



December 4, 2023

The Honorable Mike Johnson
Speaker
U.S. House of Representatives
H-232, U.S. Capitol
Washington, DC 20515

The Honorable Hakeem Jeffries
Democratic Leader
U.S. House of Representatives
H-204, U.S. Capitol
Washington, DC 20515

The Honorable Charles E. Schumer
Majority Leader
U.S. Senate
S-221, U.S. Capitol
Washington, DC 20510

The Honorable Mitch McConnell
Minority Leader
U.S. Senate
S-230, U.S. Capitol
Washington, DC 20510

The Honorable Patty Murray
Chair
Senate Committee on Appropriations
S-128, U.S. Capitol
Washington, DC 20510

The Honorable Susan Collins
Vice Chair
Senate Committee on Appropriations
S-128, U.S. Capitol
Washington, DC 20510

The Honorable Ron Wyden
Chair
Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Mike Crapo
Ranking Member
Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Bernie Sanders
Chair
Senate Committee on Health, Education,
Labor, and Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

The Honorable Bill Cassidy, M.D.
Ranking Member
Senate Committee on Health, Education,
Labor, and Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

The Honorable Kay Granger
Chair
House Committee on Appropriations
H-307, U.S. Capitol
Washington, DC 20515

The Honorable Rosa DeLauro
Ranking Member
House Committee on Appropriations
1036 Longworth House Office Building
Washington, DC 20515

The Honorable Jason Smith
Chair
House Committee on Ways & Means
1139 Longworth House Office Building
Washington, DC 20515

The Honorable Martin Heinrich
Chair
Subcommittee on Agriculture, Rural
Development, Food and Drug
Administration, and Related Agencies
Senate Committee on Appropriations
S-128, U.S. Capitol
Washington, DC 20510

The Honorable Tammy Baldwin
Chair
Subcommittee on Labor, Health and Human
Services, Education, and Related Agencies
Senate Committee on Appropriations
S-128, U.S. Capitol
Washington, DC 20510

The Honorable Andy Harris
Chair
Subcommittee on Agriculture, Rural
Development, Food and Drug
Administration, and Related Agencies
House Committee on Appropriations
H-307, U.S. Capitol
Washington, DC 20515

The Honorable Richard E. Neal
Ranking Member
House Committee on Ways & Means
1129 Longworth House Office Building
Washington, DC 20515

The Honorable John Hoeven
Ranking Member
Subcommittee on Agriculture, Rural
Development, Food and Drug
Administration, and Related Agencies
Senate Committee on Appropriations
S-128, U.S. Capitol
Washington, DC 20510

The Honorable Shelley Moore Capito
Ranking Member, Subcommittee on Labor,
Health and Human Services, Education, and
Related Agencies
Senate Committee on Appropriations
S-128, U.S. Capitol
Washington, DC 20510

The Honorable Sanford Bishop, Jr.
Ranking Member
Subcommittee on Agriculture, Rural
Development, Food and Drug
Administration, and Related Agencies
House Committee on Appropriations
H-307, U.S. Capitol
Washington, DC 20515

The Honorable Robert Aderholt
Chair
Subcommittee on Labor, Health and Human
Services, Education, and Related Agencies
House Committee on Appropriations
H-307, U.S. Capitol
Washington, DC 20515

Dear Speaker Johnson; Leaders Jeffries, Schumer, and McConnell; Chairs Murray, Wyden, Sanders, Granger, Rodgers, Smith, Heinrich, Baldwin, Harris, and Aderholt; Vice Chair Collins; and Ranking Members Crapo, Cassidy, DeLauro, Pallone, Neal, Hoeven, Capito, and Bishop:

The American Cancer Society Cancer Action Network (ACS CAN) is the American Cancer Society's nonprofit, nonpartisan advocacy affiliate. ACS CAN is making cancer a top priority for public officials and candidates at the federal, state, and local levels. By engaging advocates across the country to make their voices heard, ACS CAN influences legislative and regulatory solutions that will end cancer as we know it, for everyone.

Drug shortages have had a significant impact on cancer patients over the past year, causing difficult decisions that have included rationing drugs, reduced or skipped doses, and altered treatment regimens. Currently, there are 16 oncology drugs listed in shortage, including many that treat pediatric cancers. The vast majority of oncology shortages have occurred in older, multi-source generic sterile injectables (GSIs). Many of these oncology drugs serve as the core backbone for treatment regimens that have high efficacy cure rates. Omitting or limiting the use of these drugs would reduce the survival of those needing the drugs, lead to early and unnecessary deaths, take us backwards in the fight against cancer, and could further exacerbate inequities in health care. Unfortunately, giving lower doses, fewer doses, or no drug at all to stretch a short supply among many patients is the only option when there are no other reasonable drug alternatives to the cancer drug in shortage. Drug shortages are regularly forcing health care providers into difficult decisions, deciding which cancer patients receive critical medications and which do not.

Shortages are not isolated and are impacting real patients. ACS CAN has conducted surveys of adult cancer patients and found that 10% of those in active treatment over the past year have been impacted by a drug shortage, a majority of whom have had difficulties finding substitute medications (68%) and cited treatment delays (59%). ACS CAN is also a member of the Alliance for Childhood Cancer (Alliance), a multi-stakeholder coalition focused on the needs of pediatric cancer patients and survivors. The Alliance recently commissioned a survey to better understand the impacts of drug shortages on kids with cancer and found that nearly 53% of pediatric patients were affected by a shortage during the course of their treatment. The survey also found that over 80% of pediatric cancer providers indicated that their institution was experiencing shortages.

While shortages are acutely impacting today's patients, cancer-drug shortages in the U.S. have also caused delays and modifications to clinical trials that lead to future treatments. Trials typically test a new treatment against the standard of care, with a comparison of outcomes between the two approaches. When the standard of care cannot be provided due to drug shortages there is not a valid comparison, hence, in many cases, trials have opted to stop accruing patients. This chilling effect on research today threatens progress on tomorrow's new treatments and extends the impact of shortages beyond today's patients to patients that have not yet even been diagnosed.

Drivers of Shortages

We understand that the immediate causes of oncology drug shortages are complex and multi-faceted and include:

- Low investment in facilities and maintenance;
- Manufacturing difficulties including quality compliance that force the shutdown of production lines;
- Failure to accurately project demand for certain drugs;
- Shortages or unavailability of active pharmaceutical ingredients (APIs);
- Limited excess production capacity of a drug if one manufacturer ceases production, especially if the ceased operation has a large share of the market;
- Growth in product use without associated growth in production capacity;
- Tight production schedules that are not readily altered if a manufacturing problem occurs or if demand increases faster than anticipated.

Underlying these different immediate causes is the root problem of economic conditions in the generic sterile injectable drug market. There is little margin on these drugs and therefore little incentive for companies to invest resources to create extra capacity, improve quality, or in some cases to even remain in the market.

Approaches to Resolution

We continue to urge Congress to look at both short-term solutions to mitigate ongoing shortages as well as longer-term solutions that address the core drivers of ongoing shortages. Many individual aspects of a more comprehensive solution have already been put forth individually. To be effective, Congress must enact legislation that is comprehensive and will result in systemic changes that address both short-term and long-term needs. Risk mitigation strategies, public and private investment and partnerships, coordination and accountability, and policy reforms that ensure patient access to necessary medical treatments are essential elements of a comprehensive strategy. Components of a comprehensive solution are detailed below.

Short-term solutions are needed to equip stakeholders with the tools and knowledge needed to respond to or avert shortages in real time. These transparency policies help in crisis management, but

do not address the root causes of chronic shortages.

- **Risk Assessment Tools:** There is a need for better tools to assess both long-term and dynamic supply chain risks. This would include more data-driven models and dashboards for drugs at risk for shortage. Such models would require better transparency and visibility into API and supply chains via enhanced reporting and more clarity surrounding actual shortage statuses of drugs. Such data and assessments would be helpful for government agencies like FDA to proactively intervene; however, other stakeholders like distributors, manufacturers and hospitals also need access to timely and accurate information to foster healthy market responses.
- **Increased Agency Resources:** Agencies, like FDA, responsible for mitigating or responding to shortages need to have sufficient resources to effectively address the record level of shortages currently experienced.
- **Coordinating Supply Chain Resilience and Reliability Efforts:** Once shortages exist, unequal distribution of drugs can exacerbate local impacts, therefore the ability for hospitals or providers to redistribute local excess is important. Improved guidance from HRSA on ways that facilities can share or redistribute drugs during shortages without violating existing legal restrictions on redistribution would be crucial to addressing acute needs.

The generic sterile injectable market, which makes up the bulk of oncology drugs in shortage, is driven almost entirely on driving prices to the lowest point possible and has resulted in an unsustainable market with widespread and chronic shortages. **The long-term solutions** will require transformation of the market to recognize and reward reliability and quality in drug production and delivery capacity.

- **Measuring Performance:** Differentiating manufacturers and suppliers requires the creation and adoption of objective metrics to rate quality, reliability, and supply chain buffer capacity.
- **Targeted Incentives to Shift Market Behavior:** Incentives for quality, reliability, and buffer need to be provided within the existing market structure in a way that will work to permanently transform the market dynamics as opposed to stand-alone efforts disconnected from market dynamics. For example, the creation of buffer stock can avert shortages by providing time for production recovery after a one-time catastrophic event like a hurricane, war, or other unexpected event. If the cause of a shortage is due to chronic unsustainable market conditions that cause production capacity to exit or deteriorate, as is the case in many oncology drug shortages, then then not only is there unlikely to be sufficient capacity to build up reserves, but the underlying cause of the chronic shortages will not be addressed.
- **Enabling Market Corrections:** Government policies that may stand in the way of necessary price increases on the group of extraordinarily low-cost sterile injectables that have been at the core of shortages need to be examined and potentially modified.
- **Support Modernization and Expanded Capacity:** Financial support for facility upgrades and increased capacity may be appropriate outside of the normal market structure; however, it will

be ineffective if the market for the drugs these facilities are intended to produce is not functioning in a way that encourages utilization of such capacity.

Additional research and pilots can help generate additional insights into challenging market dynamics and test interventions on a limited scope before scaling more broadly.

While these policies are being pursued, we also urge the pharmaceutical industry to work with medical practitioners to help identify alternatives where possible to ensure that cancer patients' treatments are not delayed.

Thank you for the opportunity to comment on the request for information on drug shortages. If you have any questions, please feel free to contact me or have your staff contact Tammy Boyd, Vice President, Federal Relations and Strategic Alliances at Tammy.Boyd@cancer.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Lisa A. Lacasse". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

Lisa A. Lacasse, MBA
President
American Cancer Society Cancer Action Network