MITA AND CORAR SUPPORT HOUSE BILL TO FOSTER ACCESS TO INNOVATIVE MEDICAL IMAGING

04.10.17

MITA and CORAR Support House Bill to Foster Access to Innovative Medical Imaging

Associations Say Reps. Costello and Peters’ Bill Will Enhance Patient Access to Innovative Imaging Technology

WASHINGTON, D.C. – The Medical Imaging & Technology Alliance (MITA), the collective voice of medical imaging manufacturers and innovators, and the Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR), whose members manufacture radiopharmaceuticals and contrast agents used in medical imaging procedures, said today they fully support H.R. 2009, the “Fostering Innovation in Medical Imaging Act of 2017,” introduced by Congressmen Ryan Costello (R-PA) and Scott Peters (D-CA).

This bipartisan bill provides medical imaging device and contrast drug manufacturers a clear regulatory pathway to ensure patients have access to innovative advanced medical imaging technologies. Many of these new medical imaging technologies are indicated with previously approved contrast agents. In some instances, medical imaging technology advances have outpaced the approved contrast agent labels. This bill builds on the 2017 user fee agreements and will ultimately allow patients in all communities to access the cutting edge innovation in diagnostic imaging by labeling products with new indications for use. The bill clarifies the U.S. Food & Drug Administration’s (FDA) authority to continue to consider and clear new indications for imaging device manufacturers, while providing contrast agent manufacturers with incentives to update contrast agent labels for products that have been previously approved under FDA’s rigorous safety and efficacy standard.

Significant advances have been made in medical imaging equipment, allowing for more targeted procedures and better tools to help physicians make informed diagnoses. By clarifying the process for imaging equipment manufacturers to gain approval for new technologies that utilize formerly approved contrast agents, this bill will spur even more innovation. This is an opportunity to ensure patient access to new imaging technology and give physicians even more specific information when considering treatment options.

“MITA and its members applaud Congressmen Costello and Peters for their efforts on behalf of patients to clear regulatory hurdles and improve access to advancements in medical imaging that help physicians detect disease earlier when it’s more treatable,” said MITA Executive Director Patrick Hope. “We look forward to working in a bipartisan manner to move this bill forward so the regulatory approval process can keep pace with medical innovation that benefits patients.”

Michael Guastella, Executive Director of CORAR stated that the “Fostering Innovation in Medical Imaging Act of 2017” will provide contrast-agent drug manufacturers with better incentives to support the introduction of new and innovative imaging technologies. These

...
technological advancements will allow physicians to better diagnose and treat patients in the United States.

“We look forward to working with the FDA, Congress and other stakeholders to advance this important bill.”

The Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR) is an association comprised of companies who manufacture and distribute radiopharmaceuticals, radionuclides, and contrast agents primarily used in medicine and life science research. CORAR advocates for regulations and legislation that facilitate innovation in diagnosis and therapy to advance health care for patients and providers. Specifically, CORAR focuses on manufacturing, transportation, safety, security, government reimbursement, and regulatory issues that can impact the radiopharmaceutical, radionuclide, sealed source, and contrast agent industries. CORAR pursues a proactive agenda which includes education of the Congress and regulatory bodies on the benefits of radiopharmaceuticals, radionuclides, and contrast agents to the medical and life science communities.

MITA is the collective voice of medical imaging equipment and radiopharmaceutical manufacturers, innovators and product developers. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging technology. These technologies include: magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, and imaging information systems. Advancements in medical imaging are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. The industry is extremely important to American healthcare and noted for its continual drive for innovation, fast-as-possible product introduction cycles, complex technologies, and multifaceted supply chains. Individually and collectively, these attributes result in unique concerns as the industry strives toward the goal of providing patients with the safest, most advanced medical imaging currently available.