Opening Statement for the Honorable Brett Guthrie
"FDA User Fee Reauthorization: Ensuring Safe and Effective Medical Devices"
March 30, 2022

As Prepared for Delivery

Thank you, Madam Chair, for holding this important hearing.

Today we are building off the work we've done over the past several weeks to find additional opportunities to foster American biopharmaceutical innovation. The focus of today's hearing is to discuss the recently announced Medical Device User Fee Amendments (ma-dew-fa). This will be critical to continuing to enhance our medical device ecosystem here in the United States.

Like the prescription drug industry, innovators working to develop new and innovative medical technologies experienced significant delays in getting their products reviewed by Food and Drug Administration experts. That is why Congress, regulators, and industry all came together to develop a solution in the Medical Device User Fee and Modernization Act of 2002 that would streamline the review process and help get these devices to patients more quickly. This agreement has since been reauthorized by Congress every five years.

The original MDUFA Act gave the FDA the necessary tools to hire more clinical experts to review device applications. It also offered industry the assurance of being able to hold the FDA to higher performance standards. The successes of

this partnership are clear as the FDA's Center for Devices and Radiological Health (CDRH) has granted novel technologies four times as many approvals, marketing authorizations and clearances over the past decade, largely resulting from policies made possible by past MDUFA authorizations.

The agreement before us today represents an ambitious agenda set by industry and CDRH experts. The goal is to ensure the FDA is doing everything it can to protect patient safety, while also supporting the development of medical device technologies.

Highlights include authorizing the FDA to collect $1.78 billion from industry and potentially up to $1.9 billion over the next five years to bolster CDRH's workforce to help get products reviewed and approved as quickly and as safely as possible. Of note, is the creation of the new Total Lifecycle Advisory Program, which CDRH states will help promote the long-term sustainability of the Breakthrough Device Program.

I was proud to support the creation of the Breakthrough Devices Program that was created as a part of the bipartisan 21st Century Cures Act. In 2021, CDRH granted breakthrough designation to 213 devices, and there have been over 600 designations made since the program's inception. This includes a device that

harnesses machine learning to help health care providers diagnose autism spectrum disorder.

However, I am still frustrated by the Biden Administration's actions to undermine the bipartisan supported Trump-era Medical Coverage of Innovation Technologies rule that would have helped to get breakthrough devices to seniors once a breakthrough device was approved by the FDA. This directly conflicts with earnest efforts made by Congress, CDRH, and the medical device industry to encourage investments in these emerging technologies. I encourage CMS to work to reverse this decision and work with the industry as well as their FDA partners to address outstanding concerns.

To that end, I am also continuing to push for the codification of the 2018 FDA guidance that permits pre-approval information exchanges between product sponsors and payors. These information exchanges help get products covered more quickly once they are approved by the FDA. My bill, the Pre-approval Information Exchange Act, would do just this and help public and private payors to make coverage determinations earlier based off real-time health care economic information exchanged between entities.

Additionally, offering needed clarity around the FDA's 2016 guidance on emerging signals is another important priority of mine in the device policy space,

and I am working on a solution to offer needed regulatory certainty on this issue. Outlining a process that affords companies the chance to work with regulators on addressing reported adverse health events associated with their devices will not only protect patients, but also create regulatory predictability that will protect against gaps in care for patients who rely on these devices.

I look forward to working with my colleagues over the next several months to reauthorize this important user fee agreement that will promote even greater innovation for decades to come. Thank you, and I yield back.