Alliance for Pharmacy Compounding

APC COMPOUNDERS ON CAPITOL HILL 2022

1. A Fix for Drug Shortage and Supply Chain Issues

PATIENT ACCESS TO URGENT-USE PHARMACY COMPOUNDING ACT OF 2023

The proposal would allow 503As to fill the gap in temporary drug shortages until 503Bs can ramp up

THE ISSUE: By publishing its 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 has acknowledged the value of 503A compounding in addressing *temporary* shortages of critical drug products. House legislation, HR 167, codifies a policy, largely based on the temporary guidance document, to address both urgent need and drug shortages. Companion language should be added to any Senate pandemic preparedness or drug shortage legislation.

HR 167, the **Patient Access to Urgent-Use Pharmacy Compounding Act of 2023**, sponsored by Rep. Morgan Griffith (R-VA) and Henry Cuellar (D-TX), would create a permanent path, within tight regulatory guardrails similar to those in FDA's 2020 temporary guidance document, for 503A pharmacies to provide urgent use and shortage drugs to hospitals and physicians, *but only when those drugs cannot be sourced from the manufacturer or a 503B outsourcing facility*. The legislation was introduced in early January 2023 and has been referred to the Subcommittee on Health.

THE ASK: Members of Congress must recognize that 503A pharmacies play a safe, valuable role in alleviating temporary drug shortages – especially while 503B outsourcing facilities are ramping up to produce a shortage or urgent use drug under current good manufacturing practices.

• **House Members:** Cosponsor HR 167 and ask the Energy & Commerce committee to include HR 167 in any drug shortage or pandemic preparedness package. Contact Alicia Seagraves in Representative Henry Cuellar's office or Davis Michols in Representative Morgan Griffith's office to sign on as a cosponsor.

• **Senators:** Please sponsor an effort to include the language of HR 167 in any drug shortage or pandemic preparedness package.

2. Compounding pharmacy reporting to state boards and FDA

Pharmacy Compounding Reporting Act of 2023

This proposal would implement in law two important requirements for providing reporting on compounded drugs to FDA:

1. It would repeal a 1997 MOU requirement in the Food, Drug & Cosmetic Act – and the burden of FDA having to cajole states sign an MOU – and replace it with a requirement for reporting to state boards of pharmacy by all traditional compounding pharmacies that ship more than 50 percent of their compounded drugs out-of-state. This goes well beyond the reporting required under the 1997 MOU directive, to include reporting on compounded drugs dispensed pursuant to a patient specific prescription.

2. It would create a framework for mandatory reporting of adverse events by traditional compounding pharmacies – a requirement long sought by FDA.

THE ISSUE: In 1997, Congress directed FDA to execute a memorandum of understanding (MOU) under which state boards of pharmacy would report to the agency certain information about state-licensed compounding pharmacies that *distributed* a large percentage of their compounded drugs across state lines. Passage of DQSA in 2013 made obsolete the need for such an MOU by creating a new category of compounding facility, 503B outsourcing facilities, effectively prohibiting traditional compounding pharmacies from distributing compounded drugs in non-patient-specific batches. The MOU directive should be repealed. Yet FDA's desire for reporting by compounding pharmacies that ship more than 50% of their production out-of-state, as well as reporting of adverse events by compounding pharmacies, are not unreasonable. Along with repeal of the MOU requirement, this proposal would accomplish such reporting.

THE ASK: ????

3. The Threat to Compounded Hormone Therapy

THE ISSUE: FDA SAYS IT WILL RELY ON A DISCREDITED REPORT ON COMPOUNDED HORMONES

We are deeply concerned that FDA may attempt to restrict access to compounded hormones – life-enhancing therapies that millions of American women and other patients have relied on for years – and that it may do so based on a discredited 2020 report it commissioned from the National Academies of Sciences, Engineering, and Medicine (NASEM).

THE ASK:

It's important for Members of Congress to be aware of this threat and the potential impact FDA restrictions could have on many of your constituents. Go to www.compounding.com to read and hear stories, cataloged by state, from patients whose lives have been enhanced, even saved, by compounded hormone therapy. The outcomes reported by patients are overwhelmingly positive.

House Members: Please contact the FDA to express concern about bias and lack of scientific rigor in the FDA-funded NASEM report and FDA's implicit threat to restrict compounded hormones.

Senators: Please add your name to a letter to FDA led by Senators Baldwin (WI) and Marshall (KS) urging the agency to base any action on compounded hormones on rigorous science and stakeholder input. The letter has been included in your packet. Contact Erin Dugan in Senator Baldwin's office or Charlotte Pineda in Senator Marshall's office to sign on.