Senate HELP Subcommittee on Primary Health and Retirement Security
Why Does the US Pay the Highest Prices in the World for Prescription Drugs?
March 23, 2021
10:00 A.M., 430 Dirksen Senate Office Building

Purpose

The purpose of this hearing is to examine the issue of rising drug prices in the United States, particularly focusing on the U.S.'s high prices in comparison to other developed countries in the world.

Key Takeaways

- Drug prices in the U.S. are consistently higher than in any other industrialized country for the same drugs.
- Patent thickets as well as pay for delay tactics for brand name drugs extend exclusivity, preventing the entrance of generic and biosimilar competition.
- Many other developed nations have a system of national negotiation of price based on assessments of value of the drug.
- Drug-specific focus was on insulin and other high cost brand-name drugs that have been on the market for at least decades.

Members Present
Chairman Sanders, Ranking Member Collins, Senators Casey, Baldwin, Murphy, Kaine, Hassan, Rosen, Murkowski, Cassidy, and Braun

Witnesses

Aaron Kesselheim, MD, JD, MPH. Professor of Medicine, Brigham and Women's Hospital and Harvard Medical School. Boston, MA

Nav Persaud, MA, MAA. Canada Research Chair in Health Justice, University of Toronto. ON, Canada

Elia Spates, Derby, VT

Alex Brill, Resident Fellow, AEI. Washington, D.C.

Opening Statements

Chairman Sanders (D-VT) said the pharmaceutical industry is creating a situation where they can raise their prices to any arbitrary level whether or not substantiated by value. Drug industries make profits year after year and pay their CEOs a large amount of money. The industry charges the U.S. the highest by far, and drug prices in the U.S. are almost two times

what they are in comparable nations. Pharmaceutical companies charge Medicare, Medicaid, the Veterans Affairs (VA), and community health centers different prices, and this pricing system is opaque. This industry has paid $32 billion in fines and has committed fraud and deception. Yet, this industry is still getting away with it. The pharmaceutical drug industry exhibits great power in Washington. Drug companies have spent $7.6 billion on lobbyists in the last 23 years. The industry is not very sympathetic to either party, and they try to buy both parties. It is not Congress that regulates the drug companies but the companies which regulate Congress. Companies profit as people are suffering and dying from not being able to afford their medications. One out of five Americans could not afford to fill their prescriptions. The country can no longer tolerate companies profiting in the billions by selling drugs at a much higher price than what people can afford. Insulin is an example of a drug that is not new, yet prices continue to go up. Insulin costs $98 in US, $12 in Canada, $11 in Germany, $9 in France, $7.52 in UK, and $6 in Australia. He asked how many people need to die and get unnecessarily sicker before Congress can change pharmaceutical companies. He has introduced three bills to reduce drug prices and result in savings: Prescription Drug Price Relief Act, which would cut U.S. prices in half by pegging prices to median price of five other countries, Medicare Drug Price Negotiation Act, which would direct HHS Secretary to negotiate prices for Medicare Part D, and the Affordable and Safe Prescription Drug Importation Act, which would allow pharmacies and other purchasers to legally import drugs from Canada and other nations.

Ranking Member Collins (R-ME) said it is important for both parties to find common ground. For many people, access to these medicines is critical to their well-being and can also be a matter of life or death. Drug pricing and understanding the system has been a priority. Topics of investigation include price spikes of off patent drugs, various entities' roles in the opaque pricing system like pharmacy benefit managers (PBMs), and the rising price of insulin. The Making Pharmaceutical Markets More Competitive Act passed providing a more transparent and open application process for generic drugs and expediting the timelines for approval. Approvals and applications for generics have gone up since. By listening to patients and working with other members, they have introduced bills to reduce drug prices and streamline the Food and Drug Administration's (FDA) approval process for insulin. At the end of 2019, Congress passed legislation that will streamline the FDA approval process for insulin. The cost of insulin is among one of the most prominent examples. They have introduced a new payment model for the pricing of insulin. Recently, there has been some progress to improve insulin affordability, more than 1,700 Part D and Medicare Advantage plans have agreed to cap the copay at $35. Another focus area is biosimilar competition. She will also introduce the Biosimilar Price Transparency Act. In the past, there have been advances of bipartisan support for improving drug pricing. Prices must be more affordable and transparent so drugs can reach consumers.

<u>Testimony</u>

Mr. Aaron Kesselheim said the U.S. allows drug companies to set prices at any price they want. The U.S. spends far more per capita for drugs than any other industrialized country – over $1,200 in 2018 compared to the Organization for Economic Co-operation and Development (OECD) average of less than $600. U.S. spending on drugs is primarily on brand

name drugs, most of which have been on the market for many years. Medicare Part B drug prices of the top spend drugs were 46%-60% lower in Japan, Germany, Switzerland, and the UK. This is possible for three reasons: drug companies are allowed to set prices at any level entering the market requiring Medicare and Medicaid to pay at these levels; drug companies are allowed to raise these prices each year beyond inflation; companies build patent thickets on insignificant parts of the drug to extend market exclusivity. The first step is to evaluate and negotiate prices. Other countries evaluate the benefit of a drug and negotiate and coverage and prices. States like New York and Massachusetts have started to implement a review process for their Medicaid program. U.S. should limit the allowed price increase from year to year. Many brand name drugs provide rebates, but these only offset some of the price increases. In other countries, drug price increases are limited and often decrease. U.S. should promote a competitive market in generic and biosimilar drugs. Lessons on how to improve the U.S. system can be modeled based on other countries. They can leverage the patent appeals board to weed out invalid patents through reviewing patents by the FDA. Meaningful innovation can still be maintained. They must augment support of the National Institutes of Health (NIH), which can improve innovation. If a drug price is more adequately reflected, this would incentivize innovation and allow for investments to address unmet needs. Most importantly, policymakers can ensure more people can access these drugs at a more affordable price.

Mr. Nav Persaud said the per capita spending is approximately 40% higher in the U.S. than Canada, largely due to the regulation of patented drug prices. In Canada, there is a drug pricing review board. Posted prices for drugs are three times lower in Canada. The larger spending in the 1990s in the U.S. was largely due to patents on opioid drugs, like OxyContin. These drugs were illegally marketed by Purdue to be safer and cheaper alternatives. Pharmaceutical companies continue to profit from the opioid crisis. Pressure in lobbying has undermined reforms in both U.S. and Canada. America is a superpower that has not shown its strength against pharmaceutical companies. In Canada, they have conducted a study and found improved health outcomes and spending with greater access to drugs. VA national formulary has led to price reductions by developing a list of drugs and allowing negotiation. This can be adapted to a larger scale. Creating a new bureau to set price ceilings can keep prices low. The new bureau can cut drug spending. Negotiating power can also secure lower drug pricing and can ensure equitable access. Using existing policies can also be utilized for urgent action.

Ms. Elia Spates said she was diagnosed with Type I diabetes about 20 years ago. The rise that she has seen in her insulin prices is astronomical. The price she pays for insulin is $2,000 out of pocket per month. The cost tripled and her family has felt the financial pinch. She has cut back on her insulin use to save money. The financial side of diabetes is as much, or more, of a burden as the physical burdens. 7.5 million Americans rely on insulin. It took her over a year to get approval for one drug only for it to no longer be covered under her insurance. She said it is unethical and completely wrong to gouge people, particularly at the expense of their health. They have seen a 300% rise in the cost of insulin, compared to Canada that has seen virtually no rise in cost. Twice she arrived at the pharmacy to pick up her insulin prescribed by her doctor, and both times the pharmacy did not allow dispense that brand without prior authorization from her insurance company. This is a result of the exchange of money

between pharmaceutical companies, pharmacy benefit managers, and insurance companies. She said the companies do not feel the pressure and the burn of the rise in prices. Three major insulin products see price hikes over time. The PBMs receive rebates that are cashed in not by patients but by the PBMs themselves, in exchange for preferred status in formularies. Those perpetuating this travesty are benefiting because of greed. Pharmaceutical companies engage in pay for delay tactics to prevent the entrance of generic and biosimilar drugs. The question is who is going to fix the system.

Mr. Alex Brill said the importance of innovation in the sector is a critical role in improving health and wellbeing. This is evident with the three COVID-19 vaccines that are now available in record time. This is a product of decades of public and private investment and FDA support. With respect to drug spending, the U.S. spent $368 billion in 2019, nearly 10% of national health expenditures. It is important to note the drivers of the cost. Biologic spending is driving much of the increase. Notably, out-of-pocket (OOP) spending as a share of total spending has declined. OOP costs for those with the highest expenses with low to moderate income fell. These broad trends are important to recognize but can also mask high financial burden experienced by other patients. The current market for pharmaceutical drugs is part of a dual mandate set up by the landmark legislation known as Hatch-Waxman, allowing meaningful rewards and generic competition. The average copay for generics is about $7. There are other opportunities to foster competition. The first is for biosimilar drugs, which have yielded savings. Further work needs to be done to align rewards by proposing ASP+8% reimbursement. The second is targeting the complex generic application and the FDA approval process. Congress should ensure that the FDA has the necessary incentives and resources for timely review of complex generic drugs. The last focus should be on patent thickets surrounding around lucrative products to deter generic and biosimilar challenges.

<u>Questions and Answers</u>

Chairman Sanders said they purchased insulin in Canada for one-tenth of the price as the U.S. He asked why the same drug be purchased at this price in Canada and not in the U.S. **Mr. Persaud** said that patented medicines have their prices regulated in Canada. **Chairman Sanders** asked if there is another country that regulates the price like the U.S. **Mr. Persaud** and **Mr. Kesselheim** said no, the U.S. is unique, which means there is no pressure on companies to sell drugs at a lower price. **Chairman Sanders** said that it is estimated that 1 in 4 Americans cannot afford the drugs that doctors prescribe. He asked what impact this has on health in U.S. **Mr. Kesselheim** said that it has a large impact, such as non-adherence or extension of their prescription, which is ultimately harmful to patients. **Chairman Sanders** commented saying if he cannot afford his medicine, and he gets sicker and ends up in the emergency room and the hospital, is it reasonable to assume there are increases in spending because people get sicker. **Mr. Persaud** said yes, spending increases because people end up in the hospital. They also found that people find it easier to pay for housing, food, and other necessities with lower drug costs. **Chairman Sanders** said that high prices result in health systems spending more.

Ranking Member Collins said there was a mention of patent tickets blocking access to biosimilars and that biologics are very expensive. Even though there are several biosimilars for the best-selling drug, American patients must wait for drugs to be available due to overlapping and late filed patents. She asked how Congress can ensure they are recognizing innovation of science versus rewarding a strategy that blocks competition. **Mr. Brill** said that they are in the process of using evolving tools that can protect assets. The patent system is getting in the way of innovation. **Ranking Member Collins** said the VA has authority to negotiate favorable pricing, but they also hear complaints of people needing drugs not in the national formulary. She asked about negotiation and ensuring patient choice of medications. **Mr. Kesselheim** said that evaluating the value of drugs and providing coverage to products that are extremely effective is important.

Senator Casey (D-PA) said they have an obligation to act. He has wanted to expand low-income protections and for seniors so they can afford OOP costs. He inquired, with regards to drug importation, if the witnesses believe the prescription drugs sold by Canada are safe and effective. **Mr. Persaud** said that yes, they are safe and effective, and the U.S. should be able to negotiate prices with Canada. **Senator Casey** asked about the controls Canada has on pricing. **Mr. Persaud** said they regulate every drug and inspect every domestic and overseas companies.

Senator Murkowski (R-AK) said the price of an inhaler has increased every year for three years. She asked what prompted this change. She asked if it was from manufacturing costs or if it was a result of improved efficacy. **Mr. Kesselheim** said that it is a result of maintaining profit margins. Manufacturers can get new patents, which prevents the FDA from approving interchangeable products that can reduce prices and lack of negotiation with manufacturers on the prices they charge. **Senator Murkowski** asked how consumers can understand the justification of price hikes. **Mr. Kesselheim** commented that evaluation is necessary to compare effectiveness. The price can be increased if substantial research shows improved effectiveness. **Senator Murkowski** said they have introduced a bill to regulate price hikes and ensure transparency.

Senator Baldwin (D-WI) said she hears all the time from her constituents on their inability to afford life-saving drugs. She said she is reintroducing a bill to require manufacturers to submit a transparency and justification report 30 days before increasing a price of a drug. She asked why it is important for manufactures to justify price increases. **Mr. Kesselheim** said it's important as an incentive to justify the price increase and for high-quality research information. Another measure of this bill is that it can dissuade price increases if companies do not have justification. **Senator Baldwin** said research shows that NIH funding contributed to every single FDA approval from 2010 to 2019. In spite of this contribution, the NIH is only listed on 27 of these patents. In essence, tax payers are paying the highest price for drugs they paid for through taxes. She asked how Congress should account for the taxpayer contributions. **Mr. Kesselheim** said that research has shown that transformative drugs are more likely to come out of public funding. This shows that there are limitations to the patent system and there is no control on the prices in the market.

Senator Marshall (R-KS) said there is a difference between the list price and a net price of insulin. The list price has gone up and the OOP spending is based on the list price. The net price has gone down since 2007, and is where the opaque process starts. They are losing community pharmacies. The first issue is transparency on kickbacks, and the second issue is eliminating these kickbacks. He said that innovation is important as well. He reflects on the COVID-19 vaccine approval process and said there is balance between price controls and innovation. **Mr. Brill** said that policymakers are focused on both of these objectives. They must nurture research and the investments over time, as well as find ways to create more competition and impact the list price.

Senator Kaine (D-NH) remarked that cost savings can be done through getting more biologics into the market. He asked about international reference pricing to reduce pricing, as the U.S. pays dramatically more than other countries. **Mr. Kesselheim** said yes, that could be useful. International reference pricing is evaluating and negotiating, but relying on other countries to set parameters. The U.S. could and should make those same assessments. **Senator Kaine** asked why the U.S. does not engage in basic negotiating strategies. **Mr. Kesselheim** said that the U.S. should leverage the size of the country to negotiate through international reference pricing. **Senator Kaine** said that he is struck that the U.S. does not allow negotiating under Medicare Part D, but the VA allows negotiating. **Mr. Kesselheim** said that Medicare could save billions of dollars if it leveraged negotiating. **Senator Kaine** said this would result in savings for beneficiaries and lower healthcare premiums. It would impact the entire economy.

Senator Cassidy (R-LA) said high drug price and exclusivity must be addressed. **Mr. Brill** said that 7 out of the top 10 drugs were granted orphan drug exclusivity. The current structure extends monopoly power across all drugs. **Senator Cassidy** asked about legislation to address this issue. **Mr. Brill** commented that they should think about exclusivity and engaging with the FDA to make the recommendations. **Senator Cassidy** said the U.S. would be a purchaser of 99% of drugs produced through a single-purchaser. He said this could have a chilling effect on a company's willingness to invest in a drug knowing the return on investment would be poor. **Mr. Kesselheim** said that there are many scientists trying to find effective cures for conditions. He said there would a high pay on these drugs to reduce spending. **Senator Cassidy** asked if this would reduce innovation for drug development. **Mr. Kesselheim** said that other countries can come to valid negotiations through evidence-based valid arguments to set drug pricing. They will be able to pay a lot more money for innovation.

Senator Hassan (D-NH) said there is bipartisan support to lower prescription drug pricing. She asked who makes the majority of investments in research that leads to breakthrough research – is it the taxpayer or the company? **Mr. Kesselheim** said that a substantial amount of translational science is funded by public systems and private entities come in later in the process. He said it is combination of both forces, but agreed that a substantial part of the funding is from the taxpayer. **Senator Hassan** said drug companies receive taxpayer support at almost every step of the drug development. She inquired about what tax breaks and subsidies drug companies have received and if it has led to more innovation. **Mr. Kesselheim** said no. **Senator Hassan** said lowering the prices overall would make a difference for the

patients. She asked why companies are choosing to spend billions of dollars a year for subscribers rather than putting money towards decreasing drug prices. **Mr. Kesselheim** said that larger brand names put money towards marketing, compared to generics who do not spend as much.

Senator Rosen (D-NV) asked what Congress can do to support smaller local start-up pharmaceutical firms that can increase access and lower costs for patients. **Mr. Kesselheim** remarked saying smaller companies do not have as much support because the incentives are not necessarily there to support new products. One of the things that can be done is providing more upfront support for development, but also ensure they are made available at an affordable price for consumers. **Senator Rosen** asked how Congress can support growth in the nonprofit sector. **Mr. Kesselheim** said in other countries, neglected tropical diseases are the primary focus of the nonprofit sector. Based on other country's successes, these models can be modeled for the U.S. to bring other drugs to market in the nonprofit sector. **Senator Rosen** said the 340B drug pricing program is critical to Nevada. They have a diverse population, with hundreds of thousands of people living in rural communities spread out across the state. She asked about the importance of the 340B drug pricing program and how it has increased access and affordability. **Mr. Kesselheim** stated the 340B program is a very complicated system where they try to provide drugs at a relatively low cost to safety net hospitals, and it has impacted a lot of useful drugs to low-income patients. It has expanded over the years, perhaps beyond what it originally intended, and as a result, there have been discussions on the extent to which hospitals should qualify as 340 hospitals or not. But there is no doubt that 340B prices are among the best prices they offer for certain high cost drugs.

Senator Braun (R-IN) said the lack of transparency is a big issue in drug pricing. Healthcare consumers have grown as well. He said there is no other sector of the economy that has less transparency, less competition, and more barriers to entry as this sector. Bringing government into play is necessary. He said that it is bizarre for anyone to think full transparency is not necessary. He asked why this the case, as since it seems to be counterintuitive. **Mr. Kesselheim** said full transparency risks increasing drug prices. He would be in favor of transparency if they marry it with other proposals, but just transparency alone is not enough.

Senator Murphy (R-CT) there has been a substantial increase in drug marketing. Clearly, this would benefit companies to increase sales of the product. He asked if this is a benefit to the healthcare system and if direct-to-consumer advertising benefit patients. **Mr. Persaud** said no, it does not benefit patients. Marketing does not improve the care patients receive, which is a driver towards more expensive medicine. **Mr. Kesselheim** said that he agrees, direct-to-consumer advertising brings people to the office asking about medicines, but may not offer improvements to care.

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