April 27, 2016

The Honorable Thad Cochran
Chairman
Committee on Appropriations
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

As you consider appropriations language in the FY 2017 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies appropriations bill, we urge your continued support for patient safety through full and effective implementation of federal law intended to ensure the quality of compounded medicines. Efforts to create exemptions to the law would put patients at risk by allowing compounding by pharmacies that do not meet appropriate quality standards.

After an outbreak of fungal meningitis in 2012 and 2013 that sickened over 700 Americans—64 fatally—Congress passed the bipartisan Drug Quality and Security Act of 2013 (DQSA). This law will help avoid a repeat of these events, but only if the Food and Drug Administration (FDA) is free to proactively enforce against illegal compounding activity. To fulfill the promise of the DQSA, FDA must be able to enforce federal prohibitions on compounding without a prescription by pharmacies that do not comply with FDA regulations and do not meet quality standards designed to better protect and ensure patient safety.

Traditional pharmacies, primarily regulated by the states, should not produce supplies of compounded drugs without prescriptions, also known as "office stock" compounding. The quality standards applied to pharmacies are appropriate for patient-specific preparations, but not for operations at a larger scale where significantly more individuals are exposed. These compounded office supplies may also be stored on clinic shelves for an extended period of time, allowing any microbial contaminants to proliferate to harmful levels. Additionally, quality requirements and enforcement systems vary widely between states, as described in Pew's recent report *National Assessment of State Oversight of Sterile Drug Compounding.* Pharmacies may ship compounded drugs across state lines, further complicating individual state oversight and exposing patients to risks that are difficult to control.

FDA's recent draft guidance appropriately provides for traditional pharmacies to compound either upon receipt of a prescription for an individual patient, or in anticipation of receiving such a prescription. Under the guidance, traditional pharmacies are permitted to compound a limited supply of drugs without first receiving a prescription and to keep these on hand for a limited time, so that they have stock to dispense as prescriptions arrive. This anticipatory compounding provision provides a pathway for these pharmacies to provide compounded drugs in a timely manner while prioritizing patient safety.

Congress also recognized, and the guidance reflects, that there are times when providers need supplies of compounded drugs available for "office stock" so that they are available for use in treatment settings. Under the DQSA, Congress acted to better ensure the quality and safety of office stock products and created a clear regulatory home for facilities that produce them. Such "outsourcing facilities" must

register with the FDA and meet good manufacturing practices – more robust quality standards than those applied to traditional pharmacies—as is appropriate for larger scale and shelf life. By creating the new outsourcing facility sector, Congress both preserved access to compounded drug supplies when they are a medically necessary alternative to approved products, and it reduced the risk of patients receiving a contaminated drug that could cause serious harm or death.

As the fungal meningitis outbreak demonstrates, access to compounded medicines must not come at the expense of quality and patient safety. If traditional pharmacies are permitted to supply office stock compounded drugs outside of the new quality standards, they will have no incentive to register with the FDA and adhere to the more rigorous quality standards that are appropriate for larger scale or office stock compounding.

Congress enacted the reforms in the DQSA in the wake of the meningitis outbreak but also in response to incidents of bacterial infections, blindness and other injuries caused by subpar compounded drugs dating back years. We urge you to support full implementation of the federal compounding law by ensuring that the FY2017 appropriations language does not impede FDA's ability to ensure patient safety.

Sincerely yours,

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