APhA
American Pharmacists Association

August 25, 2023

The Honorable Cathy McMorris Rodgers
Chair
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, D.C. 20515

RE: Request for Comments: The Stop Drug Shortages Act

Submitted via email to drugshortages@mail.house.gov

Dear Chair McMorris Rodgers:

The American Pharmacists Association (APhA) appreciates the opportunity to submit comments to the House Energy and Commerce Committee on your request for feedback on the discussion draft legislation to address drug shortages. APhA is supportive of efforts by Congress to help identify causes of drug shortages and make recommendations for policy solutions to help prevent and mitigate future drug shortages in the United States. APhA recommends Congress consider APhA's House of Delegates policy on "Drug Supply Shortages and Patient Care," when identifying strategies for preventing and mitigating drug shortages.

APhA is the only organization advancing the entire pharmacy profession. APhA represents pharmacists, student pharmacists, and pharmacy technicians in all practice settings, including but not limited to community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

Title V: Food and Drug Administration
Sec. 501. Noncompliance Letters Relating to Volume Reporting
This section would require the issuance of a noncompliance letter to any person failing to comply with volume reporting requirements and make public on the FDA website such letter and any written responses within 60 days after issuing a noncompliance letter.

Noncompliance letters could serve as an incentive to ensure manufacturers comply with volume reporting requirements to ensure essential medications do not end up in a shortage. As

2215 Constitution Ave. NW
Washington, DC 20037
800 237 2742
pharmacist.com

stated by FDA, only 44 percent of companies are complying with existing requirements to report information on the volume of drugs made at each facility to the FDA.

Sec. 503. Providing for a Lag Period for Outsourcing Facilities to Compound and Distribute Drugs in Shortage
This section would allow 503B compounding facilities to compound a drug within 30 days of appearing on FDA's drug shortage list and to distribute and dispense a compounded drug within 180 days of such drug appearing on the drug shortage list.

APhA supports compounding by trained pharmacists and pharmacies for drugs on FDA's drug shortage list. However, while hospitals and health care providers can obtain a portion of their products from 503B facilities, 503B facilities cannot supply all their compounding products because compliance with current good manufacturing practice (CGMP) requirements makes it cost and/ or time-prohibitive, which is why many 503B facilities have defined formulary lists. CGMP requirements include: procurement of bulk drug product(s) that meets CGMP; authoring procedures to compound the medication that meets CGMP; proper testing (validation, release testing, stability testing), and other requirements. APhA members' conversations with 503B facilities have confirmed the inability of 503B facilities to supply many small-batch medications. Therefore APhA, strongly urges the Committee to include legislation to allow 503A pharmacies to compound "limited quantities" without a patient-specific prescription and defer to states for statutory or regulatory authority over pharmacies' office use compounding.

APhA also strongly encourages the Committee to add language from H.R. 167, the Patient Access to Urgent-Use Pharmacy Compounding Act, sponsored by Reps. Morgan Griffith (R-VA) and Henry Cuellar (D-TX) to create a permanent path, similar to that in FDA's 2020 temporary guidance, allowing 503A pharmacies to compound certain medications that were in severe shortage when those drugs could not be acquired from manufacturers or 503B outsourcing facilities for 503A pharmacies to provide urgent use and shortage drugs to hospitals and physicians.

For drug shortages of non-sterile medications, APhA also recommends the Committee add language outlined in APhA's January 2023 letter to FDA requesting FDA recognize the shortages of ibuprofen and acetaminophen oral suspensions for pediatric populations by placing them on the FDA drug shortage list and issue temporary guidance to allow the compounding of these medications with an exemption for the essential copies and prescription requirement provisions for these products until such time that sufficient supply is available across the country.

Sec. 504. Additional Information on Generic Drug Active Pharmaceutical Ingredients (API)
This section would require generic drug application holders to include information related to the API manufacturer upon which they rely on for more than 60 percent of API supply and require a sponsor to report annually on the volume of API.

APhA supports an annual report on the volume of API used in the manufacturing of a drug that would provide the data needed for greater transparency of API manufacturing. Additionally, APhA recommends providing incentives to diversify manufacturing of low-cost generics and APIs across facilities and geographic areas, as well as more robust national strategic supplies or buffer stocks of essential medications.

Sec. 505. Reporting on Use of New Authorities and Requirements with Respect to Drug Shortages
This section requires the Secretary to report to Congress no later than 90 days after the date of enactment of this act the extent to which FDA has implemented its authorities and required guidance with respect to drug shortages.

APhA supports a report from FDA to Congress on how the agency is addressing drug shortages to provide the accountability necessary to ensure FDA is implementing the steps needed to prevent and mitigate medication shortages for patients in need.

Sec. 506. New Domestic Facility Inspection Pilot Program
This section would establish a pilot program under which FDA would conduct preapproval inspections for new domestic pharmaceutical manufacturing facilities for the purposes of expediting the licensure and distribution of domestically manufactured generic drugs.

APhA supports increasing domestically manufactured generic drugs. However, Congress would need to provide FDA with additional funding to increase inspection coverage and review of new manufacturing facilities to implement this pilot program (e.g., hiring more FDA staff to conduct these inspections and assess compliance and quality of drugs produced in these facilities, as well as the ability for personnel working on drug shortage prevention and mitigation to quickly address potential shortages).

Conclusion
APhA appreciates the opportunity to provide feedback on the House Energy and Commerce Committee's discussion draft legislation to address drug shortages. Pharmacists play a critical role in helping to manage drug shortages for their patients. APhA encourages members of Congress to leverage the expertise of our nation's pharmacists and other stakeholders as you consider solutions for addressing drug shortages in the United States. If you have any questions or need any additional information please contact Heather Boyd, Director, Health Policy at hboyd@aphanet.org.

Sincerely,

Michael Baxter

Michael Baxter
Acting Head of Government Affairs