May 6, 2025

Mr. Stephen Astle
Director, Defense Industrial Base Division
Office of Strategic Industries and Economic Security, Bureau of Industry and Security
U.S. Department of Commerce

Re: **Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients**.

The Society of Nuclear Medicine and Molecular Imaging's (SNMMI) more than 15,000 members set the standard for molecular imaging and nuclear medicine practice by creating guidelines, sharing information through journals and meetings, and leading advocacy on key issues that affect molecular imaging and therapy, research, and practice. We appreciate the opportunity to provide comments to assist the United States Department of Commerce, Bureau of Industry and Security, Office of Strategic Industries and Economic Security.

The SNMMI appreciates the Administration's commitment to building reliable and resilient pharmaceutical supply chains to help healthcare professionals provide quality nuclear medicine care to all Americans. We recommend that the Department of Commerce continue to engage with stakeholders in clinical practice and industry to help foster a robust and resilient supply chain for radiopharmaceuticals.

The United States is experiencing growing demand for pharmaceuticals and pharmaceutical ingredients, particularly in the radiopharmaceutical sector. In 2024, the U.S. radiopharmaceutical market was valued at approximately $2.43 billion and is projected to double by 2033, reaching $4.86 billion with a compound annual growth rate (CAGR) of 8%. This surge in demand is driven by the widespread use of nuclear medicine, with close to 20 million diagnostic scans performed annually and approximately 2,830 hospitals providing such services to Medicare beneficiaries.

Despite this rising demand, the United States remains heavily reliant on foreign sources for key medical isotopes. Over 80% of diagnostic nuclear medicine procedures depend on Technetium-99m (Tc-99m), which is produced from Molybdenum-99 (Mo-99). The U.S. consumes more than half of the global Tc-99m supply, sourced exclusively from abroad, and trade stability has been imperative for patients to receive lifesaving nuclear medicine imaging and therapies.

The Missouri University Research Reactor (MURR) is the only U.S. facility producing Mo-99, and for research purposes only. As a result, the U.S. depends entirely on six foreign research reactors in Europe, South Africa, and Australia for commercial supply. In 2012, the American Medical Isotope Production Act (AMIPA) was passed. This Act aimed to promote domestic production of medical isotopes without the use of highly enriched uranium (HEU). Despite more than a decade of public-private collaboration and $1 billion in public-private investment between industry and federal agencies, efforts to establish a domestic commercial supply have faced persistent challenges, including high costs, strict regulatory requirements, and long development timelines. These challenges continue to impact current efforts to build a sustainable domestic Mo-99 supply chain.

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The United States imports more than 30 medical isotopes from other nations. The radiopharmaceutical supply chain is especially fragile due to the short shelf life of isotopes and limited suppliers. Geopolitical instability, unplanned reactor outages, and adverse weather can further disrupt supply. Domestic radiopharmaceutical suppliers, who receive isotopes from abroad, would be impacted by price changes and uncertainty caused by additional tariffs.

In addition, domestic capacity to produce additional medical isotopes depends on specialized equipment produced overseas such as linear accelerators, cyclotrons, and hot cells. Quickly onshoring the manufacturing of this equipment would be difficult given the complexity of the technology, the infrastructure needed, and the highly trained workforce employed by the current international manufacturers.

Isotope supply is not the only area impacted by the implementation of tariffs. American radiopharmaceutical producers will be deeply affected by disruptions in the supply chain for medical equipment, including cyclotrons and particle accelerators.

Depending on the specifications, a cyclotron — a machine used to produce radiopharmaceuticals for PET/CT, SPECT/CT, and other imaging procedures — can cost between $2 million and $4 million. These machines are produced by several international manufacturers, using proprietary technology, employing a highly trained and experienced workforce. Even the current 10 percent tariffs being levied on all nations are impacting American producers and hospitals. A $2 million imaging machine will now cost $2.2 million. This increase will disproportionately impact underserved hospitals in urban and rural areas, which already operate on razor thin budgets.

Nuclear medicine is a unique imaging and therapeutic modality. Recent breakthroughs in brain imaging have allowed for better treatment of Alzheimer's disease, and new therapeutic agents have created new personalized treatment options for patients impacted by prostate cancer. In the future, we hope to use advances in the world of theranostics to treat numerous forms of cancer and rare diseases. Given the delicate nature of the current radiopharmaceutical supply chain, SNMMI believes that leveled tariffs would increase patient costs, reduce access to nuclear medicine procedures, and impact reimbursement for populations on Medicare. We ask the Administration to consider deferring future tariffs on the radiopharmaceutical industry while we continue our goal of building a resilient and strong domestic supply chain.

SNMMI would welcome the opportunity to work with the Administration on policies which would reduce regulatory burdens, streamline licensing, and create financial incentives to foster a durable and resilient environment for innovation and business to thrive in the United States.

Sincerely,

Cathy S. Cutler

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