United States Senate

WASHINGTON, DC 20510

May 17, 2019

Norman E. Sharpless, M.D.,
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Sharpless;

We write concerning the Food and Drug Administration's (FDA) revised draft "Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the States and the Food and Drug Administration". We believe that access to safe compounded drugs is an invaluable part of patient care and are encouraged that you issued a new draft Memorandum of Understanding (MOU) regarding interstate distribution of compounded medications. While important changes are still needed, the newly reissued draft MOU is a meaningful step in the right direction.

However, we remain concerned that the draft MOU may decrease patient and provider access to necessary compounded medications. Specifically, we are concerned that under the proposed limits and reporting requirements for compounded products distributed interstate, the FDA defines distribution to include patient-specific prescriptions, which is the traditional definition of dispensing. "Dispensing" and "distributing" are typically treated as distinct and separate activities, but this proposed definition of distribution includes dispensing such that all compounded medications, with or without a prescription, would be considered subject to the oversight requirements.

We have also heard concerns that some states and state boards of pharmacy may lack the regulatory authority and resources for implementing the provisions of the MOU, which may result in an inability to sign. Comments submitted by the National Association of Boards of Pharmacy also note similar concerns. Should states not sign the MOU, the FDA would enforce a five percent limit on interstate compounding. Many residents in our states depend on compounding pharmacies in other states to meet their unique medical needs. Some travel during the year and need compounded prescriptions sent from home. A five percent limit on sending compounded drugs to other states could restrict access to vulnerable patients who depend on pharmacies that specialize in these medications, particularly for those who live in contiguous states. Further, confusion around state participation could increase regulatory uncertainty for the many compounding pharmacies that are small businesses and that would be adversely impacted under a five percent limit.

Prior to finalizing the MOU, we ask that you continue to work with stakeholders, including state boards of pharmacy, to clarify the definition of distribution in a manner that ensures that patients around the country continue to have robust access to the compounded medicines they need. We further request that you work to ensure that the provisions in the final MOU do not place an undue regulatory burden on states or on compounding pharmacies and strike the right balance between patient safety and patient access to compounded medicines from the pharmacy of their choice.

Thank you for your consideration and we look forward to your timely response.

Sincerely,

Tammy Baldwin
United States Senator

Bill Cassidy, M.D.
United States Senator