The Honorable Thad Cochran
Chairman
Committee on Appropriations
United States Senate
Washington, D.C. 20510

The Honorable Patrick J. Leahy
Vice Chairman
Committee on Appropriations
United States Senate
Washington, D.C. 20510

The Honorable John H. Hoeven, III
Chairman, Agriculture Subcommittee
Committee on Appropriations
United States Senate
Washington, D.C. 20510

The Honorable Jeff Merkley
Ranking Member, Agriculture Subcommittee
Committee on Appropriations
United States Senate
Washington, D.C. 20510

June 12, 2017

Dear Chairmen Cochran and Hoeven, and Ranking Members Leahy and Merkley:

As diverse stakeholders committed to ensuring the safety and reliability of compounded medicines in all settings, we urge you to support strong Food and Drug Administration (FDA) oversight and enforcement of the 2013 Drug Quality and Security Act (DQSA). To reinforce the Committee's oversight of this important issue, we are submitting suggested draft report language for your consideration. The language protects patients from potentially unsafe compounded medicines by supporting the FDA's final guidance on the prescription requirement for compounded products, acknowledging the significant progress that state boards of pharmacy and the agency have made toward a clear regulatory framework for compounded medicines.

The DQSA was passed under the shadow of a tragedy. In 2012 and 2013, 753 patients were sickened and 64 died in a multistate outbreak of fungal meningitis associated with contaminated spinal injections manufactured by a poorly regulated compounding pharmacy. These drugs were produced in large batches and shipped across the country. Congress responded forcefully to the outbreak by reinforcing the original compounding statute – section 503A of the FDCA – that created a framework for pharmacists to produce individualized medicines for patients without having to go through the drug approval process and demonstrate safety and effectiveness.

At the same time, to mitigate the higher risk associated with compounding activities not specific to a particular patient that result in stock supplies of compounded drugs, Congress created a new regulatory category of "outsourcing facilities," which are governed by section 503B. This new category addresses the need of hospitals and other health care providers for larger-scale production of sterile drugs that are not commercially available. The statute was explicitly written to ensure that sterile drugs that were being produced without a prescription would be held to more robust quality standards than traditional compounding in order to reduce the risk to patient safety from large-scale compounding.

Patient safety was not, however, the only goal. In addition to ensuring the availability of quality compounded drugs, another compelling congressional goal was to ensure that there were clear lines of accountability. At the time of this fungal meningitis outbreak, the governing statute – section 503A of the FDCA – was clouded by legal uncertainty and needed to be updated. As a result, there was a lack of clarity about what compounding activities were subject to federal oversight and what was subject to state regulation, and, therefore, about whether federal or state regulators were accountable if oversight was inadequate. As Congress negotiated the DQSA, substantial attention was paid not only to the quality standards that would apply, but to who would enforce those standards – that is, to use Senator Alexander's language, who would be "on the flagpole."[1]

Access to medically-needed compounded medicines is highly important. But access cannot come at the expense of quality and patient safety. Congress created the new outsourcing facility sector in order to fill practitioners' need for supplies of compounded drugs that meet good manufacturing practices without patient-specific prescriptions. However, it is the role of the states to monitor and regulate traditional pharmacies. And, if under section 503A, traditional pharmacies are permitted to supply compounded drugs without prescriptions and without complying with good manufacturing practices, outsourcing facilities will have no incentive to register with the FDA and adhere to the more rigorous quality standards that are appropriate for larger-scale compounding. This would undermine patient safety and the public health protections that Congress sought to put in place with the DQSA. If FDA is not permitted to maintain that line between traditional compounding and outsourcing facilities, patients are put at risk, states and compounding pharmacies will not have clear regulatory guidance, and the lessons of the national meningitis outbreak will have been forgotten.

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[1] *See e.g.,* Sen. Lamar Alexander, "To Help Avoid Repeat of Deadly Meningitis Outbreak, Senate Sends Alexander Compounding Legislation to President," Press Release (Nov. 18, 2013), available at: http://www.alexander.senate.gov/public/index.cfm/2013/11/to-help-avoid-repeat-of-deadly-meningitis-outbreak-senate-sends-alexander-compounding-legislation-to-president.

We look forward to continuing to stay engaged with you on this important issue as the Fiscal Year 2018 appropriations process unfolds. Please don't hesitate to contact Sarah Despres, at (202) 540-6601 if we can be of any assistance.

Sincerely yours,

American Public Health Association (APHA)
Association for Accessible Medicines (AAM)
Biotechnology Innovation Organization (BIO)
The Pew Charitable Trusts
Pharmaceutical Research and Manufacturers of America (PhRMA)
Trust for America's Health (TFAH)