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Alliance for Pharmacy Compounding

March 29, 2023

Dear Chairman Sanders, Ranking Member Cassidy, Senator Casey, and Senator Romney:

The Alliance for Pharmacy Compounding (APC) appreciates the opportunity to provide input to the Senate Health, Education, Labor and Pensions (HELP) Committee as you consider the Pandemic and All-Hazards Preparedness Act (PAHPA). APC is the voice for pharmacy compounding, representing more than 600 compounding pharmacies and compounding pharmacists and technicians in both 503A and 503B settings, as well as prescribers, educators, researchers and suppliers.

APC is supportive of the committee's efforts to analyze the challenges faced and lessons learned from the global pandemic and our government's response – and if appropriate, to amend the PAHPA to formalize in law provisions that will improve our ability to respond to the next public health emergency. Specifically, we would like to comment on ways we believe the Food and Drug Administration (FDA) could be better positioned in federal law to react to drug shortages that occur due to urgent need during public health emergencies, but also to shortages that occur every day due to supply chain and other interruptions outside the context of a public health emergency.

In the early days of the COVID pandemic, gravely ill patients began to fill America's hospitals. Hospitals ran short of essential treatment medications and were unable to source those drugs from manufacturers or from the outsourcing facilities that had been authorized by Congress in 2013 to "fill the gap" in such situations. At the urging of the APC, FDA issued temporary guidance allowing traditional compounding pharmacies to prepare 13 COVID drugs, within tight regulatory guardrails, from pure ingredients to meet hospitals' urgent need. That action almost certainly saved hundreds of lives, and an FDA official has indicated that no adverse events were reported.

Last autumn, as a triple-threat epidemic afflicted America's children and resulted in a shortage of amoxicillin suspension, compounders asked FDA for a pathway to compound amoxicillin suspension and other beta lactam antibiotics from FDA-approved tablets or capsules – something that existing FDA guidance made very difficult for compounders to do without risking disciplinary action. Three weeks later, FDA issued a guidance document that provided such a pathway, and compounding pharmacies and hospital pharmacies across the country were better able to prepare urgently needed treatments for children.

Presently, many children are suffering as pharmacies across the country are unable to stock FDA-approved, over-the-counter ibuprofen and acetaminophen suspension. Compounding can help here, too, easily creating compounded ibuprofen and acetaminophen suspension from pure ingredients – but only if FDA will add ibuprofen and acetaminophen to its Drug Shortage List and relax temporarily its requirement that pharmacies can only dispense those compounded medications pursuant to a prescription.

Amid continuing drug supply chain disruptions, we know pharmacy compounding can play an essential role in alleviating shortages of urgently needed medications if allowed to do so. These examples we've shared demonstrate that. But it shouldn't take a plea from a trade association and then a three-week lapse in time for

FDA to act when patient health is at stake. Changes to federal law are needed so that when shortage drugs are urgently needed, compounders may assist immediately, without bureaucratic delays and impediments.

That's why we urge Congress to include in any legislation addressing pandemic preparedness and drug supply chain issue provisions to equip state-licensed pharmacy compounders to provide urgent-use medications to hospitals and for in-clinic administration – within tight regulatory guardrails similar to those in FDA's temporary COVID-era guidance – when those drugs are in shortage or otherwise unavailable from a traditional drug manufacturer or a licensed outsourcing facility. We also urge that FDA's Drug Shortage list, which tends to lag the market, be supplemented by the shortage list maintained by the American Society of Health System Pharmacists, which has proven to be a much better real-time indicator of national and regional drug shortages. (If the ASHP list was currently a legal indicator of shortages, pharmacies would already be compounding ibuprofen suspension to meet the need – because ibuprofen *is* on the ASHP shortage list.)

Legislation has been introduced in the House, H.R. 167, the Patient Access to Urgent-Use Pharmacy Compounding Act of 2023, that would put a framework into federal law that will help address drug shortage issues like those discussed above, but not only those above. As the recent pandemic has shown, there are patient access gaps in our health care system that occur when critical drugs go into shortage, including those needed for administration to patients in hospitals and other clinical settings. We ask that the Senate HELP Committee consider including the provisions of this important legislation in the reauthorization of PAHPA now under consideration.

FDA has interpreted Section 503A of the Food, Drug and Cosmetic Act (FDAC) to require pharmacies to obtain a patient-specific prescription for each drug they compound before the drug leaves the pharmacy. This requirement for a patient-specific prescription for an urgent patient need is hampering patient care. For instance, certain patients may need anti-bacterial, anti-fungal, and anti-viral compounded medications to treat eye-infections in immediate if not emergency circumstances. These drugs are often unavailable commercially or from 503B outsourcing facilities authorized to compound without a patient-specific prescription.

Because a delay in providing the medication can result in patient harm, in limited circumstances it is appropriate and necessary for 503A pharmacies to compound the medications without having a patient specific prescription – and ensure that within seven days after the fact the patient-specific information is relayed from the provider to the compounding pharmacy. The patient information can then be married to the pharmacy's records. When the FDA published the temporary COVID-related guidance document 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, the FDA acknowledged that urgent patient need should outweigh prescription requirements for 503A compounding, provided that other safeguards are in place. So there is precedent for what this bill does. It strikes that critical balance.

FDA has also, through guidance for industry documents, utilized enforcement discretion for compounding identified drugs with respect to certain "essentially a copy" requirements. HR167 would codify that flexibility, while also providing safeguards to protect patients from further drug shortages by expanding the shortage definition to include the FDA's list of drug shortages and shortages identified by the American Society of Health-System Pharmacists (ASHP), given that ASHP's list encompasses local and regional (not just national) shortages.

Again, we thank you for this opportunity to provide input to the HELP Committee. We urge you to include HR 167 in the reauthorization of the PAHPA so as to put a permanent framework into law that will allow compounding pharmacists to help address drug shortages within tight guardrails that protect patient safety.

Had these provisions been in place over the past three years, we feel confident that the impact of recent amoxicillin and ibuprofen and acetaminophen suspension shortages would not have been nearly so severe and long-lasting. The same goes for shortages of numerous other drugs. It's a problem compounding pharmacies can prevent, but only if allowed to do so in law and regulation.

Please feel free to contact me at Scott@A4PC.org with questions or if the Committee would like additional input from APC.

Sincerely,

Scott Brunner, CAE
Chief Executive Officer