

**Opening Statement of Republican Leader Greg Walden
Subcommittee on Consumer Protection and Commerce
“Profits Over Consumers: Exposing How Pharmaceutical Companies Game the System”
September 19, 2019**

As Prepared for Delivery

Good morning,

Today’s hearing is focused on the pharmaceutical industry and the practice known as product hopping.

There’s no question that Americans pay too much for their health care, including the cost of prescription drugs. Over the past few years, we have made significant efforts to lower the cost of prescription drugs for consumers by advancing key priorities that are now law, including the 21st Century Cures Act, and a reauthorization of the generic drug user fee program in the FDA Reauthorization Act. And it is already working – last year FDA approved a record number of generic drugs, driving competition and giving consumers more choices. Republicans will continue to push for legislation that promotes competition, lowers the out-of-pocket cost for consumers, and establishes transparency and accountability in drug pricing.

But we should also acknowledge the investment required by the industry to remain the global leader in developing innovative and essential

treatments and the effort and ingenuity necessary to counter evolutions occurring in the diseases themselves.

On average, it costs companies more than \$2.5 billion to bring a new drug to market, but only about 20 percent of the marketed drugs ever earn enough to recoup those costs. And once the patent exclusivity period is over, brand companies face the likely loss of roughly 80-90 percent of their sales to generic versions of their drug.

In large part, this is due to state substitution laws. Every state has a substitution law that requires or allows pharmacists to offer a generic drug when a patient presents a prescription for a brand drug. However, if the brand drug and generic drug are not the same, such substitution laws do not apply.

For example, if a drug is not bioequivalent – meaning it is able to be absorbed into the body at the same rate or therapeutically equivalent – meaning it has the same active ingredient, form, dosage, strength, and safety profile, then state substitution laws do not apply. Some argue that brand drug makers engage in product hopping to usurp these state substitution laws and ensure patients use their brand drug.

Product hopping occurs when brand pharmaceutical companies attempt to switch customers from an older version of a drug to a newer version. Typically, the newer drug has a longer patent exclusivity life which helps pharmaceutical companies maintain their market position and ultimately recoup the cost of developing new drugs.

There are two types of product hopping: a hard switch and a soft switch. In a hard switch, a brand company completely withdraws their product from the market to enter a new product. A soft switch occurs when a brand company keeps their older product on the market but shifts marketing efforts to the new drug.

Courts have been clear that a product withdrawal or improvement alone is not anticompetitive. Rather whether product hopping is anticompetitive or not relies heavily on the specific facts and circumstances of any given incident and requires some additional wrongful conduct.

To be clear, innovating and replacing older drugs is part of the normal competitive process that companies engage in routinely. We must be cautious about disincentivizing innovation. We know that brand drug companies incrementally improve their drugs all the time and that we see great societal benefits from such improvements. Most innovation by

drug makers involves the development of next generation improvements, which may include new products that expand therapeutic classes, or increase available dosing options, or remedy physiological interactions of known medicines, or improve other properties of existing medications. These are good things. We benefit from them. In fact, according to the World Health Organization, more than 60 percent of all drugs deemed necessary for combatting prevalent diseases are the result of incremental innovation.

Today's discussion is important, and I am thankful to the panel and to those that traveled to be here with us today.

Before I yield, I would like to say there is a form of product hopping I do support – and that is a product hop to a legislative hearing on autonomous vehicles or a hearing on privacy, so I'll just say I associate myself with Mrs. Rodgers' remarks in that regard. We know there is bipartisan support for those two initiatives, and I know the subcommittee members are eager to work on them.

I look forward to hearing more from you all. Thank you. I yield back.