

Opening Statement
Chair Jan Schakowsky
Subcommittee on Consumer Protection and Commerce
Committee on Energy and Commerce
Hearing on “Profits Over Consumers: Exposing How Pharmaceutical Companies Game the System”
September 19, 2019

Throughout today’s hearing, you will hear many different terms used to describe the problem we are trying to address: “product hopping,” “hard switches,” “soft switches,” and “evergreening”

But whatever the word or phrase, the bottom line is: drug manufacturers are gaming the system to make more money at consumers’ expense.

Big Pharma says that high prices and exclusivity are essential to innovation.

But competition is actually most central to innovation—and the opposite of what Big Pharma wants.

Experts suggest that about 78% of the drugs that get new patents are NOT new drugs.

They are new patents for existing drugs.

Instead of truly innovating, drug manufacturers are taking advantage of the anticompetitive environment by recycling old medicines into new forms.

The problem goes beyond several bad actors you will hear about over and over again today—Humira, Revlimid, Suboxone, Namenda, Prilosec.

Of the 100 best-selling drugs, about 70% had their protection extended at least once, and 50% have had their protections extended more than once.

Many companies are actually withholding new and beneficial discoveries about their drugs from the consumers until they can use this innovation to block competition.

Mr. Carrier’s testimony provided a series of alarming examples:

One manufacturer’s main reason for not seeking FDA approval for off-label uses of their drug was that it “wanted to reserve them for a...promotional campaign for its reformulated product.”

Another manufacturer obtained FDA approval for a once-daily version of their Alzheimer’s treatment, but waited three years, until generic competition for their twice-daily drug was imminent, before releasing it.

Big Pharma actually blocked the innovation they claim to treasure—innovation that could have helped patients—until it was most profitable.

I am proud to preside over this hearing in the Consumer Protection subcommittee because Congress must take direct action to protect American consumers from the deceptive actions that drug manufactures take in their commercial practices.

FDA is responsible for protecting public health by ensuring the safety, efficacy, and security of biological products, including drugs.

FDA does not construe patent claims, and I agree with the agency's conclusion that they should not be tasked with doing so.

And though the FTC has brought some cases for anti-competitive product hopping, it does not have explicit authority to challenge anticompetitive hard and soft switches.

Americans should not have to hope the FTC can stop Pharma's gaming of the prescription drug market—they should be able to count on it.

And Americans should not have to wait years for costly lawsuits to play out—or find that the generic has decided to settle with the brand company for a hefty Pay-for-Delay sum.

I look forward to learning from our witnesses today, as I craft legislation to protect consumers from Big Pharma's evergreening tactics.

Such legislation will set a precedent that I hope will

- force courts to recognize the consumer harms in evergreening,
- and discourage manufactures from engaging in their anticompetitive practices to begin with.

We owe it to the American people to stop these practices, and I will do everything in my power to do so.