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Docket Number: BIS-2025-0022

Eric Longnecker
Deputy Assistant Secretary for Technology Security
Office of Strategic Industries and Economic Security
Bureau of Industry and Security
U.S. Department of Commerce
14th Street and Constitution Avenue, NW
Washington, D.C. 20230

Re: Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients, XRIN 0694-XC120

Dear Deputy Assistant Secretary Longnecker:

As a leading medical technology company and major US manufacturer of intravenous (IV) solutions, generic injectable pharmaceuticals, and antibiotics, B. Braun of America Inc. and its subsidiaries (collectively "B. Braun of America") appreciate the opportunity to comment on the investigation of the effects on the national security of imports of pharmaceuticals and pharmaceutical ingredients under Section 232 of the Trade Expansion Act of 1962. To help protect the national security of the United States, we urge the Administration and Department of Commerce to take steps to strengthen health products supply chains and to carefully consider the impact tariffs may have on supply chains where no US suppliers of essential materials exist, such as many of the active pharmaceutical ingredients (APIs) and excipients used to manufacture generic injectable drugs.

B. Braun of America is dedicated to protecting and improving the health of people. We achieve this by developing, manufacturing and delivering over 100 generic pharmaceutical products including generic injectable drugs, antibiotics, nutrition products, and general purpose IV and irrigation solutions. We also manufacture medical devices, pharmacy admixture products, and other medical products used by healthcare providers to prepare and administer IV solutions and other medicines. The products we manufacture enhance patient care, improve clinical outcomes, and drive cost-effectiveness in healthcare.

B. Braun of America, which is part of the B. Braun Global Group of Companies, has over 6,000 employees at 30 locations in the US. Our affiliated companies include:

- B. Braun Medical Inc.
- Central Admixture Pharmacy Services, Inc. (CAPS)
- Aesculap, Inc.
- B. Braun Interventional Systems, Inc.
- B. Braun US Device Manufacturing LLC
- B. Braun US Pharmaceutical Manufacturing LLC

Manufacturing Investments in the US

B. Braun of America has been manufacturing at multiple locations in the US for decades. Our investments in these facilities increased significantly during President Trump's first term, and will continue to expand in 2025, 2026 and beyond.

In 2019, less than two years after Congress passed the Tax Cuts and Jobs Act of 2017, B. Braun of America announced investments of over $1 billion in new and expanded manufacturing facilities in the US to help maintain a secure and resilient supply of IV therapy and other medical products for American patients. Those investments – which are now completed projects – include:

- A new 218,000 sq. ft. generic pharmaceutical manufacturing plant in Daytona Beach, FL;
- A 310,000 sq. ft. expansion of the company's medical device plant in Allentown, PA;
- Modernization of our 710,000 sq. ft. generic pharmaceutical plant in Irvine, CA; and
- A 250,000 sq. ft. 503B sterile compounding outsourcing facility in Phoenix, AZ.

Today, more than 90% of the pharmaceutical products we sell for use in the US are manufactured at our plants in the US. These include critical generic drugs used to treat millions of patients in hospitals and out-patient facilities in all 50 states.

In 2025 and 2026, B. Braun of America plans to continue expanding its manufacturing capacity in the US by investing over $120 million to boost supplies of IV fluids, nutrition solutions, generic injectable drugs, including antibiotics and other medications in short supply, 503B compounded drugs and other products.

B. Braun of America's investments have created hundreds of new jobs at our facilities. During 2025 and 2026, B. Braun of America plans to hire more than 500 employees to support the continued ramp up in production at our major manufacturing facilities to meet the growing demand for critical medicines. In the 10-year period from January 2017 – the start of President Trump's first term – to the end of 2026, B. Braun of America's employees are expected to grow by nearly 35% – from 4,700 to 6,300.

Effect of Tariffs

While B. Braun of America manufactures a large majority of our pharmaceutical products in the US and uses US-based suppliers for most of the raw materials used in those products, we import some APIs and key starting materials (KSMs) that are not available domestically from suppliers in locations including India, Spain, Italy and Brazil.

B. Braun of America is evaluating the impact of the tariffs on pharmaceutical APIs, KSMs, and other critical inputs into our manufacturing processes that we ship into the US and is taking steps to mitigate the impact including, where possible, identifying US suppliers of those critical raw materials. However, we are concerned about the impact on our business where no US suppliers of essential materials exist.

From our own experience, we know how difficult it is to open a new manufacturing facility in the US, especially one that must meet strict FDA regulatory requirements. In most cases, we expect it to take multiple years before a US supplier of the materials and products we need is available. Meanwhile, without relief, the imposition of tariffs on these materials will significantly increase costs and could undermine our ability to grow or even maintain our current level of production.

Due to long-term contractual agreements, it is very difficult for generic drug companies to pass along price increases to our customers. A tariff on generic drugs and their ingredients could force companies like ours to reduce or discontinue product lines which could quickly create or exacerbate drug shortages for patients in the US.

Conclusion

B. Braun of America has made major investments in US manufacturing since President Trump's first term in office, and we are committed to increasing the supply of IV therapy products, generic drugs and other critical healthcare products for the providers and patients in the US that need them. As we plan to build upon our legacy of focusing on affordable drug options that improve patient access and drive operational efficiencies across the continuum of care, we are concerned that any tariffs on generic pharmaceuticals or precursor materials could worsen the drug shortage problem our nation faces and increase prices for US patients. We support policies to increase domestic manufacturing, but we urge caution with the implementation of tariffs that could penalize generic pharmaceutical companies that have already made significant investments in the US, and which could have unintended consequences for patients and the healthcare system.

Thank you for your consideration of these comments.

Patrick J. Witmer