Support Letter to Chairman Chaffetz and Ranking Member Cummings to Request House Oversight and Government Reform Hearing on FDA Implementation of the DQSA

Since passage of the DQSA, FDA is implementing and enforcing the DQSA in a manner which is inconsistent with the plain language of the statute and congressional intent which is jeopardizing patient safety and access to vital compounded medications.

Despite clear congressional intent expressed by six bipartisan and bicameral statements read into the record during the 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 recording during multiple congressional hearings in several different Congressional Committees, FDA continues to issue guidance documents and take enforcement action which ignore Congressional intent and stakeholder input. FDA continues its overreach in the implementation of the DQSA by ignoring the clear congressional intent of the law and in some cases, the plain language of the law.

- FDA has taken the position that state-licensed (503A) compounding pharmacies may not compound medications 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 to include dietary supplements, despite the fact there are over 260 USP dietary supplement monographs.
- FDA has established the Pharmacy Compounding Advisory Committee (PCAC), mandated by the DQSA to include pharmacy and other stakeholder input in a process 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.

This overreach has resulted in drastically decreased patient access to vital compounded medications and undermines patient safety. In order to hold FDA accountable for implementing the DQSA in accordance with Congressional intent and preserve patient safety and access to vital medications, please support the letter sent to Chairman Chaffetz and Ranking Member Cummings requesting the House Oversight and Government Reform Committee hold a hearing addressing this broad overreach.

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