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August 27, 2013

The Honorable Joseph R. Pitts
Chairman
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
2125 House Rayburn Office Building
Washington, DC 20515

Dear Chairman Pitts:

Thank you for the opportunity to present the views of the Pharmaceutical Research and Manufacturers of America (PhRMA) before the Subcommittee on Health at the hearing entitled "Reforming the Drug Compounding Regulatory Framework" on July 16, 2013. PhRMA is pleased to respond to the questions for the record contained in your letter dated August 13, 2013.

Question from the Honorable Henry A. Waxman

1. **AHSP has indicated that hospitals have come to rely on outsourcers to produce large amounts of certain specialized sterile products that are not commercially available. Can you explain what factors might have kept drug manufacturers 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?**

PhRMA understands from Dr. Kasey Thompson's testimony on behalf of the American Society of Health-System Pharmacists (AHSP) at the July 16, 2013 hearing entitled "Reforming the Drug Compounding Regulatory Framework" before the Subcommittee on Health that hospitals have served as traditional compounders of sterile preparations that meet patient-specific needs. Both Dr. Thompson's testimony and studies conducted following the New England Compounding Center tragedy indicate that some hospitals have now outsourced some of this responsibility to large-scale compounding outsourcers. A report published by the Congressional Research Service in June of this year attributed the lack of commercial availability for some of these preparations to factors such as increases in (1) the use of drugs that are dosed by weight, rather than by standardized, commercially available dosing, and (2) the treatment of disorders requiring personalized dosing.[1] Because of the specialized nature of some of these medicines, hospitals and outsourcers engaging in compounding may have been particularly well positioned to fill this need for medicines that require personalized dosing. PhRMA is unable to predict whether its member companies will enter or exit the market for specialized sterile products if outsourcers are unable or unwilling to supply these products. In any event, if large scale outsourcers that act as manufacturers were held to the same standards as NDA or ANDA holders, *hospitals* would continue to be permitted to engage in traditional compounding of sterile preparations – i.e., compounding by a licensed pharmacist or physician pursuant to a valid prescription for an identifiable patient (or, in limited quantities based on a history of prescription orders before the receipt of prescription) under section 503A of the Federal Food, Drug, and Cosmetic Act.

[1] JUDITH M. GLASSGOLD, CONG. RESEARCH SERV., R43082, COMPOUNDED DRUGS 15 (2013).

Questions from 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, PhRMA believes that it is important to have clear lines of division demarcating the appropriate roles of FDA and State boards of pharmacy when it comes to regulating compounding.

In PhRMA's view, the dividing line is and should remain as follows: State boards of pharmacy are responsible for regulating "traditional compounding" (as described in current section 503A of the Federal Food, Drug and Cosmetic Act (FDCA)) under State practice of pharmacy and medicine laws, and FDA is responsible for regulating any medicine prepared outside of traditional compounding, i.e., "non-traditional compounding." In other words, PhRMA believes that State boards of pharmacy should regulate compounding if it involves preparations by either (1) a State-licensed pharmacist in a State-licensed pharmacy, or (2) a State-licensed physician for an identified individual patient that is based on receipt of a valid prescription order or notation and approved by the prescribing practitioner as necessary for the identified patient (or compounded in limited quantities before the receipt of the prescription based on a history of the State licensed pharmacist or State licensed physician receiving valid prescription orders for the compounded drug product). Compounding that does not fit within this definition of "traditional compounding" should be regulated by FDA. For example, any large-scale commercial compounding of prescription medicines should be required to meet the same high FDA standards for drug manufacturers, regardless of whether the commercial producer is designated as a pharmacy or as a manufacturer. These requirements would include, for example, new drug application requirements, compliance with current good manufacturing practices (cGMPs), and risk-based inspections.

PhRMA would support legislation that clarifies the regulatory responsibilities of State boards of pharmacies and FDA with respect to traditional and non-traditional compounding. Specifically, PhRMA would support any clarification that FDA retains its strong existing authority to regulate any medicine compounded outside of traditional compounding as a new drug. PhRMA would also support legislation that includes express inspection and registration authority for non-traditional compounders as manufacturers. This would include, to the extent that such authority is not already clear, the ability of FDA to inspect records to determine whether pharmacies are actually engaging in non-traditional compounding.

Finally, while recognizing the value of having clear lines of division, PhRMA would also support efforts to increase communication and coordination between State boards of pharmacy and FDA relating to compounding issues.

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

In PhRMA's view, the Federal Food, Drug and Cosmetic Act (FDCA) currently provides the requisite authority for FDA to regulate a wide range of entities that may engage in compounding, including large-scale compounding outsourcers that may be regulated as pharmaceutical manufacturers. Although as currently drafted, section 503A of the FDCA does not recognize the existence of compounding

outsourcers *per se,* section 503A's intended purpose was never to capture these activities. This section was drafted to create an express exemption for *traditional* compounding pharmacies from the current good manufacturing practice (cGMP) requirements in the FDCA's adulteration provision (501(a)(2)(B)), the adequate direction for use requirement in the FDCA's misbranding provision (502(f)(1)), and the new drug application requirements in FDCA section 505.

In other words, current section 503A exempts from these requirements compounding by a licensed pharmacist or physician pursuant to a valid prescription for an identifiable patient (or, in limited quantities based on a history of prescription orders before the receipt of prescription) *provided* the compounding meets certain other requirements described in 503A. Section 503A's exemption does not apply to non-traditional compounding, i.e., any large-scale commercial compounding by pharmacies or manufacturers that outsource compounded drugs. Such non-traditional compounding may be regulated by FDA under a risk-based approach including, among other things, the FDCA's existing requirements for new drug applications, cGMPs, adequate directions for use, and inspections.

PhRMA's view is that the FDCA currently provides FDA with ample authority to regulate compounding outsourcers. In fact, FDA exercised some of its available enforcement authority in connection with the New England Compounding Center. For example, FDA carried out inspections of compounding pharmacies, worked with state authorities to suspend operations in non-compliant facilities, and arranged for recalls of potentially violative products. PhRMA believes large-scale compounding outsourcers should continue to be regulated under the same risk-based approach as drug manufacturers. To the extent that any clarification is needed, PhRMA would support legislation that clarifies that section 503A creates a limited exemption for traditional compounders, and that all non-traditional compounders (including outsourcers) are—like other drug manufacturing activities—subject to the FDCA's requirements for new drug applications, cGMPs, adequate directions for use, and inspections.

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Thank you again for the opportunity to present PhRMA's views on this important public health issue, and please do not hesitate to contact us if we may be of further assistance.

Best regards,

Jeffrey K. Francer
Vice President and Senior Counsel
Biopharmaceutical Regulation