**Opening Statement of the Honorable Brett Guthrie**
**"FDA User Fee Reauthorization: Ensuring Safe and Effective Drugs and Biologics"**
**February 3, 2022**
***As Prepared for Delivery***

Thank you, Madam Chair, and to our witnesses for being here with us today.

Today marks the last stretch of a more than two-year process to reauthorize the four critical FDA user fee agreements that are the foundational building blocks for medical innovation in the United States. These agreements ensure safe and effective life-saving treatments and devices are approved and eventually reach patients.

We are here today to examine three of these four agreements - PDUFA, the Prescription Drug User Fee Act, GDUFA the Generic Drug Under Fee Amendments, and BsUFA the Biosimilar User Fee Act.

The U.S. Food and Drug Administration (FDA), industry, and other key stakeholders have been meeting regularly since July 2020 to identify barriers to bringing drugs to market.

Although we will not be discussing medical devices today, I look forward to discussing the Medical Device User Fee commitment with industry and FDA before this committee once an agreement is reached.

Congress originally passed the Prescription Drug User Fee Act in 1992, to address significant delays in the drug review process at the FDA. The law authorized the FDA to collect fees from companies who were submitting drug applications. These fees help ensured a timely review of drug applications by FDA drug reviewers. As a result of the early successes of PDUFA (Pahdoofah), Congress in 2002 passed the Medical Device User Fee Act and in 2012 passed the Generic Drug User Fee Amendments and the Biosimilars Drug User Fee Act to enhance competition in other parts of the life-sciences industry.

These must pass agreements are reauthorized by Congress every five years on a strong bipartisan basis. For example, the last FDA Reauthorization Act of 2017 passed under suspension in the House and by a vote of 94-1 in the Senate. Since Congress established the first user fee program three decades ago, the FDA has approved over 1,700 drugs. By approving more drugs and generic options Americans have more options and more affordable life-saving medications. User fees have also given the United States pharmaceutical industry a competitive advantage globally. In 2021, 38 of the 50 novel drugs approved globally in 2021 were first approved in the United States.

Another success of these programs has been the ability to bring more generics and biosimilars to market, providing lower cost options for patients. In the five years after the authorization of the Generic Drug User Fee Amendments in

2012, the FDA reviewed 98% of Abbreviated New Drug Applications, or generic drug applications, that had been backlogged. Further, since authorizing the Biosimilar User Fee Act the same year, the U.S. health care system is modeled to save $100 billion in annualized savings resulting from increased marketplace competition due to the availability of FDA approved biosimilars over the next five years, according to a 2020 report by IQVIA.

Since passage of the 2017 FDA Reauthorization Act, which reauthorized all four user fee agreements, members of this committee have been building on the policies this bipartisan legislation established. For example, Mr. Schrader and I introduced the Protecting Access to Safe and Effective Medicines Act, and it was signed into law last year. This law helps increase competition in the marketplace by making a technical clarification to the drug application process to prevent drug companies from gaming the system for more market exclusivity and in some cases limiting generics from coming to market sooner. I look forward to finding more opportunities to create bipartisan solutions that bring more drugs to market as safely and as quickly as possible.

Looking ahead to the next few months, this committee will have a unique opportunity to help shape the drug and medical device approval process for years to come. Members will be given the chance to raise questions directly with

industry leaders and regulators about past reauthorization agreements or specific policy priorities designed to increase innovation.

A top priority for me will be to ensure that FDA approved drugs or devices receive coverage by both public and private insurers as quickly as possible. This would be possible by allowing drug or device companies to share real-time economic and clinical data with payors which would allow payors to plan ahead for formularies placement. This policy ensures patients could receive timely access to new and novel treatments once approved by FDA. Timely coverage of a drug will not only address critical care gaps but will also further incentivize innovation.

Above all, I cannot underscore how critical it will be for this committee and for Congress to reauthorize these agreements before September 30. Doing so is imperative for patients to have access to these life-saving treatments.