MITA
MEDICAL IMAGING
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A DIVISION OF NEMA

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May 10, 2022

The Honorable Frank Pallone, Jr.
2107 Rayburn House Office
Washington, DC 20515

The Honorable Cathy McMorris Rodgers
1035 Longworth House Office Building
Washington, DC 20515

Dear Chairman Pallone and Ranking Member McMorris Rodgers,

The Medical Imaging & Technology Alliance (MITA) takes this opportunity to express support for the Committee's inclusion of a provision in the House User Fee legislation that ensures medical imaging drugs are properly classified and regulated by the FDA. We refer to Section 803 of H.R. 7667 of the Food and Drug Amendments of 2022.

MITA is a division of the National Electrical Manufacturers Association (NEMA) and is the leading organization and collective voice of medical imaging equipment, radiopharmaceutical and contrast agent manufacturers, innovators, and developers. MITA represents companies whose sales make up 90 percent of the global market for medical imaging technologies. MITA priorities include adopting uniform standards for medical imaging service providers, ensuring patient access to medical imaging, developing standards to ensure patient safety and timely access to the market, and improving the regulatory environment to promote growth and innovation.

MITA believes that FDA is lawfully regulating all medical imaging agents as drugs and that to reclassify these products as devices would violate the clear definitions of drugs and devices under the Federal Food, Drug, and Cosmetic Act (FDCA) and the intent of the law. Medical imaging agents, such as contrast agents and diagnostic radiopharmaceuticals, are administered *in vivo* and are used with various imaging modalities (such as radiography, ultrasonography, computed tomography, magnetic resonance imaging, and radionuclide imaging) for a variety of diagnostic or monitoring procedures.

Section 803 will prevent the substantial negative impact that reclassifying these agents will have on patient safety surveillance, use of FDA resources and consistency in regulation, the medical imaging industry, and goals of global harmonization. Many of MITA's Members have invested significant resources to obtain regulatory approval of their medical imaging agents as drugs and to maintain compliance with FDA drug regulations. There would be substantial impact from a transition to device status.

MITA respectfully offers its support of Section 803 of H.R. 7667 that will allow FDA to continue regulating all imaging agents as drugs. If you have any questions, please contact Sue Bunning, Industry Director for Positron Emission Tomography, at sbunning@medicalimaging.org or 703-340-4100.

Sincerely,

Patrick Hope
Executive Director, MITA

MITA is the collective voice of manufacturers of medical imaging equipment, radiopharmaceuticals, contrast media, and focused ultrasound therapeutic devices. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging innovations. These products include magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, and imaging information systems. MITA Member company technologies are an important part of our nation's healthcare infrastructure and are essential for the screening, diagnosis, staging, managing and effectively treating patients with cancer, heart disease, neurological degeneration, and numerous other medical conditions.