**Chairman Burgess**
**Opening Statement**
**Energy and Commerce Subcommittee on Health Hearing**
**"Examining FDA's Medical Device User Fee Program"**
**March 27, 2017**

The Subcommittee will come to order.

The Chair will recognize himself for an opening statement.

Dr. Shuren, welcome back to our Subcommittee. I am glad to say that your Center at FDA has come a long way since the 2012 reauthorization of the Medical Device User Fee Amendments (MDUFA).

Today is this Subcommittee's third hearing to consider the reauthorization of FDA user fee programs set to expire in September. MDUFA gives FDA authority to collect fees from the medical device industry to support product review activities, and must be renewed every five years. The Energy and Commerce Committee has taken the necessary actions to renew this authority three times before, and this Committee remains dedicated to completing this fourth authorization in a timely manner.

While there will always be room for improvement, the MDUFA program has significantly enhanced the efficiency, transparency, and uniformity of the product review process at FDA. Leading up to the 2012 reauthorization of MDUFA, this Subcommittee heard repeatedly about the slow, onerous, and arbitrary process by which devices were reviewed at the Center for Devices and Radiological Health (CDRH).

The state of affairs at CDRH was driving away investment in research and development, and significantly hindering the pace at which American patients had access to new medical technologies. Through the Food and Drug Administration Safety and Innovation Act (FDASIA) Congress reauthorized MDUFA and the paradigm started to shift in the right direction.

FDASIA included meaningful regulatory reforms, improved communication between industry and FDA, and increased accountability at CDRH. It is important that the next medical device user fee agreement continue to build upon the progress made in FDASIA, as well as the good policies members of this Subcommittee championed in the 21st Century Cures Act. I am encouraged that the proposed agreement

transmitted to Congress in January contains many promising elements that will be good for FDA, industry, and most importantly, patients.

In the proposed agreement, FDA has agreed to further decrease the total amount of time it takes from submission of an application to a final decision on approval. This is a good thing because it will get safe and effective products to doctors and patients faster.

Further, FDA would enhance patient engagement by more formally involving patient preference and patient reported outcomes in the review process. It is vital that FDA routinely incorporate the patient perspective in its decision-making process.

The proposed agreement would also establish process improvements and goals that ought to foster a more timely and efficient approval process if implemented. For instance, the process for pre-submission interactions between FDA and industry would be updated and improved upon. In addition, the proposed agreement would establish a pilot program to examine the use of real-world evidence for premarket activities.

Furthermore, the proposed agreement provides for improved transparency and greater responsibility. A wide array of new measures, tools, and reports will provide data that is necessary to ensure FDA is meeting the goals of the agreement.

Reauthorizing MDUFA and the user fee programs we have previously discussed would increase efficiency at FDA and ensure that American patients benefit from advances in biomedical technology and innovation as soon as safely possible.

I thank all of our witnesses for being here, and I look forward to hearing from each of you about how the substance of the proposed agreement will accomplish this goal.