Congress of the United States
Washington, DC 20515

June 8, 2020

The Honorable Russell T. Vought
Acting Director
United States Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Dear Director Vought,

We are writing to raise concerns with the process and the near final memorandum of understanding (MOU) between individual states and the Food and Drug Administration (FDA) regarding pharmacy compounding. This action [Docket No. FDA-2018-N-3065, OMB Control Number 0910-0800] is now under review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. We believe that many states will be unable or unwilling to sign the agreement and that it fails to consider a number of important concerns. Therefore, we urge that the document be reconsidered.

The first issue is that the FDA overestimates how many states will sign the agreement, which could seriously harm patient access to important pharmaceuticals. Currently, the FDA believes that 45 states will adopt it. This estimate is contrary to comments made by the National Association of Boards of Pharmacy (NABP) indicating that approximately 20 states had serious issues with the MOU, including its definition of distribution to include dispensing, which is contrary to most state laws and both state and federal precedent. If this agreement moves forward, patients are at risk of losing access to key medications from pharmacies in states that do not sign the MOU due to statutory limitations on certain compounding, and many state regulated pharmacies in these states could be severely affected. FDA also estimates that at least one state will withdraw from the agreement each year, meaning that in 10 years less than 35 states would participate.

As we see from the COVID-19 crisis, health care issues are both regional and national in nature. This is the same situation with the availability of many compounded medications. Some compounding pharmacies have developed specialties (e.g., treating organ transplantation, autistic children, pain management, providing total parental nutrition, and treating women with hormonal imbalance) and have a national or regional reputation for their services. If a state where one of these pharmacies is located determines it cannot sign the final MOU, access to these medications by patients in many other states could be negatively affected.

Furthermore, to ensure patient safety and provide regulatory clarity, we must remain consistent in our regulatory definitions. Under the final MOU, and per the statutory limitation, if a state does not sign, pharmacies in that state would be limited to compounded medications that can be "distributed" to other states to no more than 5 percent of their total prescriptions. Unfortunately, FDA has incorrectly included patient specific prescriptions in this limit, claiming that there is no difference between dispensing and distributing. This is inconsistent with federal and state laws, as well as industry practice and the NABP model code that most states have adopted.

Secondly, adopting this MOU in its current form places an undue burden on states. Given that states need the option to review the final document before signing it, and given that signing the MOU may require changes to state laws or regulations, it is a difficult time for them to focus on this issue, especially as states are partnering with the FDA and compounding pharmacies in providing key compounded drugs per the FDA final guidance titled *Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency*. Moreover, most state boards of pharmacy are not even meeting at this time, and are generally holding virtual meetings to conduct business. This is simply not the time for states to consider this extremely significant document.

The final MOU also allows either the individual state or the FDA to withdraw from the agreement with 60 days notice. If FDA decided for any reason that state compliance is lacking, which could result from an unforeseen increase in the actual burden to the states of enforcing the MOU, the agency can unilaterally terminate the agreement. Likewise, if a state believes FDA is being unreasonable and has underestimated the demands of the agreement, it may be forced to terminate its participation in the MOU as FDA predicts some states will do. This creates an uncertain regulatory and economic climate detrimental to the operation of compounding pharmacies and disruptive of the availability of necessary compounded medications to patients.

Lastly, we believe that the analysis submitted by the FDA underestimates the potential cost to state governments, which are finding their resources strained under the current conditions. This underestimation of burden and cost to the states is perhaps the main reason for FDA overestimating the number of states that will sign the agreement. FDA's projection is based on coordination of an "information sharing network" being developed with NABP. While this network would help reduce cost, states would still have to compile this extensive information, which is not reflected in FDA's analysis. Further, it is our understanding that this "network" has yet to be developed and may not be functional by the time that states will need to sign the MOU.

We strongly urge you to reject the final MOU and encourage further revisions. We do not believe that the minor changes made from the draft MOU issued in September 2018 will address the concerns that have been identified with individual states that will have to decide whether to sign the MOU and maintain their participation and compliance with the terms of the agreement. Alternatively, we ask that you insist that FDA correct its definition of distribution to not include patient specific dispensing, an action that would greatly reduce the burden and unfunded mandate contained in the agreement.

We thank you for the consideration. Please do not hesitate to reach out with any questions or concerns.

Sincerely,

Chris Stewart
Member of Congress

John R. Carter
Member of Congress

H. Morgan Griffith
Member of Congress

Earl L. "Buddy" Carter
Member of Congress

Gary Palmer
Member of Congress

Doug Collins
Member of Congress

Andy Biggs
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