House Energy and Commerce, Consumer Protection and Commerce Subcommittee
Profits Over Consumers: Exposing How Pharmaceutical Companies Game the System
September 19th, 2019
10:30 am, 2322 Rayburn House Office Building

Purpose
The purpose of this hearing was to understand how pharmaceutical companies protect their profits at the expense of American consumers

Members Present
Chairman Schakowsky, Ranking Member McMorris Rodgers, Representatives Dingell, Walden, Castor, Latta, O'Halleran, Bucshon, Blunt-Rochester, Carter, McNerney, Gianforte, Soto, Guthrie, and Sarbanes

Witnesses
Michael A. Carrier Distinguished Professor, Rutgers Law School, Co-Director, Rutgers Institute for Information Policy and Law
Jeff Francer, Senior Vice President and General Counsel, Association for Accessible Medicines
David Mitchell, Founder, Patients for Affordable Drugs
Joanna M. Shepherd, Professor of Law, Emory University School of Law

Opening Statements
Chairman Schakowsky said that there are many terms used to describe the problem being addressed today. But the bottom line is that producers are exploiting consumers and that has to stop. Big pharma says that high prices and exclusivity are essential to innovation, but in fact competition is essential to innovation. Most patents are not even given for new drugs, they are instead given to already existing drugs. Furthermore, the problem goes beyond several bad actors. Of the 100 best selling drugs on the market, 70 percent have their protections extended at least once, and 50 percent have their protections extended more than once. Many companies are withholding new and beneficial discoveries about new drugs from consumers until they can protect their profits related to the discovery. Congress must take direct action to protect American consumers from the predatory practices of big pharma.

Ranking Member McMorris Rodgers said that she is proud that America is a leader in innovation. However, patients need to be put ahead of profits. Patients should also be put ahead of government action which prevents access to life saving treatments. This committee should be focused on addressing bad actors without stifling innovation. Often times, the market needs new drugs to be created to increase competition and bring down prices. There are countless examples of how government regulation reduces competition and patient choice. In fact, prescription drug costs are coming down in the United States, and this is due in part to the current administrations actions regarding approving more generic drugs. On average each new drug saves 11,000 lives each year. By discouraging innovation, lives are put at risk. Any new proposal must encourage innovation and eliminate anti-competitive practices.

Rep. Dingell said that no stones can be left unturned when examining solutions to this issue. Everyone has heard horror stories of individuals rationing their medicine due to the high cost of prescription drugs. While it is important to encourage innovation, it is more vital to make sure that consumers have access to life saving medications. Competition is a solution to these high prices. Unfortunately pharmaceutical companies have been exploiting federal regulations to act in a monopolistic way. They often are successful in blocking generic drugs from entering the market and creating competition. There are few repercussions for these actions taken by large pharmaceutical companies. Inaction on this issue is not an option. All Americans are affected by this issue.

Rep. Walden said that this committee has been committed to bipartisan solutions. As the committee deals with this issue, it is troubling that Republicans have been completely excluded from discussions surrounding drug pricing. Furthermore the committee has not even received the new drug pricing proposal coming out of the speaker's office. The only way forward is to come together on these issues and quit acting in a partisan manner. It does not have to be this way. Everyone is affected by this issue and everyone deserves to be a part of the legislative process.

Testimony

Mr. Carrier said that pharmaceutical companies play games to increase their profits, and one of these games is known as product hopping. By addressing product hopping it is possible to get lifesaving drugs into the hands of consumers without curbing innovation. Generic competition is crucial. When a generic enters the market, overall price can drop by 90 percent over night. There is no other industry that has more than one party deciding the price of a product. But this trait allows for anti-competitive practices to inflate prices. One study found that 28 billion dollars' worth of drugs were subject to product hopping. This really hurts consumers when they have to pay a lot more than they should be paying. There are many concerning examples of pharmaceutical companies tweaking their product or withholding innovation to prevent generics from entering the market.

Mr. Mitchell said that he has an incurable blood cancer and pharmaceutical drugs keep him alive. The list price of his drugs are over 800 thousand dollars a year. Innovation is crucial to his survival but it remains true that lifesaving drugs mean nothing if a patient cannot afford them. Product hoping is a large reason for out of control prices. Furthermore, multiple studies show that there is no correlation between the retail price of a drug and the research and development (R&D) that went into producing this drug. Drug companies continue to charge so much because they can. There are multiple things that can be done. This includes, reforming patent laws, ending monopoly pricing powers and reducing the influence of middle men. There also needs to be more transparency around pharmacy benefit managers (PBMs).

Ms. Shepherd said that replacing older drugs for newer drugs is generally apart of the competitive process. Product hopping can often be anticompetitive and reduce innovation. When consumers are coerced into purchasing a new product because there is no viable

alternative to an old product, this is an example of reduced competition. Research shows that within 3 months of entry, generics tend to make up 70 percent of the market. Many times, brand name companies can falsely claim that there are safety concerns on old products to influence consumers towards the new more expensive drug. Patients and doctors should have accurate information on all available products to make the best decision for themselves. Legislators need to be wary of reducing innovation.

Mr. Francer said that competition through the introduction of generic and bio-similar drugs is a proven method to improve competition and reduce price. However, this practice is in jeopardy. Increasingly brand name drug companies are building patent thickets around their drugs to create decade's long monopolies. This practice reduces competition and increases the price for consumers. Another example of anti-competitive behavior is product hopping. The main goal of this practice is to extend the brand name drug companies monopoly pricing and protect profits. These tactics delay generic and bio-similar competition and keep U.S. drug prices the highest in the world.

Questions and Answers

Chairman Schakowsky asked if the FTC currently maintains a list of products that are substantially similar. **Mr. Carrier** said no. **Chairman Schakowsky** asked if there was a straight forward online resource that doctors can use to corroborate the claims made by drug manufacturers. **Mr. Carrier** said no. **Chairman Schakowsky** asked if there was a common resource that patients can use to determine if they need a generic or a brand name drug. **Mr. Carrier** said no. **Chairman Schakowsky** asked how much Mr. Mitchell pays for his drugs. **Mr. Mitchell** said that 21 capsules of one of his current medications costs $17,200 list price and his out of pocket costs are $13,000. **Chairman Schakowsky** asked what the impact of ever greening has on patients. **Mr. Mitchell** says that it reduces the incentive to be innovative and prevents other drugs from coming to the market.

Ranking Member McMorris Rodgers asked how much of an impact competition has in keeping companies accountable. **Mr. Francer** said that generics and biosimilars can bring enormous savings to patients. Furthermore, Medicare Part D should include more generics in their spending. **Ranking Member McMorris Rodgers** asked how we can balance the need for innovation with generics need to compete. **Ms. Shepherd** said that it would begin with defining anti-competitive conduct. It would also be clear about what is not anti-competitive. **Ranking Member McMorris Rodgers** asked when do actions become anti-competitive. **Ms. Shepherd** said that in the case of a hard switch it is important to see if there are generics and biosimilars ready to enter the market. And with a soft switch it is crucial to identify other fraudulent behavior.

Rep. Castor asked Mr. Carrier to describe the behavior that constitutes a hard switch. **Mr. Carrier** said that a hard switch is when a drug company removes the old drug from the market. **Rep. Castor** asked if there is a downside to consumers if a hard switch approval is delayed until after the generic is introduced. **Ms. Shepherd** said no there is no downside.

Rep. Latta asked for examples of when a hard switch is appropriate. **Ms. Shepherd** said that when a new product is clearly safer or significantly more effective than the older product. Anti- Malaria drugs are a good example of this. **Rep. Latta** asked if there is a benefit in allowing the courts to interpret anti-competitive behaviors. **Ms. Shepherd** said yes, but new legislation could make the definitions more clear.

Rep. O'Halleran asked for the witnesses' opinion on how to fix the system. **Mr. Carrier** said that he has no faith that the courts are going to get it right. By making it clear that soft switches present a real harm, this committee can help to fix the system. **Mr. Mitchell** said that congress should be able to define clear violations of Hatch-Waxman. **Ms. Shepherd** said that defining the kind of wrongful conduct in a soft switch that can be constituted as anti-competitive would be useful. **Mr. Francer** said the patent process should lead to more innovation and not less.

Rep. Bucshon asked who is best positioned to determine what constitutes a 'minor change' in a product. **Ms. Shepherd** said the market, doctors and consumers are best positioned. **Mr. Carrier** said that he does not believe the courts should be involved.

Rep. Blunt-Rochester asked what characteristics of the drug market make it susceptible to inappropriate behavior and anti-competitive practices. **Mr. Carrier** said the problem is that there is not a single party that decides the quality and pricing of a new product. There is a disconnect between advertising to doctors and the price of the product. **Rep. Blunt-Rochester** asked if greater transparency would lead to increased innovation. **Mr. Carrier** said yes.

Rep. Carter asked how rebate agreements work. **Mr. Francer** said that rebates can move generic drugs up the tier list and create a scenario where the co-pay for generic drugs is much more expensive than the co-pay for brand name drugs. **Rep. Carter** asked how wide spread the problem is. **Mr. Francer** said it is becoming an increasing problem. Sometimes generics are not covered and sometimes they are on a higher tier than brand name drugs.

Rep. McNerney asked what authority the FTC currently has to address product hopping. **Mr. Carrier** said that the FTC can go after these cases in court, however it does not tend to do it. **Rep. McNerney** asked if the FTC should do a report on product hopping. **Mr. Carrier** said yes, the FTC is in a position to gather all of this information. **Rep. McNerney** asked if legislation can be crafted to bring market prices in line with the rest of the world. **Mr. Francer** said yes.

Rep. Gianforte asked what the barriers are to getting more biosimilars into patients' hands. **Mr. Francer** said that the patent system is broken, and it allows for drugs to have an unlimited monopoly. **Rep. Gianforte** asked when product hopping is anticompetitive. **Ms. Shepherd** said that with a hard switch, it is dependent on the characteristics of the market and availability of alternatives. Concerning a soft switch, it is important to analyze other fraudulent action taken by a company surrounding the soft switch, but not necessarily the soft switch itself.

Rep. Soto asked if ever greening and product hopping are the same thing. **Mr. Carrier** said that product hopping is a component of ever greening. But they are not fundamentally the same thing. **Rep. Soto** asked if three are any other unfair and deceptive trade practices that this committee has not covered yet. **Mr. Carrier** said that biologic companies are disparaging bio-similars even though it is not allowed. Furthermore, PBMs are a huge problem. **Mr. Mitchell** said it is outrageous as a consumer to not know why certain drugs are higher on a tier list than others. There needs to be more transparency for the consumer.

Rep. Guthrie asked how to find a good balance between competition and the need for innovation. **Ms. Shepherd** said that it is about drafting legislation that is specific and not ambiguous. The language in a new bill cannot be vague and open to interpretation.

Rep. Sarbanes asked what barriers congress is facing in attempting to bring down the cost of drugs. **Mr. Mitchell** said there are too many lobbyists on behalf of pharmaceutical companies in congress. The pharmaceutical industry has an incentive to spend money on political operations in order to maintain their market share. Furthermore, the scare tactics are offensive as a patient. The fact is, there is room to lower drug profits.