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Statement of
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Thank you for the opportunity to be here today to present the AdvaMed Medical Imaging Division's perspective on MDUFA VI. I am Patrick Hope, the Executive Director of the AdvaMed Medical Imaging Division. The Imaging Division is the newest division within AdvaMed, formally the Medical Imaging and Technology Alliance (MITA) through which we were part of the proceedings in previous MDUFA negotiations. Now, our imaging member companies have fully migrated to AdvaMed, and I am pleased to be here on their behalf. Today, we have over 60 member companies within the imaging division. More than three-quarters of our imaging companies are small manufacturers.

Our imaging technologies play an essential role in our nation's health care infrastructure, as well as the care pathways of screening, evaluating, managing, and treating patients with cancer, heart disease, neurological degeneration, 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. Most importantly, it's just better for the patient. Our member companies have in recent years brought to market innovative technologies including low-dose computed tomography (CT), high Tesla magnetic resonance imaging (MRI) systems, portable ultrasound, and advanced artificial intelligence (AI) algorithms. Medical imaging companies continue to lead the industry in the development and integration of AI solutions into imaging technologies for better patient care.

Medical imaging technologies continue to revolutionize health care delivery in America and around the world, extending human vision into the very nature of disease. Technology that was once unimaginable is now the medical standard of care. The next generation of imaging technologies will further advance health care and the practice of medicine. A transparent and predictable FDA premarket review process is essential to continuing prompt patient access to these innovative technologies.

User fees provide funding for adequate FDA resources with scientific expertise to conduct rigorous yet efficient pre-market review, allowing health care providers to have access to innovative medical devices in an expedient, consistent, and transparent manner. Our companies are actively developing new, innovative technologies for patient care that will depend on the continuation of these efficient, scientifically based regulatory premarket review pathways. Simply put, our ability to bring lifesaving, innovative technologies safely and effectively to patients and health care providers has been realized by the premarket review pathway supported by the MDUFA program.

We strongly support continuing the MDUFA program as an efficient and transparent funding mechanism for premarket medical device review. Supplementing FDA funding with user fees, and maintaining the MDUFA structure and goals, ensures FDA has appropriate resources and expertise to bring stability to the device premarket review process and decision 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 our industry's ability to deliver technological advancements to patients will be compromised.

We are making tremendous strides under MDUFA V, which has produced satisfactory premarket review performance results for imaging devices, which we hope to carry into MDUFA VI. The ground that has been gained for premarket review performance under MDUFA V needs to continue to serve as the foundation for ongoing success.

Given the satisfactory performance to commitments the agency has achieved under MDUFA V, we do not currently anticipate any need for major new programmatic initiatives or major new commitments. We hope to carry forward and build on the continued success of what works. The user fee program works as intended, and this performance level should be maintained and improved upon into the future.

We look forward to discussions regarding the sixth iteration of MDUFA and anticipate reaching an 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.