

**Committee on Energy and Commerce**  
**Opening Statement as Prepared for Delivery**  
**of**  
**Chairman Frank Pallone, Jr.**

***Hearing on “FDA User Fee Reauthorization: Ensuring Safe and Effective Drugs and  
Biologics”***

**February 3, 2022**

Today the Health Subcommittee is beginning the critical process of reauthorizing the Food and Drug Administration’s (FDA) user fee programs for prescription drugs, generic drugs, and biosimilars. We will also discuss FDA’s agreements with industry stakeholders on improvements to the review and development of important medicines. The fees collected from these programs support the timely review of drug applications, and other activities needed to support drug development.

As such, these programs are essential to FDA’s mission. They ensure that the agency has the resources and personnel it needs to review and approve safe and effective medical treatments in a timely fashion. The current user fee authorizations expire later this year on September 30th, and it is crucial that we pass these reauthorizations well ahead of the deadline so that FDA can continue its operations without interruption.

Over the past two years as we have confronted the COVID-19 pandemic, the American people have witnessed the important work the FDA does every day. The agency has led the critical review process and supported the development of lifesaving vaccines that are essential to our efforts to one day end this terrible virus. The FDA has also reviewed and approved important therapies that are helping people fight the virus. It has also helped to respond to medical supply chain issues that have led to shortages of some medical products.

The unprecedented nature of the pandemic has stretched FDA to its limit over the last two years, and the entire FDA workforce should be commended for their outstanding work not only in responding to this pandemic, but also for continuing to do all of the other important work they are charged to do. As we continue to face the COVID-19 pandemic, we simply cannot put FDA’s funding in jeopardy and that’s why we must act expeditiously to reauthorize these important user fees.

It’s also why Ranking Member Rodgers and I, along with our counterparts on the Senate HELP Committee, sent a letter last week to Acting Commissioner Woodcock expressing concern that FDA and industry have not yet reached agreement on the medical device user fee program. This is troubling because we are now more than two weeks past the statutory deadline for Congress to receive the agreement. This deadline is set by law and is not a mere suggestion.

It is in everyone’s interest for FDA and industry to reach an agreement. I look forward to receiving a status update soon.

February 3, 2022

Page 2

The proposed legislation and performance goals for the drug programs before us today show the progress and improvements that can be made with these user fee agreements.

The performance goals include new policies that will help increase the consistency, efficiency, and effectiveness of drug reviews. The proposed legislation strengthens staff capacity for the review of cell and gene therapies, improves review timelines for complex generic products, and develops a more competitive biosimilar market.

It is my hope that these proposals from FDA will lead to a more efficient and effective review of drugs and biosimilars while maintaining the agency's highest standards for safety and efficacy. The focus on safe and effective development should ultimately provide for a greater number of approvals of life-saving drugs and improve competition in a way that will help lower costs for our health care systems and the American people.

Thank you.