STATEMENT

OF

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ON BEHALF OF

THE MEDICAL IMAGING & TECHNOLOGY ALLIANCE (MITA)

REGARDING A HEARING ON

"Examining FDA's Medical Device User Fee Program"

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

Tuesday, March 28, 2017

Summary of Testimony:

The Medical Imaging and Technology Alliance (MITA) represents manufacturers of medical imaging equipment and radiopharmaceuticals. Without a consistent and timely FDA review process, conducted by a well trained staff, access to new diagnostic imaging equipment is delayed and industry's ability to deliver technological advancements is compromised.

The medical imaging community has been consistent in its desire for more predictability, consistency, transparency and timeliness throughout the device premarket review process. MITA and its members believe that all MDUFA commitments should be backed by appropriate, measureable and predictable performance goals that support these principles. MITA worked in good faith with other industry stakeholders and the FDA to negotiate the MDUFA IV agreement. We are particularly interested in:

- Reduction in 510(k) total time to approval;
- Performance metrics for the pre-submission process;
- The center-wide Quality Management program;
- The Accreditation Scheme for Conformity Assessment (ASCA) Program; and
- Third party independent assessment

We are committed to ensuring the ultimate beneficiaries of these negotiations, the American public, benefit from continued improvements in timely access to the innovative devices and diagnostics necessary for the public health. MITA urges Congress to move quickly to reauthorize MDUFA IV. This agreement, negotiated between FDA and the medical device industry, advances our shared goals of ensuring that patients have timely access to the most innovative devices and diagnostics necessary for the public health.

Chairman Burgess, Ranking Member Green, 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, J.D., RAC, Executive of Regulatory Affairs for GE Healthcare. I'm here today to testify 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. I served as a MITA industry representative to the MDUFA IV negotiations with FDA.

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.

Value of Medical Imaging:

Medical imaging helps detect and diagnose disease at its earliest, most treatable stages and guides physicians and patients in determining the most appropriate and effective care. Our

technologies are fundamental to standards of care. By catching disease early, reducing the need for invasive, in-patient 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, medical imaging enables a new and more powerful generation of diagnosis and intervention.

Over the last 20 years, imaging has contributed to significant advances in healthcare delivery, leading to better health outcomes and reduced costs. For example, 20 years ago, an X-ray was used to detect lung nodules, but was limited in its capacity to detect small nodules. Now, low dose lung computed tomography (CT) finds tiny tumors the size of a grain of rice. This reduces lung cancer deaths by 20% compared to chest x-ray.

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 devices.

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 and 2012. We participated in the MDUFA IV negotiations and believe that this agreement, if enacted, will improve FDA review of medical devices, ensuring that American patients have timely access to safe and effective medical devices. 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.

User fees provide for a more efficient pre-market clearance process allowing for life-saving devices to get to market more quickly. We believe that enhanced FDA funding brings stability and predictability to the device review process and timelines. The goals that the medical device industry and FDA agree on 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 equipment is delayed and industry's ability to deliver technological advancements is compromised.

MDUFA IV:

With this in mind, the medical imaging community has been consistent in its desire for more predictability, consistency, transparency and timeliness throughout the device premarket review process. MITA and its members believe that all MDUFA commitments should be backed by appropriate, measureable and predictable performance goals that support the principles of predictability, consistency, transparency and timeliness.

We are particularly pleased to see performance metrics for reduction in total time to review for 510(k)s to 108 days. The MDUFA IV agreement will make key improvements to the device review program, providing the Agency will the resources necessary to expedite the pre-market process while maintaining FDA's standards for safety and effectiveness. Similarly, we support the metrics for the pre-submission program. A pre-submission includes a formal written request from a device sponsor for feedback from the FDA which is provided either in writing or during a meeting or teleconference. A pre-submission provides the opportunity for a manufacturer to obtain feedback prior to the submission of a device application. This program

has brought value to industry and will continue to do so in a more predictable, consistent and timely way with specific, measureable metrics under the MDUFA IV agreement.

To support the reduction in total time to decision, MITA believes that the FDA intention to include the basis for deficiencies in all deficiency letters will lead to a more consistent approval process. Being able to trace deficiencies to specific sections of a rule, final guidance, recognized standard or scientific or regulatory issue will lead to reduced total time to decision, align reviewer practices across branches and divisions and provide more predictability for sponsors.

Intense negotiations between FDA and industry led to the inclusion of a variety of programs in the MDUFA IV agreement that MITA is committed to working with the FDA to implement. Real World Evidence, Patient Input, Digital Health and 3rd Party 501(k) Review have the potential to support MITA's tenets of predictability, consistency, transparency and timeliness, and we look forward to participating in the development of appropriate infrastructure for these programs to ensure that they align with industry expectations, patient needs and support FDA's mission of protecting the public health by assuring the safety, effectiveness, quality and security of medical devices.

MITA fully supports the center-wide quality management program. We believe that an effective quality management framework will support more consistent and predictable device review. The FDA will identify an annual audit plan and conduct those audits with an eye for sharing high-performing premarket review processes between divisions in the Agency. MITA believes that identifying good practices throughout the Agency and sharing them will lead to improved efficiency and effectiveness.

Included in the MDUFA IV agreement is the establishment of an Accreditation Scheme for Conformity Assessment (ASCA) Program

. This program allows for devices to be evaluated according to specific recognized consensus standards by certified testing laboratories. FDA has agreed not to review full test reports from certified testing laboratories except as part of a periodic audit. MITA is a strong proponent of the use of voluntary consensus standards and believes that the ASCA program will reduce time to decision and provide more predictability to the process.

Finally, MITA believes that a third party independent assessment is critical to determine whether the investment in the premarket review program is providing a more consistent, predictable and timely decision by the FDA. We look forward to participating in the comprehensive assessment of the process for the review of device applications and think that it's important to not only complete the evaluation that was started under MDUFA III but to also begin evaluating the programs funded by MDUFA IV.

MITA maintains that the performance goals set forth in MDUFA IV are achievable and have easily understood and transparent metrics. These goals focus on reducing pre-market review times and improving the consistency of reviews.

Advancements in medical imaging are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. MITA looks forward to working collaboratively with FDA and Congress to develop a robust legislative proposal providing improved performance goals and reasonable user fees for value. We believe that the MDUFA IV agreement will lead to an improvement in patient access to safe and effective medical devices. Most importantly we are committed to ensuring the ultimate beneficiaries of

these negotiations, the American public, benefit from continued improvements in timely access to the innovative devices and diagnostics necessary for the public health.

MITA urges Congress to move quickly to reauthorize MDUFA IV. This agreement, negotiated between FDA and the medical device industry, advances our shared goals of ensuring that patients have timely access to the most innovative devices and diagnostics necessary for the public health.

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