May 7, 2025

The Honorable Howard Lutnick
Secretary
United States Department of Commerce
1401 Constitution Ave. NW
Washington, DC 20230

Re: XRIN 0694-XC120 Pharmaceuticals 232 Notice

Dear Secretary Lutnick:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on the National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients as posted in the Federal Register (Docket No. 250414-0065). ACS CAN advocates for evidence-based public policies to reduce the cancer burden for everyone. As 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.

**Impacts on Cancer Patients**

Patients rely on drug therapies to effectively treat cancer, and oncology drugs have been among the largest class of new drugs approved by the U.S. Food and Drug Administration (FDA) each year. In addition to new drugs, older generic drugs play a key role either as stand-alone treatment, or as a core component of combined therapy with newer drugs. Drugs, however, are only effective if they are available, and the U.S. has repeatedly experienced chronic drug shortages over the past decade. The FDA currently lists eight oncology drugs in shortage. The majority of oncology drugs that have experienced shortage are older, generic sterile injectable drugs (GSIs). 2023 saw the most recent wave of drug shortages which resulted in delays and rationing of key GSIs that led to increased risk of adverse events and medication errors that impacted patient outcomes[1].

Drug shortages have also caused delays and modifications to clinical trials because cancer clinical trials typically test a new treatment against the standard of care, with a comparison of outcomes between the two approaches. Without the drugs that provide the standard of care—which often include GSIs—there is not a valid comparison; hence, in shortage situations, trials have had to stop accruing patients.[1] Shortages such as these create a chilling effect on research today and therefore threatens progress on tomorrow's new treatments. This in turn extends the impact of shortages to those in the future who that have not yet been diagnosed.

**International Supply Chains of Oncology Drugs**

While both branded and generic drugs involve supply chains that are global, shortages have been concentrated in GSIs due to the underlying economic model of generic drugs. Generics have long competed on price alone, leading to progressively lower prices and profit margins for manufacturers. This has driven production to lower

cost environments. India is the largest supplier of the active pharmaceutical ingredients (API) that go into generic drugs, providing 35% of the supply, followed by the European Union (18%), the U.S. (12%) and China (11%).[2] While these statistics apply to the broad sourcing of ingredients across all generics, the production of individual products may be far more concentrated in certain countries, or even in specific facilities. For example, the 2023 shortage of the oncology GSI cisplatin was triggered when one plant in India that made 50% of the U.S. supply of the drug was shut down due to quality issues.[3]

While some name-brand drugs may have similar concentration of production, the higher margins on these products mean that manufacturers are likely to have more modern and reliable production facilities, redundant capacity, or additional finished product in reserve. GSIs, on the other hand, have slim profit margins, meaning that manufacturers neither have excess capital to invest in manufacturing upgrades nor do they have the incentive to create redundancy or product reserves that might help respond to unexpected disruptions. The resiliency of the drug supply, therefore, appears to have more to do with the economic drivers of drug manufacturing than where production is physically located.

**Efforts to Spur Domestic Production**

The U.S. does not currently have the capacity to produce all of our oncology GSI needs. While developing domestic production capacity may be appealing, the creation of such capacity would take years to realize and require significant capital investment. Different strategies for driving that investment have been proposed, ranging from tariffs on non-U.S. products; to purchasing incentives for domestic products; to subsidies, grants, or tax breaks for construction of domestic production facilities.

Tariffs alone are unlikely to drive production of GSIs to the U.S. due to the unique economics of this sector. Normally, the general mechanism by which tariffs spur domestic production is through increasing the price of non-U.S. products until the prevailing market price of a product is high enough to sustain domestic production. For GSIs, however, private contracting practices and Medicare and Medicaid policies that do not allow price increases beyond the rate of inflation make it difficult for the prices of GSIs to increase sufficiently to spur domestic manufacturing. The economics of the GSI market have already led many manufacturers to reduce or end production of products that had no profit margin, or in some cases were produced at a loss. The addition of tariffs to the equation would likely trigger additional market exits and lead to further, serious widespread shortages. Non-tariff policies, such as purchasing incentives or construction subsidies, would be more likely to trigger new production capacity, but would not immediately address shortages and such policy changes would need to ensure that new domestic production would be economically sustainable.

Any policy changes that are applied to pharmaceuticals, whether incentives or tariffs, that are proportional to the product's value, could further disadvantage domestic generic production in the short term due to competition. Tariffs, for example, are applied as a fraction of a product's price, so for name-brand drugs the incentive to onshore would be greater than for generics. Brand manufactures would theoretically be able and willing to spend far more than generic manufacturers to build production facilities or increase capacity, which may require a similar investment for the two categories of drugs. New facilities take years to build, but existing capacity could be more quickly retrofitted and current generic facilities could be targeted for purchase and conversion to brand production, causing shortages and further eroding domestic production.[4]

While the U.S. is traditionally the country where novel cancer drugs are first approved, some portion of drugs are initially approved in other countries. For drugs not yet approved in the U.S., or for those with a lag in approval compared to other countries, it is unlikely that production would occur domestically. As an example, trabectedin was approved in the U.S. over eight years after approval elsewhere. Tariffs hampering imports of such drugs for research purposes or patient use would not be in the interest of patients.

**Conclusion**

The supply chain that is involved in supplying GSI to patients with cancer is both multinational and fragile. That fragility has been manifested as both acute and chronic shortages that have had life-altering impacts for patients. ACS CAN would like to see more secure and reliable production of these drugs and has offered feedback on legislative proposals to reach this goal.[5] Most analyses of the chronic shortages of GSIs have pointed to an unsustainable economic model as the core difficulty.[4,6] The trend to produce these drugs outside of the U.S. is therefore seen primarily as a result of the same economic drivers of shortages rather than a cause of them. Instituting tariffs on GSIs without addressing the broader underlying economic model risks further damaging the fragile supply chain of GSIs production, making shortages worse and endangering the health and safety of Americans with cancer. We urge the administration to avoid such tariffs.

Thank you for the opportunity to comment. If you have any questions, please feel free to contact Mark Fleury at mark.fleury@cancer.org.

Sincerely,

Lisa A. Lacasse
President
American Cancer Society Cancer Action Network

References:

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6- HHS Assistant Secretary for Planning and Evaluation, An Examination of the Return on Investment of Generic Injectable Prescription Drugs, (2024). https://aspe.hhs.gov/reports/roi-generic-injectable-prescription-drugs