

Senate Finance Committee
Drug Pricing in America: A Prescription for Change, Part 2
February 26, 2019
10:15 a.m., 215 Dirksen Senate Office Building

Purpose

Today's hearing was the second in a series of hearings to inform the Committee as it addresses the issue of high prescription drug prices.

Members Present

Chairman Grassley, Ranking Member Wyden, and Senators Roberts, Stabenow, Cantwell, Cornyn, Menendez, Carper, Thune, Isakson, Cardin, Hassan, Lankford, Cassidy, Bennet, Whitehouse, Brown, Cortez-Masto, Daines, and Young

Witnesses

Richard A. Gonzalez

Chairman and Chief Executive Officer
AbbVie Inc.
North Chicago, IL

Rascal Soriot

Executive Director and Chief Executive Officer
AstraZeneca
Wilmington, DE

Dr. Giovanni Caforio, M.D.

Chairman of the Board and Chief Executive Officer
Bristol-Myers Squibb Co.
New York, NY

Jennifer Taubert

Executive Vice President, Worldwide Chairman, Janssen Pharmaceuticals
Johnson & Johnson
New Brunswick, NJ

Kenneth C. Frazier

Chairman and Chief Executive Officer
Merck & Co., Inc.
Kenilworth, NJ

Dr. Albert Bourla, DVM, Ph.D.

Chief Executive Officer
Pfizer
New York, NY

Dr. Olivier Brandicourt, M.D.

Chief Executive Officer

Sanofi
Bridgewater, NJ

Opening Statements

Chairman Grassley said the information from the witnesses will help inform the committee where to go in combating the rising costs of prescription drugs. People skip doses to save medications until the next paycheck, and others go entirely without when they cannot afford it. There is a balance in incentivizing innovation while also keeping costs reasonable for consumers. As of last Friday, along with Ranking Member Wyden, an investigation has been launched into the cost of insulin. Today we expect open and honest answers from pharmaceutical companies to understand how we got to where we are today. One of the most important questions to be answered today is list price. For a patient taking a drug with no competition, the list price becomes very meaningful as they are paying more out-of-pocket. Every link in the supply chain has continued to point fingers. This is the time for solutions. The American people deserve straight answers.

Ranking Member Wyden said today there is a focus on bipartisanship. Prescription drugs did not become outrageously expensive overnight. Prices are astronomically high because that is where pharmaceutical companies want them. It is morally repugnant when patients cannot afford prescriptions; it is morally repugnant when patients must choose between putting food on the table and refilling a prescription. Drug makers treat patients as if they are ATM machines. Patients cannot opt for generic options. Drug companies are making astronomical amounts of money and bonuses are tied to sales of drugs. Companies have huge incentive to keep prices high and keep sales going. The central argument from the pharmaceutical industry is that the fault is always someone else: PBMs, health plans, or legislators. Companies don't set and raise list prices for fun; these prices are directly tied to out-of-pocket costs to patients. Pharmaceutical companies rely on sleek branding to keep the cash rolling in, yet don't face any of the consequences.

Testimony

Mr. Gonzalez said AbbVie is a company dedicated to creating drugs for some of the most difficult diseases. While tackling some of medicine's most daunting problems, there are serious costs. Patient access to life saving medicines is a critical issue. AbbVie is prepared to work together with the healthcare system, the administration, and the committee to find effective solutions. Medicare Part D has worked well, encouraging competitive price discounts. However, despite cost savings, Part D out-of-pocket costs have continued to rise. It is also important to acknowledge the cost of science that goes into treating or curing major diseases. Patients are charged based on the list price and not impacted by rebates. The proposed rule eliminating rebates is a step in the right direction, however there is more to be done. The focus solely on list price does not fully address access problems. AbbVie is prepared to discuss how pharmaceutical companies can shoulder more of the costs for Medicare Part D patients to help alleviate out-of-pocket costs and increase access.

Mr. Soriot said AstraZeneca is dedicated to science and innovation; 28% of product sales is put toward research and development. In the past two years there have been 18 new drugs approved by the FDA. However, these statistics are useless if patients cannot afford drugs. The current

system of rebates is not sustainable. He stated that AstraZeneca is prepared to reduce list prices, reducing costs for patients and the government. Out-of-pocket caps for Medicare patients could also help increase access. Prices could also be linked to value to patients, providers, and overall in the healthcare system. This could be especially effective for specialty medicines. A vigorous biosimilar market could create greater competition and reduce overall prices. AstraZeneca is dedicated to finding solutions that continues to allow companies to innovate while providing affordable medications to patients.

Dr. Caforio said we should be proud American companies lead in the pharmaceutical industry. There are significant innovations that lead to lower rates of disease and illness. Not all patients respond to current drugs that are on the market, there is still more innovation within the pharmaceutical market. Drugs, however, are only effective if patients can afford them. The average increase for the cost of drugs have been slowing, and there is not a projected increase in list price for 2019. Bristol-Myers Squibb is supportive of the proposed rule which would make drugs more affordable for patients by eliminating rebates. They also support value-based pricing as they lead to better outcomes. They do not, however, support the international drug pricing proposal. More than anything, we must ensure that patients have access to new innovations.

Ms. Taubert said the Janssen pharmaceutical company focuses on creating innovative medicines that treat some of the most devastating diseases. Janssen is one the world's top research and development companies, and these innovations help patients and families and ultimately lower overall healthcare costs. Medicines cannot make a difference if patients cannot afford them. Patients today need access to medicines and patients tomorrow need future breakthroughs. Last year discounts and rebates amounted to \$21 million. While overall prices have decreased in the past two years, patient out-of-pocket costs have increased. Above all, we need an American solution to an American problem. Open dialogue is essential across the entire healthcare system. Janssen has decided to post list price and potential out of pocket costs in TV advertising. An out of pocket cap in Medicare Part D is essential. Janssen supports rebate reforms that increase patient savings.

Mr. Frazier said Merck's mission is to save lives around the world, and research is at the core components of this goal. Merck not only focuses on diseases in the industrial world, but also where there isn't any capital payout. Our industry has a duty to be responsible in pricing practices, and Merck has a history of responsible pricing. Patients need to receive the greatest impact of rebates and cost reductions. Patient cost sharing is often based on list prices. We urge Congress to utilize more biosimilars. We need to move to a value based system, but there are significant regulatory barriers. There are needed reforms to encourage generic drug choices. We also support eliminating coupons for branded drugs where generic drugs exist. These changes could bring real savings to today's patients while continuing to invest in innovations for tomorrow.

Dr. Bourla said when you hear you or a loved one has a serious disease, there is one question: is there a cure for this disease. Many times the answer is yes; there continue to be more and more cures for diseases. However, many drugs continue to be too high in cost. Transparent upfront discounts could be passed on to patients as rebates. Value based payment could be based on good results, where pharmaceutical companies receive payments based on how many heart attacks are

prevented. Patients are increasingly required to take on a disproportionately high percent of pharmaceutical cost. Patients forgo refilling prescriptions, possibly leading to hospitalization. Capping out-of-pocket costs for seniors could help prevent these complications and increase compliance. Pfizer is all about breakthroughs in saving patient's lives.

Dr. Brandicourt said the anger over out-of-pocket costs is understandable. The situation is unacceptable and unsustainable for many patients. Insulin is a clear example between list and net prices. Since 2015 the net price has declined 25%, but out-of-pocket costs for patients has continued to rise. Addressing list prices alone will not be sufficient to address patient out of pocket costs. Every actor in the system has a role to play in reducing costs and increasing access. Changes to drug pricing must be holistic, factoring in all actors with the majority of benefits passed on to patients. Also, the government should not determine prices, or worse, give the power to other countries.

Questions and Answers

Chairman Grassley said he heard each panelist state that everyone is open to collaborating to find a solution. He said pricing decisions were heavily investigated for Hepatitis C drugs. It was found that factors included in pricing included public outcry and the likelihood from Congress. He asked if each of their companies considered public outcry in establishing a list price. All of the panelists stated that they do consider the possibility of public outcry when determining list price. **Chairman Grassley** also asked if the likelihood of a Congressional inquiry is considered. All of the panelists stated that they do not consider the potential of a Congressional inquiry when determining list prices.

Chairman Grassley also asked if the companies considered whether the federal government is a key purchaser when determining list prices. All of the companies represented do.

Chairman Grassley said some of the panelists expressed support for the proposed rebate rule. He asked if each of the represented companies would support the rule. All the panelists expressed support. **Ms. Taubert** emphasized that there would be a greater support if the changes occurred on the commercial side as well as the government side. And **Dr. Brandicourt** emphasized that the savings from the rule must be passed along to the patients.

Ranking Member Wyden asked Dr. Bourla if Pfizer sets the list price. He said it is a negotiation with PBMs. But they do set the final list price. Ranking Member Wyden said high prices are tied to what the consumer pays at the pharmacy counter. All the other discounts and rebates are window dressing. He believes that companies are stonewalling on the key issue: actually lowering list prices and this would be the main way patients could save at the pharmacy counter.

Ranking Member Wyden asked Mr. Gonzalez if they make a profit on the drugs that are sold in Germany or France. **Mr. Gonzalez** said yes, they make a profit selling drugs overseas. **Ranking Member Wyden** asked if they can turn a profit in other countries with dramatically lower prices, how these drastically different prices are not price gouging in America. **Mr. Gonzalez** said that prices vary dramatically around the world. Overall in America prices are higher. The

fundamental issue is that our system supports the research and development model. If the system in the U.S. would collapse to what it is around the world, research and development would stagnate. **Ranking Member Wyden** said that people around the world are getting a better deal, yet Americans are footing the bill for research and development and this is why people are so angry.

Ranking Member Wyden asked Mr. Gonzalez, in writing, to state whether drugs in other Western industrialized countries make money. **Mr. Gonzalez** stated that they make money in every country where they sell drugs.

Sen. Roberts said he worries about the cost, access, and the value of prescription drugs. He asked the panel what a main concern is for each of the companies to continue to be a viable company. **Dr. Brandicourt** said his main worry is to ensure that there is a pipeline of new products which is innovative enough to alleviate disease burden. **Dr. Bourla** said that creating new products is the reason employees come to work. If they cannot deliver on the promise of creating new drugs, they will not be able to fulfill on their promise to society, nor their promise to investors. **Mr. Frazier** said his concern is that the kinds of solutions that are generally discussed do not address the large systemic issues that prevent patients from getting access to and being able to afford effective pharmaceuticals. **Ms. Taubert** said it gets increasingly more difficult to continue to invest in cures and diseases that we really want to solve. **Dr. Caforio** said he is concerned with diseases that continue to be untreated, and ensure that all patients have access to medications. **Mr. Soriot** said that scientists have the best environment to discover new medications and engaging with patients so they know what treatments are available and what are effective or not. And how do we demonstrate the value drugs bring and lowering overall healthcare costs. **Mr. Gonzalez** said his concern is the costs of medicine will continue going up and that systems find it difficult to measure the cost effectiveness.

Sen. Stabenow said research is essential. Between 2006 and 2015 the largest drug companies had a profit between 15%-20%. In the pharmaceutical industry, if patients cannot afford drugs their lives can be significantly impacted. The price of Humira has continued to rise. She asked Mr. Gonzalez if the drug has improved as new patents have been filed. **Mr. Gonzalez** said the patent portfolio evolved as the drug evolved. **Sen. Stabenow** said in Europe, when the patent expired, the prices dropped significantly. She asked why the same low prices are not offered to American families. **Mr. Gonzalez** said these inventions that are patented have evolved as new uses have been discovered. There are new licenses for biosimilar that will come to the market within the year. **Sen. Stabenow** said that she believes Humira costs most here because the pharmaceutical companies can charge more.

Sen. Cantwell said she wants feedback on the market type mechanisms and whether they would drive down costs. She asked if states negotiated on behalf a group of citizens, would prices decrease. **Mr. Frazier** said depending on the system it would decrease prices. **Sen. Cantwell** said allowing states to negotiate down prices would drive down prices directed to consumers. **Mr. Gonzalez** said the point is valid in driving down costs. There are two different affordability issues: the affordability for patients and the affordability within the system.

Sen. Cornyn said maintaining the most innovation is essential to continue to provide lifesaving cures. The patent system encourages the investment in new drugs. Humira has 247 patents, with some not expiring until 2034. He asked if it is the company's position that they should have a monopoly on the medication. **Mr. Gonzalez** said there are 136 patents on Humira. It is 9 different drugs; one drug treating different conditions. The number of patents does not prevent generics. Composition of rights would prevent generics. AbbVie has given licenses for biosimilars. **Sen. Cornyn** said he supports drug companies gaining a profit to offset research and development costs. But at some point patients need affordable access to drugs. He asked if AbbVie blocked companies from obtaining patents for generics. **Mr. Gonzalez** said they have entered into licensing agreements with these companies.

Sen. Menendez said many Americans believe drug prices are too high. Many Americans reject the idea that reducing costs would reduce research and development. If pharmaceutical companies do not make meaningful effort to reduce costs, policy actions are not long to come. He asked the panel if tax breaks were used to lower the prices of prescription drugs. **Mr. Gonzalez, Dr. Caforio, Ms. Taubert, Mr. Frazier, and Dr. Brandicourt** all said no tax break money was used to lower list prices. **Mr. Soriot and Dr. Bourla** said their companies did use tax break money to offset costs and lower list prices, either directly or in a roundabout way.

Sen. Menendez asked the panel if the company restricts the access to or blocked the purchase of samples at full market price. All the panelists said they have not.

Sen. Carper said for many, the cost of drugs is personal, especially as many people have loved ones that suffer from disease. He asked the panel if they would support three things: eliminating rebates to PBMs, value-based arrangements; increasing transparency industry-wide on how prices are set. **Mr. Gonzalez** said AbbVie supports eliminating rebates, value based pricing, and transparency in price setting and more broadly across the system including where rebates are in the 340B program. **Mr. Soriot** said they support all three items. Additionally if rebates were removed from Part D and in the private sector, prices would be reduced. **Dr. Caforio** said they support all three elements. **Ms. Taubert** said they are very supportive of all three. **Dr. Bourla** said these three elements would be transformative for the industry. **Dr. Brandicourt** would support all three, especially if patients received all the benefit of these changes.

Sen. Carper asked the panel to submit, in writing, their thoughts on the pharmaceutical industry in Germany.

Sen. Thune said each of the panelists referenced the recently proposed rebate rule. He asked Mr. Frazier and Dr. Bourla how list prices would then be set. **Mr. Frazier** said as long as the same rebates were removed from the private market, list prices would decrease. **Dr. Bourla** said if the rule applied to all, list prices would go down. The list price is currently not irrelevant. But with the pass of the rebate rule, the list price would become less important.

Sen. Thune said he is a believer in value-based payments. **Dr. Bourla** said that value-based system would align all players with the goal of improving the health of patients. This system would encourage competition to improve health. **Mr. Gonzalez** said that the pharmaceutical

industry cannot capture all of the value, but the best way to work within this system is with competition.

Sen. Isakson said is a firm believer in pharmaceutical companies and the work that they do. He cannot explain the cost increases for prescription drugs and the different negotiations that go into the price. He asked the panel who sets the discounts and who sets the rebates. **Mr. Gonzalez** said the pharmaceutical company negotiates with PBMs. There is a consensus that PBMs are the main negotiators.

Sen. Isakson asked Ms. Taubert to describe the changes in price. **Ms. Taubert** said the intermediaries are very effective. PBMs and insurers essentially set the prices. **Sen. Isakson** asked if there is anyone else that contributes to the cost beside PBMs and insurers. **Dr. Brandicourt** said wholesalers are encouraged to set the list price at a certain level.

Sen. Cardin said there have been incredible discoveries in pharmaceuticals. The challenge is why Americans should be shouldering the cost of research and development. The international pricing index would set prices for Part B drugs. If these drugs are competitive in other nations, it should not be a problem. He asked why we wouldn't move toward a system where Americans pay a similar amount as other nations. If there is a larger consumer base, isn't the company is a better negotiating spot. **Ms. Taubert** said open competition is the best route to go to benefit patients.

Sen. Hassan said the system needs to be a viable system for patients. Pseudo-addiction is an unproven concept that patients who are addicted to opioids are actually suffering from too little opioids. One physician stated that this was a way for patients to be overprescribed opioids. Janssen promoted pseudo-addiction. In the marketing and promotion of pain medications, Janssen stated that this is appropriate and responsible marketing. She asked Ms. Taubert how this is responsible when this is simply just a tactic to maximize sales of opioids. **Ms. Taubert** said that she is not familiar with the term. But opioids represent less than 1% of sales. **Sen. Hassan** asked if she knows how many Americans died from drug overdoses last year; over 70,237. Companies like hers approved marketing tactics that maximize profits and are now refusing to take responsibility. **Sen. Hassan**, one again, asked if the company will take responsibility. **Ms. Taubert** said marketing that happened in the past has always been appropriate and responsible. Now they are taking a leadership role in helping curb the opioid epidemic. **Sen Hassan** said it is difficult to take claims from pharmaceutical companies that promote health with the role that they played in creating the epidemic.

Sen. Lankford said that each of the panelists mentioned the rebate issue and how effective PBMs are in negotiating. If a list price is higher and a rebate is higher, the insurance provider makes this drug more preferential. He asked Mr., Frazier why it is difficult for biosimilars to get into the market when they are significantly less expensive. **Mr. Frazier** said that educating providers and reducing the out-of-pocket cost for biosimilars on the side of patients would be beneficial. And that it is also necessary to look at incentives for having higher list prices. **Dr. Bourla** said in closed systems, like Kaiser, there is a greater utilization of biosimilars.

Sen. Cassidy said that Medicare has a very limited ability to negotiate. He asked Ms. Taubert if she believes that Medicare should have the ability to negotiate based on value. **Ms. Taubert** said they are very supportive of value-based pricing. She said that the government might not be as effective at negotiating. **Mr. Frazier** said transparency might be the solution and empower patients to effectively make choices about medications for themselves. **Sen. Cassidy** said biosimilars have had much greater success in Europe.

Sen. Cassidy said France has a government entity that oversees transparency and price for the drug is negotiated based on the added benefit to the market. Sen. Cassidy asked if it is safe to say that it still pays to innovate in France and to offer them access to cutting edge drugs. **Dr. Brandicourt** said not all of the drugs are offered because there is not enough payment to offset research and development costs.

Sen. Bennet said there isn't a town hall in which someone mentions the cost of prescription drugs. There has been a lot said about the importance of research and development. He asked about the government spending in research and development and how prescriptions continue to be unaffordable. **Mr. Gonzalez** said there is a consensus that no patient should go without a prescription. There are two fundamental shifts that need to happen. Copays are such that it makes it difficult to pay for prescriptions. There is more to be done for patients, but there are barriers that need to go away for companies such as AbbVie to help more patients.

Sen. Whitehouse asked if anyone on the panel disagrees that there are off patent monopolies and if they are used to create monopoly pricing. All the panelists agree. **Sen. Whitehouse** said it is not difficult to prove the existence of monopolies. It is a scandal of the pharmaceutical industry. There is no place that is addressing this problem. Lobbyists for pharmaceutical companies don't allow Congress to address the issue of corporate raiding and the increase in monopoly pricing.

Sen. Brown asked the panel if it's true that pharmaceutical companies benefit from tax payer research. All panelists agree that this is true. **Sen. Brown** asked if it is true that no other nation invests more money in research in pharmaceuticals. Unanimously, yes. **Sen. Brown** asked if the US has the longest period of exclusivity for biologics. Unanimously, yes. **Sen. Brown** asked if Medicare cannot negotiate directly. Again, unanimously, yes. **Sen. Brown** asked if it is true that the tax payers subsidize marketing for pharmaceutical companies. Unanimously, yes. **Sen. Brown** asked if the average price paid for drugs is the highest in the world. On average, yes pharmaceuticals cost most. **Sen. Brown** asked if it is true drug manufactures set list prices. Unanimous yes, for list price. **Dr. Bourla** added that different market factors heavily influence list price.

Sen. Cortez-Masto asked if any of the companies spend more on research and development than what is spent on marketing. Unanimous yes. **Sen. Cortez-Masto** said that television advertisements are described as ways to help patients identify symptoms and are used a critical public health tool. She asked why public health outcomes are not better when the US allows advertisements and other nations do not. **Dr. Bourla** said that there are numerous number of other factors that impact public health. But, he added, when patients want to be treated, people prefer to be treated in this country because of all the research and innovation.

Sen. Cortez-Masto asked the panel if they have authorized generics, why are branded drugs continually sold. **Mr. Frazier** said it comes down to transparency. We need to support patients to help empower them to understand what options are available.

Sen. Cortez-Masto asked the panel if they would support legislation that required advanced notification for price increases. The panelists all supported a consistent standard. **Ms. Taubert** said that there is concern about having the notice be an advance notice, but ultimately, they do support transparency.

Sen. Daines asked who pays the list price. **Mr. Frazier** said there is a small percentage of patients who have to pay list price. Those who can least afford it, pay the list price. The system is backwards. **Sen. Daines** asked if the list price is a starting point for negotiation. The panelists all agree. **Sen. Daines** asked what the incentives are in determining the list price. **Dr. Brandicourt** said the pharmaceutical companies are trying to get a premier position in formularies. **Mr. Frazier** said there is incredible incentive for all the players in having a higher list price.

Sen. Daines asked if any of the pharmaceutical companies withheld generic samples. All the panelists said no. **Sen. Daines** asked if the panel is supportive of legislation such as the CREATE act would be positive. All the panelist agreed.

Sen. Young asked the panel if the Trump administration is accurate in setting best price and the impact on other price setting. **Mr. Gonzalez** said in theory yes, he agrees but it wouldn't encourage manufacturers to decrease list prices. **Mr. Frazier** said best price goes away from value based pricing.

Sen. Young asked what changes the panel would suggest. **Dr. Caforio** said going toward value based pricing would be very valuable for patients and reduce overall healthcare costs. The rest of the panel agreed. **Sen. Young** asked if the panel would be willing to work with the administration to create a more effective model. The panel unanimously agreed.

Sen. Young asked if any of the companies have reevaluated strategies in other countries. **Mr. Frazier** said they do everything in their power to prevent free loading from governments in other countries. Governments know they can establish a price and know that pharmaceutical companies will not walk away because patients would have negative consequential outcomes. **Mr. Soriot** said in America, patients have access to medicines much earlier. **Mr. Gonzalez** said if it was possible to negotiate to create a more balanced sharing among countries, and not rely on the U.S. for innovation.

Ranking Member Wyden said Mr. Gonzalez had a \$4.3 million bonus in 2017 was tied to the financial performance of Humira. He asked if he would receive a smaller bonus if the price of Humira was dropped. **Mr. Gonzalez** said there are many factors in determining his bonus.

Sen. Wyden said he would like each of the panelists to provide, in writing, their response to if rebates went away, would each of the companies reduce list prices by the same amount of rebate reduction.

Sen. Cassidy, referencing the ability for drug companies to walk away, said Medicare cannot walk away. He asked how to give patients the same tools to negotiate. **Mr. Frazier** said for practical purposes it would be immoral to walk away. The UK delays when they put the drug on the market, and it is not the drug company that delays the prescription. There are ways of lowering the prices of the six protected classes of drugs. **Dr. Bourla** said trade agreements could help lower costs in America as other countries are taking a free

Chairman Grassley asked if there is anything, within the scope of the company, which could change pricing in Medicaid or Medicare. **Dr. Brandicourt** said they don't have any control. If they were able to lower their list price it would benefit the patient at the end of the line at the pharmacy counter. However his could not be done without other changes because they would lose formulary placement. **Dr. Bourla** said he could take responsibility of controlling the price of drugs, and doing so responsibly. **Mr. Frazier** said he would pledge to do everything they could, but there need to be recognition that no one company can lower list prices without losing out financially. **Ms. Taubert** said Johnson & Johnson wants to be a part of the solution. They strongly advocated for rebate reforms that would aid in patients getting greater access. **Dr. Caforio** said their company look forward to working with the committee to increase access. **Mr. Soriot** said they could reduce pricing and continue pushing toward value based pricing. We are within a system that cannot fix itself and the government needs to lead out in how to reform the system. **Mr. Gonzalez** said the ultimate fix is to realign the system that would require legislative changes. They are committed that no patient goes without medications.