Congress of the United States
Washington, DC 20515

Co-Sponsor H.R. 2871, The Preserving Patient Access to Compounded Medications Act

Dear Colleague:

Subsequent to the passage of the Drug Quality and Security Act of 2013 (DQSA), the FDA has implemented and enforced the laws related to the practice pharmacy in a way that is contrary to congressional intent and that is jeopardizing patient access to critical medications. Despite clear statements read into the congressional record, multiple bipartisan letters from Congress, stakeholder input, questions for the record submitted in committee hearings, and clear directives in the last two FDA appropriations bills, the agency continues to misinterpret the law and overstep the regulatory authority Congress intended to give FDA over state-licensed and compliant pharmacies.

The DQSA was never intended to preempt state pharmacy laws that allow doctors to receive limited quantities of compounded medications needed for administration to their patients in office or clinical settings ("office-use" compounding), nor was it intended to authorize FDA to inspect state-licensed and compliant pharmacies as if they were drug manufacturers. Yet, that is exactly how the FDA is interpreting and enforcing laws related to the practice of compounding, and it is causing an unnecessary gap in patient access to critical compounded medications. FDA is using guidance for industry (GFI) documents that do not have the force of law to redefine key statutory terms like "distribute" and "dispense" to assert regulatory authority over the patient-specific dispensing of medications, the very essence of the practice of pharmacy and something Congress never intended. The agency is substituting its desired, broad regulatory authority over pharmacy for the very limited authority actually given to the agency. H.R. 2871 will clarify for FDA key provisions they are misinterpreting and better balance patient safety and patient access by:

- Authorizing "office-use" compounding by state-licensed pharmacies where allowed by state pharmacy laws and regulations.
- Defining the terms "distribute" and "dispense" to clarify that the law gives FDA regulatory authority to limit interstate "distributions" of compounds, but not patient-specific "dispensing" by state licensed and compliant pharmacies.
- Clarifying that dietary supplements that have a USP or National Formulary monograph can be used in compounding when a doctor determines they are necessary to meet a patients' medical needs.
- Clarifies that state-licensed and compliant compounding pharmacies, that are not drug manufacturers, are to be afforded the same rights and protections of other pharmacies during FDA inspections.
- Requiring the FDA to follow formal rulemaking procedures to implement the DQSA rather than issuing non-binding guidance documents with policies that do not adhere to the statute.

Please join us in cosponsoring H.R. 2871, The Preserving Patient Access to Compounded Medications Act of 2017. Please contact Kristin Seum (Kristin.seum@mail.house.gov) on Rep. Griffith's (R-VA) staff or Patrick Malloy (Patrick.malloy@mail.house.gov) on Rep. Cuellar's (D-TX) staff to co-sponsor.

Sincerely,

H. MORGAN GRIFFITH
Member of Congress

HENRY CUELLAR
Member of Congress