American College of Radiology™

May 7, 2025

Submitted via Regulations.gov

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: (BIS-2025-0022; XRIN 0694-XC120) Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients; Comments of the American College of Radiology

The American College of Radiology (ACR)—a professional association representing more than 40,000 physicians practicing diagnostic radiology, interventional radiology, radiation oncology, and nuclear medicine, as well as medical physicists—appreciates the opportunity to comment on the "Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients" ("the Notice"), issued by the Bureau of Industry and Security ("BIS") of the Department of Commerce ("Commerce").

Radiologic contrast agents (or "contrast media") are used in medical imaging to improve the visibility of specific organs, blood vessels, or tissues and to distinguish selected areas of the body from surrounding tissue. Radiopharmaceuticals combine a pharmaceutical (drug or biological molecule) with a radioactive element (radioisotope). Radiopharmaceuticals are administered to a patient and then detected with specialized imaging equipment. Radiopharmaceuticals are used in diagnostic tests and therapy, particularly in cancer treatments.

Contrast agents and radiopharmaceuticals are used in millions of advanced medical imaging studies in the U.S. annually. They are a critical part of diagnostic, screening, and/or therapeutic procedures and, in many cases, there are no available alternative materials. Radiologists, nuclear medicine physicians, and radiation oncologists rely on radiologic contrast media and radiopharmaceuticals to achieve the most accurate, cost effective, and beneficial diagnoses and treatment outcomes for their patients.

The ACR is concerned radiologic contrast agents and radiopharmaceuticals could be included in Commerce's Section 232 investigation of "pharmaceuticals and API" and impacted by any resulting tariffs or other trade restrictions. Such an outcome would almost certainly drive up the cost of life-saving imaging and therapeutic procedures and potentially disrupt patient access to medically necessary imaging and

radiopharmaceutical therapies. Any increase in the cost of these materials would, by necessity, be passed directly to U.S. patients and payers. As these materials are components of medical procedures and can only be administered by appropriately qualified healthcare providers, we do not believe these materials are the intended target of this investigation. Rather, "pharmaceuticals" are generally understood to be patented, generic, or over-the-counter products purchased by patients and self-administered for a prescribed period. **Accordingly, we strongly recommend exclusions or deferrals for radiologic contrast agents and radiopharmaceuticals.**

The ACR has long supported strengthening U.S. and North American production of imaging technology and adjacent products used in medical imaging and therapeutic procedures. For example, the ACR advocated for the American Medical Isotopes Production Act and subsequent implementation activities within the Department of Energy and other federal agencies. Nevertheless, we acknowledge the complexities associated with this matter. Therefore, we believe it is important that radiologic contrast agents and radiopharmaceuticals be excluded from this Section 232 process or that tariffs be deferred until greater domestic production capacity/supply is available.

The ACR appreciates the opportunity to comment, and we welcome further communications on this topic. For questions, please contact Michael Peters, ACR Senior Director, Government Affairs, at mpeters@acr.org.

Regards,

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American College of Radiology