

May 7, 2025



**Stephen Astle**

Director

Office of Strategic Industries and Economic Security

Bureau of Industry and Security

Department of Commerce

1401 Constitution Ave. NW

Washington, DC 20230

**Subject: Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients (250414-0065)**

Dear Director Astle:

On behalf of the National Association of Nuclear Pharmacies, I appreciate the opportunity to submit public comments in response to the Department of Commerce's (the Department) Section 232 investigation into the national security implications of imports of pharmaceuticals and pharmaceutical ingredients.

The National Association of Nuclear Pharmacies is the leading association representing nuclear pharmacies in the United States, representing over three hundred nuclear pharmacies in the U.S. that prepare and distribute FDA-approved radiopharmaceuticals used in diagnostic and therapeutic nuclear medicine procedures. These prescription drugs help clinicians to diagnose and plan the most effective treatment for diseases such as cancer, Alzheimer's, Parkinson's, and cardiovascular diseases, and to treat cancers of the thyroid, prostate, and neuroendocrine system.

We support the Administration's commitment to strengthening domestic supply chains and advancing national security. However, we caution that imposing tariffs on pharmaceuticals and their ingredients—particularly critical materials used in the production, preparation, and delivery of radiopharmaceuticals—would have a harmful impact on the nuclear medicine supply chain. These consequences could include disruptions in the availability of patient-ready doses, increased manufacturing, and handling costs, and ultimately, reduced access to critical diagnostics and radiotherapies relied upon by patients nationwide. Strategies to defer tariff implementation not only mitigate the risk of immediate harm to patient care but also provide space for a more deliberate, evidence-based evaluation of the long-term impacts such trade actions could have on healthcare delivery, reimbursement systems, and continued innovation in nuclear medicine.

**Current and projected demand for pharmaceuticals and pharmaceutical ingredients in the United States**

Demand for radiopharmaceuticals in the United States is growing steadily due to the increased use of precision medicine in oncology, cardiology, and neurology. With an aging population and a rising incidence of chronic disease, procedures utilizing radiopharmaceuticals are expected to grow significantly in the next decade. According to industry estimates, over 20 million nuclear medicine procedures are conducted annually, a number projected to increase as new diagnostics and therapies are approved.<sup>1</sup>

**Extent to which domestic production of pharmaceuticals and pharmaceutical ingredients can meet domestic demand:**

The United States lacks the domestic production infrastructure to fully meet the demand for

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<sup>1</sup> Society of Nuclear Medicine and Molecular Imaging. (n.d.). *Fact Sheet: Nuclear Medicine and Radiation Safety*. Retrieved from <https://snmmi.org/Patients/Patients/Fact-Sheets/Fact-Sheet--Nuclear-Medicine-and-Radiation-Safety.aspx>

radiopharmaceuticals. Key isotopes and precursor chemicals—such as Molybdenum-99 (Mo-99), Lutetium-177 (Lu-177), and Gallium-68 (Ga-68)—are sourced from a limited number of foreign suppliers.<sup>2</sup> While domestic capacity is expanding through programs supported by the Department of Energy, full self-sufficiency is not yet feasible.

### **Role of foreign supply chains, particularly of major exporters, in meeting United States demand for pharmaceuticals and pharmaceutical ingredients:**

Foreign supply chains are critical to U.S. nuclear pharmacies. The Netherlands, Belgium, Australia, and South Africa supply the majority of Mo-99 used in diagnostic imaging. European producers of Lu-177 and Ga-68 also provide essential isotopes for newly approved targeted therapies. These suppliers are vital, and any disruption to these supply chains could result in nationwide shortages.

### **Concentration of United States imports of pharmaceuticals and pharmaceutical ingredients from a small number of suppliers and the associated risks**

Radiopharmaceutical ingredients are imported from a small number of specialized facilities around the world. This concentrated import structure creates a substantial risk of disruption from geopolitical tensions, manufacturing failures, or transportation issues. Because these products have short half-lives and cannot be stockpiled, even short-term interruptions can jeopardize patient care.

### **Impact of foreign government subsidies and predatory trade practices on United States pharmaceuticals industry competitiveness**

Some foreign governments support radiopharmaceutical production through direct subsidies or by operating public facilities.<sup>3</sup> These practices can lower global prices, making it difficult for emerging U.S. producers to compete. However, artificially suppressed prices can also mask the true cost of production and distort the market, deterring long-term domestic investment.

### **Potential for export restrictions by foreign nations, including the ability of foreign nations to weaponize their control over pharmaceuticals supplies:**

There is real concern that foreign governments could impose export restrictions on medical isotopes or precursors during emergencies. The COVID-19 pandemic highlighted this vulnerability, as several nations restricted exports of healthcare products.<sup>4</sup> Such actions would have immediate and severe impacts on nuclear medicine services.

### **Feasibility of increasing domestic capacity for pharmaceuticals and pharmaceutical ingredients to reduce import reliance:**

Expanding domestic capacity is feasible and already underway through public-private partnerships. Initiatives like the Department of Energy's Mo-99 program, and new commercial investments are promising.<sup>5</sup> **However, these efforts require years of regulatory review, capital investment, and infrastructure development before they can fully replace imports.**

### **Impact of current trade policies on domestic production of pharmaceuticals and pharmaceutical ingredients, and whether additional measures, including tariffs or quotas, are necessary to protect**

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<sup>2</sup> Fornell, D. (2024, November 27). *Why is the US still dependent on foreign medical isotope production?* Health Imaging. <https://healthimaging.com/topics/medical-imaging/molecular-imaging/why-us-still-dependent-foreign-medical-isotope-production>

<sup>3</sup> OECD Nuclear Energy Agency. (2020). *The supply of medical radioisotopes: Implementation of the HLG-MR policy approach – Results from a self-assessment by the global 99Mo/99mTc supply chain*. OECD Publishing. [https://www.oecd-neo.org/upload/docs/application/pdf/2020-08/implementation\\_hlg-mr\\_policy.pdf](https://www.oecd-neo.org/upload/docs/application/pdf/2020-08/implementation_hlg-mr_policy.pdf)

<sup>4</sup> Sidley Austin LLP. (2021, February). *Export restrictions on medical supply amidst a pandemic*. Retrieved from <https://www.sidley.com/en/insights/publications/2021/02/export-restrictions-on-medical-supply-amidst-a-pandemic>

<sup>5</sup> U.S. Department of Energy. (n.d.). *NNSA's Molybdenum-99 Program: Establishing a Reliable Domestic Supply of Mo-99 Without the Use of Highly Enriched Uranium*. National Nuclear Security Administration. Retrieved from <https://www.energy.gov/nnsa/nnsas-molybdenum-99-program-establishing-reliable-domestic-supply-mo-99-without-use-highly>

**national security:**

Current trade policies support continued access to critical imports, which are essential to sustaining the radiopharmaceutical supply chain. Imposing tariffs on imported pharmaceutical ingredients—without viable U.S. alternatives—would increase costs, delay treatments, and reduce availability of life-saving diagnostics and therapies.

**Additional Factors:**

Radiopharmaceuticals are essential not just to individual patient care but to public health preparedness, veterans' health, and national emergency response capabilities. Ensuring a stable and affordable supply is a national priority that requires collaboration—not disruption—across international and domestic partners.

**Conclusion**

The National Association of Nuclear Pharmacies urges the Administration to recognize that the continued advancement of nuclear medicine depends on uninterrupted access to imported critical minerals, isotopes, and their derivatives. While we strongly support the goal of enhancing domestic production capacity, the imposition of tariffs on these essential materials used in radiopharmaceutical production at this stage would not strengthen national security. Instead, it would disrupt the fragile global supply chains that nuclear medicine professionals and healthcare providers rely on, delaying or denying patient access to time-sensitive, life-saving diagnostic procedures and therapy.

**We respectfully encourage the Department to adopt strategies which seek to defer implementation of tariffs on these products to prevent avoidable harm while allowing policymakers to fully understand the complex and significant implications for public health, medical supply chains, and the future of nuclear medicine in America.** Preserving international access during this transition is essential to ensuring that patients continue to benefit from the full potential of nuclear medicine while the United States builds the infrastructure needed for long-term resilience.

Sincerely,



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