

**House Ways & Means Committee**

*More Cures for More Patients: Overcoming Pharmaceutical Barriers*

February 5, 2019

2:00 PM, 1100 Longworth House Office Building

Purpose

*The purpose of this hearing is to examine barriers to drug innovation and discuss policies to improve accessibility and affordability of these drugs.*

Members Present

Chairman Doggett, Ranking Member Nunes, Representative Thompson, Schneider, Buchanan, Kind, Smith, Blumenauer, Kelly, Chu, Evans, Holding, Horsford, Higgins, Wenstrup, Kildee

Witnesses

**Juliana Keeping**, Patient Advocate, Mother to a Child with Cystic Fibrosis

**Brad W. Setser**, Senior Fellow for International Economics, Council on Foreign Relations (CFR)

**Ge Bai, PhD, CPA**, Associate Professor of Accounting, Johns Hopkins Carey Business School

**Aaron S. Kesselheim, MD, JD, MPH**, Professor of Medicine, Harvard Medical School/Brigham and Women's Hospital

**Tara O'Neill Hayes**, Director of Human Welfare Policy, American Action Forum

Opening Statements

**Chairman Doggett** said last night, Donald Trump lied to the American people by claiming that drug prices have gone down. In fact, over his administrations tenure, drug prices have gone up. Today's hearing represents a chance to examine how pharmaceutical manufacturers continue to make a profit while millions of Americans struggle to afford lifesaving medications. Pharmaceutical manufacturers are masters of innovation. Unfortunately, most of their innovation comes in the form of patent manipulation and other predatory practices. Much of the research and development conducted by manufacturers goes to tweaking already existing products, as opposed to creating new products. Charity carried out by pharmaceutical manufacturers almost always benefit themselves as opposed to consumers.

**Ranking Member Nunes** said that lowering drug prices is a bipartisan objective. However, Democrats talk about wanting more cures, when in fact all of their bills would reduce drug innovation. Every Republican on this committee believes the status quo is unacceptable. However, H.R. 3 is the wrong path forward. Instead this committee should be considering H.R. 19, which represents an effective bipartisan bill which could be signed by the administration. Both parties agree on so much. It would be silly and unwise to advance in a highly partisan manner and fail to achieve savings for American consumers.

Testimony

**Mr. Kesselheim** said that the process of pharmaceutical innovation is long and expensive. These innovations are crucial as it leads to the development of drugs that can enhance or save a patient's life. Currently, the United States provides incentives for drug manufacturers to develop and bring a new drug to market. One of these incentives is offering a period of exclusivity to pharmaceutical manufacturers. However, this incentive allows manufacturers to charge significantly more for the same drugs sold in the United States as overseas. The United States also encourages manufacturers to innovate by providing tax payer funded research and development and by providing tax credits to manufacturers. Recent studies have showed that almost all of the new drugs brought to market can be tied back to tax payer funded research. Furthermore, many manufacturers have found loopholes which allow them to receive tax credits when they would be otherwise ineligible.

**Mr. Setser** said that America has a large and growing trade deficit in pharmaceutical products. Furthermore, the Tax Cut and Jobs Act created new incentives for the offshoring of pharmaceutical production. Additionally this same tax cut has incentivized manufacturers to move profits overseas, while achieving zero savings for consumers. Currently, American consumers pay the highest price for drugs in the world. The United States also imports far more drugs than it exports. Perverse financial incentives encourage companies to conduct research and development in the United States and then move their intellectual property overseas to game the system. The Tax Cuts and Jobs Act of 2017 increased profits for pharmaceutical manufacturers while failing to achieve savings for consumers. The US tax code should not have been designed to reward other countries and large manufacturers. It is possible to rewrite the tax code to eliminate these perverse incentives.

**Dr. Bai** said that drug manufacturers donate in cash to patient assistance and advocacy organizations. These same manufacturers donate products to providers who then dispense them to patients. These drug manufacturers have infiltrated independent organizations with the purpose of flooding the market and influencing policy. These actions create inequity in the market and harm consumers. However, this practice serves to increase the profits for manufacturers. American taxpayers and programs like Medicare are often left to foot this bill. Advocacy organizations have become saturated with conflicts of interest. They often advocate for policies that in return harm the patients they claim to represent. Tax deductions must be eliminated for cash contributions to these organizations. The goal is to improve transparency and protect patients.

**Ms. Keeping** said that two weeks after her son was born, he was diagnosed with cystic fibrosis. Almost immediately, the high cost of drugs became an abject reality. After enrolling in a patient advocacy program, Ms. Keeping was able to afford the necessary lifesaving medications. Unfortunately, Ms. Keeping did not qualify for the program in the following year. Ms. Keeping said that her family struggles to afford even the basic medications and are constantly applying to patient assistance programs. Unfortunately, drug manufacturers determine eligibility based on how much their insurance company will pay. A drug company will gladly cover a \$4,000 deductible if the insurance company will

pay the \$300,000 price tag on drugs. As drug prices increase, the costs get shifted onto all American consumers. The solution is to lower drug prices. H.R. 3 is an important step forward. The Secretary of HHS should be able to negotiate drug prices on behalf of Medicare patients.

**Ms. Hayes** said that her family has been personally impacted by every side of the drug pricing issue. One member of her family passed away because there was not a cure available. Meanwhile, her father has rheumatoid arthritis and cannot afford his daily medication. Drugs should be affordable, however, innovation should also be encouraged. By redesigning the Medicare Part D benefit, it is possible to achieve both of these goals. Currently, payers and manufacturers have incentives to increase drug prices. By placing liability on the manufacturers, it is possible to encourage them to lower drug prices. Furthermore, Medicare Part D beneficiaries should also have an out-of-pocket cap in order to provide financial predictability and security. H.R. 19 would not only save the federal government money, but also American consumers.

#### Questions and Answers

**Rep. Thompson** asked how pharmaceutical companies have used the money they've made as a result of the Tax Cuts and Jobs Act of 2017. **Mr. Setser** said a bulk of the tax cut has been given back to shareholders. **Rep. Thompson** asked if the price of drugs has decreased meaningfully. **Mr. Setser** said no, the prices have gone up. **Rep. Thompson** asked if the tax cut has led to an increase in jobs in the pharmaceutical industry. **Mr. Setser** said no. **Rep. Thompson** asked if H.R. 3 would stifle innovation. **Dr. Kesselheim** said there is no evidence to suggest H.R. 3 would reduce innovation.

**Ranking Member Nunes** asked how Medicare Part D works. **Ms. Hayes** said that currently, there are several perverse incentives that exist. H.R. 19 would change this by requiring manufacturers to be liable for a percentage of costs in the catastrophic phase. Furthermore, H.R. 19 would reduce the government's reinsurance liability and impose an out-of-pocket cap for beneficiaries. **Ranking Member Nunes** asked how H.R. 3 would affect part D. **Ms. Hayes** said her analysis has limitations and assumptions. The manufacturer liability in H.R. 3 would be much more burdensome than under H.R. 19.

**Rep. Schneider** asked if other members of Ms. Keeping's community would benefit from lowering drug prices. **Ms. Keeping** said that older individuals with cystic fibrosis would also benefit. **Rep. Schneider** asked what short comings exist in the Medicare extra help program. **Dr. Bai** said the extra help program should have increased eligibility. Currently the eligibility is too stringent.

**Rep. Buchanan** asked what financial savings are associated with H.R. 19. **Ms. Hayes** said any beneficiary who spends above the deductible would have cost savings. Additionally, beneficiaries would have an out of pocket cap. While not every beneficiary would benefit from this directly, many would be insulated from high drug prices.

**Rep. Kind** asked if it is important for the secretary of HHS to negotiate drug prices. **Dr. Kesselheim** said it is vitally important. Negotiation is the most effective way to bring down the price of drugs to better reflect the value consumers actually receive. **Rep. Kind** asked if price negotiation will threaten innovation. **Dr. Kesselheim** said no, because most innovation stems from public investments. **Rep. Kind** asked if hospital price transparency or the sale of junk insurance would lower the cost of drugs. **Dr. Kesselheim** said no.

**Rep. Smith** asked if Mr. Setser is advocating for undoing the Tax Cuts and Jobs Act of 2017. **Mr. Setser** said there are a significant amount of options that would be a better alternative than the Tax Cuts and Jobs Act. There are a lot of steps that could be taken that come short of repealing the Tax Cuts and Jobs Act.

**Rep. Blumenauer** asked if it's true that drug manufacturers make a profit in countries that have negotiated drug prices. **Dr. Kesselheim** said yes. **Rep. Blumenauer** asked if it's true that assistance programs provide perverse incentives for drug manufacturers. **Dr. Bai** said yes.

**Rep. Chu** asked how transparency measures would help to bring down the cost of drugs. **Dr. Bai** said that it will deter any wrong doing or actions by providers that are against the patient's best interest. **Rep. Chu** asked about the burden that high cost drugs place on the health care system as a whole. **Dr. Kesselheim** said that fundamentally, high cost drugs often do not have high value relative to the cost. Furthermore, these drugs increase the cost for tax payer.

**Rep. Evans** asked how the Tax Cuts and Jobs Act of 2017 has affected the trade deficit. **Mr. Setser** said that the Tax Cut and Jobs Act has created a new set of incentives that distort the market. This Act encourages companies to take advantage of the low tax rate of global intangibles. Furthermore, this Act incentivizes off shore production.

**Rep. Holding** asked how H.R. 19 would incentivize innovation. **Ms. Hayes** said that there is a lot of basic research that happens at the NIH. Furthermore, relative to the Senate Finance bill, H.R. 19 more evenly spreads liability throughout the plan benefit. There would be less risk on manufacturers and venture capitalists.

**Rep. Horsford** asked if it is true that drug manufacturers get tax discounts for charitable contributions to patient assistance programs. **Dr. Bai** said yes. **Rep. Horsford** asked if it is true that these assistance programs do not help those most in need. **Dr. Bai** said yes.

**Rep. Higgins** asked if it is true that drug price negotiation will thwart innovation and research. **Dr. Kesselheim** said no.

**Rep. Kildee** asked how easy it is to navigate patient assistance programs. **Ms. Keeping** said that patient assistance programs are not always accessible when needed. Patient assistance programs should not be necessary. **Rep. Kildee** asked if a significant change in financial status caused Ms. Keeping to no longer be eligible for the patient assistance program. **Ms. Keeping** said no. **Rep. Kildee** asked how patient assistance programs affect pricing overall. **Dr. Kesselheim** said that patient assistance programs maintain high prices across the system. **Dr. Bai** said these programs insulate patients from high costs, and thus make it easy to increase the price.

**Chairman. Doggett** asked what the panels' opinion was of a study that came out of Tufts center for the study of drug development. **Dr. Kesselheim** said that there are many significant flaws to this study. It over estimates the amount of money spent on research and development.

**Chairman Doggett** asked if direct public investment is the best way to develop new cures. **Dr. Kesselheim** said yes, tax breaks are not the answer. **Chairman Doggett** asked if it is reasonable to negotiate prices, considering taxpayers are already paying for research and development. **Dr. Kesselheim** said yes. **Chairman Doggett** asked if the Tax Cuts and Jobs Act of 2017 encouraged drug manufacturers to harbor their intellectual property offshore. **Mr. Setser** said yes.

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