DATE

The Honorable Norman E. (Ned) Sharpless M.D.
Acting Commissioner, U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Sharpless:

As the FDA moves forward with the implementation of the Drug Quality and Security Act, we are writing to thank you for issuing a new draft Memorandum of Understanding (MOU) with the States regarding interstate distribution of compounded medications. While important changes are still needed, the newly reissued draft MOU released in September 2018 is a meaningful step in the right direction.

We are writing to ask FDA to correct the definition of distribution in the reissued MOU so that it does not include patient specific dispensing. Our hope is that this change would result in an MOU most if not all states could sign, and that would resolve the patient access issues we all want to prevent. We are greatly concerned that many states will not sign the draft MOU as written, especially if it continues to define distribution to include patient specific dispensing – the result being that patients would no longer be able to receive their medication from the pharmacy of their choice or need.

The FDA's current definition of this term contradicts well-established precedent in both state and federal laws. It is also contrary to the model state pharmacy act developed by the National Association of Boards of Pharmacy (NABP)[1] and to the statutes and regulations enacted by the states. In submitting comments to FDA, NABP references approximately twenty states that would have serious problems signing the MOU because of the expanded definition of distribution. NABP goes on to state that "based upon the input from a number of states, unless the language in the MOU is corrected, a number of state boards of pharmacy will not be able to or will refuse to sign the MOU."

If states do not sign the MOU and if the definition of distribution is not corrected, pharmacies in those states would be limited to shipping only five percent of their prescriptions to their patients outside the state where the pharmacy is located. Many pharmacies have developed specialties or national reputations for quality and service, and fill prescriptions nationwide or to broad regions of the country. Absent robust access to the medications they provide, vulnerable patient groups could have problems accessing the compounded medications they need based solely on their geographic location. Moreover, it would make it difficult for compounding pharmacies, almost all of which are small businesses, to have the regulatory certainty they need knowing that if their state does not sign the MOU, or if it signs and subsequently withdraws from the agreement, their

[1] https://nabp.pharmacy/publications-reports/resource-documents/model-pharmacy-act-rules/

businesses could be severely affected for reasons beyond their control, and the patients they serve would suffer.

We are also concerned that many states may not have the legal authority to enter into an MOU with the FDA without consulting with numerous state agencies, potentially requiring changes in state law. Given the potential for protracted legislative or regulatory consideration, some states might not be able to accomplish these changes within the 180 days after the final MOU is released, as currently proposed by the FDA. Additionally, some states indicate that they simply do not have the resources to conduct the safety inspections required by state law and also meet the additional unfunded mandates currently proposed in the MOU.

We ask that you please continue to work with stakeholders, including state boards of pharmacy, on the definition of distribution in the reissued MOU so that it does not include patient specific dispensing. Our hope is that this change will result in an MOU most if not all states could sign, and that it would resolve the patient access barriers we all want to prevent. This definitional change also corresponds with multiple years of appropriations report language approved by Congress, and would prevent costly and disruptive litigation that Congress intended to avoid when the Drug Quality and Security Act was enacted.

Thank you again for the policy improvements contained in the revised September 2018 MOU. We look forward to working with you so that patients can maintain access to their compounded medications from the pharmacy of their choice, no matter where they live.

Sincerely,

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PETER WELCH
Member of Congress

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H. MORGAN GRIFFITH
Member of Congress