July 18, 2019

The Honorable Ned Sharpless, M.D.
Interim Commissioner
Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

[Submitted Electronically to Docket FDA-2018-N-3065]

Dear Commissioner Sharpless:

The undersigned organizations represent thousands of independent and compounding pharmacists who continue to have serious concerns with the current revised Draft Memorandum of Understanding Addressing Certain Distributions of Compounded Drug Products Between the [insert State] Board of Pharmacy and the U.S. Food and Drug Administration (the "MOU"). We appreciate the FDA's efforts to work with the various stakeholders on the MOU, including through the recent listening sessions at the White Oak campus. However, we respectfully request that FDA rescind the current revised draft MOU and issue a new proposed draft MOU, available for public comment, that better balances patient access with public safety.

As we discussed with the FDA Center for Drug Evaluation and Research (CDER) and Compliance teams at the June 20, 2019, listening session, the one issue related to the MOU that unites every stakeholder our organizations have spoken to and worked with on this matter, including pharmacists, prescribers, state pharmacy associations, state boards and others, is the current MOU's defining of the term "distribution" to include the patient-specific dispensing of compounded medications across state lines. By defining the term "distribution" to include patient specific dispensing for purposes of both the MOU and the statutory default 5% cap for pharmacies in states that do not sign the MOU, FDA has asserted regulatory authority over the very essence of the practice of pharmacy in a way that is inconsistent with the Federal Food, Drug, and Cosmetic Act (FDCA) and that will lead to serious patient access problems throughout the country. This issue is foundational to our members' ability to serve our patients – and must be addressed before the MOU is finalized.

Additionally, our organizations, which are established nationwide, share many of the concerns expressed in the comments submitted to the December 2018 docket related to the proposed requirements the MOU would place on the States. One such comment, submitted by the National Association of Boards of Pharmacy (NABP), stated that NABP was informed by approximately 20 States that the current MOU presented a serious conflict because of FDA's use

of the term "distribution." Specifically, these states indicated that they would be unwilling to sign a final MOU that redefines the key term "distribution" to include patient specific dispensing. These states maintain that "distribution" does not include patient specific dispensing, and the use of the term "distribution" throughout the MOU should not be misconstrued to reference the act of dispensing or provide FDA with regulatory authority over the act of dispensing. Thus, as it stands, the current draft MOU is clearly not viable for nearly half the country.

The NABP comments included a redline version of the MOU with their suggested changes, including clarifications about the applicability of the MOU to physician compounding, methods for determining a pharmacy has distributed inordinate quantities, and the reporting requirements on boards, among other concerns. (We do not, however, agree with the footnoted attempt in NABP's redline version to clarify the MOU's definition of "distribution" but does not address the fundamental problems with that definition as discussed above). We believe the FDA should incorporate the suggested redline changes to the MOU (related to requirements on the states but without the footnote on "distribution") submitted by NABP into a new, revised draft MOU. It is imperative that the final MOU be a workable document that all states will be willing and able to sign.

We therefore request that FDA continue to work with stakeholders, including our organizations, NABP, individual state boards of pharmacy, and others, on a workable solution comprised of a new revised draft MOU for public comment that includes NABP's recommendations on the requirements on states, a new definition of "distribution" that does not include patient specific dispensing, as well as a published position that clarifies the penalties for compounders that exceed the 50% threshold.

We believe this workable solution strikes a better balance between FDA's need for data on the interstate shipments of compounded medications (i.e., data regarding whether a pharmacy has exceeded the 50% threshold) and the ability of patients to get their compounded medications from the state licensed and compliant pharmacy of their choosing. Our proposed solution to allow for robust patient access is for FDA to rescind the current draft MOU and issue a new revised draft MOU for public comment that accomplishes the following:

- For purposes of the MOU and the 5% cap, define the term "distribution" to mean a transfer of a compounded human drug product to a prescribing physician (where authorized under applicable state pharmacy laws), pursuant to a prescription drug order from the physician that indicates a medical need for administration to the patient in an office or clinical setting.
- "Distributions" could only be done by 503A pharmacies pursuant to the statutory language in 503A(a)(2) and accompanying Guidance for Industry (GFI) that allow for compounding in limited quantities prior to receipt of a valid prescription order. The statute clearly requires a patient name, but does not indicate ***when*** the pharmacy must obtain the patient name and does not state ***how*** a compounded medication can leave a pharmacy after it has been compounded.
- Establish within the revised draft MOU and within a revised GFI on the prescription requirement that a 503A pharmacy is permitted to "distribute", pursuant to a drug order, a

limited quantity (within the same 30-day supply, prior history and other limitations in the current statute and GFI).

- Establish within the revised draft MOU and within a revised GFI a requirement that a drug order for a limited quantity distribution must indicate that the compounded medication is not currently available from outsourcing facilities in the limited quantity needed by the prescriber.
- For purposes of the 50% inordinate quantities threshold that triggers tracking, investigating and reporting requirements on the state BOPs, include both "distribution" and "dispensing" of human health compounds (i.e. all interstate shipments).
- Establish within the MOU and within a revised GFI a requirement that the administering physician must provide the pharmacy with an electronic or written prescription within 30 days of administration of the drug to the patient. For pharmacies and physicians in the same health system, a requirement for patient names within 30 days.
- Establish a good faith/reasonable effort safe harbor clause for pharmacies on the prescription requirement in the MOU and any related GFI.
- Define what will happen when compounders exceed the 50% interstate shipment threshold, which will include a statement that FDA will be using the information it collects on interstate shipments only to inform its risk-based inspection schedule.
- Establishes that either party to the MOU (state or FDA) may terminate with 120 days advanced notice.

This proposal for a revised MOU and GFI on the prescription requirement would settle the legal questions surrounding FDA's redefining of key statutory terms, would draw broad stakeholder support, and would have the effect of greatly incentivizing states to sign the MOU. It would give the FDA key data on interstate distributions (and dispensing) of compounded drug products to better inform the agency's risk-based inspection schedule, while not applying an arbitrary cap on patient specific dispensing that is not consistent with the statute and that would severely limit access to medications.

By allowing very limited 503A distributions under the existing statutory and GFI framework, the access gap now present for drugs that the 503B outsourcing facilities are unable or unwilling to produce would be solved. Physicians are certainly able to store sterile and non-sterile compounds under these limitations under the same standards as pharmacies. Patient safety would be increased in that sterile compounds could be delivered directly to the prescribing and administering physician instead of directly to the patient, which decreases the likelihood for contamination or exposure to temperature extremes prior to administration by the physician.

Again, we appreciate the willingness of the FDA to continue working with our organizations and other stakeholders on our shared goal of a final MOU that all states will be willing and able to sign. We look forward to your response to this proposal and stand ready to work with you on the details that will so greatly impact our members and the patients they serve. We also stand committed to working with the FDA to educate state boards of pharmacy on a new revised draft MOU that meets this framework, and to being able to encourage all the states to sign it. Please contact David Pore at dpore@hslawmail.com, or by phone at 202-223-8881 if you have any questions or require additional information. Thank you in advance for your consideration of our proposal.

Sincerely,

American Pharmacists Association (APhA)
International Academy of Compounding Pharmacists (IACP)
National Community Pharmacists Association (NCPA)