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November 27, 2020

VIA ELECTRONIC DELIVERY

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: FDA-2020-N-0907, Medical Device User Fee Amendments for Fiscal Years 2023 Through 2027, Request for Comment

Dear Dr. Shuren:

As the leading trade association representing the manufacturers of medical imaging equipment, radiopharmaceuticals, contrast media, and focused ultrasound therapeutic devices the Medical Imaging & Technology Alliance (MITA) is responding with comments on the Medical Device User Fee Amendments (MDUFA) program for fiscal years 2023 through 2027.

In this request for comment, the Food and Drug Administration (FDA) solicits input on four questions:

1. What is your assessment of the overall performance of MDUFA IV thus far?
2. What programs/commitments under MDUFA IV are working well?
3. What programs/commitments can be added or improved to enhance the efficiency and effectiveness of the medical device review process for MDUFA V?
4. What should the medical device ecosystem, and our medical device program in particular, look like at the end of MDUFA V (i.e., September 2027), and how can MDUFA V support achieving that future state?

MITA strongly supports the MDUFA program and believes it should continue as an efficient, consistent, and transparent methodology for funding the premarket review of medical devices for safety and efficacy prior to these products entering the market.

Our technologies play an essential role in our nation's health care infrastructure, as well as the care pathways of screening, staging, evaluating, managing, and effectively treating patients with cancer, heart disease, neurological degeneration, and numerous other medical conditions. Under the User Fee program, medical imaging technology manufacturers have been able to deliver and iterate on safe and effective innovations for patients in a timely manner. MITA Member companies have in recent years brought to market innovative technologies including low-dose computed tomography (CT), high Tesla magnetic resonance imaging (MRI) systems, ultrasound elastography, and advanced artificial intelligence (AI) algorithms. Our Member companies' ability to bring these innovative technologies safely and effectively

to patients and healthcare providers has been supported by the efficient, predictable, and transparent premarket review pathway created by the Medical Device User Fee program.

1. **What is your assessment of the overall performance of MDUFA IV thus far?**

Under the current iteration of the User Fee program, MDUFA IV, the FDA has produced satisfactory premarket review performance results which we hope to carry into MDUFA V. The ground that has been gained for premarket review performance under MDUFA IV needs to serve as the foundation for ongoing success during MDUFA V.

2. **What programs/commitments under MDUFA IV are working well?**

Under MDUFA IV, the Agency has launched new initiatives, pilot programs, and special projects to investigate new sources of data, the use of Standards, novel digital technologies, and other emerging regulatory considerations. These initiatives are in various stages of maturity, some having only very recently been launched. The value proposition of these ancillary programs remains to be seen, but we look forward to continuing to work with the Agency over the remainder of the current User Fee iteration to determine the value for premarket review of these initiatives. As these programs progress, and as discussions concerning MDUFA V commence, we will work with FDA to determine whether these programs should be funded or not in MDUFA V. A key area of discussion will be whether these programs should continue to be funded by User Fees or in other ways.

3. **What programs/commitments can be added or improved to enhance the efficiency and effectiveness of the medical device review process for MDUFA V?**

Given the satisfactory performance to commitments the Agency has achieved under MDUFA IV, as well as the fact that the value proposition of special initiatives funded under MDUFA IV is still outstanding, we do not currently anticipate any need for major new programmatic initiatives or major new commitments in MDUFA V. We hope to carry forward what has been working and leave behind what has not.

4. **What should the medical device ecosystem, and our medical device program in particular, look like at the end of MDUFA V (i.e., September 2027), and how can MDUFA V support achieving that future state?**

As it enters its third decade, the User Fee program has achieved maturity, delivering consistently satisfactory results for industry, and enabling safe and effective innovative technologies to reach patients and healthcare providers in an efficient and expeditious manner. It is our perspective that, at this point, the User Fee program is working as intended and that this performance level should be maintained into the future. It is our position that User Fees be stabilized around current funding levels, well below 50% of total program costs. MDUFA V should be re-focused on driving efficiency in the premarket review of medical devices, recognizing that the Agency has at its disposal the appropriations process to fund other programs and objectives.

MITA strongly believes that the existing 510(k) substantial equivalence pathway continues to be viable and we support its maintenance and utilization into the future under MDUFA V. The 510(k) substantial equivalence pathway is a cornerstone of efficiently bringing safe and effective medical devices to market.

In the 510(k) substantial equivalence pathway, manufacturers generally rely on comparative testing against predicate devices to demonstrate that a new device is as safe and effective as the predicate device. The predicate substantial equivalence comparison methodology has enabled innovators to iterate products

and build on well-established science and medicine. Medical device technologies have matured and thrived under this pre-market review paradigm. We fully expect that MDUFA V will support the ongoing viability of this premarket review pathway.

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We look forward to discussions regarding the fifth iteration of MDUFA and anticipate coming to agreement across industry and with the Agency on a program which continues to allow safe and effective technologies to efficiently come to market while also maintaining appropriations as the majority share of program funding. If you have any questions, please contact Peter Weems, Senior Director, Strategic Operations and Policy, at pweems@medicalimaging.org or 703-841-3228.

Sincerely,

Patrick Hope
Executive Director, MITA

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.