Rep. Joseph R. Pitts
Opening Statement
Energy and Commerce Subcommittee on Health Hearing:
"Examining Implementation of the Biologics Price Competition and Innovation Act"
Thursday, February 4, 2016 (10:30 a.m.)

The Subcommittee will come to order.

The Chairman will recognize himself for an opening statement.

Biologics are used to treat a number of serious diseases and conditions and have improved the lives of millions of Americans. They are produced from living cells using biotechnology and are often significantly more time consuming and resource intensive to consistently manufacture than small molecule, chemical drugs. Due in large part to these complexities, biologics tend to be more expensive and why the traditional generic approval pathway is not suited for bringing lower cost alternatives to the market.

In 2009, this Committee passed the Biologics Price Competition and Innovation Act (BPCIA) by a vote of 47 to 11. Enacted in 2010, BPCIA established a new abbreviated pathway at FDA for biological products determined to be "biosimilar to" or, potentially, "interchangeable with" a previously approved reference product.

FDA approved the first biosimilar in March 2015 and is convening an advisory committee next week to consider a second application. And while there are close to 60 additional proposed biosimilar products enrolled in FDA's Biosimilar Development Program, the agency has yet to issue guidance documents on several key policy issues that could have a significant impact on patient safety, prescriber decision-making, and market competition.

I look forward to hearing from Dr. Woodcock about where these documents are in the review process and would like to walk away from today's discussion with a better understanding of the agency's current thinking on issues such as naming, labeling, and interchangeability.

Meanwhile, in preparation for biosimilars coming to market, the Centers for Medicare and Medicaid Services (CMS) recently issued payment guidance related to Medicare Part B for biosimilars. Members will want to understand the implications of this broad payment policy and if it will account for variations in differences between biosimilar products and moreover, what might that payment policy mean for the eventual growth in this market and innovation.

With both witnesses here we will be able to explore how could or should pending issues before FDA, for example, naming and interchangeability, impact the reimbursement policy under the Medicare program as well as access and affordability for beneficiaries?

The Committee will have an opportunity to hear directly from FDA and CMS on their progress with implementation of BPCIA and the future outlook.

I yield the balance of my time to the Chairman Emeritus, Mr. Barton.