"Examining Improvements to the Regulation of Medical Technologies"

Testimony of
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Chairman Walden, Ranking Member Pallone, Chairman Burgess, Ranking Member Green, and members of the committee:

Thank you for having me here today. I am Jeff Shuren, Director of the Center for Devices and Radiological Health (CDRH) at the Food and Drug Administration (FDA). I am pleased to be back here today to discuss potential changes to the medical device program.

I first want to say that I greatly appreciate your support for timely reauthorization of the Medical Device User Fee Amendments, or MDUFA IV.

As you know, MDUFA has been reauthorized every five years since Congress first created the program in 2002. In fact, several current members of this committee were instrumental in the enactment of MDUFA I. As the program has evolved, FDA and industry have successfully negotiated agreements to improve patient access to safe and effective medical devices and streamline regulatory processes.

As we discussed a few weeks ago, timely reauthorization of MDUFA is critical to maintain adequate staffing levels and support our mission of protecting and promoting the public health, with the ultimate goal of getting treatments to the patients who need them. Like you, we at CDRH want patients and providers to continue to have timely access to safe, effective, and high-quality medical devices, first in the world. Retaining the knowledge and expertise of our scientific staff is critical to providing predictable and timely medical device reviews.

Changes we have made at CDRH to our culture, policies, and processes—in addition to user fee funding and changes to federal law—have resulted in reduced decision times, an improved medical device pipeline, and innovative technologies being introduced in the U.S. earlier than in the past. We want to continue this upward trend.

While reauthorization of MDUFA is the key to maintaining this trajectory, we know that there are additional areas of shared interest to improve patient access to safe and effective medical devices. Today's hearing is an important opportunity to explore some of these options. FDA is ready to work with Congress to make measurable improvements consistent with the approach outlined in the Administration's Blueprint Budget, which proposes a different way of financing the program.