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Thank you Chairman Burgess, Ranking Member Green and Members of the subcommittee for this opportunity to testify today. My name is Robert Kieval and I'm the Founder of CVRx, a small company that provides implantable medical technologies to treat patients suffering from heart failure or problematic high blood pressure. These are among the most prevalent, debilitating and expensive diseases for our health care system to manage, and our therapy, which is available today in Europe and hopefully will be soon in the U.S., stands to both improve patients' lives and significantly reduce the staggering costs associated with their care.

I'm also here today on behalf of the Medical Device Manufacturers Association, which was founded in 1992 to be the voice of the innovative and entrepreneurial sector of our industry**.** 98% of med tech companies have fewer than 500 employees, while more than 80% have less than 50, yet we are the major source of innovation and America's competitive advantage in medical technology. Together, we comprise a diverse group of engineers, physicians and entrepreneurs who dedicate our lives to alleviating human suffering and improving patient care. My personal journey with CVRx is now in its 16th year.

As a small company with one product and no other revenue streams, CVRx, like many others in our position, remain dependent on outside investment to be able to continue our work. To garner financing, our investors need assurance that the regulatory process be reasonable and consistent. Our capital is limited and precious, and regulatory delays can have devastating consequences for our company and for the patients whom we're working to serve.

When colleagues of mine testified before this committee five years ago, our industry faced a crisis. A grandmother with heart failure in Sweden or an injured construction worker in Sicily could be treated with American medical technology years before they could have been here in the U.S. The regulatory pathways had become unreasonable, unpredictable and opaque, and the harsh reality was that American patients who desperately needed our innovations couldn't get access to them.

Over the past five years, under MDUFA III and other reforms including the FDA Safety and Innovation Act (FDASIA), the process has become more reasonable,

consistent and transparent. Implemented correctly, we believe that the proposed MDUFA IV agreement will further improve access for American citizens to safe and effective new medical technologies.

While speed is always important when lives hang in the balance, the MDMA membership overwhelmingly endorsed prioritizing quality, predictability and transparency in our negotiations. MDUFA IV contains ongoing provisions that include shared performance goals and process improvements, and important new elements including the establishment of a quality management infrastructure at FDA, consideration of patient perspectives in the design of clinical trials, and steps toward incorporation of real world evidence in the approval process. Here are just a few highlights:

As innovators, it's frustrating to us when we receive requests for data or deficiency letters that are unreasonable, without reason or aren't germane to the evaluation of a product's safety or efficacy. These result in needless delays and wasted resources for both us and the FDA. Under MDUFA IV, reviewers would now need to cite the

specific justification and applicable regulation for any deficiency letter or data request. This will ensure that queries are meaningful and that time spent by both parties is productive.

As FDA continues to grow and evolve, it's critical that it remains efficient, and MDUFA IV institutes a quality management program for this purpose. The team will report on the performance across the various branches of the agency, and help ensure that deficiencies and inefficiencies are identified and addressed. This will provide more transparency within the FDA, and help ensure that our new heart failure therapy receives the same quality of review in the cardiovascular division that a new incontinence treatment would in the urology division.

Finally, the agreement establishes new performance goals aimed at placing new technologies into the hands of patients and providers within a reasonable period of time. These include updated decision time targets for 510(k)s and PMAs, and now also review time goals for *De Novo* technologies and pre-submissions.

We believe that MDUFA IV can strengthen and provide increased confidence in the regulatory process. We also acknowledge it's incumbent upon industry to ensure that our work and our submissions are also of the highest quality. We thank FDA for these productive negotiations, and we look forward to continuing to work with them and with you to maintain a regulatory environment that rewards innovation while ensuring patient safety.

Surely, our health care system will continue to face pressing challenges in the 21st century. Patients and providers will continue to seek therapies that alleviate suffering and save lives. My colleagues and I remain committed to finding the solutions they need, and to working with our fellow stakeholders in health care to deliver these as quickly and efficiently as possible. Thank you.