

The Honorable Jefferey I. Kessler
Undersecretary of Commerce for Industry and Security
Bureau of Industry and Security
U.S. Department of Commerce
1401 Constitution Avenue, N.W.
Washington, D.C. 20230

Subject: Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients – RIN: 0694-XC120

Docket No: BIS-2025-0022-0001

Dear Under Secretary Kessler,

On behalf of West Pharmaceutical Services, Inc. ("West"), thank you for the opportunity to comment in response to the request by the Bureau of Industry and Security ("BIS") for public input on the ongoing Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients.

West intends to highlight key aspects of the highly complex nature of the pharmaceutical containment industry and urges BIS to proceed with thoughtful restraint when contemplating an appropriate and tailored trade regime for the industry. To achieve the goal of establishing a robust manufacturing base in the United States to respond to national security needs, West supports the use of grants and tax credits to incentivize further domestic investment in pharmaceutical containment manufacturing. In the event that BIS elects to impose tariffs on certain raw materials necessary to manufacture pharmaceutical containers in the United States, West supports the adoption of a fair and transparent exclusions system.

Background on West

West is a Pennsylvania-based manufacturer of innovative, high-quality containment solutions for injectable medicines. Founded in Philadelphia in 1923, West began by manufacturing grinding wheels for the dental trade, along with rubber droppers, plungers, and stoppers for the pharmaceutical industry. More than one-hundred years later, West continues to innovate, helping to ensure the safe, effective containment and delivery of lifesaving and life-enhancing medicines for patients. West is a global leader in the production of vial containment solutions and syringe components, drug administration and reconstitution devices, and drug delivery devices.

West is a trusted partner of established and emerging drug developers, as evidenced by the fact that West's products may be found in more than 90% of all new biologics targeted for market in the next few years. West employs more than 4,700 employees in the United States, which includes R&D and manufacturing centers in Arizona, Florida, Michigan, Nebraska, North Carolina, and Pennsylvania. Since 2020, West has invested over \$300 million in its U.S. manufacturing footprint and added 325 U.S. jobs. In 2024, West had nearly \$3 billion in sales and shipped 41 billion components and devices, impacting the lives of hundreds of millions of Americans and billions more patients around the world.

The Importance of Pharmaceutical Containment to National Security

Protecting critical infrastructure for public health is a national security concern, especially in the rapidly growing injectable medicines field. Injectable medicines are liquid medications, fluids, or nutrients that are delivered into a patient's bloodstream to achieve a desired therapeutic effect. Injectable medicines are most commonly administered using a needle and syringe and are generally stored in a glass vial with a rubber stopper.

The injectable medicine market is one of the fastest growing today, encompassing products ranging from mRNA vaccines to chemotherapies to new GLP-1 diabetes drugs. Many of these therapies are at the cutting edge of innovation, with incredible potential to treat a wide variety of acute and chronic diseases. In 2023, worldwide injectable drug sales were \$507B and sales are estimated to grow to \$933B by the end of the decade, with topline growth projected to be close to 10% annually. Certain products, including mRNA and GLP-1s, are projected to grow more than 15% annually.

Because the physical packaging and delivery devices are critical for the safe storage and administration of injectable medicine, protecting the supply of these components and devices is also important to national security. Without safe, effective, and plentiful production of highly specialized, medical-grade plungers, rubber stoppers, wearable injection devices, and other similar products, the United States will not be able to consistently store and administer the new generation of pharmaceuticals that will be developed in the next decades. Exercising a thoughtful and tailored approach in the pharmaceutical containment and delivery industry is essential to ensure that West's U.S. manufacturing jobs remain competitive on a global scale in furtherance of U.S. economic security objectives.

West's Role in Pharmaceutical Containment

West is a global leader in manufacturing pharmaceutical containment products, and our American manufacturing presence allows the company to produce billions of these products domestically, and a commitment to innovation ensures that West can respond to U.S. needs by remaining at the forefront of the advancement of pharmaceutical containment.

For example, twenty years after the company's founding, during World War II, West partnered with Eli Lilly to supply penicillin in mass quantities for the U.S. Government. West developed novel packaging so that the U.S. military could receive and maintain an adequate, safe supply of penicillin, saving countless lives and contributing to America's victory.

A century later, during the COVID-19 pandemic, West helped the first Trump Administration facilitate the rapid development, approval, manufacture, and distribution of vaccines. West's manufacturing capabilities ensured that every vial of Pfizer-BioNTech and Moderna COVID-19 vaccine was safely sealed with a West rubber stopper and/or aluminum seal, ensuring that millions of Americans could be vaccinated.

West's products are also found in the packaging for many of the promising GLP-1 drugs for individuals managing diabetes and obesity. The American Diabetes Association reports that diabetes has reached epidemic proportions, impacting more than 38 million Americans who are facing the severe consequences of this disease. West manufactures plungers and stoppers used to deliver these products at our Jersey Shore facility in Pennsylvania and our Kinston facility in North Carolina.

As established by President Trump's America First Investment Policy, protecting critical infrastructure in the United States, like West's U.S. manufacturing, is a matter of national security. West delivers products that are essential components in the supply chain of its customers and protecting the availability and supply of those critical components is a national security concern.

State of the Pharmaceutical Containment Industry

Patient safety demands that the pharmaceutical containment industry provide containment solutions that keep medicine sterile and remain unadulterated while stored or shipped. West's containment components are made from specialized rubber formulations to ensure sealing performance over a wide range of temperatures while in storage or transit and are laminated with inert barrier films on their surfaces to prevent extractable materials from diffusing into the medicine or any of the ingredients in the medicine from leaching into the rubber.

To meet these high standards, West requires the highest quality medical-grade materials and exacting specifications. Unfortunately, there are many raw materials which can only be sourced from a single location and for which there is no U.S. supply. Other key raw materials are made using protected trade secrets and production of these materials cannot be moved to America. For example, halo-butyl rubbers are uniquely suited as the raw material for forming pharmaceutical components like stoppers because of their chemical resistance and ability to self-heal after being punctured. The supplier of halo-butyl rubbers that is able to provide the quality and quantity needed for West's operations is based in Europe. Similarly, the special medical grade aluminum

used to manufacture the seals that secure the rubber stoppers to their vials is only available from a non-U.S. source.

Notably, West sources the vast majority of its raw materials from countries that are long-term allies of the United States—West's supply chain has minimal exposure to countries like China and Russia. For example, inert barrier film that is laminated to our rubber components is sourced from Japan. Components for our on-body delivery devices and many of our reconstitution devices are supplied from Israel. Encouraging trade with trusted partners is likely to have a more positive impact on our national security by ensuring the supply of critical components for the pharmaceutical industry.

These factors make the pharmaceutical containment industry unique. Unlike other products for which the Administration has initiated Section 232 investigations, such as steel, aluminum, copper, and lumber, West's products are not commodities that can be sourced from multiple locations or easily relocated to the United States. Instead, they are highly specialized, technologically sophisticated products essential for ensuring safe delivery of medicine.

Most importantly, Section 232 duties are not needed to bring the pharmaceutical containment industry back home. The domestic industrial base to produce pharmaceutical containers already exists and is thriving across the country, and particularly in states like Arizona, Florida, Michigan, Nebraska, North Carolina, and Pennsylvania, where we have our advanced precision manufacturing facilities. West leads the critical pharmaceutical containment industry from America, supporting thousands of quality jobs and having invested hundreds of millions of dollars. The COVID-19 pandemic demonstrated that in the event of a crisis, West is prepared to scale up production to meet the needs of not only America, but the entire world.

The Effect of Tariffs on West's Operations

The current impact of the Administration's use of tariffs to bolster domestic industry has so far increased costs for West and will likely continue to raise costs. West imports some raw materials, components, and packaging, as well as machinery, molds, dies, and tooling in support of our manufacturing activities at our U.S. facilities. As discussed above, alternate U.S.-based sources for many of these products either do not exist or would require extensive, time-consuming, and costly testing to either comply with FDA regulations or to qualify a new supplier. Tariffs on these raw materials would not further the objectives of the America First Investment Policy to protect critical infrastructure and American economic security. They would, rather, cause significant harm to West as the provider of pharmaceutical containment and packaging solutions, which are made here and sold for the benefit of billions of people across the globe.

West's primary competitors are European and many of its largest customers are also European. Tariffs on raw materials will increase costs, making products sold to the European market more

expensive, thereby giving European competitors an advantage and could undermine the America First Investment Policy by encouraging investment in European facilities, which benefit by not having tariffs on raw material imports.

As previously noted, West's products are crucial for the safe and effective delivery of injectable medicines, and West is deeply integrated into the American medical supply chain. Tariffs on imports, such as those used by West, would have the undesired effect of increasing costs on our customers, and, ultimately, U.S. patients. Worse yet, tariffs could reduce the availability of injectable medicines for Americans at a time of rapid breakthroughs and unprecedented growth in the industry.

Recommendations

Right now, West is a national champion, leading key aspects of the world's pharmaceutical packaging and containment supply chain from America. We urge the Administration to proceed with careful consideration in the area of pharmaceutical containment as tariffs could undermine a currently thriving domestic industry.

Access alone to lifesaving or life-enhancing medication for U.S. patients is not enough. What is more critical for U.S. patients is access to **affordable** medications. As America's population grows and lives longer, the demand for West's products will increase. West encourages the Administration to adopt a cautious approach in seeking to achieve a stable domestic supply of materials needed for the pharmaceutical industry. Grants that promote innovation in manufacturing technology to reduce the cost of domestic production and tax credits for investing or purchasing goods from domestic suppliers to increase capacity would strengthen domestic production without burdening U.S. patients with higher costs for pharmaceuticals.

If the Administration elects to impose Section 232 tariffs on the pharmaceutical containment upstream supply chain, West recommends the adoption of a fair and transparent exclusions system. American companies that can provide evidence of a substantial contribution to domestic manufacturing, such as West, should be considered for exclusions from the increased duties.

Conclusion

West appreciates the opportunity to submit comments for the Department of Commerce's Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients. West respectfully urges BIS to proceed with caution and account for the unique and complex landscape in pharmaceutical containment. West believes that the status quo currently promotes sufficient domestic manufacturing of pharmaceutical containers. However, if BIS finds that the status quo presents a threat to national security, we recommend either an alternative to the imposition of increased tariffs or an exclusions process to avoid increased manufacturing

costs that may potentially limit access to lifesaving and life-enhancing drugs. Thank you for your attention to this critical issue and your consideration of our industry's needs.

Sincerely,

Eric M. Green

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President, CEO and Chair of the Board

West Pharmaceutical Services, Inc.