



**Response of the
American College of Physicians
to the U.S. House Ways and Means Health Subcommittee
on
Examining Chronic Drug Shortages in the United States
February 6, 2024**

The American College of Physicians (ACP) is pleased to provide this statement to the House Ways and Means Health Subcommittee on its hearing to examine the harmful effects of drug shortages on patient care. We commend Chairman Buchanan and Ranking Member Doggett in conducting this hearing to find solutions that address this critical issue. ACP policy supports legislation to: 1) ensure pricing transparency among prescription drug manufacturers and suppliers; 2) allow Medicare to negotiate the prices of a larger number of prescription drugs; and 3) ensure a robust and competitive market for generic and biosimilar drugs to combat drug shortages.

ACP is the largest medical specialty organization and the second largest physician membership society in the United States. ACP members include 161,000 internal medicine physicians, related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge, clinical expertise, and compassion to the preventive, diagnostic, and therapeutic care of adults across the spectrum from health to complex illness.

Effect of Drug Shortages on Patients

The effect of drug shortages on the healthcare system and patients cannot be overstated. Drug shortages have been on the rise over the past several decades, leading to increased costs, additional labor efforts, and heightened safety concerns.¹² These shortages can arise from a variety of causes, including manufacturing issues, supply and demand issues, issues with raw materials, and discontinuation, amongst other and unknown causes. The issue of drug shortages is particularly important to physicians because prescription drugs are a key part of a physician’s comprehensive toolkit and have been crucial in improving the health and lives of millions of our patients. ACP is concerned that under the status quo, a lack of strategy to mitigate drug shortages will result in the

¹ Drug Shortages Statistics.” ASHP, 2020. <https://www.ashp.org/Drug-Shortages/Shortage-Resources/Drug>

² Shortages-Statistics 2 Vail et al. Association Between US Norepinephrine Shortage and Mortality Among Patients With Septic Shock. JAMA. 2017

development of more serious health issues and, in turn, lead to diminished quality of life, poorer outcomes, and additional financial burden to the health care system.

The drug shortage crisis is hindering patient access and affecting medication adherence. It is estimated that medication non-adherence results in increased hospitalization and mortality rates and costs the U.S. healthcare system anywhere from \$100-\$300 billion a year.³

ACP is encouraged by the proactive steps that Congress has taken to address this important issue. We urge Congress to continue championing bipartisan policies that will strengthen the supply chains of essential medications in this country. The College [recommends](#) that the federal government and private sector stakeholders work together to ensure that there is an adequate supply of drugs, including vaccines, available to safeguard and treat the U.S. population.

ACP is part of the Group of Six, representing more than 560,000 physicians and medical students, who believe it is imperative that policymakers come up with solutions to rising drug prices and shortages of vital medications. The Group of Six has adopted [principles](#) for addressing rising prescription drug costs and shortages. Our members care for individuals and families in communities large and small, urban and rural. They see first-hand how devastating it can be to their ability to help their patients maintain and improve their health, when needed and often lifesaving medications are simply unaffordable or unavailable to them.

The barriers to care created by rising drug prices and shortages also are undermining the patient-physician relationship, as physicians are sometimes forced to prescribe less effective medication to their patients because the preferred and most effective drug is unaffordable, unavailable, or not covered by the patient's insurer. Solutions to the problems of high drug prices, lack of affordability, and shortages of vital medications should consider the United States' acknowledged global leadership in investing in research, development, and innovation to bring forward new and life-saving medications to market, while recognizing that the benefits of such research and development are undermined if the medications brought to market are unaffordable to those who need them and to the overall health care system, if prices do not moderate through the life-cycle of the drug, and if there are shortages of such drugs.

³ Viswanathan, Meera, Carol E. Golin, Christine D. Jones, Mahima Ashok, Susan J. Blalock, Roberta CM Wines, Emmanuel JL Coker-Schwimmer, David L. Rosen, Priyanka Sista, and Kathleen N. Lohr. "Interventions to improve adherence to self-administered medications for chronic diseases in the United States: a systematic review." *Annals of internal medicine* 157, no. 11 (2012): 785-795.

Support Legislation that Promotes Pricing Transparency and Lower Drug Costs and Improves Access to Generics and Biosimilars

There are several pieces of legislation before Congress that could help improve consumer access to affordable prescription drugs and mitigate the effect of chronic drug shortages. ACP urges Congress to:

- Pass the [Lower Costs, More Transparency Act](#), H.R. 5378, to promote price transparency among health care entities.
- Support the [Drug Shortage Prevention Act of 2023](#), H.R. 3009/S. 2362, to require that manufacturers of over the counter and prescription drugs notify Food & Drug Administration when they are unlikely to meet demand.
- Support the [Cutting Copays Act, H.R. 5386](#), to eliminate cost-sharing for generic drugs for low-income subsidy (LIS) beneficiaries, helping to incentivize the use of generic drugs.
- Support the [Increasing Access to Biosimilars Act of 2023](#), to encourage adoption of biosimilars in Medicare and improve biosimilar accessibility.
- Support the [Lowering Drug Costs for American Families Act](#), H.R. 4895, to expand number of prescription drugs which Medicare can negotiate under the Inflation Reduction Act from 20 to 50 starting in 2029.

Pricing Transparency Legislation

ACP supports pricing transparency by health care organizations. We support the passage of the Lower Costs, More Transparency Act, which passed the House. It contains price publication requirements for hospitals, ambulatory surgical centers, imaging services, clinical laboratories, health insurers and pharmacy benefit managers (PBMs). With respect to PBMs, the legislation requires them to semi-annually provide employers with detailed data on prescription drug spending, including the acquisition cost of drugs, total out-of-pocket spending, formulary placement rationale, and aggregate rebate information.

ACP supports transparency of reliable and valid price information, expected out-of-pocket costs, and quality data that allows consumers, physicians, payers, and other stakeholders to compare and assess medical services and products in a meaningful way. Health plans and health care facilities should clearly communicate to a consumer whether a provider or clinician is in-network or out-of-network and the estimated out-of-pocket payment responsibilities of the consumer. ACP recommends that payers, plans, and other health care organizations develop patient-targeted health care value decision-making tools that are written for patients at all levels of health literacy that make price, estimated out-of-pocket cost, and quality data available to consumers. This information should be communicated in an easy-to-understand way.

ACP supports the availability of accurate, understandable, and actionable information on the price of prescription medication. ACP believes health plans, PBMs, and pharmaceutical manufacturers should report the amount paid for prescription drugs, aggregate number of rebates, and nonproprietary pricing information to HHS and make it publicly available. Any disclosure mandate should be structured in a way that deidentifies negotiated rebates with specific companies and protects confidential information that could be considered trade secrets or could have the effect of increasing prices.

Drug Shortage Legislation

The Stop Drug Shortages Act would provide patients with better access to generic prescription drugs that are currently experiencing shortages or are at risk of being in shortage. This bill requires drug manufacturers to notify the FDA if there is an increased demand for certain critical essential medicines that may result in a shortage. Currently, drug manufacturers are required to notify the FDA in the event of a discontinuation or interruption in the supply of prescription drugs that are life-supporting, life-sustaining, or used for a debilitating disease or condition, including those used in medical emergencies, surgeries, or public health emergencies. The bill requires manufacturers of prescription and nonprescription drugs to also notify the FDA if there is an increased demand for such drugs that lasts for at least six weeks and that may result in a shortage. The legislation also requires drugmakers to provide information about their suppliers of active pharmaceutical ingredients and in-process materials to the FDA. Passage of this legislation will strengthen our national response to the drug shortage crisis Americans are facing.

Legislation to Improve Access to Generic Drugs

ACP has long [supported](#) the Medicare Part D low-income subsidy program (LIS) that assists seniors with fewer resources in paying for their prescription drugs. Twelve million Medicare Part D beneficiaries are enrolled in the LIS program. Although use of low-cost generic drugs by Part D beneficiaries is relatively high and continues to increase as more generics become available, the generic drug use rate is lower among LIS enrollees than among other Medicare beneficiaries. We support modifications to this program to encourage the use of lower-cost generic or biosimilar drugs by eliminating cost sharing for generic drugs for LIS enrollees. Therefore, the College endorses the Cutting Copays Act. This legislation would eliminate cost-sharing for generic drugs for LIS beneficiaries, helping to incentivize the use of generic drugs.

Another approach to address the rising costs of health care and drug shortages is to remove barriers to biosimilars market entry and improve patient access to biosimilars. Research shows that biosimilars will [reduce direct spending](#) on biologic drugs by \$54 billion from 2017 to 2026. We are supportive of the Increasing Access to Biosimilars Act of 2023. This legislation would encourage adoption of biosimilars in Medicare and improve biosimilar accessibility, by establishing a new pilot program – a voluntary, shared savings demonstration program – for providers of biosimilars in Medicare Part B.

Legislation to Lower Prescription Drug Costs

ACP supports the Lowering Drug Costs for American Families Act. This legislation would build upon the historic drug pricing provisions in the Inflation Reduction Act of 2022, further strengthening Medicare's Drug Pricing Program. This bill would expand the annual number of prescription drugs selected for negotiation in the Drug Pricing Program from 20 to 50, starting in 2029. By expanding the number of high-costs drugs that Medicare can negotiate, more Americans will have access to care, which is in alignment with ACP's goal to improve access to care for patients across the country.

Conclusion

We commend you for holding this hearing to examine how drug shortages are adversely affecting patient's health and to consider bipartisan approaches to addressing the crisis. We believe Congress passage of the bills listed in this statement will help curtail high drug prices and shortages. If you have any further questions or if you need additional information from ACP, please contact George Lyons at (202) 261-4531 or glyons@acponline.org.