May 7, 2025

By Electronic Submission

Howard Lutnick
United States Secretary of Commerce
U.S. Department of Commerce
1401 Constitution Avenue NW
Washington, DC 20230

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

Dear Secretary Lutnick:

On behalf of the Health Industry Distributors Association (HIDA), I write to submit comments regarding the Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients.

Healthcare distributors share the goal of ensuring a resilient U.S. supply chain. HIDA member companies work every day to deliver critical products to the nation's healthcare providers at hospitals, nursing homes, physician offices, surgery centers, EMS First Responders, and the home. Medical product distributors streamline procurement so clinicians can focus on patient care.

This investigation was initiated "to determine the effects on the national security of imports of pharmaceuticals and pharmaceutical ingredients, including finished drug products, medical countermeasures, critical inputs such as active pharmaceutical ingredients, and key starting materials, and derivative products of those items." HIDA is concerned that including the term "medical countermeasures" will result in unintentionally subjecting certain medical products to additional tariffs.

As defined by the U.S. Food and Drug Administration (FDA), "Medical countermeasures, or MCMs, are FDA-regulated products (biologics, drugs, devices) that may be used in the event of a potential public health emergency stemming from a terrorist attack with a biological, chemical, or radiological/nuclear material, or a naturally occurring emerging disease." The FDA states that MCMs can include, "Devices, including diagnostic tests to identify threat agents, and personal protective equipment (PPE), such as gloves, respirators (certain face masks), and ventilators." By including the term MCMs, the scope of this investigation goes beyond pharmaceuticals and pharmaceutical ingredients to include some devices and PPE. We ask that this investigation and any resulting tariffs do not apply to medical products and devices.

The pharmaceutical industry focuses on developing and manufacturing drugs, while the medical products industry encompasses devices and equipment used in providing healthcare. These products range from gloves for patient examinations to laboratory tests for diagnosing diseases.

Because of these differences, pharmaceuticals and medical products have unique methods of manufacture and distribution and additionally move through the supply chain in a different way. For the purposes of the U.S. Harmonized Tariff Schedule (USHTS), medical products and devices are classified differently than pharmaceuticals and pharmaceutical ingredients. Similarly, they should be considered separately and should not fall within the scope of this investigation.

Thank you for the opportunity to provide comments on the Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients. If you have any questions, I can be reached at dibitetto@hida.org.

Sincerely,

Kathryn DiBitetto

Kathryn DiBitetto
Vice President of Government Affairs
Health Industry Distributors Association