

July 26, 2017

The Honorable Morgan Griffith (R-VA)
U.S. House of Representatives
2202 Rayburn HOB
Washington, D.C. 20515

The Honorable Henry Cuellar (D-TX)
U.S. House of Representatives
2209 Rayburn HOB
Washington, D.C. 20515

Dear Rep. Griffith and Rep. Cuellar:

The undersigned organizations represent patient advocates, physicians, pharmacists and other healthcare providers who are united in a mission to preserve patient safety and patient access to compounded medications. Since 2014, our organizations have been meeting and working together as part of a coalition (“the DQSA Coalition”) to provide input to the FDA, to State Boards of Pharmacy and to the Congress about our concerns with FDA’s implementation and enforcement of the Drug Quality and Security Act of 2013 (“DQSA”, P.L. 113-54) and to seek solutions and policies that better balance patient safety with access to compounded medications.

The DQSA Coalition strongly supports H.R. 2871, *The Preserving Patient Access to Compounded Medications Act*, and we urge the Congress to pass this important legislation as soon as possible. H.R. 2871 will clarify key provisions of the Food, Drug and Cosmetic Act (FDCA) as amended by the DQSA that the FDA has been misinterpreting in a way that has jeopardized access to compounded medications for the patients that need them.

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 reports, the agency continues to misinterpret the law and overstep the regulatory authority Congress intended to give FDA over state-licensed and compliant pharmacies. FDA is using non-binding guidance for industry (GFI) documents that do not have the force of law and that do not adhere to the congressional intent or plain language of the DQSA to unnecessarily restrict patient access to compounded medications. H.R.2871 is needed to clarify for FDA that state-licensed and compliant pharmacies play an important role in our health care system by providing compounded medications to patients and physicians, and do so while protecting patient safety.

For these reasons, the DQSA Coalition endorses and supports H.R. 2871, *The Preserving Patient Access to Compounded Medications Act*. We look forward to working with other stakeholders and the Congress on passing this important legislation during the 115th Congress.

Alabama Pharmacy Association
Alaska Pharmacists Association
American Academy of Dermatology Association
American Academy of Ophthalmology
American Society of Cataract and Refractive Surgery
American Society for Dermatologic Surgery Association

American Society for Mohs Surgery
Arizona Pharmacy Association
Arkansas Pharmacists Association
California Pharmacists Association
Colorado Pharmacists Society
Compounding Pharmacists of Texas
Connecticut Pharmacists Association
Delaware Pharmacists Society
Florida Pharmacy Association
Georgia Pharmacy Association
Idaho State Pharmacy Association
Illinois Pharmacists Association
Indiana Pharmacists Association
International Academy of Compounding Pharmacists
Kansas Pharmacists Association
Kentucky Pharmacists Association
Louisiana Pharmacists Association
Massachusetts Pharmacists Association
MEDISCA
Michigan Pharmacists Association
Minnesota Pharmacists Association
Mississippi Pharmacists Association
Missouri Pharmacy Association
Montana Pharmacy Association
National Community Pharmacists Association
National Home Infusion Association
Nebraska Pharmacists Association
New Jersey Pharmacists Association
North Dakota Pharmacists Association
Ohio Pharmacists Association
Oklahoma Pharmacists Association
Oregon State Pharmacy Association
PCCA
Pennsylvania Pharmacists Association
Pharmacists Society of the State of New York
South Carolina Pharmacy Association
South Dakota Pharmacists Association
Tennessee Pharmacists Association
Texas Pharmacy Association
Utah Pharmacy Association
Virginia Pharmacists Association
Washington D.C. Pharmacy Association
Washington State Pharmacy Association
West Virginia Pharmacists Association