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Mr. Eric Longnecker
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Bureau of Industry and Security
Office of Strategic Industries and Economic Security
Department of Commerce
1401 Constitution Ave NW
Washington, DC 20230

PUBLIC DOCUMENT
BIS-2025-0022
XRIN 0694-XC120

Re: **Comments for Inclusion in Response to the U.S. Department of Commerce's Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients** [XRIN 0694-XC120; Docket No. 250414-0065; Notice BIS-2025-0022]

I am writing on behalf of the Medical Imaging & Technology Alliance (MITA) to comment on the Department of Commerce's Section 232 investigation with respect to pharmaceuticals, pharmaceutical ingredients and derivative products (232 Pharma Investigation). MITA represents small, medium and large manufacturers in the medical imaging drug sector. Our primary mission is to improve patient care through the advancement of innovative medical drugs and adjacent technologies. Our radiopharmaceutical diagnostics, therapies, radioisotopes and contrast agents diagnose and treat patients with Alzheimer's, cancer, heart disease and other conditions.

There has been growing demand in the US radiopharmaceutical sector over the last several years. The demand for the use of nuclear medicine is close to 20 million diagnostic scans performed annually.[1] Many of the key inputs and the supply chain are considered challenging due to the short half-life, or shelf life, of the isotopes and reliance of foreign

[1] https://world-nuclear.org/information-library/non-power-nuclear-applications/radioisotopes-research/radioisotopes-in-medicine#:~:text=The%20most%20common%20radioisotope%20used,scans%20in%20nuclear%20medicine%20worldwide.

manufacturers for key APIs and precursors. It has been estimated that building commercial-scale of Molybdenum-99 (Mo-99), a widely used imaging agent, and other medical isotope facilities in the U.S. requires 10-15 years and significant private sector investment, as well as public sector support in the form or regulatory clearances and tax incentives. Currently, the United States imports many medical isotopes from other nations.

While there has been much work with the US Department of Energy over recent years to expand domestic production, creating tariff barriers for suppliers from outside the U.S. would add significant costs to our manufacturers and would disrupt the intricate global supply chain. To this end, we are concerned about any potential 232 action that would impact our companies, the healthcare providers who use our products and the patients who are diagnosed and treated using radiopharmaceuticals.

The imposition of tariffs on medical imaging drugs and related technologies will increase costs for healthcare providers, leading to reduced access to advanced diagnostic tools, particularly in settings like rural areas that have limited resources. With higher costs, hospitals and healthcare facilities may be forced to delay or cancel the purchase of vital medical equipment, hindering their ability to provide the best care possible to patients. This could result in delayed diagnoses, poorer treatment outcomes, and, ultimately, higher long-term healthcare costs for the country.

We are also concerned that barriers will place an additional burden on the broader supply chain, which is already complying with complex regulatory and economic challenges. The disruption of global supply chains and increased manufacturing costs will stifle innovation and delay the development of new technologies that are critical for advancing patient care. This, in turn, will limit the ability of the healthcare system to keep pace with emerging health threats and continue to provide high-quality care to patients across the nation.

For these reasons it is vital to ensure medical imaging drugs; radiopharmaceutical diagnostics, therapies, radioisotopes and contrast agents, and ancillary supply chain equipment/supplies are exempt from tariffs and other barriers until such time the industry is able to build the necessary infrastructure while recognizing that we may always be reliant on certain critical inputs not found in the U.S.

The following is a non-exhaustive list of examples of imaging drug-adjacent technologies critical to the supply chain.

- Raw Materials, inputs and production equipment:
    - O18 water (starting material for F18)
    - Precursors/APIs for drug production

- Reference standard for radiochemical identity testing
- Cassette kits/synthesis consumables (Proprietary)
- Ge68/Ga68 generator and HCl used to elute the generator
- Mo99/Tc99 generator
- Other isotopes that require a nuclear reactor
- Immunological products
- Specialized radiochemistry reagents
- GMP grade cartridges and purification components

At MITA, we believe that the United States must remain a leader in medical technology innovation. The introduction of tariffs and other barriers on medical imaging undermines our nation's ability to attract investment, foster technological progress, and maintain its competitive edge in the global healthcare market. As a result, we respectfully encourage the Administration to reconsider its stance on tariffs and trade actions and at a minimum, to delay critical medical imaging radiopharmaceutical drugs and related technologies and inputs from any proposed action, until such time the industry is able to build the necessary infrastructure from any proposed action.

Moreover, we remain deeply concerned about the tariffs introduced via Executive Order on April 2nd, both the baseline 10% tariff and the country-specific tariffs, covering medical devices and medical imaging capital equipment. These tariffs will diminish industry's ability to continue strengthening and reshoring our U.S. manufacturing activities and will have a significant negative impact on the medical imaging industry, which is vital for accurate, early diagnosis and effective treatment planning which improves patient outcomes and overall public health.

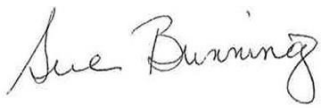
Further, we urge the Administration to clarify the U.S. content exemption provided in the April 2nd Executive Order by specifying that the value of U.S. intangibles such as intellectual property, trademarks, or copyrights, as well as U.S. R&D costs, and that the value may be allocated to the customs entries and offset against foreign component content. This change would help incentivize U.S. investment and leadership in the innovation and development of critical medical devices, imaging technologies, and pharmaceuticals by blunting some of the impact of the tariffs for companies already investing in domestic U.S. manufacturing leadership in this area.

In conclusion, we strongly urge the Administration following its 232 Pharma Investigation, to broadly maintain the tariffs exemption for pharmaceuticals and to consider incentive-based alternatives instead. Finally, we urge the Administration to reconsider the broader April 2nd Executive Order's tariffs as they relate to MedTech and medical imaging. The well-being of patients and the future of the U.S. healthcare system depend on policies that

prioritize innovation, accessibility, and affordability in healthcare. We ask that the Administration will take these considerations into account as it continues to shape trade policy.

Thank you for your attention to this matter. We stand ready to work with the White House, Congress and other stakeholders to ensure that our healthcare system remains strong, sustainable, and capable of meeting the needs of patients across the country.
Should you have any questions or require additional information, please do not hesitate to reach out.

Sincerely,



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