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"FDA User Fee Agreements: Advancing Medical Product Regulation and Innovation for the Benefit of Patients" Hearing

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Thank you Chairwoman Murray, Ranking Member Burr and Members of the committee for this opportunity to testify today. My name is Mark Leahey and I am the President and CEO of the Medical Device Manufacturers Association ("MDMA"), a national trade association representing hundreds of medical technology companies. MDMA was founded in 1992 to be the voice of the innovative and entrepreneurial sector of our industry**.** While the industry is broadly represented throughout the United States, one of the unique components of this vibrant part of America's innovation ecosystem is that the majority of companies are small businesses. According to data from the Department of Commerce, over 98% of med tech companies have fewer than 500 employees, and more than 80% have less than 50 employees, yet they are the major source of innovation and America's competitive advantage in medical technology. Our industry is dedicated to one mission: to alleviate human suffering and improve patient care.

Our industry has a proud tradition of answering the needs of patients and providers, and perhaps no example is more profound than what innovators have done since the outset of the COVID-19 pandemic. Whether it was respiratory technologies, diagnostics, advanced patient monitoring, or personal protective equipment, the medical technology industry worked tirelessly to help the United States and the entire world to confront this challenge, and they continue to do so today. In addition to the extraordinary efforts of this industry and health care professionals, I would also like to take a moment to acknowledge the dedicated professionals at the FDA who worked 24/7 on COVID and non-COVID medical technologies to improve patient care during the pandemic. Their efforts ensured that patients had timely access to safe and effective medical technologies.

MDUFA V – A Historic Investment

The MDUFA V draft agreement that we are discussing today, and the historic increase in user fee funding that it contains, demonstrates our commitment to provide additional capacity and expertise to further advance FDA's mission.

MDUFA V provides over $2B in investable funding to FDA. As a point of reference, MDUFA I totaled approximately $150M over the five years of the program. While each MDUFA typically provides funding for an additional 200 new hires, under MDUFA V, FDA will be able to hire a minimum of 273 FTEs and up to 387 new FTEs to support the MDUFA program. This represents a historic increase in both overall funds and people, and it is our hope and expectation that this will be the last major investment needed for the MDUFA program and that moving forward, any necessary increases will be much more modest and targeted.

With these significant investments, MDUFA V also establishes more transparency around the use of the funds, including ensuring that annual hiring targets are met. FDA will also conduct a HR assessment during MDUFA V to identify how many MDUFA funded vacancies exist. Currently, CDRH is only able to track MDUFA IV and later FTEs. Public reports in 2016 indicated MDUFA funded vacancies exceeded 25%, and innovators want to ensure that the additional capacity we are funding through user fees is realized in the new additional hires and backfilling any vacancies that arise.

Beyond the financial accountability and transparency provisions that MDUFA V contains, performance goals associated with De Novos and PMA Total Time to Decision (TTD) also improve over the course of the agreement. One goal that was elusive under MDUFA IV was the 510(k) Total Time to Decision Goal in FY22 of 108 days. As was mentioned earlier, COVID did impact FDA capacity, including the ability to meet certain MDUFA IV goals. Under MDUFA V, the 510(k) TTD goal will ramp down each year, hopefully achieving 108 days by FY26. Also, for the first time, the agreement incorporates add on payments that will provide the agency up to $115 million in additional funding above the baseline in the final years of the agreement if FDA meets modest but important performance goals in the first two years of the agreement.

Maintaining FDA's Gold Standard

The United States medical technology ecosystem is the envy of the world, and this is in no small part due to the FDA's gold standard of reviewing the safety and efficacy of medical devices. The billions of dollars in user-fees provided by industry under this agreement will enable FDA to hire hundreds of new reviewers and scientific experts strengthening the agency's ability to maintain its strong track record. The agreement also makes targeted investments to enhance device safety. This includes increased funding for patient perspective and engagement in the product evaluation process to better incorporate their experiences, as well as new funding to improve the use of real-world evidence in the review process.

The agreement contains resources to start a pilot for the "Total Product Lifecycle Advisory Program," also known as "TAP." Medical technologies that serve patients with unmet needs unfortunately can take longer to navigate the regulatory process, despite the fact that these patient populations often have no other alternatives. This is often due to the complexity and novel approach that breakthrough devices encompass. Beyond breakthroughs, TAP will support devices developed to significantly improve the safety of currently available devices and diagnostics under the Safer Technologies Program (STeP). FDA was very vocal during negotiations about the importance of piloting the TAP concept. TAP is designed to allow FDA and innovators to share early feedback to improve this process. Based upon the data and assessment of the TAP pilot, industry and FDA will determine whether to continue, expand or terminate the TAP pilot during MDUFA VI negotiations.

Conclusion

As we all know, America's medical technology ecosystem was not built overnight. It took decades of work between countless stakeholders, including Congress, the FDA, innovators, physicians, patient groups and more to design the regulatory pathways that has resulted in the gold standard of safety and efficacy. At the same time, we all recognize that this is a delicate balance to ensure that the right policies are in place to support innovation, and to spur the next generation of cures, therapies and diagnostics that so many patients are relying on. As I noted, this is a historic investment in the FDA, and it will be critical over the coming years to meet the goals and milestones within this user fee agreement to help ensure that the United States remains the global leader in medical technology development. It is also critical that Congress continues its vital oversight role, and providing the necessary resources and investments to FDA for it to achieve its mission. MDMA and our members remain committed to working closely with you to reach our shared goal of providing safe and effective medical technologies to patients and providors in a timely manner. Thank you once again Chairwoman Murray and Ranking Member Burr for your passionate leadership on this important work, and I look forward to answering any questions that the committee members might have.