Chairman Burgess
Opening Statement
Energy and Commerce Subcommittee on Health Hearing
"Examining FDA's Generic Drug and Biosimilar User Fee Programs"
March 2, 2017

The Subcommittee will come to order.

The Chair will recognize himself for an opening statement.

Today's hearing marks the Health Subcommittee's first public discussion on the reauthorization of several key user fee programs at the U.S. Food and Drug Administration (FDA). This hearing will focus on the generic drug and biosimilar user fee programs and we will turn our attention to reauthorization of the Prescription Drug User Fee Act (PDUFA) and the Medical Device User Fee Amendments (MDUFA) later this month. All four of these programs expire in September and must be reauthorized for Fiscal Years 2018-2022. Chairman Walden and I are committed to moving the user fee legislation through Committee, following regular order, with ample time to spare.

I want to welcome Dr. Woodcock back to this Subcommittee. I would also like to commend the FDA and industry for the various briefings they provided our members' staffs throughout the negotiation process, and for transmitting the proposed agreements to Congress in a timely manner pursuant to the process laid out in statute. Committee staff has been working on a bipartisan basis with the Senate HELP Committee to review the agreements in detail, and develop the necessary authorizing language for our consideration. I appreciate the technical assistance FDA has provided, not to mention the expertise of our legislative

counsels. It because of these efforts that we are well on track for a timely reauthorization.

Since 1992, with the initial authorization of PDUFA, revenues generated from regulated industry fees have supplemented Congressional appropriations and significantly enhanced FDA's ability to review product applications in a more efficient and predictable manner. Based in large part on the success of PDUFA, medical device user fees were authorized in 2002, followed by the Generic Drug User Fee Amendments of 2012 (GDUFA), and the Biosimilar User Fee Act of 2012 (BsUFA)—both of which are the focus of today's hearing. I look forward to learning more about their implementation to date and ways to improve these important programs going forward.

Approval of additional biosimilars will undoubtedly increase competition in the complex and often costly biological drug market. Small molecule generics already account for billions of dollars in savings each year. Nonetheless, for a variety of reasons, generic competition is lacking for certain drug products, despite the absence of patent protection. We will hear from FDA and industry about how improving and reauthorizing GDUFA will help close these gaps.

We will also hear from our colleagues Kurt Schrader (D-OR) and Gus Bilirakis (R-FL) about H.R. 749, the Lower Costs Through Competition Act—a bill they recently introduced along with a bipartisan roster of co-sponsors. H.R. 749 aims to encourage market entry by generic manufacturers in situations where it may not otherwise make sense from a business perspective. I understand that introduction of this bill has led to a robust discussion about additional and alternative ways to spur such competition. That is a good thing. I appreciate the sponsors' willingness

to hear from a variety of stakeholders and work with bipartisan Committee staff to improve the bill before proceeding to markup.

I want to welcome all of our witnesses and thank you for being here. I look forward to your testimony.