On January 29, 2019, the Senate Finance Committee (Committee) held a hearing entitled, *Drug Pricing in America: A Prescription for Change, Part I*. The hearing focused on prescription drug pricing in America and potential policy options to lower drug costs. Witnesses included:

- Kathy Sego, Mother of a Child with Insulin-Dependent Diabetes (Patient Advocate);
- Douglas Holtz-Eakin, Ph.D., President, American Action Forum (AAF);
- Mark Miller, Ph.D., Vice President of Health Care, Laura and John Arnold Foundation (Arnold Foundation); and
- Peter Bach, M.D., Director, Memorial Sloan Kettering Center for Health Policy and Outcomes (Sloan Kettering).

**Opening Remarks**

Chairman Chuck Grassley (R-IA)\(^1\) said he intends to reintroduce the *Creating and Restoring Equal Access to Equivalent Samples (CREASES) Act of 2018*\(^2\) and that this legislation will be a priority for the Committee. He said millions of Americans rely on prescription drugs, especially those with chronic diseases. Chairman Grassley said many individuals are unable to access life-saving drugs because of cost. He also said the costs of generic drugs are rising even though they are intended to increase competition. Chairman Grassley said he has heard stories of people rationing their life-saving drugs, like insulin, to save money. He said that is unacceptable. He said the Committee will hold additional hearings on drug pricing. Chairman Grassley thanked the panelists for testifying and stated that he had sent invitations to drug manufacturers to testify. He said almost all manufacturers declined the opportunity to testify publicly while only offering to speak in private. Chairman Grassley was disappointed in that response and urged manufacturers to testify in the next drug pricing hearing. Chairman Grassley also said he introduced the *Right Rebate Act*,\(^3\) which would impose civil penalties on manufacturers who knowingly misclassify drugs in the Medicaid rebate program. He also said he supported policies to display drug list prices in television advertisements.

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\(^2\) Bill text is available here: [https://www.congress.gov/115/bills/s974/BILLS-115s974rs.pdf](https://www.congress.gov/115/bills/s974/BILLS-115s974rs.pdf)

Ranking Member Ron Wyden (D-OR)⁴ said addressing high drug prices is a bipartisan issue and expressed his frustration that drug manufacturers have not been willing to testify. He also committed to holding multiple hearings on drug costs. He said the drug cost “crisis” threatens millions of lives and “bankrupts” Americans. Ranking Member Wyden said Americans are rationing medication because they cannot afford their medication. He also said the rising price of insulin has been unacceptable. He explained that there has been no changes to insulin yet prices have steadily increased. Ranking Member Wyden said insulin manufacturer Eli Lilly raised its product’s (Humalog) price from $21 in 1996 to $275 in 2018. Ranking Member Wyden said this is unacceptable because the drug has not improved in clinical value. Ranking Member Wyden also said Gilead had set its Hepatitis C drug, Sovaldi, at $1,000 a pill when it launched. He said, according to Gilead’s public documents, the price setting was not related to research and development (R&D) costs or a standard of care. Ranking Member Wyden said the price was based on “what they could get away with.” Ranking Member Wyden said drug manufacturers have too much power in setting prices unacceptably high. He also said pharmacy benefit managers (PBM)s inflate drug prices and it is unclear if any savings from negotiations are passed to consumers. Additionally, Ranking Member Wyden suggested that Medicare should be able to negotiate for lower drug prices.

Witness Testimony

Kathy Sego (Patient Advocate)⁵ shared a story about her son and how he rationed insulin. She explained his difficulty obtaining affordable insulin and the health effects of limiting his insulin. She also shared a story on how she could purchase insulin in Hungary for $10 per prescription yet it cost $400 in America. Ms. Sego expressed her frustration that manufacturers are charging such high costs for insulin although there have been no changes in value.

Douglas Holtz-Eakin (AAF)⁶ said 40 percent of Americans have a chronic disease that needs some sort of medication. For this reason, he argued that there is a continuing need for lower costs, but also innovative drugs to treat or cure chronic diseases. He said that the term “rising drug costs” is ambiguous. He explained that there are many reasons why drug prices are rising. For example, he said only eight percent of drugs in the production pipeline will be sold to consumers and the average drug development timeline is 15 years. He said R&D costs are immense and drive costs. He also said costs are being driven up by an aging population and the development of high cost specialty drugs. However, Dr. Holtz-Eakin also pointed out that drug spending is only 10 percent of the total U.S. health care expenses, and per capita drug spending has only increased by approximately one percent. He recommended Congress reduce barriers to competition by allowing more generics to enter the market. He also suggested punishing companies that sell “off-patent sole source drugs” at exorbitant prices. Lastly, he said Congress should develop a strategy to address the high R&D costs associated with specialty drugs and the limited populations they treat.

Mark Miller (Arnold Foundation)⁷ said drug costs are a major issue for Americans and it is unfortunate that the U.S. pays more for drugs than other developed countries. Dr. Miller explained that government-granted monopolies (i.e., patents) drive up drug prices. He also said R&D investments do not explain drug prices and manufacturers continually try to block competitors from entering the market. Dr. Miller also outlined a number of policy options to address the rising costs of prescription drugs. Those policy options include: restructuring Medicare Part D to improve competitive pricing; providing additional transparency for drug rebates or changing the rebate

⁵ Witness testimony is available here: https://www.finance.senate.gov/imo/media/doc/29JAN2019SEGOSTMNT.pdf
⁷ Witness testimony is available here: https://www.finance.senate.gov/imo/media/doc/29JAN2019MILLERSTMNT.pdf
compensation model for PBMs; developing tools to address single source high cost drugs; reducing or reforming the average sales price (ASP) add-on payment for physician-administered drug reimbursement; allowing physicians to form purchasing groups and negotiating their own formularies for physician-administered drugs; and providing states additional flexibility to manage their drug benefit programs. Dr. Miller also supported the CREATES legislation.

Peter Bach (Sloan Kettering)8 said the Medicare Part B program incentivizes physicians to prescribe expensive drugs. Dr. Bach said there should be a flat fee for Part B drugs or some other payment mechanism that would separate the physician from the drug price. Dr. Bach also advocated for a subscription-based payment model for high cost drugs (referred to as the “Netflix model”). Dr. Bach explained that Louisiana has implemented a policy that would allow state Medicaid programs to negotiate directly with manufacturers for a flat fee for Hepatitis C drugs. Dr. Bach explained that this Netflix model allows states to have unlimited access to high cost Hepatitis C drugs without exhausting the state budget. Dr. Bach also said R&D expenses do not justify drug costs and that $1 million drug prices are too high. Lastly, Dr. Bach said Congress should focus on improving competition while preserving innovation.

Question and Answer

Chairman Chuck Grassley (R-IA) said many people are traveling to foreign countries to purchase medication because it is too expensive in the U.S. Chairman Grassley asked Ms. Sego how often she travels to other countries to purchase medication. Ms. Sego said it is too expensive to consistently travel to other countries and urged the Committee to work on lowering domestic drug costs. Chairman Grassley asked what would be the best way to lower drug costs. Dr. Holtz-Eakin said the 340B Drug Pricing Program (340B or 340B program) should be reformed because it encourages utilization of high drug costs and does not target low income patients as intended. Dr. Miller said there is not one solution to the drug pricing problem. However, Dr. Miller said Part D should be able to use binding arbitration or reference pricing for sole source high cost drugs. Further, Dr. Miller explained that if a generic drug entered the market for the sole source drug then the drugs could be brought back into the traditional Part D pricing process (i.e., negotiating with Part D sponsors). Dr. Bach suggested developing value-based pricing methods which would align patient outcomes with drug prices. Dr. Bach also said there needs to be shorter exclusivity periods but did not specify on a new exclusivity length.

Ranking Member Wyden (D-OR) said insulin drug prices are up 13 percent since 1996 yet insulin is no more effective. Ranking Member Wyden said he was committed to lowering the price of insulin. Ranking Member Wyden said there needs to be reform for Part D as it is structured to incentivize manufacturers to set high list prices. Ranking Member Wyden asked whether the government could negotiate for better drug prices. Dr. Miller said the question is whether the government can negotiate more effectively than PBMs. Dr. Miller said Congress should encourage “efficiencies” in how PBMs operate to ensure beneficiaries are getting the best deal possible. As for sole source high cost drugs, Dr. Miller suggested developing a value-based pricing method to set pricing on patient outcomes.

Senator Debbie Stabenow (D-MI) shared a constituent story about the rising prices of insulin and how patients feel they need to ration their medication. Sen. Stabenow said the top 15 drug companies charge U.S. consumers 40 percent more than foreign consumers. Sen. Stabenow also said many opponents to drug importation argue that foreign countries do not have as strict safety regulations as the U.S. However, Sen. Stabenow did not believe that argument. She said if a company sells a drug in Canada it is very likely it is just as safe as the drug sold in the U.S. yet Americans pay more. Sen. Stabenow also generally disagreed that the 340B program was a major issue for drug pricing. Additionally, Sen. Stabenow said the Department of Veteran Affairs successfully negotiates for lower

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8 Witness testimony is available here: https://www.finance.senate.gov/imo/media/doc/29JAN2019BACHSTMNT.pdf
prices, which is proof that the government can negotiate effectively. Sen. Stabenow asked how value-based drug pricing would operate and suggested that it would lead manufacturers to set high list prices. Dr. Bach said value-based pricing models would be based on the outcomes of the patient. He explained that it would encourage innovation by encouraging drug makers to produce effective drugs while saving money by paying less for ineffective drugs that are currently very expensive.

Senator Mike Enzi (R-WY) asked how high cost drugs have impacted the Part D program. Dr. Miller said higher drug costs have forced the government to pay more for beneficiaries’ prescription drugs. Additionally, because there are so many high cost drugs, more beneficiaries are hitting the catastrophic coverage phase, resulting in more government expenditures on prescription drugs.

Senator Robert Menendez (D-NJ) asked if drug prices should be capped by the consumer price index instead of the index for medical care. Dr. Miller said capping price increases may be a part of a solution, but on its own it would incentivize manufacturers to set higher list prices. Sen. Menendez asked whether drug coupons were a legitimate solution to drug costs. Dr. Bach said coupons are advantageous to manufacturers because they can help to retain sales and customers. Dr. Bach also said coupons are offered to patients who cannot afford their prescriptions through their health insurance. Dr. Bach suggested that if manufacturers lowered their drug prices, insurers could cover the drug without raising premiums. Ultimately, Dr. Bach said coupons are helping patients under the current system, but there are better ways to help patients afford their medication. Dr. Miller agreed that coupons are helping patients but suggested forcing manufacturers to provide the drug to the patient throughout the patient’s financial hardship period and not allow manufacturers to receive tax relief for providing coupons.

Senator Ben Cardin (D-MD) said the government should treat sole source high-cost drugs differently than drugs that have competition. Sen. Cardin proposed that the government review each drug and identify whether or not there is a generic version. Once identified, Sen. Cardin said the drugs with no competition could be priced based on international reference pricing while the government could then negotiate for lower prices for the drugs that have competitors. Dr. Miller said this is a good policy, however, it would be administratively difficult to implement. Dr. Miller explained that it would be challenging to identify each drug without a generic and negotiate a price for each drug. Dr. Miller suggested having a value-based model or binding arbitration for sole source drugs. Dr. Bach said drug pricing issues differ among the drug purchasing programs. For example, he said Part B involves the physician coding and billing process and is not structured for drug negotiation. Dr. Bach said there would have to be major changes to the Part B program in order to implement such a policy. Dr. Holtz-Eakin said physicians must be separated from drug prices in the Part B program, in general. Dr. Holtz-Eakin said Congress should focus on off-patent sole source drugs.

Senator Maggie Hassan (D-NH) expressed her frustration that manufacturers misclassify certain products in order to gain more profits under the Medicaid rebate program. Sen. Hassan also said manufactures give money to physicians and patient groups for unethical reasons. She asked whether drug transparency policies should include manufacturers’ practice of paying organizations and physicians. Dr. Miller said there are existing laws that address payments to physicians and patient groups.

Senator John Cornyn (R-TX) said there are rules against kickbacks for physician referrals yet manufacturers are able to receive kickbacks in some form or another. Sen. Cornyn said if physicians cannot receive “kickbacks” then neither should manufacturers. Sen. Cornyn asked whether PBM rebates are passed to patients. Dr. Holtz-Eakin said it is unclear. Sen. Cornyn also said manufacturers have raised drug prices even though there have been no improvements to the drug. Further, he expressed his frustration that manufacturers are raising drug prices although it is not because they are recapturing R&D costs, citing insulin as an example.
Senator Jonny Isakson (R-GA) asked if drug manufacturers provide patient assistance programs. Ms. Sego said yes but she did not qualify for the program.

Senator Catherine Cortez Masto (D-NV) said there have been multiple attempts to lower drug prices for Part B. However, Senator Cortez Masto said attempts to reform the Part B drug purchasing model have been criticized. Specifically, she said opponents have expressed concern it would negatively impact access to life-saving medication. Sen. Cortez Masto asked how new Part B drug purchasing proposals can be safely implemented. Dr. Bach explained that physicians are incentivized to prescribe higher cost drugs because physicians receive reimbursement based on the cost of the drug. Dr. Bach further explained that the higher the cost of the drug purchased under Part B, the higher reimbursement for the physician. Further, Dr. Bach said this runs counter to traditional market-based norms. Traditionally, Dr. Bach said, a customer will demand low cost products from a manufacturer. However, under the Part B program, the customer (physician) is incentivized to purchase high cost drugs and the manufacturer will not lose customers for selling high cost products. Dr. Bach said this scheme ultimately drives prices up. Dr. Bach said there should be a “hybrid” payment scheme for Part B drug purchases that separates physicians from the price of the drug. Dr. Bach also said he supported recent regulatory action9 regarding Part B drug purchases because it attempts to separate or remove the incentive for physicians to prescribe high cost drugs.

Senator Pat Toomey (R-PA) displayed a chart that showed the percentage of overall health care spending in the U.S. compared to other developed countries. Sen. Toomey said the U.S. spends less on pharmaceutical drugs compared to other countries. Sen. Toomey said pharmaceutical drugs only account for 10 percent of overall health care spending. Additionally, Sen. Toomey said Americans have less out-of-pocket expenses than other developed countries. Sen. Toomey asked if the facts he presented were correct. Dr. Miller said the 10 percent figure may be misleading because it does not account for all hospital purchases. Dr. Bach said 14 percent is closer to the actual total U.S. spend on drugs, if all hospital purchases were included. Sen. Toomey argued other countries may not account for all hospital spending either therefore European overall spending amounts would increase too. Sen. Toomey suggested that the U.S. was on par with other countries’ spending.

Senator James Lankford (R-OK) said Oklahoma has implemented a value-based purchasing model and his office is tracking its efficacy. Sen. Lankford then asked why Congress should reform the 340B program. Dr. Holtz-Eakin said 340B has grown enormously and the benefits of the program are not passed onto low-income patients as intended. Sen. Lankford also asked whether manufacturers spend more on marketing and administrative costs than R&D. Dr. Miller said revenues for manufacturers exceed R&D and marketing costs.

Senator John Thune (R-SD) asked how the Part D program could be improved to lower out of pocket costs for beneficiaries. Dr. Holtz-Eakin suggested forcing plans to cover more costs once a beneficiary goes above the catastrophic threshold. Sen. Thune asked how Civica RX10 is working to lower drug prices. Dr. Miller said it is trying to address the shortage of generic drugs by manufacturing certain generic drugs.

Senator Todd Young (R-IN) asked what broad strategies can be employed to help lower drug prices, including programs to address social determinants of health (SDOH). Dr. Holtz-Eakin said there is no definitive body of evidence to show how to broadly affect SDOH. Dr. Holtz-Eakin said he would like to see increased utilization of wellness programs, which could address the broad issue of SDOH. Dr. Miller said the current payment system does not encourage addressing SDOHs and Congress could look at broadening payment policies.

9 Dr. Bach was referring to the regulation entitled, Medicare Program; International Pricing Index Model for Medicare Part B Drugs. Regulatory text is available here: https://www.govinfo.gov/content/pkg/FR-2018-10-30/pdf/2018-23688.pdf
10 Additional information on Civica RX is available here: https://www.arnoldventures.org/work/civica-rx
Senator Steve Daines (R-MT) asked why reforming the 340B program should be a priority for Congress. Dr. Holtz-Eakin reiterated that the 340B program is growing and it is not passing the benefits to low-income individuals. Additionally, Dr. Holtz-Eakin said the 340B program is artificially raising drug prices. Sen. Daines said one percent of drugs account for 40 percent of spending. Sen. Daines asked if Congress should look at high cost drugs and other highly utilized drugs, like insulin, then legislate on different categories of drugs (i.e., a policy for high cost drugs and a policy for highly utilized drugs). Dr. Bach said the treatment of diabetes should be scrutinized by Congress in general. Dr. Bach also said Congress should review sole source high cost drugs and find strategies to lower their costs.

Senator Bill Cassidy (R-LA) said the recent reference price proposed rule\(^\text{11}\) is based off of European countries’ spending, including Croatia and Serbia, which distort the actual amount European countries spend on drugs. Dr. Holtz-Eakin agreed that some countries skew the European reference price. However, Dr. Holtz-Eakin said the U.S. still pays higher prices than other developed countries and the U.S. “subsidizes” R&D for other countries by paying higher prices. Sen. Cassidy also expressed his frustration that some drugs are priced far above their clinical value. Dr. Holtz-Eakin said a value-based model would help reign in drug costs over time.

Senator Maria Cantwell (D-WA) said Medicare should be able to negotiate for lower prices and asked why that has not been implemented. Dr. Holtz-Eakin said Medicare does not have a formulary so its negotiation power is limited. Dr. Holtz-Eakin explained that the Medicare program would not want to limit access to drugs by having a formulary. Dr. Miller disagreed and said Medicare could negotiate to lower prices. Dr. Miller explained that Medicare could institute value-based payment schemes for certain high cost drugs or use other tools to lower the cost of the drug. However, Dr. Miller said it is possible a manufacturer would refuse to offer the drug, which would ultimately restrict access for Medicare beneficiaries.

Senator Tom Carper (D-DE) asked the panelists for bipartisan policy options. Dr. Holtz-Eakin said there is bipartisan support for reforming the Part D program and developing value-based payment models. Dr. Miller agreed and added that there should be a change to the add-on for Part B drugs and Congress should address anti-competitive behavior. Dr. Miller said there are also issues to be addressed in the 340B program that could be bipartisan but did not elaborate. Dr. Miller also said there should be greater examination of reference pricing.

Ranking Member Ron Wyden (D-OR) said he would like more information on National Institutes of Health-funded R&D efforts that are leveraged by manufacturers. Dr. Miller said the Arnold Foundation is studying the issue and will reach out to the Committee when it is finished.

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