Statement of Ranking Member Frank Pallone, Jr.
House Committee on Energy and Commerce
Subcommittee on Health
Hearing on "Examining FDA's Generic Drug and Biosimilar User Fee Programs"

March 2, 2017

Thank you, Mr. Chairman. The user fee programs that we are discussing today will help provide for more generic and biosimilar approvals that will save people's lives, bring greater competition to the market, and reduce drug costs for consumers. But it is not enough. This Congress must seriously address skyrocketing prescription drug costs. We can't wait any longer – the time to act is now.

The medical product user fee programs, which expire in September, provide FDA with critical resources to conduct medical product reviews, meet and communicate with drug and device sponsors, draft guidance that offers clarity around regulatory and scientific expectations, and hire and train the needed reviewers and staff to carry out all of these responsibilities. The

resources provided strike a careful balance of encouraging efficiency from the agency while also providing certainty for industry.

Today we will specifically look at the Generic Drug User Fee Amendments and the Biosimilar User Fee Act. The first ever user fees for generic drugs and biosimilars were part of the Food and Drug Administration Safety and Innovation Act in 2012. Both of these programs strive to expedite access to high quality, lower cost drugs for American families.

As we consider reauthorizing both GDUFA and BsUFA, it is important that we take into consideration the successes and lessons learned from both of these programs.

To that end, under GDUFA I, I was pleased to hear that FDA has addressed the backlog of generic applications and is committed in GDUFA II to meeting a 10-month review timeline moving forward for traditional applications. I am also pleased to see that the agreement makes progress towards improving communication between FDA and sponsors throughout the

review process and will institute early communication to aid sponsors in the creation of complex generic drug products. These steps will help to move FDA and sponsors closer to first cycle approval.

BSUFA II also builds on the lessons learned under BSUFA I. It ensures that there is sufficient resources and qualified staff to respond to the growing interest in biosimilar development, improving meeting opportunities in order to provide sponsors with meaningful feedback, and instituting a similar review model to PDUFA, which will allow for greater communication during the review process.

It is my hope that these enhancements will lead to a more efficient and effective review of generic drugs and biosimilars, and ultimately provide for a greater number of approvals of drugs that hold the potential to provide great savings to our health care systems and to patients.

Today also serves as the start of a conversation around how we can work to provide lower cost drugs for American families. Drug prices continue to

soar each day. Who can forget the outrageous sticker shock of the 5,500 percent increase in the cost of the lifesaving drug Daraprim? Or the shocking 500 percent increase in the cost of EpiPen. And then there was the $84,000 price tag for Sovaldi. While there may not be a silver bullet to address this problem, this Congress must address the rising cost of prescription drugs. It is my hope that this Committee will take a comprehensive look at all solutions and work together to identify meaningful policies that will help American families to afford the medications they depend on.