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Alliance for Pharmacy Compounding

August 25, 2023

Dear Chairwoman Rodgers:

The Alliance for Pharmacy Compounding (APC) appreciates the opportunity to provide input to the House Energy and Commerce Committee on the discussion draft legislation released by the Committee on July 28, 2023.

APC is the voice for pharmacy compounding, representing more than 600 compounding pharmacies and facilities, including compounding pharmacists and technicians in both 503A and 503B settings, as well as prescribers, educators, researchers and suppliers. Pharmacists' ability to compound medications from pure ingredients is authorized in federal law and for good reason: manufactured drugs don't come in strengths and dosage forms that are right for everyone, and prescribers need to be able to prescribe customized medications when, in their judgment, a manufactured drug is not the best course of therapy for a human or animal patient.

Beyond its role in providing customized medications when a commercially available drug is not suited to a patient, *pharmacy compounding can play an essential role in addressing disruptions in our nation's drug supply chain – and empowering pharmacy compounders to alleviate temporary drug shortages must be a component of any drug shortage legislation.*

In this era of rampant drug shortages, the focus of Congress has rightly been on root causes and long-term fixes. But we urge that Congress also attend to alleviating supply chain gaps in the near-term – the shortages that are resulting here and now in patients not receiving urgently needed medications. There already exists a system for addressing such temporary shortages – the components are in place – but certain restrictions hinder the ability of those components to act. What is needed – and what we propose – is a regulatory framework that facilitates rapid and urgent response by compounding pharmacies and outsourcing facilities, in tandem, to meet the *immediate* medication needs of patients in hospitals and clinics when those drugs are commercially unavailable.

To this end, APC is supportive of Section 503 of the Committee's discussion draft, which would allow 503B outsourcing facilities to compound a drug within 30 days of it appearing on FDA's shortage list and to distribute and dispense compounded drugs within 180 days of such drug appearing on the drug shortage list. This provision strengthens the economic incentive for outsourcing facilities to make the time and financial investment and undertake testing required under current Good Manufacturing Practices (cGMP) – which is why it often takes several months for 503Bs to begin production – with a higher level of assurance that they will be able to distribute or dispense those shortage drugs within the lag period in Section 503 envisioned by the discussion draft.

However, APC believes that discussion draft should clarify in statute that both 503A state licensed pharmacies and 503B outsourcing facilities can compound drugs on either the FDA drug shortage list or the American Society of Health System Pharmacists (ASHP) drug shortage list. Why add the ASHP list? Because it is updated much more frequently and reflects regional drug shortages, it's widely seen as a better real-time indicator of drug shortages than the FDA shortage list. This suggestion is discussed in more detail below.

But 503Bs alone, even with the provisions we support above, are not sufficient to address temporary drug shortages. Traditional 503A compounding pharmacies must also be empowered in law to assist – a sort of cascading *system* in which the 503A fills the temporary gap in supply until the 503B can ramp up production. Currently, the FDA does not seem to recognize the simplicity of such a systematic approach to temporary drug shortage. The agency touts 503Bs, but without seeming to recognize the lengthy ramp-up time to produce certain drugs in shortage. What about in the interim? Also, earlier this year the agency very publicly engaged a Chinese manufacturer to provide urgently needed cancer drugs and did so without conversation with or consideration of what 503Bs, much less 503As, could do to help.

That must change.

In addition to supporting Section 503 of the draft, APC supports the inclusion of additional provisions in the draft that will improve the ability of compounding pharmacies to help respond to drug shortages, including those that will undoubtedly occur with the next public health emergency.

There is clear precedent for the approach we propose. 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 503A 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, APC asked FDA for a pathway to allow 503A pharmacies 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.

More recently, many children suffered as pharmacies across the country were unable to stock FDA-approved, over-the-counter ibuprofen and acetaminophen suspension. Compounding could have helped here, too, easily creating compounded ibuprofen and acetaminophen suspension from pure ingredients – but they could not because ibuprofen and acetaminophen never appeared on the FDA Drug Shortage List, and FDA did not relax temporarily its requirement that pharmacies only dispense compounded medications pursuant to a prescription. Few prescribers even knew to write a prescription for a compounded version of those over-the-counter medications.

And most recently, a July 19, 2023 tornado damaged the Pfizer manufacturing facility in Rocky Mount, NC. Most of the damage caused by the tornado was not to the production area of the facility but to the warehouse facility where raw materials, packing supplies, and finished medicines were stored. In a July 21, 2023 letter to customers, Pfizer identified drugs manufactured at the facility for which they anticipate supply disruptions due to the damage caused to the facility by the tornado. *Of the 66 drugs identified in the Pfizer letter to customers (see Pfizer customer letter and drug list analysis attached) 13 of those drugs appear on the ASHP drug shortage list but have not, as of the date of this letter, been included on the FDA shortage list – currently putting them out of reach of pharmacy compounders to prepare.* The vast majority of these drugs are intended for distribution to hospitals or other clinical settings for administration to patients without a patient-specific prescription.

While outsourcing facilities are allowed under Section 503B of the FDCA to compound drugs on the FDA shortage list and to distribute to hospitals and other prescribers without a patient-specific prescription, they would not be able to compound those 13 drugs on the ASHP shortage list that are not yet on the FDA shortage list. Additionally, some of the drugs Pfizer has identified will require extensive testing under cGMP requirements required under Section 503B, creating a weeks- or months-long delay before the 503B will be able to compound those drugs. How will hospitals and clinics source those shortage drugs in the interim?

In this circumstance, while 503B outsourcing facilities are ramping up testing and production of a shortage drug, 503A pharmacies must be allowed to compound urgently needed drugs, in limited quantities and within tight regulatory guardrails, and to distribute those to prescribers when urgently needed for administration to patients – but only until such time that the outsourcing facilities are able to provide the drug. This model is quite similar to the framework established under FDA temporary emergency guidance during COVID. And, as we have indicated, the components are already in place: 503A sterile compounding pharmacies are already *equipped* to do this if *allowed* to do so under the law.

It is a common-sense solution that would make an immediate impact on this unnecessary gap in patient access in the current legal and regulatory framework.

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 weeks-long 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 drug shortages 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 ASHP, 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 many of these drugs to meet the need).

Legislation has been introduced in the House, H.R. 167, the Patient Access to Urgent-Use Pharmacy Compounding Act of 2023, that would put this framework into federal law to help address temporary drug shortages 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 House Energy and Commerce Committee consider including the provisions of this important legislation in the drug shortage legislation 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 when a drug is in shortage it is appropriate and necessary for 503A pharmacies to compound the medication 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 its 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 agency 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 ASHP.

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 impending shortages of numerous other drugs, such as those resulting from the tornado damage to Pfizer's Rocky Mount manufacturing facility. These are problems compounding pharmacies can help mitigate, but only if allowed to do so in law and regulation.

Again, we thank you for this opportunity to provide input to the Energy and Commerce Committee. We urge you to include HR 167 in any legislation intended to address drug shortages in order to put a permanent framework into law that will allow compounding pharmacists to help address drug shortages within tight guardrails that protect patient safety.

Please 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