March 7, 2016

The Honorable Robert Aderholt
Chairman
House Committee on Appropriations:
Subcommittee on Agriculture, Rural Development,
Food and Drug Administration, and Related Agencies
Washington, DC 20515

The Honorable Jerry Moran
Chairman
Senate Committee on Appropriations:
Subcommittee on Agriculture, Rural Development,
Food and Drug Administration, and Related Agencies
Washington, DC 20510

The Honorable Sam Farr
Ranking Member
House Committee on Appropriations:
Subcommittee on Agriculture, Rural Development,
Food and Drug Administration, and Related Agencies
Washington, DC 20515

The Honorable Jeff Merkley
Ranking Member
Senate Committee on Appropriations:
Subcommittee on Agriculture, Rural Development,
Food and Drug Administration, and Related Agencies
Washington, DC 20510

Support Patient Protections in Federal Drug Compounding Law, Do Not Weaken Them

Dear Chairman Aderholt, Chairman Moran, Ranking Member Farr and Ranking Member Merkley:

We urge you to support strong federal oversight of drug compounding, and Food and Drug Administration (FDA) enforcement of federal law to protect patients from adulterated compounded medicines. **In particular, language that impedes FDA's ability to enforce compounding law, including prescription and quality standard requirements, should not be included in FY2017 appropriations legislation.**

After over 700 were sickened and 64 patients lost their lives in a national meningitis outbreak linked to contaminated compounded drugs shipped across the country, Congress passed bipartisan legislation to address clear oversight gaps. To fulfill the promise of that law, FDA must be able to enforce federal prohibitions on traditional compounding without a prescription by pharmacies that do not comply with FDA regulations and do not meet appropriate quality standards.

Patient deaths dictate that we need to move beyond business as usual. The meningitis outbreak revealed that the compounding sector had expanded over the years to include pharmacies that were acting as suppliers of standardized compounded drugs, sometimes at a very large scale, outgrowing existing regulatory regimes. Under this business model, more patients are harmed when something goes wrong, as we saw dramatically three years ago.

Congress recognized that supplies of compounded drugs – drugs compounded without patient-specific prescriptions – are sometimes needed by providers when an FDA-approved product is not available, but also that we needed to better ensure the quality of these drugs. Under the Drug Quality and Security Act of 2013, Congress created a clear regulatory home for these companies: they must register with the FDA as "outsourcing facilities" and meet good manufacturing practices – more robust quality standards than those applied to traditional pharmacies. By creating the new outsourcing facility sector, Congress both preserved access to compounded drug supplies when they

are medically necessary alternatives to approved products, and reduced the risk of patients receiving a contaminated drug that could cause serious harm or death.

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 traditional practice, but not for operations at a larger scale where more patients are exposed. These compounded office stock supplies may also sit on clinic shelves for an extended period of time, allowing any microbial contaminants to proliferate to harmful levels. Further, specific state quality requirements and enforcement systems for pharmacies vary, as described in a report released last week by Pew: *National Assessment of State Oversight of Sterile Drug Compounding*. A pharmacy in one state may ship compounded drugs to others, further complicating individual state oversight, and exposing patients to risks that are difficult to control.

Most importantly, however, Section 503A of the Federal Food, Drug and Cosmetic Act does not allow traditional pharmacies to conduct office stock compounding. Section 503A makes clear that for traditional pharmacies to receive federal exemptions, they must compound pursuant to a prescription for an individual patient, or in limited quantities before receipt of a prescription for an individual patient. The law does not contemplate compounding without a prescription. But office stock compounding is just that – the act of compounding and providing a stock of drugs to a clinic for later use, entirely without pharmacy reference to an individual patient prescription.

In your FY2016 appropriations report accompanying the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies division of the omnibus, you included the following language: "The Committee understands the intent of the DQSA was not to prohibit compounding pharmacists from operation under existing 503A exemptions; therefore, the Committee directs the FDA to issue a guidance document on how compounding pharmacists can continue to engage in 'office-use' compounding before the receipt of a patient-specific prescription consistent with the provisions of 503A within 90 days after the enactment of this Act". As discussed above, section 503A does permit compounding *before* the receipt of a patient-specific prescription, but it does *not* permit compounding *without* a prescription, e.g. compounding for office use. A pharmacy may prepare limited quantities of compounded drugs in advance, but must receive an individual patient prescription before providing that drug to a doctor or clinic.

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 to fill the need for non-prescription based compounding, without sacrificing quality standards and patient safety. If traditional pharmacies under Section 503A are permitted to supply compounded drugs without prescriptions outside of these new quality requirements, they will have no incentive to register with the FDA and adhere to the more rigorous quality standards that are appropriate for compounding at that scale. If FDA is not permitted to maintain that line between traditional compounding and outsourcing facilities, patients are put at risk, and the lessons of the national meningitis outbreak have been forgotten.

We urge you to preserve the patient protections in federal compounding law and support FDA implementation of that law. Language that impedes FDA's ability to enforce compounding law, including prescription and quality standard requirements, should not be included in FY2017 appropriations legislation.

Sincerely yours,

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The Pew Charitable Trusts is an independent, nonpartisan research and public policy organization dedicated to serving the public. For more information, visit pewtrusts.org/drugsafety.

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CC: Members of the House Committee on Appropriations: Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies