United States Senate
WASHINGTON, DC 20510

June 28, 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 regarding the Food and Drug Administration's (FDA) September 2018 revised draft "Memorandum of Understanding (MOU) Addressing Certain Distributions of Compounded Human Drug Products between the States and the Food and Drug Administration." Although we believe important revisions are still necessary, the recently issued draft MOU is an impactful step and on the correct path. We consider patients' access to safe and effective drugs an invaluable part of their care, and thank you for your attention to this issue.

We remain concerned that patients' and providers' access to compounded medications may be reduced should the draft MOU be finalized without modifications. We are specifically concerned that for compounded products distributed interstate, the FDA defines distribution to include patient-specific prescriptions which is the traditional definition of dispensing. The terms, "dispensing" and "distributing" have long been treated as distinct activities from each other, but the definition in the draft MOU would make dispensing of all compounded medications subject to the same requirements.

For the past several years, the North Dakota State Board of Pharmacy (NDSBP) has participated in discussions with the FDA regarding the statutory need to enter into a MOU with the state, and the impact that doing so will have on compounding pharmacies ability to dispense interstate prescriptions. As you are likely aware, should the NDSBP not sign the MOU, the FDA would enforce a five percent limit on interstate compounding. Many patients in North Dakota and surrounding states, including Western Minnesota, Eastern Montana, and Northern South Dakota depend on compounding pharmacies in North Dakota to meet their unique medical needs.

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, including those with allergies, compromised digestive systems, or the inability to swallow a pill.

Prior to finalizing the MOU, we ask that the FDA continue to work with stakeholders, including the NDSBP, patient safety advocates, and compounding pharmacies in the state, to consider revisions to the MOU that will ensure that patients in North Dakota can continue to have access to the safe and effective medications that they need.

Thank you for your consideration. We look forward to your timely response.

Sincerely,

John Hoeven
United States Senator

Kevin Cramer
United States Senator