Committee on Energy and Commerce

Opening Statement as Prepared for Delivery
Of
Subcommittee on Health Chairwoman Anna G. Eshoo

Hearing on "FDA User Fee Reauthorization: Ensuring Safe and Effective Medical Devices"

March 30, 2022

Every day Americans rely on safe and effective medical devices. From the joy of an ultrasound during pregnancy to the distress of a cancer diagnosis via MRI, medical devices treat, diagnose, and monitor the health of patients.

When I was working on the original legislation that created the Medical Device User Fee Agreement process in 2002, we couldn't imagine the innovative devices that are on the market today. And, without the user fees supplementing the FDA for the past 20 years, many of these innovations would be stuck in a backlog instead of helping patients.

A few months ago, I visited El Camino Hospital in my district, which is using radiation technology with AI to individually target tumors. This is just one example of the hundreds of devices that the FDA has approved or authorized since MDUFA was last reauthorized in 2017.

With this impressive innovation comes an increasingly complex FDA review process. Over the past 20 years, the User Fee Agreements have evolved to make sure that the FDA has the resources necessary so that its reviews are timely, transparent, and predictable.

MDUFA V is the latest evolution. The recently announced draft agreement provides FDA $1.78 billion over five years in user fees. This is about ten times the amount provided in the original 2002 user fee agreement.

With this funding, the FDA's Center for Devices and Radiological Health will be able to hire 387 new full-time employees while also meeting rising payroll costs.

The user fees will also fund successful FDA policies, such as the use of real-world evidence, the harmonization of international medical device regulatory activities, and patient engagement to inform the evaluation of products.

While MDUFA V is a significant increase in user fees from medical device makers, it's important to keep in mind that user fees cannot and should not relieve Congress from its responsibility to fund the FDA in a robust way. That's why I was pleased to see President Biden's budget included a $95 million increase for FDA's medical product safety work.

Today, we will hear from representatives from the FDA, private industry, and public health about the negotiated medical device user fee agreement. As the mother of MDUFA, I look

forward to shepherding this agreement through a swift reauthorization before the program expires on September 30th.