COMMITTEE ON ENERGY & COMMERCE
DEMOCRATS
RANKING MEMBER FRANK PALLONE, JR.

FOR IMMEDIATE RELEASE
February 4, 2016

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Statement of Ranking Member Frank Pallone, Jr., as prepared for delivery
House Energy and Commerce Committee
Subcommittee on Health
Legislative Hearing on "Examining Implementation of the Biologics Price Competition and Innovation Act"

Good morning. Thank you Mr. Chairman for holding this hearing today, and thank you to Dr. Woodcock and Director Cavanaugh for being here to discuss the implementation of the Biologics Price Competition and Innovation Act.

Biosimilars hold enormous potential to offer patients with serious and life-threating diseases access to more treatment options, and potentially lower cost options. I look forward to hearing your testimony today about how FDA and CMS are working to establish a clear pathway for approval, as well as an appropriate reimbursement structure. These are both critical elements to ensuring the success of this market.

The use and sale of biologics continues to rise here in the United States and elsewhere. By 2017, sales of biologics are estimated to be between $205 and $235 billion, approximately 20 percent of the global pharmaceutical marketplace. This is why encouraging and facilitating competition in this space is so critical.

While biosimilars have been available in Europe for some time, Congress did not establish an abbreviated pathway here in the U.S. until the passage of BPCIA as a part of the Affordable Care Act in 2010. I supported the creation of a pathway for biosimilars, and for empowering FDA with the authority and resources to ensure that biosimilars are safely available here in the U.S. for the patients that need them the most. I was pleased when FDA approved the first biosimilar, Zarxio, in March 2015. This action demonstrated that the approval process is working, but I've also heard that greater clarity is needed from FDA.

Since 2012, FDA has issued important guidance meant to inform industry sponsors as they consider developing biosimilar products, including scientific and quality considerations.

Additional guidance is still needed though, particularly in the areas of developing and marketing biosimilars. Guidance on interchangeability, labeling, and naming are still outstanding, and FDA's thinking in these areas will be vital to companies looking to enter the biosimilars market.

We've seen how our health care system has benefited from the competition that comes with a robust market. Competition has helped to lower health care costs for small molecule drugs, saving the U.S. health system $254 billion in 2014. It is my hope that we continue to do all we can to lay the foundation for these types of savings.

Our federal health programs will also play a large role. CMS has the ability through both Medicare and Medicaid to encourage this new marketplace. And that's why I was concerned that CMS finalized its Part B payment policy for biosimilars last year combining all biosimilars into one average sales price calculation and payment code. I worry that this inappropriately treats biosimilars like generic drugs and will disincentivize manufacturers from entering the biosimilars marketplace. Biosimilars are not generics; each is its own unique product, and biosimilars go through a much more stringent approval process. In fact, Medicare Part D and Medicaid both acknowledge this in their respective programs.

This marketplace is only just emerging, with only one approved biosimilar. So it's important that we hear from both FDA and CMS not only about what they're doing in this space, but how they are coordinating to ensure that the biosimilar marketplace is both safe and robust.

I look forward to hearing more today. Thank you.

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