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Statement of
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Good morning, and thank you to the FDA for the opportunity to speak today as we begin the important process of planning for the next MDUFA program.

My name is Zach Rothstein, and I am the Executive Director of AdvaMedDx, a division within AdvaMed that speaks for the innovators and manufacturers of vitro diagnostics products that lead to accurate and timely diagnoses and are relied upon in more than 70 percent of all health care decisions. More than three-quarters of our Division's members are small businesses, which are significant drivers of innovation in our field.

The technologies our members create detect disease at its earliest, most treatable stages. They unlock the unique biology of each patient to guide personalized therapeutic decisions. And they serve as essential guideposts throughout the care continuum, informing not just if to treat, but how to treat, and when to change course.

Simply put: Modern medicine is impossible without modern IVDs. And it is on behalf of this critical, life-saving industry that I speak today.

As Janet stated, our North Star remains unchanged: ensuring patients have timely access to safe and effective medical technology. For the diagnostics industry, this means ensuring that the tests physicians and patients rely on to make critical health care decisions are accurate and available when needed most.

I want to acknowledge and commend the tremendous efforts of OHT 7, the Office of In Vitro Diagnostics, during the current MDUFA program. We recognize the extraordinary challenges OHT 7 faced during the COVID-19 pandemic, when the demand for diagnostic reviews surged to unprecedented levels. The office's dedication to addressing, and ultimately clearing, the resulting backlog while maintaining review quality has been remarkable.

As we consider the next iteration of MDUFA, we see it as an opportunity to "fine tune" a program that has matured significantly over the last two decades. For the IVD industry, this fine-tuning should build on the successes of prior agreements. For instance, the focus on the pre-submission process in MDUFA IV was a significant step forward, as early engagement with the agency is critical for the cutting-edge technologies and novel applications common in diagnostics.

Also, the expansion of international regulatory harmonization programs in MDUFA V is an area of great importance to our members. The global nature of the diagnostics market makes alignment on standards and regulatory approaches essential for getting critical tests to patients in the U.S. and around the world. We believe the MDUFA VI program should continue to enhance and support these global harmonization activities.

And lastly, with more than 75 percent of our members being small businesses, we have a particular interest in ensuring the MDUFA program continues to support small company success. Small diagnostic companies often develop innovative tests but may lack the regulatory resources of larger organizations. Programs like the presubmission process, small business fee waivers, and dedicated FDA small business assistance have been invaluable.

These small business support mechanisms that should be maintained because, as we know, today's small diagnostic startup may develop tomorrow's breakthrough cancer screening test or point-of-care infectious disease diagnostic.

In closing, AdvaMedDx and our member companies remain committed to our shared mission: ensuring patients have timely access to accurate, reliable, and innovative diagnostic tests. We look forward to working with all stakeholders to develop a MDUFA VI program that serves patients, supports innovation, and maintains the United States' leadership in diagnostic development and regulation.

Thank you and we look forward to the discussions ahead.