On January 29, 2018, the House Committee on Oversight and Reform (Committee) held a hearing entitled, *Examining the Actions of Drug Companies in Raising Prescription Drug Prices*. The hearing was intended to determine why drug companies are increasing prices so dramatically, how drug companies are using the proceeds, and what steps can be taken to reduce prescription drug prices.

Witnesses present included:

- Antroinette Worsham, Mother of Two Insulin-Dependent Daughters;
- Catherine Alicia Georges, Ed.D., RN, FAAN, National Volunteer President, AARP;
- Aaron Kesselheim, M.D., J.D., M.P.H., Associate Professor of Medicine, Program on Regulation, Therapeutics and Law, Harvard Medical School;
- Gerard Anderson, Ph.D., Professor of Health Policy and Management, Bloomberg School of Public Health, Johns Hopkins University; and
- Avik Roy, M.D., President, Foundation for Research and Equal Opportunity.

**Opening Remarks**

**Chairman Elijah Cummings (D-MD)** said prescription drug costs are one of the most important issues that demands immediate attention. He said the hearing will focus on examining the actions of drug companies in raising prescription drug prices in the United States and the effects of those actions. He said drug companies have been “aggressively” increasing prices on existing drugs and setting high prices for newly launched drugs. He noted that the Committee has launched an investigation into drug prices. Chairman Cummings said the first witness, Antroinette Worsham, is the mother of a daughter who died because she could not afford the insulin needed to treat her diabetes. He said one in four patients with type 1 or type 2 diabetes have reported using less insulin than prescribed and said Ms. Worsham is representing thousands of fellow Americans. He said drug companies often raise the prices of their drugs without justification. Chairman Cummings said the pharmaceutical industry is one of the most profitable and powerful in the world. He said there is a strong bipartisan consensus that Congress must do something meaningful to address drug prices. While Congress recognizes the value of pharmaceutical research and development (R&D), he said the ongoing increases in drug prices is not sustainable.

**Representative Peter Welch (D-VT)** said pharmaceutical companies argue that allowing the government to negotiate drug prices will result in price fixing. However, he said pharmaceutical companies are able to set whatever price they choose for a drug. Additionally, he said pharmaceutical companies claim high prices are essential to innovation, but pharmaceutical companies spend more on advertisements than R&D. Rep. Welch said the Committee’s mission is to restore competition and transparency in the pharmaceutical market and lower drug prices.
Ranking Member Jim Jordan (R-OH) said that Chairman Cummings, President Trump, and he are committed to making reforms to lower the price of prescription drugs. He said the Democrats are eager to blame the private sector, but the problem is more complicated. He said government intervention in the market has distorted incentives. Ranking Member Jordan said the Committee needs to consider the role of government in rising prices. Additionally, he said the Committee must look at the manner and scope of the “limited monopolies” given to brand pharmaceutical companies through patents and exclusivities noting that these limited monopolies have been improperly used to broadly exclude others from selling similar drugs.

Witness Testimony

Antroinette Worsham (Mother of Two Insulin-Dependent Daughters) said her older daughter was diagnosed with type 1 diabetes at 16 and died at 22 because she was rationing her insulin. She said her younger daughter was diagnosed at 12 years old and she fears her daughter will also die as a result of not being able to afford her insulin. She said type 1 diabetics need insulin to live and high drug prices are forcing patients to be noncompliant with their medication regimen. Ms. Worsham said high copays and deductibles also have an impact on the affordability of insulin. She said insulin manufacturers say they have programs to help offset the costs of insulin for low-income patients, but affordable health care is needed for all people, including the middle class. Ms. Worsham urged Congress to investigate and address pharmaceutical price gouging.

Dr. Catherine Alicia Georges (AARP) said prescription drug prices are a high priority for AARP and its members. She said older Americans struggle to afford needed and life-saving medications noting that most Medicare beneficiaries live on limited incomes. She said AARP members consistently tell her that they cannot afford their medications. She described a cancer patient who was prescribed Gleevec, but had to stop taking the drug and risk her cancer retuning because of the high price of the drug. Dr. Georges said AARP found that the retail price of brand name drugs increased by an average of 8.4 percent in 2017, 4 times the rate of inflation. She said virtually all of the manufacturers AARP has been tracking since 2004 have consistently raised prices over the past 12 years. Dr. Georges said high drug prices affect all Americans and are not sustainable. She said Americans pay the highest brand-name drug prices in the world and urged Congress to take action to lower drug prices.

Dr. Aaron Kesselheim (Harvard Medical School) said drug prices have risen rapidly over the past decade. He said the main driver of drug spending increases is brand drugs, which account for about 10 percent of prescriptions, but over 75 percent of spending on prescription drugs. Dr. Kesselheim said high drug prices arise from the following complementary forces:

- The government gives patent and other market exclusivities to brand name manufacturers and allows manufacturers to charge whatever the market will bear;
- The purchasing market that is expected to act as a counterweight is extremely inefficient because various laws and factors prevent payers form effectively negotiating; and
- Manufacturers often extend their exclusivity rights through various strategies and use their lobbying power to block sensible reforms.

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Dr. Kesselheim said during the exclusivity period, there are limits on public and private payers that prevent them from pushing back on prices from manufacturers. For example, he said Medicaid must cover all Food & Drug Administration (FDA) approved drugs and Medicare Part D must cover all drugs in the six protected classes. He said the only type of competition that lowers drug prices come are the introduction of interchangeable generic drugs onto the market after the exclusivity period for the brand drug ends. However, Dr. Kesselheim said the introduction of interchangeable generics can be delayed or prolonged because manufacturers obtain extended patents on new formulations. To improve competitive price negotiation during the market exclusivity period, he said Medicare could be authorized to create a program-wide formulary and negotiate drug prices based on the value of the drug.

Dr. Kesselheim said another range of policies that should be enacted are those that remove barriers for new drugs to enter the market. He said Congress could provide the Federal Trade Commission (FTC) with guidance to help the FTC exclude problematic patent settlements with the goal of preventing pharmaceutical companies from indefinitely extending a patent on a drug. Dr. Kesselheim said studies show that much of the most important drug innovation arises from publicly-funded research paid for by the National Institutes of Health (NIH) and occurring in government or academic laboratories. Therefore, as long as the US government continues to invest in research, there will continue to be innovative drug development. He said bringing US drug prices in line with the value of the drug means high value drugs may have high costs, but the costs would be appropriate. Further, he said Medicare and Medicaid would be able to afford the high value, high cost drugs because money would not be spent on high cost, low value drugs.

**Dr. Gerard Anderson (Johns Hopkins University)** said the Committee should pay attention to the following areas:

- How do branded companies justify price increases?
- Why does it cost so much to develop a new drug?
- Why do pharmacy benefit managers (PBMs) and prescription drug plans (PDPs) place the most expensive drugs in preferred positions on formularies?
- Why do some blockbuster drugs also have an orphan designation?
- How do PDPs manipulate direct and indirect remuneration (DIR) to increase cost to the Medicare program and Medicare beneficiaries?
- How do drug companies attempt to influence the patient assistance programs they support financially?
- How do drug companies attempt to influence the patient advocacy groups they support financially?

**Dr. Avik Roy (Foundation for Research and Equal Opportunity)** focused his testimony on the following two “excuses” often heard about high drug prices: (1) high prices are not set by manufacturers, but by middlemen, such as PBMs; and (2) rising prices are necessary to fund innovation. He said the first is not true because drug companies set high prices and in the absence of competition manufacturers generally charge the highest prices they can. He said PBMs structure insurers’ formularies to keep lower cost drugs on the lower cost formulary tier with low copays for patients. However, he said drug makers use rebates to get their high cost drugs on the lowest formulary tier. Dr. Roy said Congress should eliminate rebates to restore transparency and accountability to prescription drug prices. With respect to the second “excuse,” he said the business model of drug makers is to increasingly focus on ultra-rare, orphan diseases where R&D costs are low due to the limited supply of patients for clinical trials while still

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charging high prices, sometimes nearly $1 million. He said virtually all increases in prescription drug spending come from price hikes on older drugs like Avonex (a drug used to treat multiple sclerosis). Dr. Roy said companies are able to take advantage of patients with chronic diseases that are well-controlled on a given drug and for whom switching to a lower-cost alternative would be considered bad medical practice, by increasing the price of that drug.

Question & Answer

Representative Eleanor Holmes Norton (D-DC) asked how drug prices affect seniors. Dr. Georges said seniors are making choices to ration or not adhere to treatment.

Representative Mark Green (R-TN) said the cost of pharmaceuticals is concerning, but he is also concerned about cost increases across the healthcare system as a whole. He said the problems are structural. He asked Dr. Roy how the government is creating inappropriate monopolies for brand drugs. Dr. Roy said the Biologics Price Competition and Innovation (BPCI) Act of 2009 mandated that biologic drugs have 12 years of exclusivity after FDA approval even if there is no intellectual property.

Representative Stephen Lynch (D-MA) said Service Employees International Union and the Teamsters Union found that when a federal employee pays for their drugs under their plan, which is negotiated by a PBM, they pay more than a person who has no insurance and signs up for a discount program. He said under the Department of Veterans Affairs (VA) system, patients pay an $8 or $9 copay because the VA negotiates directly with drug manufacturers. Rep. Lynch asked if Medicare should be able to negotiate directly with pharmaceutical companies. Dr. Anderson said the VA has access to almost all of the drugs in the US, but Medicare Part D beneficiaries have access to about half the number of drugs because the formularies are more limited. Rep. Lynch said there is a lack of transparency.

Representative Thomas Massie (R-KY) said the patent system incentivizes companies to develop life-saving drugs and devices. He asked Dr. Roy about issues related to the development of generic drugs after the patent on the brand drug has expired. Dr. Roy said with respect to biologics, there have not been many biosimilar approvals. He also said it is very competitive for companies to develop biosimilars because even when they get FDA approval, they sometimes withdraw the drug because the price they would have charge is too high. Rep. Massie asked about the role of the delivery device for the EpiPen in the price of the drug. Dr. Roy said epinephrine was discovered over 100 years ago, but the delivery device has patents. Dr. Roy said Congress should create a statutory pathway for complex generics to be approved more rapidly.

Representative Gerald Connolly (D-VA) said high drug prices are an issue that touch every family. He asked why there is a difference in price for drugs in the US and other countries. Dr. Kesselheim said other countries are able to negotiate prices because the country determines whether the drug will be included on the country’s formulary. He further stated that other countries use the value of the drug as the basis of their price negotiations. Dr. Anderson said in the US once a drug is launched the prices go up, but in other countries the prices go down. Rep. Connolly said an example of this is Humira, which costs $2,669 in the US and $822 in Switzerland. Rep. Connolly said insulin has been around since 1921 and asked why the price has “skyrocketed.” Dr. Kesselheim said there have been some changes to the insulin molecule over time, but, in general, he said the issue is typically the patent on the delivery devices rather than on the drug itself. Dr. Kesselheim said this prevents effective competition that would lead to lower prices.

Representative Mark Meadows (R-NC) said President Trump would like to work with Chairman Cummings to lower drug prices. Rep. Meadows asked about the potential impact of the Trump Administration’s proposals related

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Representative Raja Krishnamoorthi (D-IL) said biologics represent 2 percent of all prescriptions, but account for 26 percent of spending. He said biologic manufacturers are granted a 12 year exclusivity and said the recently signed Agreement between the United States of America, the United Mexican States, and Canada Text (USMCA) synchronizes the exclusivity period, which means the exclusivity period cannot be shortened without the approval of the other countries. Rep. Krishnamoorthi said asked why Dr. Georges wrote a letter opposing this provision. Dr. Georges said AARP is concerned with the length of exclusivity for biologics. Rep. Krishnamoorthi asked about the impact of the exclusivity period. Dr. Kesselheim said the exclusivity period was set based on the time it would take for pharmaceutical companies to recoup R&D costs, but if it is found that a shorter period is needed to recoup the costs, then the US would not be able to adjust the exclusivity period.

Representative Jody Hice (R-GA) asked about the connection between higher drug costs and the Affordable Care Act (ACA). Dr. Roy said the changes to Medicare Part D that lowered the out-of-pocket costs for seniors resulted in higher drug costs because pharmaceutical companies were able to charge more without affecting seniors’ out-of-pocket costs. Dr. Roy said on the exchanges, the ACA requires that plans cover branded drugs that do not necessarily have economic value. Rep. Hice asked if ACA repeal would lower drug costs. Dr. Roy said out-of-pocket costs for some individuals would increase, but overall spending would decrease. Rep. Hice asked for an overview of the drug supply chain. Dr. Anderson said the drug supply chain begins with a drug company setting the list price. He said the drug company then negotiates with the PBM for the price that the PBM will pay for the drug. Dr. Anderson said the PBM then keeps some of that money, but the amount of money the PBM keeps is unknown. He said the pharmacy buys the drug from the PBM, but when the consumer picks up the drug from the pharmacy, the out-of-pocket costs are based on the list price.

Representative Harley Rouda (D-CA) said there should be transparency throughout the drug supply chain, including the rebates. He also said drug companies should not be able to abruptly raise the price of a drug that has been on the market for years. Rep. Rouda asked Dr. Kesselheim about examples where a company games the patent process. Dr. Kesselheim said there are a number of examples where companies are able to use the patent system to extend the market exclusivity of their products. He said there are ways that companies can patent new formulations of their product to prevent generic versions of their drug from coming to market. He further said that if a generic manufacturer sues a brand manufacturer over a patent, the brand company can settle the claim to continue to “prop up the weak patent.” Rep. Rouda asked how this issue can be addressed. Dr. Kesselheim said Congress can evaluate

\[1\] More information available here: https://innovation.cms.gov/initiatives/ipi-model/.
Representative James Comer (R-KY) asked about the effect of a Medicare for All proposal on drug prices. Dr. Roy suggested that this would increase prices as private insurers provide more efficient coverage than the federal government. He said Medicare Advantage (MA) is an example of this. Rep. Comer asked how the Department of Health and Human Services (HHS) would manage the task of negotiating the price of drugs. Dr. Anderson said it would be very difficult to negotiate the price of every drug. Therefore, Dr. Anderson said HHS would have to start with a limited set of drugs. He suggested that HHS focus on the drugs commonly used during the catastrophic phase where Medicare pays for 80 percent of the drug. Rep. Comer asked about the effect of further government involvement on pharmaceutical companies’ R&D. Dr. Roy said while academic medical centers and NIH perform clinical trials, pharmaceutical companies typically take the research and fully develop the drug for FDA approval.

Vice Chair Katie Hill (D-CA) said drug companies often argue that they must set high drug prices to recoup R&D costs. However, she noted that drug companies spend a significant amount of money on direct-to-consumer (DTC) advertising. She asked if DTC drug advertisements improve health outcomes. Dr. Kesselheim said DTC advertising drives prescribing of high cost drugs because generics are not typically advertised. Vice Chair Hill asked what AARP views as potential harms of DTC advertising. Dr. Georges said she is concerned that the price of the drug is never advertised. Vice Chair Hill said drug companies spend money on payments to physician and hospitals and asked about the purpose of such payments. Dr. Kesselheim said there are many reasons why there is a financial relationship between physicians and pharmaceutical companies such as research, but he said pharmaceutical companies also spend billions of dollars advertising drugs to physicians, which can drive the prescribing of high cost drugs.

Representative Bob Gibbs (R-OH) said he is concerned about R&D and said Congress must ensure they do not disincentivize R&D by pharmaceutical companies. Dr. Anderson said NIH funds much of the initial R&D that drug companies later buy to fully develop a drug and bring it to market. Rep. Gibbs said, with respect to orphan drugs, there are some orphan drugs that can be used for non-orphan indications. Dr. Anderson said six of the top ten drugs in the US have an orphan indication, which was not the intent of the orphan drug program. Rep. Gibbs asked about the role of risk evaluation and mitigation strategies (REMS). Dr. Anderson said the purpose of REMS is to ensure the safety of drugs, but pharmaceutical companies have used REMS to refuse to sell a sample of a drug to a generic companies. Rep. Gibbs said there are also problems with how the PBMs are operating. He expressed support for addressing these issues without disincentivizing innovation.

Representative Debbie Wasserman Schultz (D-FL) said prescription drugs that are too costly can kill people. She said insulin has not changed much since its development in 1921, but in a five year period the cost of insulin almost doubled. Rep. Wasserman Schultz said only three companies—Eli Lilly, Novo Nordisk, and Sanofi—account for the entire insulin market in the US and 90 percent of the market around the world. She asked how drug companies can justify price increases for drugs with minimal changes. Dr. Anderson said there is no real justification. Rep. Wasserman Schultz said drug companies are setting higher launch prices for their new drugs and asked why drug companies are setting these high prices. Dr. Anderson said Medicare Part B pays a physician an additional six percent of the cost of a drug he or she administers, which encourages physicians to use higher cost drugs.

Representative Glenn Grothman (R-WI) said the number of generics being approved by the FDA has increased and asked if this has an effect on the overall cost of drugs in the US. Dr. Anderson said it is great to have more generics, but the brand companies are now essentially paying PBMs to keep the brand drug, and provide favorable placement, on insurers’ formularies. Dr. Anderson said that he previously testified that FDA should do an expedited review of drugs when there is no competition for a drug in the market to avoid unjustifiable price increases. Rep.
Grothman asked how many biosimilars have been approved in the US. Dr. Anderson said the US has only 3 or 4 biosimilars that are on the market, as opposed to Europe, which has almost 50 on the market. Dr. Anderson said that when they are introduced on the market, it will be important to ensure that the PBMs give biosimilars favorable placement. Dr. Kesselheim said introducing more biosimilars onto the market should help lower prices.

Representative John Sarbanes (D-MD) asked if pharmaceutical companies have too much influence on Congress. Ms. Worsham said she does not know, but she urged Congress to help Americans live healthier lives by reducing the cost of drugs. Rep. Sarbanes said the pharmaceutical industry spent more on lobbying last year than any other industry and had 14,000 lobbyists last year. Ms. Worsham said Congress should enforce drug price transparency.

Representative Chip Roy (R-TX) asked if AARP opposed the American Health Care Act of 2017 (AHCA). Ms. Georges said AARP was concerned that the AHCA included an age tax. Rep. Roy asked if AARP has made approximately $4.5 billion in revenue since the ACA was passed. Ms. Georges said she is not sure, but that should be public information. Rep. Roy asked Dr. Georges to confirm that AARP makes a royalty from United Healthcare, which sells AARP branded Medigap policies. Dr. Georges was not sure. Rep. Roy said he is concerned about the extent to which AARP has made money on Medigap plans that do not have to cover people with preexisting conditions.

Representative Peter Welch (D-VT) said the prescription drug market is broken and is being exploited. He said he believes some actions Congress can take include stopping: (1) evergreening; (2) pay-for-delay; (3) abuse of REMS; and (4) exploitation of the orphan drug designation. Rep. Welch asked if there is transparency around how formularies are set by PBMs. Dr. Anderson said there is no transparency related to how or why drugs are placed on an insurer’s formulary. Dr. Anderson said the Medicare Part D formularies, which are established by PBMs, are half as large as the VA formulary. Rep. Welch asked if there is any other country that does not play a role in protecting people from the pricing practices of pharmaceutical companies. Dr. Kesselheim said other countries are involved in setting the prices for prescription drugs and noted that our government sets prices for physician services under Medicare.

Representative Mark DeSaulnier (D-CA) said transparency would be helpful and asked Dr. Kesselheim about the role of transparency. Dr. Kesselheim said the most important thing is that patients and doctors understand the relationship between the effectiveness of drugs and how they are priced. Rep. DeSaulnier asked what the right rate of return on investment would be for pharmaceutical companies. Dr. Kesselheim said pharmaceutical companies have a 22 percent profit margin, while other fortune 500 companies have around a 7 percent profit margin. Dr. Kesselheim said it is most important to ensure that investments in R&D are being made to develop drugs that are needed the most.

Representative Ro Khanna (D-CA) asked about the role of public dollars in innovation. Dr. Kesselheim said there was a study that found that all drugs that come to the market can be connected to NIH research. However, he said pharmaceutical manufacturers invest in drug development, often at a later stage in the process, and play an important role in drug development. Rep. Khanna said that it does not make sense that the NIH would not be able to meet FDA’s standards for drug approval.

Representative Alexandria Ocasio-Cortez (D-NY) asked if the public is seeing a return on investment from the drugs that are developed based on NIH research. Dr. Kesselheim said no. Rep. Ocasio-Cortez asked if there are any models around the world under which the public receives a return on investment for publicly funded research. Dr. Anderson said it is relatively uncommon. Rep. Ocasio-Cortez asked if the VA has lower drug prices. Dr. Anderson said the drug prices are about 30 percent lower for the VA than under Medicare. Dr. Kesselheim said this is partially

due to the fact that the VA receives statutorily mandated rebates and uses its collective bargaining power to negotiate drug prices. Rep. Ocasio-Cortez asked about the most important action that Congress can take. Dr. Anderson said external reference pricing, such as the proposed IPI Model for Medicare Part B drugs. Dr. Kesselheim said it would be important to develop a system where the government can identify the reasonable price for a drug based on its value and use that information when negotiating prices. Dr. Georges said AARP would like HHS to negotiate prices.

Representative Ayanna Pressley (D-MA) asked about the impact of drug prices on providers. Dr. Kesselheim said providers often do not understand the cost of drugs they are prescribing, which can make treating patients difficult. Rep. Pressley asked if this exacerbates health disparities. Dr. Kesselheim said yes. Dr. Anderson said Maryland has a rate setting commission, which does not allow Maryland hospital spending to grow by more than 3 percent per year. As a result, Dr. Anderson said when drug companies increase prices, they have to find another way to save money, such as by laying off nurses. Rep. Pressley asked Dr. Georges about choices older Americans are making to afford their drugs. Dr. Georges said older Americans are choosing between food and their drugs.

Representative Rashida Tlaib (D-MI) said as of 2015, more than 100 million Americans have diabetes or prediabetes. She said people with type 1 diabetes rely on insulin to live and only three companies hold 90 percent of the global market for insulin with no generic version available. Rep. Tlaib asked why these companies have increased the price of insulin. Dr. Anderson said drug companies are doing everything in their power to keep control of the insulin market, but said Congress can take action to ensure generic forms of insulin are available. Rep. Tlaib asked how high insulin prices affect patients, particularly those of color. Dr. Kesselheim said patients are struggling with the price of insulin. He noted that a study found patients did just as well using the older (i.e., cheaper) versions of insulin as they did with newer versions.

Representative Carolyn Maloney (D-NY) said it is a national scandal that a child can die because they were unable to afford their insulin. Rep. Maloney asked how to ensure patients have access to the older, more affordable version of insulin. Dr. Kesselheim said it is not available because companies are not producing it, but said the government can choose to produce the insulin. Dr. Anderson said there is a nonprofit drug company that will start making drugs for hospital patients. Rep. Maloney said that three drug companies are subject to a lawsuit for price fixing. Rep. Maloney asked if Congress should require that the older version of insulin be included on Medicare formularies. Dr. Anderson said yes.

Ranking Member Jim Jordan (R-OH) asked what has been the most significant change in healthcare. Dr. Anderson said the ACA. Ranking Member Jordan said since the ACA, prices throughout the healthcare system have risen. Dr. Anderson said prior to the ACA, the US still had the most expensive healthcare system in the world. Ranking Member Jordan asked if the witnesses support a single payer system. Dr. Kesselheim said the government should use its negotiating power to get better prices for prescription drugs. Dr. Anderson said he supports a public option.

Chairman Elijah Cummings (D-MD) said he is concerned that the Committee members will debate, but not take action. Chairman Cummings said people are suffering because they cannot afford their drugs noting Ms. Worsham’s daughter died because she could not afford her insulin.

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We hope this summary was helpful to you. Please do not hesitate to contact us if you have any questions.