

Congress of the United States
Washington, DC 20515

June 12, 2023

To Interested Parties:

We write today seeking information from stakeholders on the ongoing surge in drug shortages that continues to jeopardize patient access to care across the country. Emerging and persistent shortages currently impact medicines for a wide range of conditions, from pediatric cancer to the common flu.¹ Between 2021 and 2022, new medication shortages spiked by close to 30 percent,² and according to the American Society of Health-System Pharmacists (ASHP), “Ongoing and active shortages are the highest since 2014.”³ The *New York Times* recently reported that shortages have begun to approach an “all-time high.”⁴

For American families, these trends can pose dire consequences, from life-threatening delays in treatment to drug rationing and devastating financial strain. A May 2023 study from the Office of the Assistant Secretary for Planning and Evaluation (ASPE) found that the average shortage affects roughly half a million consumers and triggers a host of direct and indirect costs for both patients and frontline health care providers.⁵ While some shortages resolve relatively quickly, others can last for well over a decade,⁶ denying access to crucial therapies and forcing those living with even the most serious medical conditions to seek out alternatives or suffer from debilitating lapses in care.

Most experts and officials agree that, as summarized by the Food and Drug Administration (FDA) in a 2020 report, “economic forces are the root causes of drug shortages,”⁷ as market distortions,⁸ misaligned incentives,⁹ and warped pricing dynamics¹⁰ have resulted in sprawling supply chains¹¹ and rising disruption risks. Low-cost generic medications, which account for more than 90 percent of retail prescriptions filled across the U.S.,¹² have proven particularly vulnerable, comprising around two-thirds of shortages at any given time.¹³ Given that generic prescriptions drive vital savings for consumers, with American prices averaging roughly 16

¹ <https://qualitymatters.usp.org/whats-driving-drug-shortages-during-cold-and-flu-season>

² <https://www.hsgac.senate.gov/wp-content/uploads/Drug-Shortages-HSGAC-Majority-Staff-Report-2023-03-22.pdf>

³ <https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics>

⁴ <https://www.nytimes.com/2023/05/17/health/drug-shortages-cancer.html>

⁵ <https://aspe.hhs.gov/sites/default/files/documents/87781bc7f9a7fc3e6633199dc4507d3e/aspe-rtc-costs-drug-shortages.pdf>

⁶ <https://www.npr.org/2023/03/26/1166141399/drug-shortages-and-national-security>

⁷ <https://www.fda.gov/media/131130/download>

⁸ <https://www.goodmaninstitute.org/wp-content/uploads/2023/03/GI-Why-Are-There-Drug-Shortages.pdf>

⁹ https://d1dth6e84htgma.cloudfront.net/Witness_Testimony_Sardella_5_11_23_b932ed112a.pdf?updated_at=2023-05-10T18:13:11.412Z

¹⁰ <https://www.jmcp.org/doi/full/10.18553/jmcp.2022.28.5.573?mobileUi=0>

¹¹ <https://www.healthaffairs.org/doi/10.1377/hlthaff.2022.01120>

¹² <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>

¹³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7099531/>

percent less than in non-U.S. countries,¹⁴ weaknesses in our ability to supply these products with reliability and predictability could lead to catastrophic effects for affordability, access, and quality moving forward.

While some policymakers have looked to the FDA as the sole source of prospective solutions for these steep challenges, on-the-ground realities tell a far different story. Current FDA Commissioner Robert Califf, for instance, has emphasized the need for policy approaches that address the “fundamental economics” at the heart of the ongoing shortage surge,¹⁵ and a March 2023 report by the Government Accountability Office (GAO) further underscores the limitations facing federal agencies, including FDA, as they seek to exercise oversight of the global medication supply chain.¹⁶

Unfortunately, a range of leaders and analysts have indicated that federal programs, which account for a large and growing share of retail drug spending, have likely contributed to, rather than combated, medicine shortages. Former FDA Commissioner Scott Gottlieb, for instance, recently asserted that the inflation-based price controls enacted under the Inflation Reduction Act (IRA) seem likely to “exacerbate” shortages in the months and years ahead,¹⁷ and the *Wall Street Journal* Editorial Board has similarly contended that “Shortages of essential medicines...are a portent of what’s to come with the Inflation Reduction Act’s price controls,”¹⁸ as government-imposed price caps constrain low-margin manufacturers’ ability to respond to disruptions or other supply shocks. Scholars and stakeholders have also pointed to existing federal price-containment programs and mandates, such as the 340B Drug Discount Program¹⁹ and the Medicaid Drug Rebate Program,²⁰ as drug shortage drivers. The role of key intermediaries, including wholesalers and group purchasing organizations, may also warrant attention as policymakers look to understand the economics shaping shortage dynamics, particularly in light of the high market concentration among these entities.^{21, 22}

On May 11, the Oversight and Investigations (O&I) Subcommittee of the Energy and Commerce Committee held a hearing entitled “Examining the Root Causes of Drug Shortages: Challenges in Pharmaceutical Drug Supply Chains,” where Members raised bipartisan concerns around the complex factors fueling medication shortages, along with the geopolitical risks posed by current drug supply chain structures.²³ Calls for a closer look at shortage risks also arose in the context of a March 30 Senate Finance Committee hearing on the prescription drug ecosystem.²⁴ The

¹⁴ <https://aspe.hhs.gov/reports/international-prescription-drug-price-comparisons>

¹⁵ <https://docs.house.gov/meetings/IF/IF14/20230511/115917/HMTG-118-IF14-Transcript-20230511.pdf>

¹⁶ <https://www.gao.gov/assets/gao-23-105650.pdf>

¹⁷ <https://twitter.com/ScottGottliebMD/status/1660327896395726849>

¹⁸ <https://www.wsj.com/articles/drug-shortages-price-controls-government-fda-white-house-cancer-treatments-b2d08ba4>

¹⁹ <https://www.goodmaninstitute.org/wp-content/uploads/2023/03/GI-Why-Are-There-Drug-Shortages.pdf>

²⁰ https://www.accessiblemeds.org/sites/default/files/2017-09/Bates-White-White-Paper-Report-CPI-Penalty-09-12-2017.pdf?_ga=2.109268933.1769573342.1685577485-537230923.1685380720

²¹ <https://www.commonwealthfund.org/publications/issue-briefs/2022/jul/impact-pharmaceutical-wholesalers-drug-spending#:~:text=Wholesalers%20Can%20Improve%20or%20Worsen%20Drug%20Shortages&text=In%202021%2C%20more%20than%20100.has%20a%20quality%20control%20problem.>

²² <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7099531/>

²³ <https://energycommerce.house.gov/events/oversight-and-investigations-subcommittee-hearing-examining-the-root-causes-of-drug-shortages-challenges-in-pharmaceutical-drug-supply-chains>

²⁴ <https://www.finance.senate.gov/hearings/pharmacy-benefit-managers-and-the-prescription-drug-supply-chain-impact-on-patients-and-taxpayers>

growing bipartisan, bicameral interest in exploring policy options for addressing drug shortages necessitates a comprehensive, thoughtful, and deliberative approach, with substantial input from both nongovernmental and federal entities.

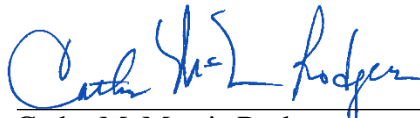
As our committees work to examine the drivers of life-threatening medication shortages, as well as to pursue potential policy solutions to bolster patient access and shore up our critical drug supply chains, we request feedback on the inquiries outlined below. Please submit any responses to drugshortages@mail.house.gov by July 7. If you have questions about this request, please contact Caitlin Wilson of the Energy and Commerce Committee staff and Conor Sheehey of the Senate Finance Committee staff.

1. How would you define the scope and impact of the recent and ongoing U.S. drug shortages?
 - a. For drugs currently in shortage, what percentage of their market is reimbursed through public payers, such as Medicare and Medicaid?
 - b. What are the impacts of recent and recurring shortages of generics and other critical medicines on patient care?
2. What market and economic conditions undermine pharmaceutical supply chains or the availability of drugs? Please discuss any specific barriers in public payment programs.
3. What are the regulatory challenges to manufacturing drugs in the United States, as compared to other countries? Please specify which agency issued and enforced such regulations.
4. How can federal agencies, such as Centers of Medicare and Medicaid (CMS), better address the economic forces driving shortages? Are these agencies using their current authorities effectively?
5. How does the current generic drug reimbursement structure in federal programs, including those programs' mandatory discounts and rebates, contribute to drug shortages, and what solutions exist?
6. Given that supply chain issues can trigger manufacturing delays and disruptions that result in shortages, are further incentives necessary to address manufacturing issues?
7. What role, if any, has growth in the 340B program played in drug shortage trends?
8. Would innovative CMS reimbursement models for drugs at risk of shortage status better allow manufacturers of these drugs to meet production and patient demand? What factors should be incorporated into any model seeking to address shortages?
9. How do existing inflation penalties in Medicaid and Medicare create additional barriers for generic manufacturers, leading to drug shortages? How does the discretion given to CMS to reduce or waive these penalties for drugs on the FDA's Drug Shortage list, as

well as certain drugs facing severe supply chain disruptions, introduce additional uncertainty into drug development, and what can be done to remedy that uncertainty?

10. How might uncertainty in the drug coverage process, particularly as it relates to National Coverage Determinations (NCD) and coverage paradigms like Coverage with Evidence Development (CED), affect competition and, ultimately, the supply of drugs? What can be done to promote greater certainty in that process for FDA-approved drugs?
11. Are there any guardrails that Congress should to consider related demonstration projects, including via the CMS' Innovation Center, that would help protect against drug shortages? Are there any proactive demonstrations that would prevent drug shortages?
12. How has consolidation among Group Purchasing Organizations and Prescription Drug Wholesalers led to less redundancy in the drug supply chain? Has this consolidation contributed to drug shortages, especially among generic drugs? Have business practices, such as just-in-time deliveries and limited-source contracts contributed to the drug shortage issue we are seeing?
13. What factors would lead to a generic drug receiving approval but not coming to market?
14. Are there any other issues leading to drug shortages that we have not considered in this RFI?

Sincerely,



Cathy McMorris Rodgers
Chair
House Energy and Commerce Committee



Mike Crapo
Ranking Member
Senate Finance Committee