STATEMENT

OF

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ON BEHALF OF

THE MEDICAL IMAGING & TECHNOLOGY ALLIANCE (MITA)

REGARDING A HEARING ON

"FDA User Fee Reauthorization: Ensuring Safe and Effective Medical Devices"

BEFORE THE
U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON HEALTH

Wednesday, March 30, 2022

Statement:

Intro
Chairman Pallone, Ranking Member McMorris Rodgers, Chairwoman Eshoo, Ranking Member Guthrie, and distinguished members of the Subcommittee:

Thank you for the opportunity to appear before you today to discuss the FDA's Medical Device and User Fee program. I am Diane Wurzburger, , Executive of Regulatory Affairs for GE Healthcare, testifying on behalf of the Medical Imaging and Technology Alliance (MITA). I am an active MITA member, serving on the Board of Directors as well as Chair of the Technical and Regulatory Committee and have served as a MITA industry representative to multiple MDUFA negotiations with FDA.

MITA
MITA is the primary trade association and standards development organization representing the manufacturers of medical imaging equipment, radiopharmaceuticals, contrast media, and focused ultrasound devices. It represents companies whose sales comprise more than 90 percent of the market for medical imaging technologies, including magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, AI-enabled imaging software, and other products.

Value of Imaging
MITA member companies' technologies play an essential role in our nation's healthcare infrastructure and are integral to the care pathways of evaluating, staging, managing, and effectively treating patients with cancer, heart disease, neurological degeneration, COVID-19, and numerous other medical conditions. By catching disease early, reducing the need for invasive, inpatient procedures and facilitating shorter recovery times, medical imaging saves money and improves efficiency in the health care system. Medical imaging technologies have revolutionized health care delivery in America and around the world, extending human vision into the very nature of disease. Today, technology that was once unimaginable is now the medical standard of care. The next generation of imaging technologies will further advance healthcare and the practice of medicine. A consistent and timely FDA review process is essential to timely patient access to these technologies.

MDUFA
MITA continues our strong support for an effective, well-resourced FDA capable of fulfilling its mission to protect and promote the public health. The medical imaging industry supported enactment of FDA's user fee program in 2002 and its subsequent reauthorizations in 2007, 2012, and 2017. We participated alongside our other industry colleagues in the MDUFA V negotiations and support enactment of the proposed agreement. This agreement, if enacted, will provide the device program with ample resources, bring new accountability measures to the program, and allow for exploration of new review paradigms through the Total Product Lifecycle Advisory Program also known as TAP.

User Fees provide for an efficient pre-market review process allowing for innovative medical devices to get to patients and healthcare providers in an expedient, consistent, and transparent manner. MITA member companies are actively developing innovative new technologies that will depend on efficient regulatory pathways to patient access. The User Fee program will enable premarket review of advanced imaging platforms such as photon counting CT, high-tech focused ultrasound therapeutics, and new artificial intelligence-enabled digital health technologies. Supplementing FDA funding with User Fees brings stability and predictability to the device review process and timelines. The goals that the medical device industry and FDA commit to and FDA's subsequent performance are critical to timely patient access to safe and effective medical advancements. Without a consistent and timely FDA review process,

conducted by a well-trained staff, access to new diagnostic imaging technologies will be delayed and industry's ability to deliver technological advancements will be compromised.

We support the FDA in proposing this
agreement to Congress and we will continue to partner with FDA and other stakeholders in asking Congress to reauthorize this important program that supports patient access to medical imaging innovations.

MDUFA V

MDUFA V was negotiated during turbulent times for all parts of our healthcare system, including innovators, regulators, healthcare providers, and patients. The COVID-19 pandemic strained every part of our society with a tremendous toll of death, illness, and suffering. FDA and industry strived to meet the challenges presented by the public health emergency by ensuring safe and effective medical devices could be delivered to patients in an expeditious manner. The last several years created significant resource challenges for FDA and as it seeks to recover its operations and get back on track, it will need to be sufficiently resourced to meet its obligations and continue to review products for safety and effectiveness.

The MDUFA V agreement will raise the Center for Devices and Radiological Health's (CDRH) funding significantly, allowing the Center to meet its premarket review commitments. These new investments will enable the Center to increase headcount, expand current programs, and test new review models such as TAP.

Under the MDUFA V agreement, CDRH will be able to hire up to 387 new FTEs and meet rising payroll costs. The Agency will also continue to invest in successful programs that support:

- the use of standards and real world evidence in regulatory premarket decisions;
- promote the advancement of digital health technologies;
- harmonize international medical device regulatory activities and promote ongoing global US FDA leadership;
- expand patient engagement opportunities to inform the development and evaluation of innovative technologies ; and
- fund continued collaboration with accredited third party reviewers to support a voluntary alternate review pathway.

FDA will also be able to launch a limited pilot for its TAP program to enhance communication, collaboration and engagement between the agency and medical device stakeholders for breakthrough and other eligible devices; with review and assessment milestones along the way.

MDUFA V will also bring to bear new accountability measures that ensure User Fee dollars are being appropriately invested in shared goals. Review staff are a critical component of the Center's work, so FDA will be expected to meet certain hiring targets. Industry wants FDA to be appropriately staffed. But if there are staffing shortfalls, we want the User Fee dollars to be reinvested in the premarket program via offsetting of future fees. There will also be a new cap on the accrual of carryover balances. FDA should not be holding user fee funds for purposes other than to meet its performance goals and commitments. If the carryover balance exceeds the specified cap, then those excess funds will be used to offset future fees or otherwise invested in a mutually agreed upon way. Industry and FDA will also support multiple independent assessments to generate recommendations on how the Center can continue to improve its operations.

Closing

MITA urges Congress to move quickly to enact MDUFA V. This agreement, negotiated between FDA and the medical device industry over the last year and a half, will ensure ongoing patient access to safe and effective medical devices.

Thank you for the opportunity to present our views today. I am happy to answer any questions you may have.