MEMORANDUM

To: Subcommittee on Health Members and Staff
From: Committee on Energy and Commerce Majority Staff
Re: Health Subcommittee Hearing on September 14, 2023

The Subcommittee on Health will hold a hearing on Thursday, September 14, 2023, at 10:00 a.m. (ET) in 2123 Rayburn House Office Building. The hearing is entitled "Legislative Proposals to Prevent and Respond to Generic Drug Shortages."

I. Witnesses

- **Michael Ganio, Pharm.D., M.S., BCSCP, FASHP,** Senior Director, Pharmacy Practice and Quality, American Society of Pharmacy Professionals (ASHP)
- **Todd Ebert, R.Ph.,** President and CEO, Healthcare Supply Chain Association (HSCA)
- **Chester "Chip" Davis, Jr., JD,** President and Chief Executive Officer, Healthcare Distribution Alliance (HDA)
- **Melissa Barber, PhD**, Postdoctoral fellow at the Yale School of Medicine, Yale Law School, and Yale Collaboration for Regulatory Rigor, Integrity, and Transparency (CRRIT)
- **Allan Coukell**, **BScPharm**, Senior Vice President, Public Policy, Civica
- **David Gaugh, R.Ph.,** Interim President and CEO, Association for Accessible Medicines (AAM)

II. Background

Currently, the U.S. Food and Drug Administration (FDA) drug shortage database is reporting 138 drug products as in shortage and, according to the American Society of Health System Pharmacists (ASHP) ongoing and active drug shortages are at the highest level they have been in a decade.[1][2] Many of these products are critical, life-sustaining medications, including chemotherapeutics for the treatment of cancer, or albuterol, used to resolve acute asthma attacks. Drug shortages negatively impact patient health outcomes and contribute to significant financial costs to the U.S. health care system. An FDA report on the root causes of drug shortages estimates that drug shortages costs hospitals $559 million each year in labor costs and in efforts to identify alternatives for drug products facing supply disruptions.[3]

[1] U.S. Food & Drug Administration, *FDA Drug Shortages Database*, *https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm* (last accessed September 5, 2023)
[2] American Society of Health-System Pharmacists (ASHP), *Drug Shortages Statistics: National Drug Shortages, New Shortages by Year, January 2001 to June 30, 2023*. https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics
[3] U.S. Food & Drug Admin., Drug Shortages: Root Causes and Potential Solutions (2019),

The causes of drug shortages are multifactorial and occur at various points across the pharmaceutical supply chain. There is consensus among industry experts and federal agency officials that the driving forces underlying recent and ongoing shortages are economic in nature, resulting from market distortions and misaligned incentives within the supply chain, particularly affecting low-cost generics, which comprise more than 90 percent of retail prescriptions filled in the U.S.[4] and two-thirds of shortages at any given time.[5] Various pricing mechanisms including "race to the bottom" pricing, particularly for sterile injectable drugs, have impacted the sustainability of low-cost generic manufacturing and ultimately reduced investments directed towards foreign and domestic manufacturing capacity.[6,7] These and other economic pressures contribute to less redundancy and increased quality and compliance risks across the supply chain.

Congress, the Biden administration, health care providers, and stakeholders across health care, have considered a range of policy solutions aimed at addressing the underlying causes of shortages and the public health risks posed by these supply disruptions. Members of Congress have proposed policy options that examine all parts of the supply chain, including federal reimbursement programs, existing FDA supply chain authorities, and transparency regarding supply chain intermediaries, such as wholesale drug distributors and group purchasing organizations.

III. Legislation

H.R.___, Stop Drug Shortages Act – Discussion Draft (Rep. Cathy McMorris Rodgers, R-WA)

H.R. ____, the Stop Drug Shortages Act, addresses drug shortages through a number of provisions to increase reimbursement for sterile generic injectable drugs in shortage or those made by multiple manufacturers indicated for a serious disease or condition. Specifically, the bill would suspend additional inflationary rebates for sterile, injectable, generics and generic drugs at risk of or in shortage, exempt certain generic, sterile, injectables from 340B rebates, and require the Centers for Medicare and Medicaid Services (CMS) to phase-out the rebate reduction in Medicare Part D and Part B for drugs exiting a shortage. Specifically, the bill would suspend additional inflationary rebates for sterile, injectable, generics and generic drugs at risk of or in shortage, exempt certain generic, sterile, injectables from 340B rebates, and require CMS to phase-out the rebate reduction in Medicare Part D and Part B for drugs exiting a shortage.

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[4] IQVIA Institute, The Use of Medicines in the U.S. 2023,https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/the-use-of-medicines-in-the-us-2023/the-use-of-medicines-in-the-us-2023.pdf

[5] Hernandez, Immaculda, PhD et. al. *National Library of Medicine, National Center for Biotechnology Information* (2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7099531/

[6] Anthony Sardella, US Generic Pharmaceutical Industry Economic Instability, Washington University (Apr. 21, 2023), https://olin.wustl.edu/docs/Research/CABI-US-Generic-Pharmaceutical-Industry-Economic-Instability.pdf

[7] U.S. Food & Drug Admin., Drug Shortages: Root Causes and Potential Solutions (2019), https://www.fda.gov/drugs/drug-shortages/report-drug-shortages-root-causes-and-potential-solutions

The bill would also require the Department of Health and Human Services (HHS) to study market-based pricing for shortage drugs under Medicare Part B and Medicare coding for drugs in shortage or in danger of shortage and requires the Center for Medicare and Medicaid Innovation (CMMI) to launch a model testing market-based pricing reimbursement policy for generic, sterile injectables and other Part B drugs in shortage for the purpose of updating Medicare billing and coding policies. H.R. ___ would also put in place disclosure requirements for group purchasing organizations (GPOs) and reporting metrics for hospitals as conditions of participation in Medicare.

Finally, the bill would require the FDA to report on its existing authorities related to the drug supply chain and generic application holders to provide more transparency on the sources of active pharmaceutical ingredient (API), provide FDA authority to list publicly those not in compliance with existing reporting requirements, and would establish a pilot program requiring FDA to inspect new domestic sterile injectable manufacturing facilities more rapidly. H.R. ___ would also award additional market exclusivity for drugs submitting shelf-life extension studies and would also provide 503B compounding facilities, from the date a drug comes off the U.S. FDA database for drug shortages, 30 days to continue compounding such drug and 180 days to distribute such drug.

H.R. 3008, Drug Shortage Prevention Act of 2023 (Rep. Sara Jacobs, D-CA)

H.R. 3008 would expand existing drug shortage notification requirements by requiring drug manufacturers to notify the FDA of a permanent discontinuance or interruption in the manufacture of an excipient (inactive ingredient in a drug), or API that is likely to result in meaningful disruption in supply. The legislation would also expand the requirement so manufacturers would be required to notify the FDA when that manufacturer experiences an increase in demand of the finished dosage form, API, excipient, or any other input such that it is likely to lead to a shortage of the drug, API, excipient, or any other input. The bill would require the FDA to issue guidance on such notifications, through consultation with industry and public health officials, not later than 180 days after the enactment of the bill.

H.R. 3810, Drug Origin Transparency Act of 2023 (Rep. Anna Eshoo, D-CA)

H.R. 3810 would expand existing API reporting requirements by requiring quarterly reporting (rather than annually) to the FDA on the identity of API suppliers and amounts of drugs manufactured, prepared, propagated, compounded, or processed using API and other in-process materials from each supplier. The bill would also require that a drug containing an API include on its label the name and place of business of the API supplier and the unique facility identifier of the original manufacturer of such drug or API.

H.R. 3793, Ensuring Access to Lifesaving Drugs Act of 2023 (Rep. Elissa Slotkin, D-MI)

H.R. 3793 would authorize the FDA to require manufacturers of life-saving drugs to submit expiration and stability testing studies and make labeling changes regarding its expiration date or storage and handling of the drug based on the studies, and include civil monetary penalties and criminal penalties if manufacturers do not comply with the order of the FDA.

H.R. 167, Patient Access to Urgent-Use Pharmacy Compounding Act of 2023 (Rep. H. Morgan Griffith, R-VA)

H.R. 167 would allow 503A facilities to compound drugs when a licensed prescriber certifies to the pharmacist that such prescriber has made reasonable attempts to obtain but has not been able to obtain, a drug to address an urgent medical need, so long as other conditions are met. It would also expand when a compounded drug does not meet the definition of "essentially a copy of a commercially available drug product" to include drugs on both the FDA Drug Shortages Database or the American Society of Hospital Pharmacists Drug Shortages List.

IV. Staff Contacts

If you have questions regarding this hearing, please contact Caitlin Wilson, Clare Paoletta, or Seth Gold of the Committee staff at 202-225-3641.