

**Opening Statement of Chairman Member Frank Pallone, Jr.  
House Energy and Commerce Committee  
Subcommittee on Health  
Hearing on “Lowering the Cost of Prescription Drugs: Reducing Barriers  
to Market Competition”**

*March 11, 2019*

Today this Committee begins the process of fulfilling our commitment to provide some much-needed relief to Americans struggling to pay for skyrocketing prescription drugs.

I am pleased that we will be examining policies that will help to bring the high costs of prescription drugs down.

The American people have justifiably been demanding Congressional action to make prescription drugs more affordable, and who can blame them. Prices are so high that recent data shows that nearly a quarter of Americans didn't fill a prescription in the past year

due to the high cost. Nineteen percent say they skipped a dose or cut pills in half because they wanted to make them last longer. These are choices Americans simply should not have to make. It is unacceptable and could in fact lead to greater illness and higher medical costs down the road.

It is time for Congress to help make prescription drugs more affordable.. One way to achieve this goal is to facilitate greater competition from generic and biosimilar manufacturers. I believe reducing barriers to generic drugs and increasing competition in the pharmaceutical market will benefit American families who are struggling to afford their medications.

Generic drugs play a critical role in increasing access and reducing costs in our health care system. In 2017, the entry of generic drugs to the market saved patients and the public \$265

billion, including over \$82 billion for Medicare alone – that’s more than \$1,900 per enrollee. These numbers alone demonstrate the substantial cost savings for consumers when we ensure generic products can come to market as soon as possible.

The proposals before us today will close loopholes that some drug companies are exploiting to game the system, unfairly raise drug prices and take advantage of American families.

More specifically, the bills address three key barriers for generics – patent listing, drug development and market entry, and market barriers.

Two of the bills we will be discussing — the Orange Book Transparency Act of 2019 introduced by Rep. Kelly, and the Purple Book Continuity Act of 2019 introduced by Chairwoman Eshoo — would help to increase accuracy and transparency of the two

databases that guide development decisions for generic and biosimilar manufacturers. These bills would help generics overcome the barrier of patent listing.

Two other bills, the CREATES Act and the FAST Generics Act, led here on the Committee by Reps. Welch and McKinley, would help address the barrier of drug development and market entry. Today, the use of restricted distribution systems, including REMS, by certain manufacturers delays access to samples of branded drug products for development purposes. It also impedes market entry through delays in negotiations on single-shared system REMS. This important legislation would eliminate these barriers.

And finally, we are considering three policies focused on market barriers. The BLOCKING Act, introduced by Reps. Schrader and Carter, would address delays that occur when first time generics are

unable to be approved. This blocks the approval of other generics. .  
The Protecting Consumer Access to Generic Drugs Act of 2019,  
introduced by Rep. Rush, would discourage the use of pay-for-delay  
agreements that result in generics delaying development or market  
entry. And finally, the FAIR Generics Act, introduced by Rep.  
Barragán, which would strengthen incentives for generic first  
applicants to enter the market on the earliest possible date and  
disincentive patent settlement agreements that delay generic entry.

These are all commonsense solutions that will remove  
unnecessary barriers to competition. These bills are a strong first step  
in making prescription drugs more affordable and providing real  
relief to hardworking Americans that are being price gouged at the  
pharmacy counter.