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WRITTEN SUBMISSION OF THE ADVAMED MEDICAL IMAGING DIVISION

Request for Public comments on

Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients

Docket No. 250414-0065 | BIS-2025-0022 | XRIN 0694-XC120

May 7, 2025

AdvaMed Medical Imaging Division (hereinafter "AdvaMed Imaging") is making this submission in response to the request for comments 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" or "DoC"). This submission focuses specifically on contrast agents, which are used in medical imaging procedures. For reasons outlined below, AdvaMed Imaging believes contrast agents should not fall within the scope of the Section 232 investigation and any remedies.

About AdvaMed Imaging

Medical Imaging Technology at AdvaMed™ represents the world's largest, leading companies that are providing healthcare professionals with the ability to screen, diagnose, treat, and monitor patients by providing accurate, detailed images. In December 2023, AdvaMed®, the Medtech Association, announced the establishment of a new Medical Imaging Technology division focused on advocating on behalf of large and small companies for the essential role of medical imaging technology, radiopharmaceuticals, contrast media, and focused ultrasound devices in our nation's health care system.

Overview

On April 14, the Department of Commerce's Bureau of Industry and Security announced the initiation of a Section 232 investigation into the effects on US national security of imports of pharmaceuticals and pharmaceutical ingredients. As critical suppliers of America's health infrastructure, AdvaMed Imaging members believe these are important issues that should be

reviewed carefully. However, we believe contrast agents represent a distinct class of product and market and should be excluded from this investigation and any remedies it recommends.

Discussion

Contrast agents are used exclusively in connection with medical imaging procedures. Contrast agents are substances used to enhance the visualization of a body part during a diagnostic imaging procedure and are used in conjunction with X-rays, computed tomography (CT), magnetic resonance (MR), and ultrasound. When consumed orally, or injected into the body, contrast agents enable better anatomical imaging, allowing clinicians to see certain anatomical structures in more detail and definition; this in turn supports a more accurate means of diagnosing and effectively treating disease. Contrast agents are broken down over time and eventually eliminated from the body by normal processes.

As medical imaging manufacturers, the members of AdvaMed Imaging do not believe the contrast agents used in conjunction with imaging procedures conducted on the devices we make should be part of this investigation of "pharmaceuticals." These products are adjuncts used in imaging processes specifically to enhance and improve the value of the image being taken. Despite being regulated as prescription drugs by the FDA, principally in reflection of their route of administration through injection into the body, contrast agents are distinct from other pharmaceuticals.

Their classification in the Harmonized Tariff System of the United States (HTSUS) reflects this: contrast agents are imported under HTSUS 3006.30 ("Opacifying preparations for X-ray examinations; diagnostic reagents designed to be administered to the patient"), part of a four-digit sub-heading (3006) that contains a number of other 'pharmaceutical-adjacent' products (for some reason classified under HTSUS 30) that the Administration has already excluded from the scope of this investigation by not including them in Annex II announced on April 2: e.g., sterile surgical catgut and similar sterile suture materials; dental cements and fillings; first-aid boxes and kits; appliances for ostomy use; and waste pharmaceuticals.

Furthermore, we wish to highlight the following characteristics which differentiate contrast agents from those commonly considered to be 'pharmaceuticals':

1. Contrast agents are only used in conjunction with medical imaging devices, and only for a specific procedure, not on a recurring basis. Unlike branded and generic pharmaceuticals which are prescribed to and taken by patients for a defined period (or indefinitely), contrast agents are used only once and during a specific medical imaging procedure. Contrast agents serve no treatment purpose; they serve to enhance anatomical detail which optimizes the physician's diagnostic capability at the time of a medical imaging scan.

2. Contrast agents are administered by clinicians, and only in healthcare settings, and are not self-administered at home by patients. Unlike branded and generic pharmaceuticals which patients obtain at a pharmacy and take at home as prescribed, contrast agents are only administered on-site by technicians in hospitals or clinics.

3. Contrast agents are purely for diagnostic rather than therapeutic or preventive purposes. Contrast agents do not address or prevent the symptoms of an ailment and have no therapeutic purpose; their only role is to assist in diagnosis.

4. Contrast agents are one-time expenses that are added to hospital bills, not recurring costs incurred at pharmacies. The cost of a contrast agent is generally added to a hospital or clinic bill for an imaging procedure, not paid separately by patients and their insurers like branded and generic pharmaceuticals obtained at a pharmacy.

5. Contrast agents are significantly less expensive than most pharmaceuticals. Compared to average US prescription costs of over $100 (often significantly higher) for branded pharmaceuticals and over $40 for generic pharmaceuticals, and per capita retail prescription drug spending of $1227 (2022, Department of Labor), the cost of contrast agents is less than $20 for a procedure.

6. Many contrast agents are off-patent products with lower margins than patented pharmaceuticals. Any tariffs on them likely could not be absorbed but would be passed on to providers and patients.

7. Contrast agents are not on the list of 227 drugs on the FDA's list of (patented and generic) "Drug and Biologic Essential Medicines, Medical Countermeasures and Critical Inputs."

Conclusion

AdvaMed Imaging believes the foregoing distinguishing characteristics, combined with the FDA's 2020 determination that contrast agents should not be included on the list of over 200 "essential" medicines, underscores the reason that contrast agents should not be included within the scope of this Section 232 investigation. The Administration has launched the Section 232 investigation solely into pharmaceuticals but not into medical devices, a decision which the members of AdvaMed Imaging strongly support. While AdvaMed Imaging does not suggest that contrast agents are medical devices, we do strongly believe that these agents are most appropriately viewed as an adjunct to the medical device ecosystem: as such, exclusion from the scope of the Section 232 investigation would be most appropriate.

AdvaMed Imaging appreciates the opportunity to submit our views on this important matter. Should you have any further questions related to these comments or any other matter involving contrast media, please contact Patrick Hope, Executive Director, AdvaMed Medical Imaging at phope@advamed.org.

Sincerely,

Patrick Hope
Executive Director
AdvaMed Imaging Division