Opening Statement
Chairwoman Anna G. Eshoo
Committee on Energy and Commerce
Subcommittee on Health
Hearing on "Lowering the Cost of Prescription Drugs: Reducing Barriers to Market Competition"
March 13, 2019

Welcome to the first hearing of the Health Subcommittee on drug pricing.

For too long, the American people have been subjected to the abuse of the patent system by pharmaceutical companies and generic companies entering into agreements and employing tactics that block competition and keep prices high.

When brand and generic manufacturers employ these tactics, the American people lose out by having to pay more for their prescription drugs because there is less competition.

We know that when generics come to market, they can drive prices down exponentially for consumers.

The United States has the lowest generic drug prices in the world, so where there's competition between brand drugs and multiple generics, it works.

The bills we're considering today will inject competition in the system sooner, move drugs to the market more quickly, and lower costs.

We're examining the CREATES Act authored by Representatives Cicilline, Sensenbrenner, Nadler, Collins, Welch and McKinley, and the FAST Generics Act authored by Representatives Welch, McKinley, and Cicilline, address barriers to generic development. Both bills take a different approach to address the stalling tactics brand manufacturers use to restrict access to samples of their products.

Generic companies rely on samples of the brand product to ensure that the generic is identical to the brand drug so that patients can use the products interchangeably.

The second group of bills addresses marketing abuse barriers.

The BLOCKING ACT introduced by Representatives Schrader and Carter targets generics that have been granted exclusivity and then block other products from coming to market. This delaying of their exclusivity periods is referred to as "parking."

When a company delays the start of the exclusivity period of a product, it not only delays other generics from coming to market. It also delays lower prices reaching patients sooner.

During our hearing on the FY2020 Budget yesterday, Secretary Azar explained that this "parking" behavior leads to an average delay of 12 months for a generic to come to market.

The Protecting Consumer Access to Generic Drugs Act introduced by Representative Rush, and

the FAIR Generic Drugs Act introduced by Representative Barragan, target pay-for-delay agreements. This is brand manufacturers paying generic companies to delay entering the market with generic versions of the drug. It takes two to tango and manufacturers and generic companies are both wrong.

The Protecting Consumer Access to Generic Drugs Act prohibits these Pay for Delay agreements outright, while the FAIR Generics Act sets up a different legal framework that discourages brand manufacturers and generic companies from entering into these agreements.

The last group of bills make important updates to the Orange and Purple Books at the FDA by amending what information must be included and requiring these resources to be published in a user friendly way online.

When manufacturers are considering where to invest their research and development dollars, they use the Orange and Purple Books to determine what patents are currently active and which patents will be expiring soon.

The Orange Book Transparency Act was introduced by Representative Kelly, and I introduced the Purple Book Continuity Act.

This is a legislative hearing to debate bills that will close loopholes and eliminate bad practices in the drug system in order to bring down costs. I look forward to passing bills that will be considered in the full House.

Welcome to our witnesses and we look forward to your testimony.