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House Energy and Commerce Committee
Subcommittee on Health
"FDA User Fee Reauthorization: Ensuring Safe and Effective Medical Devices"
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As Prepared for Delivery

Thank you, Madam Chair….

INTRO

Today this Subcommittee will hold its third hearing to consider the reauthorization of the FDA user fee programs.

Congress has acted to authorize the Medical Device User Fee Amendments, or MDUFA (ma-doof-ah), four times before… and we remain committed to renewing this authority on time and through regular order.

I'd like to thank our witnesses for testifying today, and would also like to welcome back Dr. Shuren.

Dr. Shuren came before this Subcommittee when we last reauthorized these programs in 2017.

LATE SUBMISSION

Before we discuss the proposed agreements and the two bills for today's hearing, I'd like to express my disappointment with the failure of FDA and regulated industry to deliver their proposed agreement to Congress by the January 15 statutory deadline.

MDUFA negotiations have been ongoing for over a year, and we've had just ***one week*** to review the proposed amendment language and commitment letter before this hearing.

This delay hinders Congress's oversight responsibilities.

Reauthorizing these programs on time is a goal shared by all of us on this Committee and failure to do so will result in delayed patient access to needed medical technologies.

Further, I have raised serious concerns about a lack of transparency throughout this process.

In November, I wrote to then Acting Commissioner Woodcock about the delay in posting meeting minutes from FDA-industry negotiations.

To ensure transparency and progress… documentation of meeting outcomes and action items are supposed to be made part of the official record and made publicly available.

While this posting minutes publicly usually takes no more than 2 to 3 weeks...

…., during MDUFA Five negotiations, we saw delays of more than six months.

Even today, there are no meeting minutes posted for any meetings that took place after June 30, 2021.

I know that my colleagues and I are looking forward to getting answers today on what took so long for the proposed agreement to be delivered to our Committee…

….and how we can improve this process going forward.

Proposed Enhancements

Now, regarding the proposed MDUFA Five agreement…

…as well as two pieces of legislation – introduced by Representatives Burgess and Schrier.

Dr. Burgess's bill ensures the cybersecurity of devices is approved or cleared by FDA.

Dr. Schrier's advises on the real-world impact of medical device diagnostics.

We want to make sure FDA has the resources to keep up with cutting edge medical technology, such as artificial intelligence, robotic prosthetics...

…. and facilitate innovation and production of the more routine devices we rely on – syringes, gloves, gowns.

We need to make sure those resources are used wisely and improve people's quality of life.

The promise of American innovation will allow medical technology to help keep patients healthier, enable treatment at or close to home, and improve timely diagnosis and treatment.

This reauthorization requires FDA to leverage digital health technologies and real-world evidence in the review and clearance or approval of medical devices where appropriate.

The proposed enhancements also direct significant investment in hiring and retaining world-class scientific and technical staff.

There is no question that the COVID-19 pandemic severely disrupted business as usual for FDA to review applications and make timely decisions.

The Center for Devices and Radiological Health has especially had a daunting task.

FDA has fallen behind on the accountability part of the deal, missing 3 review goals during FY2020 and 6 during FY2021, according to Dr. Shuren's testimony.

I hope that FDA will improve going forward and that the hiring commitments and performance goals agreed to under MDUFA Five will get FDA back on track.

I am also encouraged that the commitment letter contains enhancements to improve performance accountability and financial transparency.

FDA has committed to publishing an annual 5-year financial plan, which will include hiring targets and a full accounting of where user fee funds are being spent.

MDUFA Five will also continue enhancing its Patient Science and Engagement program, which will prioritize including the voice of patients in the review process.

The goal of these improvements will improve pre-submission communication with innovators, make sure patients are heard,

…. and, overall improve the efficiency, integrity, and effectiveness of medical device reviews.

CONCLUSION

Reauthorizing MDUFA before September's deadline will allow agency operations to continue …

…and will also ensure patients benefit from our biomedical innovation and advancements in medical technology.

This is a goal I believe is shared by each of my colleagues, and I look forward to today's discussion.

I yield back.