June 8, 2016

The Honorable Jason Chaffetz  The Honorable Elijah Cummings
Chairman  Ranking Member
House Committee on Oversight and House Committee on Oversight and
Government Reform  Government Reform
2157 Rayburn House Office Building  2471 Rayburn House Office Building
Washington, DC 20515  Washington, DC 20515

Dear Chairman Chaffetz and Ranking Member Cummings:

Since passage of the Drug Quality and Security Act of 2013 (DQSA), we have become increasingly concerned that the Food and Drug Administration (FDA) is implementing and enforcing the DQSA in a manner inconsistent with the plain language and congressional intent of the law, which is jeopardizing patient safety and access to critical medications.

Despite clear legislative intent expressed in statements read into the record during passage of the DQSA, written correspondence from multiple Members of Congress, directives in report language in appropriations bills, and questions asked and submitted for the record during congressional hearings in several committees, the FDA continues to issue guidance documents and enforcement decisions which ignore congressional and stakeholder input and substitute the agency’s own policy preferences for the letter and intent of the law. FDA’s actions and the information being provided by the agency to State Boards of Pharmacy and Medicine have caused confusion amongst pharmacists on what they can and cannot compound and increasingly providers have encountered difficulties in finding the necessary compounded medications needed to treat their patients. This regulatory overreach by the FDA is unacceptable, and has resulted in a loss of patient access to critical medications and has undermined the very patient safety the agency purports to be concerned about.

Therefore, we write to respectfully request the House Committee on Oversight and Government Reform hold a hearing on the FDA’s implementation and enforcement of the DQSA and to make recommendations for regulatory and/or statutory changes needed to better align the agency’s actions with the plain language and congressional intent of the law. Specifically, we ask the Committee examine FDA’s authority under the DQSA as it relates to the following actions the agency has taken in implementing and enforcing the law:

- FDA has taken the position that state-licensed (503A) compounding pharmacies may not compound medications without a patient-specific prescription and transfer them to a physician for administration in an office setting (“office-use compounding”) even when authorized by state law. FDA has issued a draft memorandum of understanding on interstate distributions of compounded medications which improperly defines “distribution” to include patient specific dispensing of compounded medications over state lines.
• FDA is inspecting 503A compounding pharmacies under Current Good Manufacturing Standards (cGMPs) instead of under US Pharmacopeia (USP) or other standards established by state pharmacy laws and regulations.
• FDA has interpreted the requirement that 503A compounding pharmacies compound from bulk ingredients containing a USP or National Formulary monograph as not including dietary supplements, despite the fact over 260 dietary supplements currently hold USP monographs.
• FDA has established the Pharmacy Compounding Advisory Committee (PCAC), mandated by the DQSA to include pharmacy and other stakeholder input, to approve pharmaceutical ingredients for compounding, in a way that has minimized input from compounding pharmacists and other stakeholders who dissent from FDA’s positions on nominated drugs and reduced the PCAC to a “rubber-stamp” of the agency’s recommendations.

The undersigned organizations are united in a mission to preserve patient access to needed compounded medications, consistent with state and federal laws and regulations, and in a way which protects patient safety. For these reasons, we respectfully request your committee hold an oversight hearing on the issues we raise in this letter and we stand by ready to participate in any way you deem helpful. Thank you in advance for your consideration of this request for a hearing.

Sincerely,

Alliance for Natural Health – USA (ANH)
Alliance of Independent Pharmacists of Texas (AIP-Texas)
American Academy of Dermatology Association (AADA)
American Association of Naturopathic Physicians (AANP)
American Pharmacists Association (APhA)
American Society of Consultant Pharmacists (ASCP)
International Academy of Compounding Pharmacists (IACP)
National Alliance of State Pharmacy Association (NASPA)
National Community Pharmacists Association (NCPA)