member Pallone,

GPhA would like to submit the following in response to your recent additional questions for the record for the July 16, 2013, hearing before the Subcommittee on Health entitled “Reforming the Drug Compounding Regulatory Framework.”

**The Honorable Henry A. Waxman**

- 1. ASHP has indicated that hospitals have come to rely on outsourcers to produce large amounts of certain specialized sterile produces that are not commercially available. Can you explain what factors might have kept drug manufactures from manufacturing these products? If outsourcers were unable or unwilling to make these specialized non-commercially available products, do you believe your members would begin to do so?**

Sterile injectable manufacturing is highly complex, and the products produced require significant science, quality, and regulatory expertise to develop, gain approval from the FDA, and then manufacture and release. Additionally, cGMP standards and Agency regulations, as established by the FDA, require substantial resources. As such, commercially available products must be cost effective for manufacturers to engage in their development, approval, and sustainable manufacturing. Due to the specialized patient needs, some products may not reach the volume required to be cost effective for a pharmaceutical manufacturer to consider as part of its portfolio. In these cases, traditional pharmacy compounding always has and always will play a critical role in patient care. We support the role of the traditional compounders and believe that all patient care needs can be met by the premise of “one patient, one prescription, one drug.”

Therefore, while “hospitals have come to rely on outsourcers to produce large amounts of certain specialized sterile produces that are not commercially available,” these needs can and should be met by the premise of “one patient, one prescription, one drug.”

## The Honorable John D. Dingell

- 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.**

Yes. GPhA believes that there should be a bright-line standard between traditional compounding and pharmaceutical manufacturing. We believe that if a new category of “compounding manufacturers” is created by legislation, that this legislation should require the “compounding manufacturers” to comply with *all* the same FDA standards that apply to pharmaceutical manufacturers and that the FDA should have full regulatory oversight. This requirement is critically important to ensure the quality and sterility of products and therefore patient safety.

GPhA supports the role of the traditional compounders and believes that compounding pharmacies and pharmacists should compound products only in response to a prescription – one patient, one prescription, one drug. We also believe that oversight of traditional compounders should remain under the oversight of State boards of pharmacy.

- 2. Does Section 503(a), as currently drafted and interpreted, recognize the existence of these compounding outsources and our reliance on them? Please elaborate.**

No. Current law needs to be clarified to ensure the registration, inspection, and proper oversight of “compounding manufacturers.” It should be noted, however, that there are certain complex, high-risk products for which patient safety concerns preclude compounding under any circumstances. Several additional requirements are also needed to ensure the quality and sterility of products and therefore patient safety.

As noted previously, GPhA believes that there should be a bright-line standard between traditional compounding and pharmaceutical manufacturing. Any new category of “compounding manufacturers” should be required to comply with *all* the same FDA standards that apply to pharmaceutical manufacturers, and FDA should have full regulatory oversight.

Additionally, a compounding pharmacy that seeks to “compound manufacture” a copy of a commercially available drug on the drug shortage list should be overseen by the FDA. It should not only have to notify the FDA prior to initiating compounding, but the facility should be inspected by the FDA prior to beginning the compounding of that product. In the interest of protecting public health, the safety and manufacturing standards of compounders producing commercially available products on the drug shortage list should not be lowered below the standards required of pharmaceutical manufacturers.

Requiring the facilities of “compounding manufacturers” to be subject to pre-marketing inspections is paramount to ensuring the quality and sterility of products and therefore patient safety. Given that “compounding manufacturers” must meet cGMP requirements and that building or retrofitting a facility to comply with cGMP requirements will take many months if not years, it would be reasonable to require compounding manufacturers

to notify the FDA of their intentions and be subject to a pre-approval inspection prior to initiating the compounding. Following notification, the FDA should be given the authority to deny a compounding manufacturer's request based on prior risk or other factors. These measures are critically important to ensure the quality and sterility of products and to protect patients.

Thank you again for the opportunity to testify before the Subcommittee.

Sincerely,

A handwritten signature in blue ink, appearing to read "D.R. Gaugh". The signature is fluid and cursive, with the first name "David" and last name "Gaugh" clearly legible.

David R. Gaugh, R.Ph.  
Senior Vice President for Sciences and Regulatory Affairs