

Senate Finance Committee

Drug Pricing in America: A Prescription for Change, Part I

January 29, 2019

10a.m., 215 Dirksen Senate Office Building

Purpose

Today's hearing was the first 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, Senators Young, Stabenow, Enzi, Menendez, Cardin, Hassan, Cornyn, Isakson, Cortez Masto, Toomey, Lankford, Thune, Daines, Cassidy, Cantwell, and Carper.

Witnesses

Kathy Sego, Mother of a Child with Insulin-Dependent Diabetes

Douglas Holtz-Eakin, Ph.D., President, American Action Forum

Mark E. Miller, Ph.D., Vice President of Health Care, Laura and John Arnold Foundation

Peter B. Bach, MD, MAPP, Director, Memorial Sloan Kettering Center for Health Policy and Outcomes

Opening Statements

Chairman Grassley said for many Americans with chronic conditions, prescription drugs are a necessity of life. We need a strong research engine to develop new treatments, but we must have a discussion about the affordability of drugs. Seniors have seen their drug prices increase month to month without apparent reason. This is unacceptable, and he hopes to get to the bottom of the insulin price increase. Tackling high prescription drug costs is one of the first priorities of both sides of the Finance Committee. They will look at all aspects of the prescription drug market. It starts with transparency – you should not need a PHD in economics to understand drug prices. He believes in putting a price on prescription drug commercials to start. He was disappointed only two small companies offered to discuss drug pricing with the committee in a public setting.

Ranking Member Wyden said the largest pharmaceutical companies are not tripping over themselves to testify before Congress. The drugmakers are going to have to show up soon. This hearing is the first in a series of hearings the Committee plans to hold. They are ready to compel drug company CEOs to show up to Congress. Insulin, for example, has been saving lives for nearly 100 years. The list price has skyrocketed to \$275 per vial for no reason. The price-hiking drug makers have turned American patients into beggars. They recently investigated Gilead on Sovaldi's prices. According to their investigation, based on the company's own documents, the price was not about recovering R&D costs. The company charged a list price because they knew they could get away with it. There's no shortage of evidence about what the problem is. Companies charge high prices because

they know they can get away with it. He is troubled by health care middlemen who skim enormous sums of money when there is scant evidence that patients get a better deal. This is the case with PBMs. They're supposed to negotiate better deals, but it sure seems like they take a big cut. He appreciates what the chairman has said on this to pull back the curtain on PBMs to see who really benefits. On Medicare Part D, the Chairman was a lead author, he supported the bill because it was the first step in helping seniors pay for medicine. The structure of Part D encourages manufacturers to set high prices. Medicare ought to be able to use its bargaining power to get a better deal for seniors. Private plans have not been able to correct the pricing problem with sole-source drugs. He is concerned that private companies can privatize the gains from publicly-financed research and development.

Testimony

Ms. Sego said access to insulin is a matter of life and death. She said her son began to self-regulate his insulin intake by only purchasing one vial of insulin, not the four he needed. He stopped eating to ration his insulin. During a trip to Hungary, her family found that insulin cost \$10 US dollars there. Her son is about to graduate from college after recovering from his rationing actions. His life depends on his ability to pay for insulin, and he is about to start a life with new costs. More than seven million Americans depend on insulin.

Dr. Holtz-Eakin said the demand for prescription drugs is high, and rising. The population is aging and will have more chronic diseases. They need to monitor the drug markets to understand the supply and demand. People interchange the list price of the drug with the net price with any rebates, which is the difference in out-of-pocket prices for consumers. He urges the Committee to consider the problem they care about, the performance of markets. The question comes down to putting drugs onto the market, and reducing barriers to entry in the market. They need to understand the incentives provided by Medicare and Medicaid. Oncology drugs are expensive with small populations to treat; there will be more of these drugs coming onto the market in the future.

Dr. Miller said they believe in markets and evidence-based intervention when markets fail. Excessive hospital and physician prices and finding better ways to provide care for patients is a priority. On Medicare Part D, they suggest the Committee consider a series of reforms to increase pressure to better negotiate drug prices, perhaps by requiring a pick up of 80% of drug costs, not 15%, when the catastrophic cap is triggered. They suggest increasing transparency around rebates and other fees. They could consider whether the rebate compensation model should be changed to a fee-based model. Where there's no competition, and PBMs have little leverage to negotiate new prices, Congress should consider new tools, such as reference pricing, paying for the clinical value of the drug, or binding arbitration. He also suggests creating an inflation rebate, empowering physicians to form their own groups, and legislatively support reform legislation in the states. At the federal level, CMS could have greater authority to make sure drug companies don't misclassify drugs to skirt the system.

Dr. Bach said pharmaceutical companies seek to make a profit, but other forces in the drug market should act as countervailing forces, but they do not. 340B hospital prescribing shows a similar pattern. They should delink the bottom line from pricing, by creating a flat fee. Inserting more price competition in the Medicare model would be a good step. Plans should take on the risk borne by Medicare, so patients can have full enjoyment of negotiated price concessions. Value-based pricing has been proposed for drugs with no competition. This constructive idea is different than drug companies' value-based pricing. Long-term financing for new treatments should be viewed cautiously. He would focus on the impact on future innovation, and they have already seen amazing one-time treatments have come to market under the current system.

Questions and Answers

Chairman Grassley asked if Ms. Sego has considered obtaining insulin from Mexico or online. **Ms. Sego** said they have considered it, but they can't afford a trip to purchase insulin. **Chairman Grassley** said they need to address the high cost of drugs, but preserve innovation. He asked for an explanation of the single best way to lower the cost of drugs from each panelist. **Dr. Holtz-Eakin** said the first thing to do is stop policies which push up prices, like the 340B program, which is in need of reform. It was well-intentioned, but it's not targeted on the low-income patients it was designed for, but it is leading to higher drug costs. He suggested reforming the 340B program. **Dr. Miller** said there's room between the prices being charged, and how much is spent on R&D. He suggests restructuring the Part D program to maximize the incentive for PBMs to negotiate. Then, for drugs with extremely high prices, consider things like reference pricing and binding arbitration. **Dr. Bach** said the notion of value-based pricing is a better way to align the incentives in the market. **Chairman Grassley** asked what problems exist in Medicaid Drug Rebate Program. **Dr. Miller** said there are changes to make to the rebate structure to capture more savings for the taxpayer. **Dr. Holtz-Eakin** said Medicare best pricing diminishes best pricing. The ACA added about 100 million in drugmakers' costs over the past few years. Capping the rebate at 100% of the drug price is counterproductive. Raising the cap would raise the incentive for higher launch prices.

Ranking Member Wyden said there are 43 million seniors in Medicare Part D, but now reform is needed. Medicare Part D is set up if the prices of drugs are high, manufacturers and insurance companies win, and seniors lose. It seems if they're talking about sole-source drugs with no competition, Part D as structured today will not protect the senior and taxpayer. He asked how Part D relates to sole-source drug pricing. **Dr. Miller** said the question is why the government can negotiate a better price than a PBM. First, they need to reform the structure to get the PBMs to operate as efficiently as possible. They could price drugs using a value-based approach. **Ranking Member Wyden** said their goal is to end the days when big companies can get away with high prices.

Senator Stabenow asked what Ms. Sego would say to drug company executives, if they were present. **Ms. Sego** said there are patients going without medication at risk of dying. Senator Stabenow said Eli Lilly Canada is on one side of the Michigan-Canada bridge, but Eli Lilly America says getting drugs from Canada is not safe. She wants to work with the chairman to create competition through international trade on safe, FDA-approved

prescription drugs. **Senator Stabenow** said she doesn't believe 340B is the reason for high drug prices, and when Congress looks at negotiation under Medicare, the VA negotiation model works and could be a model. She supports value-based purchasing, and she has promoted that idea in the Affordable Care Act (ACA). If the argument is that a drug should have a higher price because it has a higher value, that's a problem. Risk to a patient's life shouldn't drive pricing. **Dr. Bach** said the point of value-based pricing isn't that the patient shouldn't pay more, the drug company should cover more cost. Patient co-payment should be low for access to high-quality drugs.

Senator Enzi said there is interest in moving away from the rebate model. If they did move towards up-front discounting, how could value-based payments still factor in? **Dr. Miller** said the price would be the price through the supply chain, unlike now where there is a back end adjustment. In this scenario, a price would be set up front which carries through.

Senator Menendez said he hopes they can also speak with Administration officials about these proposals. He asked if the panelists would support a proposal to cap drug price increases in Medicare to CPI and not medical inflation. **Dr. Holtz-Eakin** said a blanket cap of that model might have some unexpected bad consequences, it gives an incentive for a very high introductory price. The problem is that the price is already too high. He supports solutions that keep prices from rising. **Dr. Miller** said he would support that as part of a solution, there might be an inflation cap, but if the problem of the launch price is not dealt with, which might involve things outside of Medicare, the problem should be considered in a wider context. **Dr. Bach** said in the absence of any data from a drug company that their drug is more effective, there shouldn't be price inflation.

Dr. Bach said they should be open to the possibility that companies should be able to price their drugs on the benefits they provide. **Senator Menendez** said coupons distort spending. He has seen the commercials advertising coupons for prescriptions. He asked if there is a way to track use of coupons in the drug marketplace and asked who benefits from coupons. **Dr. Bach** said the drug companies are benefiting from coupon use. They should be concerned that patients have access to drugs they need, and they should be critical when coupons provide that access. Coupons undo what insurers are trying to do to counteract high drug prices.

Senator Cardin said for competitive drugs, he doesn't understand why they don't want to put in competitive pricing in the US and have the largest possible purchasing power. He asked if his concept would bring down pricing. **Dr. Miller** said the administrative burden for the government to negotiate for the range of drugs is daunting, and a private intermediary could do the negotiating. He would suggest for drugs with little competition, that might be a better place to start with binding arbitration. That assumes that Medicare Part D is working well, which it isn't. **Dr. Bach** said the issue of competition is problematic. Putting the drugs in the same billing code would lower the overall pricing. Product competition in the same disease area could have drugs competing. **Dr. Holtz-Eakin** said there isn't a one-size-fits-all solution. Not all drugs are priced outrageously. He is confused why the FTC doesn't go after the outrageously priced drugs.

Senator Hassan said there are a lot of bad actors out to pad their pockets. One way drug makers play games is with the rebate program, especially for authorized generic drugs. She asked if it is important to prevent manufacturers from engaging in these behaviors. **Dr. Miller** said that misclassification should be addressed. **Senator Hassan** said there's a need for more transparency. **Dr. Miller** said on the sunshine legislation, he has recommended it and developed the design that Congress uses. There should be line-of-sight for drug companies for contributions to actors in the system. Payments to patient groups should be added to sunshine legislation.

Senator Cornyn asked what the rationale is for excluding prescription drugs from the anti-kickback or anti-rebate law under the Social Security Act. **Dr. Miller** said he does not understand the rationale. **Senator Cornyn** said the situation is not transparent, and it does produce upward pressure on drug prices, and on the negotiation between the PBM and the pharmaceutical company. If the PBM charges a certain price, but then negotiates a kickback, that kickback is not delivered to the consumer as a cost-savings. **Dr. Holtz-Eakin** said Senator Cornyn's summary is correct, and he emphasized that if the negotiation were about the upfront price, that negotiated upfront price would be the price the consumer would pay. Insurance companies would then look to make up that price elsewhere, by raising premiums. That change would raise costs slightly for consumers who have low costs, and lower the costs for patients with very high drug costs, which is what insurance is supposed to do. The rebate system is undercutting the purpose of insurance. **Senator Cornyn** said he thought the reason why patents are granted to develop drugs was based on the sunk cost in R&D. It is bizarre, then, that they still have a system that guarantees a high price for recouping R&D costs for 100 year old medicine. **Dr. Bach** said the recouping of costs is supposed to be for a limited time. For biologic drugs, that period of monopoly is far longer than 12 years. If they wait for the biosimilar process to play out, consumers will always be unsatisfied with what they receive.

Senator Isakson asked if Ms. Sego qualified for any sort of patient assistance program. **Ms. Sego** said no, they can't use the rebates or coupons mentioned earlier either because they have employee-based insurance. **Senator Isakson** said he recently received a prescription that he needs to be on for 30 days. He found out his price was \$309 for 90 days, an increase from \$20 or so he previously paid. He asked if that was an odd amount. **Dr. Bach** said the issue is highly complex, and it's not just with the manufacturer.

Senator Cortez Masto asked how they can keep beneficiaries safe, and if there are guardrails or other benefits to help patients. **Dr. Bach** said one of the core distortions is the percentage markup above the cost of the drug in hospitals for Part B. Every study that has looked at this shows that prescribers tend towards the more expensive drug. Ideally, the user would be incentivized towards lower prices, but instead, they're prescribed higher priced drugs. They should get rid of that markup. The concerns about patient access are marched out every time there's a proposed change to Part B. They have examined the claims, none of their concerns actually occurred. He's confident that there won't be an impediment to access.

Senator Toomey asked if moving Part B reimbursements towards a flat fee is not recommended. The panelists said no. **Senator Toomey** said it seems US drug price costs are not that high compared with other countries. **Dr. Miller** said the chart Senator Toomey referenced is only part of the spend in the US. It might not be a comparable number.

Senator Lankford asked why 340B is an adverse incentive in the market. **Dr. Holtz-Eakin** said the benefits from 340B do not flow through to lower-income Americans. It shifts costs around, and doesn't lower them. **Senator Lankford** said Oklahoma doesn't do PBMs and actually beats the prices of some PBMs. **Dr. Miller** said keeping in mind it's a public program, the motivation for requiring a rebate is to get a good spend on the taxpayer dollar. Getting rid of the rebate will increase costs, which will require an aggressive structure to prevent high costs.

Senator Thune asked how patients can enjoy better pricing at the counter, and how changes might impact competition in Part D. **Dr. Holtz-Eakin** said patients should pay the price negotiated in the Part D plan. The majority of price negotiation in Part D comes in the form of rebates, but patients experience the list price. When they pay that price, they're paying more even though the plan has negotiated a lower price. **Dr. Miller** said they could start with a discounted price, which avoids the whole rebate problem. The PBM would work with the reduced price, it wouldn't involve back-end action.

Senator Young asked what strategies can be employed to prevent the upstream issue, like public research and education programs for social and environmental determinants of health. **Dr. Holtz-Eakin** said public awareness of personal choices in effects on chronic diseases is important.

Senator Daines asked for more information on 340B reforms. **Dr. Holtz-Eakin** said it is not meeting its objectives, and is artificially raising prices. He's also worried about the Medicaid best price program. 340B is growing like mad, and doesn't look like low-cost charity to needy individuals. **Senator Daines** asked for the 3 or 4 widely-prescribed drugs to be case studies for better policy. **Dr. Bach** said focused policy can deal with certain categories of drugs driving pricing. Diabetes medications is a problem of substance in and of itself. Hepatitis C needs a bespoke solution.

Senator Cassidy asked what the mechanism is to lower drug prices based on Senator Toomey's international study. **Dr. Holtz-Eakin** said the target is to get prices 30% below where they are now, of the 27 drugs in the study, only 11 were available in all countries. It's interesting. There isn't a free market that works well for drugs. The US has a tradition in favor of the most recent therapies. **Senator Cassidy** said the back-end rebate system came about because of a lawsuit. On the rebates, what if they limited rebates to 10-20%, and the rebate is not over that, which would give the plan room to negotiate. **Dr. Holtz-Eakin** said the issue is if there is value in PBM, and the answer is yes. The current system of after-the-fact rebates is a reward, but there are other ways to do it. **Senator Cassidy** said PBMs are important, but they can still limit rebates.

Senator Cantwell said she would put the PBM issue towards some other market function. She asked how buying in bulk could be a solution to pricing issues. **Dr. Holtz-Eakin** said for the VA and some Medicaid, there is already cost savings by buying in bulk.

Senator Carper asked the panel to reflect on where there might be consensus to give Congress guidance to proceed. **Ms. Sego** asked for the committee to come up with a plan that's viable for the high cost of prescription drugs. **Dr. Holtz-Eakin** said it's valuable to reform the Part D program to make better negotiations; the current system of back-end rebates may not serve the consumer well; and a particularly vexing problem is understanding the value of high-cost drugs. **Dr. Miller** said there's agreement on changing the percentage add-on in Part B, and to reevaluate the rebate scheme. There's some agreement on transparency requirements. There are issues with 340B that need to be addressed. **Senator Carper** asked which Administration proposals are most promising, and which may have the most unintended consequences. **Dr. Miller** said they should examine the international price index issue. **Dr. Bach** noted the ASP reduction for 340B, and that's a good idea.

Ranking Member Wyden noted that there were a lot of opportunities in bipartisanship that have come up in the hearing.