

**THE COST OF PRESCRIPTION DRUGS:
EXAMINING THE PRESIDENT'S BLUEPRINT
'AMERICAN PATIENTS FIRST' TO LOWER
DRUG PRICES**

HEARING
OF THE
**COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS**
UNITED STATES SENATE
ONE HUNDRED FIFTEENTH CONGRESS

SECOND SESSION

ON

EXAMINING THE COST OF PRESCRIPTION DRUGS, FOCUSING ON EXAMINING THE PRESIDENT'S BLUEPRINT 'AMERICAN PATIENTS FIRST' TO LOWER DRUG PRICES

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JUNE 12, 2018
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**THE COST OF PRESCRIPTION DRUGS:
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Tuesday, June 12, 2018

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The Committee met, pursuant to notice, at 10:03 a.m., in room SD-430, Dirksen Senate Office Building, Hon. Lamar Alexander, Chairman of the Committee, presiding.

Present: Senators Alexander [presiding], Enzi, Burr, Isakson, Paul, Collins, Cassidy, Young, Murray, Sanders, Casey, Bennet, Baldwin, Murphy, Warren, Kaine, Hassan, Smith, and Jones.

OPENING STATEMENT OF SENATOR ALEXANDER

The CHAIRMAN. The Senate Committee on Health, Education, Labor, and Pensions will please come to order.

Today, we're holding our fourth hearing this Congress on drug pricing, and we'll hear from Health and Human Services Secretary Alex Azar on President Trump's Blueprint to reduce the cost of prescription drugs. This is the first hearing on the Administration's Blueprint. Senator Murray and I will each have an opening statement. Then I'll introduce the Secretary.

I welcome him. I encourage him to take the time he needs. He's the only witness today, so if he needs a few extra minutes to explain the Blueprint, he's welcome to do that. Then each Senator will have 5 minutes to ask questions. The Secretary must leave at noon, so I'm going to be a little strict on the 5-minute limit, and if Senators ask their questions with 2 seconds remaining, I'll ask the Secretary to provide the answer in writing so every Senator can have a chance to ask questions.

On May 11, President Trump announced a comprehensive Blueprint to reduce the cost Americans pay for their prescription drugs, and today we're pleased to hear from Secretary Azar to help us understand that Blueprint, what the Administration itself can do to implement it, and what legislation might be necessary to help you implement it.

Hearing Secretary Perdue talk about farm issues is helpful, I think, because of his background as a family farmer and as a veterinarian, and most of us think Dr. Scott Gottlieb's background in business and service in the Bush administration has made him a more effective head of the Food and Drug Administration. In the

same way, I believe it's helpful that Secretary Azar also knows these issues well. He was Deputy Secretary and General Counsel at the Department of Human Services in the Bush administration, and he was an executive with significant responsibilities at a pharmaceutical company.

One of the things we've learned during our first three hearings on drug prices is that the amount we spend on prescription drugs can vary widely from year to year. Sometimes the amount we spend on drugs grows by as little as 1.3 percent over the previous year, as in 2016, and in other years by as much as 12.4 percent, as in 2014, according to the Centers for Medicare and Medicaid Services.

But we also know that according to CMS, spending on prescription drugs is expected to grow at an average of 6.3 percent a year between 2017 and 2026, faster than hospital stays, doctor visits, or any other healthcare sector.

In our hearings, we've also learned it's difficult to track the billions of dollars Americans spend each year on prescription drugs, which in 2015 was \$457 billion according to the Assistant Secretary for Planning and Evaluation at the Department of Health and Human Services.

We learned that one of the reasons tracking where the money goes is difficult is the use of rebates to reduce list prices, which is when a pharmacy benefit manager negotiates a discount on a drug with the manufacturer.

We also learned that while the \$457 billion we spent on drugs in 2015 is a big dollar amount, drug spending is only about 6.7 percent of what we spend overall on healthcare in America, according to the Assistant Secretary for Planning and Evaluation, and that number includes not only drugs purchased at the pharmacy but also drugs given in hospital settings.

The Administration is taking action for the same reason we held our hearings. We all know many Americans struggle to afford their prescriptions. According to Kaiser Family Foundation, about half of Americans, 160 million people, take a prescription drug, and about one in eight say it's difficult to afford those prescriptions.

But when we talk about the cost of prescription drugs, we have to keep in mind what we've learned in other of our hearings, which is we're living in a time of remarkable biomedical research that's leading to new and lifesaving drugs. These miracle drugs may take billions of dollars and several years to develop, and so they may be very expensive. For example, we now have drugs that can cure Hepatitis C. These are expensive drugs up front, but curing a patient with a one-time treatment can be significantly less expensive than treating someone with Hepatitis C over the course of his or her life.

In addition to our three hearings, this Committee has taken some steps already to reduce drug prices. In the 21st Century Cures Act, we included provisions to cut the red tape at the Food and Drug Administration to increase competition as a way to bring down drug prices. And in the FDA User Fee Agreements that this Committee worked on and the President signed in August was a provision from Senators Collins, McCaskill, and Cotton to improve generic drug competition.

In the Blueprint, there are some steps the Administration has started to take already or is intending to take. For example, FDA is going to start going after bad actors gaming the system to delay generics from going to market. This is a place where Secretary Azar can use the bully pulpit. Dr. Gottlieb has already released a list of companies blocking access to their drugs and delaying generics coming to market, shining light on the questionable behavior of these companies.

Another action FDA is considering is requiring drug manufacturers to include the list price of a drug in television commercials or other advertising materials. The Blueprint also proposes ending the so-called gag rule that prevents a pharmacist from telling a patient a drug would be cheaper if paid out of pocket instead of with insurance. The Administration has proposed ending this rule on Federal plans such as Medicare Part D. Senators Collins, Cassidy, Smith, and others have a bill to end the rule on all insurance plans that this Committee hopes to consider later this year.

I also want to hear specifically how Congress can help reduce drug prices. At our previous hearings, I questioned the need for rebates, because they make it difficult to track where the money goes, and I understand the Administration may need some additional authority to modify or end the use of rebates to increase transparency.

These are a few of the proposals in the Blueprint, and I look forward to hearing from Secretary Azar about others.

Senator Murray.

OPENING STATEMENT OF SENATOR MURRAY

Senator MURRAY. Well, thank you, Mr. Chairman.

Thank you for joining us, Secretary Azar.

As a candidate, President Trump talked a big game on lowering drug prices. But after 500 days, the only healthcare price he has dropped is his former secretary. So while the Administration hyped its drug pricing plan as a big step forward to address this broken promise, it is very clearly not. In fact, when President Trump finally announced his big plan to bring drug companies' prices down, their stocks actually went up.

Meanwhile, too many families in my home State of Washington and across the country are struggling to make ends meet because of skyrocketing drug prices. Meanwhile, about one in four people report that someone in their family didn't get a prescription filled because of cost. Meanwhile, about one in four cancer patients avoided filling a prescription for the same reason. And instead of giving these families a clear plan to address the issue, President Trump gave us a Blueprint that has more questions than answers.

In fact, the Blueprint has 135 questions. That's not a plan. That's a questionnaire, and it left me asking some questions, too. For example, where are all the big bold ideas, ideas like negotiating drug prices through Medicare, something Democrats and some Republicans have been pushing to make happen for years and could actually have a meaningful impact. As a candidate, President Trump constantly brought up that idea. He told the crowds he would negotiate like crazy. He said he could save hundreds of billions of dollars. He said drug companies were getting away with murder, and

yet this plan doesn't include that idea or any ideas that would really change the situation for patients struggling to afford the drugs they need.

As with so many other issues, President Trump talked a big game in the campaign, and then instead of backing it up, he backed away. And not only did President Trump abandon the idea of having the government negotiate prices through Medicare, but he proposed steps that gave pharmacy benefit managers more negotiating power instead. Now, that's not just a 180 from what President Trump said during the campaign. Despite his claim that he was, quote, "very much eliminating the middle man," this proposal to shift payments from Medicare Part B to Part D would have the opposite effect, empowering the companies he calls middle men without any data to suggest it will bring down prices for our families.

While the big takeaway from this proposal is how little the Trump Administration intends to do to address drug prices, in some ways, it also reveals how much the Administration has not done. For example, I was surprised by the misleading decision to list updating Medicare's drug pricing dashboard as an immediate action. Since the dashboard was actually something the Obama administration actually started, the update to the dashboard released last month actually should have been released many months ago, and the Trump Administration's version actually is missing information that was in the previous one.

I've got to tell you, as a former preschool teacher, I can tell you even our youngest students know you can't simply turn in someone else's work months late, incomplete, and expect to get extra credit for it.

I was surprised reading the section on so-called accomplishments, in which the Administration brags about the proposals it included in its latest budget, despite the fact that that budget was an absolute partisan nonstarter, despite the fact that many of the policies won't actually do anything for patients, and despite the fact that the budget is only a proposal, not a policy that's been enacted. That's like saying you've served dinner when you've only written a grocery list, and in this case, most of the ingredients on the list are a big nothing burger.

The few exceptions are actually ideas that Democrats have been fighting for and congressional Republicans have been fighting against. For example, the idea of requiring drug ads to include prices. Senator Durbin actually introduced a bill with Senator Hassan and others to do this last year, a bill no Republican yet has signed on to co-sponsor. Or the idea of requiring pharmacy benefit managers to pass rebates along to patients. Senator Wyden introduced a bill to do that last year, also without a Republican co-sponsor. Or the idea of preventing generic drug manufacturers from gaming the Food and Drug Administration's regulatory incentives to keep other affordable products off the market. Fifteen Democrats introduced a bill last year to push for these changes without any Republican co-sponsors.

I'm particularly curious about what our Republican colleagues think about our ideas now and whether they're now ready to join us at the table. There are policies in the Blueprint with which

Democrats agree. But make no mistake. Those are targeted changes that come nowhere close to solving this very large problem. We need an ambitious plan to drive drug prices down, not one so small that it sends pharmaceutical stocks soaring in relief.

I've heard from families across my state about how desperately they need us to address this, and I know many families across the country are in the same boat. In fact, two out of every five families can't afford a \$400 emergency. That means they can't afford drug prices that keep creeping up. The price for Nitrostat, a drug for chest pain, has gone up 29 percent. Advair for asthma has gone up 15 percent, and NovoLog, an insulin injection, has gone up 10 percent. Families cannot afford for us to keep waiting for a real plan, which is why Democrats are going to keep fighting for common-sense solutions that would actually make a difference, like negotiating lower prices through Medicare.

I also want to take a moment to note that accountability for drug companies isn't just about drug prices. Senator Sanders and several other Members of this Committee have requested that we hold a hearing with pharmaceutical executives about their role in the opioid crisis, and I think that is an excellent idea. I hope the Chairman will work with us on that. I think it's critically important.

Finally, Mr. Secretary, while you're here, I do want to express my personal alarm and outrage at the Trump Administration's effort to separate families at the border. That's just unacceptable. It is morally reprehensible, and it shouldn't be happening, and I'm deeply concerned about the children impacted by these separations and the crisis that this is actually creating in your department. So I want to be clear. I will have questions about that today as well.

The CHAIRMAN. Thank you, Senator Murray.

I'm pleased to welcome Secretary Azar, the Secretary of Health and Human Services. He leads a \$1.1 trillion organization which oversees many agencies, including the Centers for Medicare and Medicaid Services, the Substance Abuse and Mental Health Services, the National Institutes of Health, the Food and Drug Administration.

He served the Department as General Counsel for 4 years and Deputy Secretary for 2 years in the George W. Bush administration. He spent a decade in a leadership position at one of the country's major pharmaceutical companies. He has the experience to know the system. Many committees have invited him to appear before them, and we welcome him today as the first opportunity to discuss the President's Blueprint.

Welcome, Secretary Azar.

STATEMENT OF HON. ALEX M. AZAR II, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Secretary AZAR. Mr. Chairman and Ranking Member Murray and Members of the Committee, thank you very much for the opportunity to appear before you today to discuss a very important issue, which is why prescription drug prices are too high and what we're going to do about it.

I know all of you care deeply about this challenge, and I've appreciated the opportunity to speak with many of you about it. It's one of the very first topics that I mentioned when I appeared be-

fore this Committee during my confirmation process earlier this year, and I applaud the effort of the HELP Committee to illuminate and address this issue.

From day one of his administration, President Trump has directed HHS to make drug pricing a top priority. Earlier this year, the President's 2019 budget laid out a range of proposals for lowering drug prices, including through reforms to Medicare and Medicaid. In May, building on that budget, the President released a Blueprint to put American patients first, a plan of action for how to bring prices down while keeping our country the world's leader in biopharmaceutical innovation.

Over the last decade, four significant problems have arisen in the pharmaceutical market: high list prices, seniors in government programs overpaying for drugs due to the lack of the latest negotiating tools, rising out-of-pocket costs, and foreign governments freeriding off of American investment and innovation. The President's Blueprint lays out four strategies for tackling these problems, and we've begun taking action on each of them already.

First, we need to create the right incentives for lowering list prices. I know firsthand how serious the problem is with today's complex system of drug pricing. Right now, everybody in the system makes their money off of a percentage of list prices, both drug companies and pharmacy benefit managers as well as the distributors. Everybody wins when list prices rise except for the patient, whose out-of-pocket cost is typically calculated based on that price.

One of HHS's initial actions is working to require drug companies to include their list price in their television ads. For example, I believe Americans deserve to know the price of a wonderful new drug they hear about on TV before going to ask their doctor about a product that they may find to be unaffordable.

But, more fundamentally, we may need to move toward a system without rebates, where PBMs and drug companies just negotiate fixed price contracts. Such a system's incentives detached from these artificial list prices would likely serve patients far better as would a system where PBMs receive no compensation from the very pharma companies that they're supposed to be negotiating against.

We also recognize that a real market for drugs requires improvements in open, responsible communication between drug companies and those who make drug reimbursement decisions. That is why this morning, the FDA issued guidance to advance that goal, providing clarifying recommendations for how drug companies can share certain information with insurers and payers about drug effectiveness and other matters. We want to encourage competitive contracting based on measures of value that matter most to purchasers and patients, and this guidance will help advance that.

Our second strategy for lower prices is better negotiation within Medicare. That is what President Trump has promised, and it's what we're going to deliver. In Medicare Part D—that's the prescription drug program for seniors when they go to the pharmacy to pick up their drugs—HHS will work to give private plans the market-based tools they need to negotiate better deals with drug companies.

Part D is a tremendously successful program, but it has just not kept pace with innovations in the private marketplace. Well intended patient protections may be preventing prescription drug programs from appropriately managing utilization, even in accordance with the formulary created by doctors and pharmacists and approved by CMS. While everybody agrees on the importance of drugs in the Part D's protected class list, manufacturers often use that list as protection from paying rebates, providing discounts, or reducing list prices.

President Trump also wants to bring negotiation for the first time ever to Medicare Part B. These are the physician administered drugs like infusion products. Right now, HHS just pays the bill. That's it. The system may actually be driving doctors to prescribe more expensive drugs while potentially tempting drug companies to develop drugs that fit into Part B rather than Part D. We're going to look at ways to merge Part B drugs into Part D to create competition where savings can be safely obtained, leverage existing private sector options within Part B, but ensure that the patient remains at the center.

Third, we need a more competitive pharmaceutical marketplace. Thanks to the reforms that Congress passed in the 1980's, America has the strongest generic drug market of any country in the world. But there are still too many ways in which drug companies are unfairly blocking competition. Since the rollout of the Trump Administration Blueprint, FDA has already publicized the names of companies who may be using safety programs to block competition, and we've issued two new guidances to help lessen the effects these actions may have on generic approvals. This work follows many FDA accomplishments under Commissioner Scott Gottlieb, including record-setting generic drug approvals in 2017 and measures to build on Congress' work to build a genuine competitive market for biosimilars.

Finally, we need to bring down out-of-pocket costs for American patients. Patients should not be dropping their drug regimen because of high cost. Since the Blueprint rollout, CMS has reminded Medicare Part D plans that it is unacceptable to bar pharmacists from working with patients to identify lower cost options. More broadly, you ought to know how much a drug costs, how much it's going to cost you, and whether there are any cheaper options long before you get to the pharmacy counter. We look forward to working with Congress and stakeholders to understand how best to deliver this level of transparency.

What I've laid out are just some elements of an aggressive, comprehensive, long-term plan to solve the problem we all care deeply about. Thank you for having me here today, and I look forward to taking your questions and having a productive discussion.

[The prepared statement of Secretary Azar follows:]

PREPARED STATEMENT OF ALEX M. AZAR II

Mr. Chairman, Ranking Member Murray, and Members of the Committee, thank you for the opportunity to appear before you to discuss an important issue: why prescription drug prices are too high, and what we are doing about it. I know all of you care deeply about this challenge, and I have enjoyed the opportunity to speak with many of you about it.

It was one of the very first topics I mentioned when I appeared before this Committee during my confirmation process earlier this year, and I applaud the effort of the HELP Committee to illuminate and address this issue.

From Day One of his administration, President Trump has directed HHS to make drug pricing a top priority. Too many of our family members, neighbors, and friends have worked hard their entire lives only to see their savings wiped out just to afford drugs they need to live.

Earlier this year, the President's 2019 Budget laid out a range of proposals for lowering drug prices, including through reforms to Medicare and Medicaid.

In May, building on the budget, the President released a blueprint to put American patients first by lowering drug prices and reducing out-of-pocket costs. This blueprint is a plan of action for how to bring prices down while keeping our country the world's leader in biopharmaceutical innovation, and lays out dozens of possible ways HHS and Congress can address this vital issue. Some of these proposals came out of Congress, and we look forward to working with you as we take action.

Over the last decade, four significant problems have arisen in the pharmaceutical market: high list prices set by pharmaceutical manufacturers; seniors and government programs overpaying for drugs due to lack of the latest negotiation tools; rising out-of-pocket costs; and foreign governments free-riding off of American investment in innovation.

The President's blueprint lays out four strategies for tackling these problems, and we have begun to take action on each of them already.

First, we need to create the right incentives for list prices. I know firsthand the serious problems with today's complex system of drug pricing. Right now, everyone in the system makes their money off of a percentage of list prices: both drug companies and pharmacy benefit managers, who are supposed to keep prices down. Everybody wins when list prices rise—except for the patient, whose out-of-pocket cost is typically calculated based on that price.

One of HHS's initial actions is working to require drug companies to include their list price on their television commercials. For example, Americans deserve to know the price of a wonderful new drug they hear about on TV—before going to ask their doctor about a product they may find unaffordable. But more fundamentally, we may need to move toward a system without rebates, where PBMs and drug companies just negotiate fixed-price contracts. Such a system's incentives, detached from artificial list prices, would likely serve patients far better.

Second, we need better negotiation for drugs within Medicare—that is what President Trump has promised, and it's what we're going to deliver.

In Medicare Part D, HHS will work to give private plans the market-based tools they need to negotiate better deals with drug companies. Part D is a tremendously successful program, but it has just not kept pace with innovations in the private marketplace, leading seniors and taxpayers to lose out. Well-intended patient protections may be preventing prescription drug plans from appropriately managing utilization, even in accordance with the formulary created by doctors and pharmacists and approved by CMS. And while everyone agrees on the importance of the drugs in Part D's protected class list, manufacturers often use that list as protection from paying rebates.

We also want to bring negotiation to Medicare Part B, physician-administered drugs. Right now, HHS just gets the bill, and we pay it. This system may actually be driving doctors to prescribe more expensive drugs, while potentially tempting drug companies to develop drugs that fit into Part B rather than D. We are going to look at ways to merge Part B drugs into Part D, to create competition where savings can be safely obtained, and leverage existing private-sector options within Part B.

Third, we need a more competitive pharmaceutical marketplace. Thanks to the reforms Congress passed in the 1980's, America has the strongest generic drug market of any country in the world.

But there are still too many ways that drug companies are unfairly blocking competition. Since the rollout of the Trump Administration blueprint, FDA has publicized the names of companies who may be using safety programs to block competition, and issued two new guidances to help lessen the effects these actions may have on generic approvals. This work follows many FDA accomplishments under Commissioner Scott Gottlieb, including record-setting generic drug approvals in 2017 and measures to build on Congress's work to build a market for biosimilars.

Finally, we need to bring down out-of-pocket costs for American patients. Patients should not be dropping their drug regimen because of high costs. Since the blueprint

rollout, CMS has reminded Medicare Part D plans of its existing policy which requires plan sponsors to ensure enrollees pay the lesser of the Part D negotiated price or copay, or be subject to CMS compliance actions making it unacceptable to bar pharmacists from working with patients to identify lower cost options. More broadly, you ought to know how much a drug costs, how much it's going to cost you, and whether there are any cheaper options, long before you get to the pharmacy counter. We look forward to working with Congress and stakeholders to understand how best to deliver this level of transparency.

Thank you again for having me here today. What I have laid out are just some elements of an aggressive, long-term plan to solve the problem we all care deeply about. I look forward to taking your questions and discussing ways we can work together to bring down prescription drug prices and help American patients.

The CHAIRMAN. Thank you, Mr. Secretary, for being here.

As I said earlier, when the Secretary agreed to come, he said he had to leave at noon. We're going to respect that. That should allow every Senator a chance to ask questions. I'm going to enforce the 5-minute time limit, though.

Mr. Secretary, my view is that a blueprint is a helpful approach. It gives us a chance to have a back-and-forth discussion, which you're doing today. It includes some things that you can do on your own, the executive branch, and some things that we need to do in order for you to do them.

Could you succinctly give us two or three examples of some things that you can do on your own and some things that you need our help to do?

Secretary AZAR. You bet. Thank you, Mr. Chairman. So some of the things that we believe we can do on our own—we do believe we have the authority to require list price disclosure in FDA's TV ads. But we would also welcome Congress acting there to ensure that our statutory authority is shored up as big pharma will most certainly challenge us in that effort and that work.

We also believe that Congress could act to remove the 100 percent cap on rebates that drug companies have to pay—that's the inflation penalty that was part of the Affordable Care Act—that cap of 100 percent on rebates that could actually bring in billions of dollars for taxpayers and create a significant disincentive to list price increases if Congress were to act there. We also think Congress could act to end the gaming by generic companies of this 180-day exclusivity period where one company may sit on their exclusivity and prevent the entry of additional generics, driving down prices and creating more competition.

As you mentioned in your opening, I believe that Congress could act to ban these gag clauses on pharmacists that prevent pharmacists from telling patients about lower cost options. We'd ask Congress to support site neutral payments. The payments should be based on the quality of the product and the service, not based on where it's administered or where the drug is received.

We also believe that Congress could make clear that we will not tolerate PBMs penalizing drug companies that actually lower their list prices for patients and that there should be transparency to their downstream customers when they receive offers to lower list prices and actually act against that.

The CHAIRMAN. Mr. Secretary, I mentioned, you mentioned rebates transparency. We've heard about them in our hearing. Eighty percent of Americans get their drugs through pharmacy benefit

managers who negotiate a rebate from the list price with a pharmaceutical company. Should we eliminate rebates as a way of making it clearer where the money goes and that the benefit goes to customers? If we should eliminate or change those rebates, do you have the authority to do that, or does Congress need to act?

Secretary AZAR. We believe that discussing the removal of rebates, certainly within Part D, the prescription drug program, is something that is and should be on the table. So we, for the first time ever, have provoked that discussion as a regulatory matter. We do believe we have the regulatory authority.

Rebates are allowed under an exception to the anti-kickback statute, and that's an exception that we believe by regulation we could modify. But, of course, if Congress were to take action, that would obviously shore up our authority and allow thoughtful consideration by Congress about what would be fairly far-reaching impacts of moving to a different system of using instead fixed price discounts.

The key is can we detach the incentives of everybody in the system from these artificial list prices. Rebates are a cut, a percent of that artificial list price, and they basically foment this game we have of list price goes up, rebate goes up, list price goes up, rebate goes up, where everybody is winning except the patient who ends up paying out of pocket.

The CHAIRMAN. Well, build on that just a minute. Would eliminating the rebates eliminate or reduce the condition that as list price goes up, everybody wins except the patient?

Secretary AZAR. It would absolutely create—it would remove one of the major incentives to list price increases that we have today. What happens now—if you have a \$100 drug and offer a 30 percent rebate to the PBM for your formulary coverage of that drug, the next day, you may turn around and increase the price by 20 percent. The rebate goes up, the PBM pockets that difference that they don't pass down necessarily to their customers, depending on their contracts. They win, the drug company wins. They keep a cut, and even the employer may win by higher payments. The patient loses there.

If instead the contract said on that \$100 drug, "We'll get 70 bucks. It doesn't matter what your list price is—70 bucks," you take all that incentive for the list price increase away.

The CHAIRMAN. Thank you, Mr. Secretary.

Senator Murray.

Senator MURRAY. Thank you, Secretary Azar. I do want to focus mostly on drug pricing, but as I mentioned, I'm very concerned about what's happening with children of refugees. This administration, I believe, is tearing families apart at the border unnecessarily. But they're sending the children to ORR while the families are shipped off to Federal prosecution. That is causing a crisis for your department, because ORR shelter beds are nearing capacity.

What is being done to make sure that the parents know where their children are, whether they're safe, and when they will see them again?

Secretary AZAR. Thank you, Senator Murray, for asking that question. We take our obligation to take care of these minor children very seriously. Actually, 50 percent of the outplacements from

the Office of Refugee Resettlement of these minor children that we receive who are separated only because their parents have crossed the border illegally and have been arrested, as any American who gets arrested, your child is taken away—

Senator MURRAY. I have very little time, so—

Secretary AZAR. We do keep in touch with the parents, because if they are released from detention, 50 percent of the children do end up with their parents as sponsors.

Senator MURRAY. Well, I am asking you, specifically, because the ORR shelter beds are nearing capacity. There is nowhere to put these. What is the plan? And I don't have time for you to answer that, but I want an answer—

Secretary AZAR. I'll be happy to respond in writing, absolutely.

Senator MURRAY. All right. So let me focus on prescription drug prices. Since the inception of Medicare Part D, Democrats and some Republicans have supported using the government's buying power to negotiate lower drug prices for seniors. A bipartisan majority of people in this country also support that, along with many experts. However, a majority of my colleagues on the other side and drug companies do not. So I was actually pleasantly surprised when President Trump campaigned on allowing negotiations.

Does the President's Blueprint include a recommendation to allow you to negotiate the price of drugs?

Secretary AZAR. The proposal actually has, for the first time ever, negotiation of drug prices in Part B, where we get no discounts, and enhancing the negotiation that's already done for us in Part D to make us ever more effective in Part D. So, yes, it fulfills the President's promise completely to bring negotiation and negotiate hard to Medicare.

Senator MURRAY. Well, that was not how I or anybody else who heard it understood it. It was Medicare Part D, allowing us to negotiate drug prices under that part that will allow the drugs to come down. So I am concerned that that doesn't fulfill the promise of how people heard it and how I expect it would have a much bigger impact.

There's a number of proposals that, as I said, Democrats already proposed, putting list prices in direct-to-consumer advertisements, keeping companies from gaming FDA regulatory incentives—a number. I hope that you'll push Senator McConnell to bring those up, as they've already been introduced, and we can get some of those steps done. So I just wanted to reiterate that.

Secretary AZAR. I think most of what's in our Blueprint we will agree on. You all may have different views about some additional things you'd like to see, but most of what we have in the Blueprint, I think there's significant bipartisan consensus to drive forward on, and we'd love to work with you and others on that.

Senator MURRAY. Well, as we saw in a recent report from our colleagues on the Homeland Security and Government Affairs Committee, of the 20 most prescribed drugs in Medicare Part D, most of their prices are increasing much faster than inflation since President Trump took office. So I'd like to know when you think this Blueprint will pay off for patients, for patients, and reverse those price increases, not of cost sharing or some measure other

than list price. Is it next year, 5 years from now, 10 years? What do you think that—

Secretary AZAR. Well, we're talking about the wholesale restructuring of the drug pricing and drug distribution system in this country, and what the President has taken on in this Blueprint is nothing short of comprehensive reform of how drugs are priced and done. That doesn't happen in just a week or two. This is comprehensive reform. The issue I talked with the Chairman about of eliminating rebates, the issue of stopping any compensation from big pharma to these PBMs who negotiate—across the board change will take time. But we are committed to delivering lower list prices and better negotiation, so lower out-of-pocket costs for our patients.

Senator MURRAY. I know you agree that competition between brand drugs and generics or biosimilars is one way to bring prices down. I do as well. But drug companies are doing everything they can now to delay competition in order to get the longest market monopoly as possible and pad their bottom line.

Last year, AbbVie settled in court to extend the market monopoly for Humira to 20 years. Biogen extended its monopoly on its MS drug to 15 years by getting additional patents that cover only the drug's dosage amount, and Allergan tried to protect its more than 15-year monopoly on Restasis by selling it to the Mohawk Indian tribe and later settled with the generic challenger to keep it off the market for another 7 years.

Does your Blueprint address that type of gaming of our patent system?

The CHAIRMAN. Mr. Secretary, I'm going to ask you to provide that in writing since the 5-minutes is up, and we've got all these Senators.

Secretary AZAR. Certainly.

The CHAIRMAN. Thank you, Senator Murray.

Senator ENZI.

Senator ENZI. Thank you, Mr. Chairman.

Mr. Secretary, I want to thank you for appearing here today and also for putting out the list of potential things that can be done—improving competition, doing the better negotiation, lowering the list prices, and lowering the out-of-pocket costs—so that we can review them and so that people can comment on it. I appreciate you soliciting the comments before anything is finalized.

Value-based purchasing arrangements can provide an opportunity to leverage the health outcome data to ensure that what we pay for drugs reflects their value. One example is indication-based pricing which may allow different payments to be charged depending on the indication a drug is used to treat. We usually don't track indication data in public programs, certainly not in standardized or precise fashion.

Can you talk about the scope of data infrastructure that would be needed to support indication-based pricing and whether your health information technology systems might need to be modernized to support those efforts?

Secretary AZAR. Senator, thank you for raising the important question of indication-based pricing for drugs. We actually, right now, stand in the way of indication-based pricing, and I look forward to the opportunity to work with Congress on statutory modi-

fications that could open the door to that. In Part B—those are those physician-administered drugs, for instance—there’s a single unified price. So we’re not able to permit, as far as I know right now, a drug to be priced at a higher price, say, for a limited population where it has a really huge impact and at a lower price in perhaps a larger population where it might have a lesser impact.

On Part D, the retail program, we basically prevent indication-based utilization management. So if you’re a really big drug that, say, has five indications, you can actually bundle those effectively, because we require that you cover all indications the same way. So you may treat this one disease state and this other disease state, and you can’t have differential rebates, you can’t have differential utilization pathways for those. That’s something that, working with Congress, we could remove those barriers and let more value-based, outcome-based contracting happen and reduce the leverage of big drugs that have multiple indications like that.

Senator ENZI. Thank you. The Blueprint also asks what effect would imposing a fiduciary duty on pharmacy benefit managers on behalf of the ultimate payor have on the PBM’s ability to negotiate drug prices. Many states have considered imposing a fiduciary duty on the PBMs, but many abandoned the idea after debating it.

Can you explain what challenges might be needed to be addressed in order for the fiduciary duty to be realized and whether the factors you’re considering are any different than the PBM is negotiating for drugs that are paid for in the traditional manner?

Secretary AZAR. I’m glad that with your banking expertise you raise this question. The word, fiduciary, was meant more directionally than any type of incorporation or suggestion of state law type financial fiduciary obligations. It was meant to get at, as I said in my opening, just the receipt of compensation.

Our view is that pharmacy benefit manager that has been hired by either employers or individuals or insurance plans to negotiate the best deal possible against the drug company ought not be getting any compensation from those drug companies. They shouldn’t be getting a hold-back of rebates, they shouldn’t be getting administrative fees that are based as a percent of list price, and they shouldn’t be getting other types of fees from big pharma. They ought to be looking only out for the interest of their clients. That’s the proposal that we want to get comment on.

Senator ENZI. Appreciate it. If done right, value-based purchasing agreements bring the patient experience into drug pricing decisions because they align incentives to increase patient access to drugs that are appropriate and effective for them. What ideas are you considering to ensure that these types of entities are designed to benefit the patient?

Secretary AZAR. We do want to open the door to more value-based and outcome-based contracting. One of the big barriers is our government price reporting requirements, and so we want to work with CMS to see how can we effectively make it easy for these contracts to happen. They’re quite burdensome to put in place. I tried to do this.

Most drug companies would like to do outcome-based contracting, put their money where their mouth is, but the cost of implementing can be quite high. So we can probably reduce those compliance

costs, but we do, of course, have to ensure that whatever we do protects the public best as we go through that. But that is part of our agenda. We're working on that as we speak, how we could put out rules and guidance that would enable more value-based contracting there.

Senator ENZI. Thank you, and I'll have several questions on 340B drug pricing, too, but I'll submit those in writing to stay in the time limit.

The CHAIRMAN. Thank you, Senator Enzi.

Senator Bennet.

Senator BENNET. Thank you, Mr. Chairman. Thanks for holding this hearing.

Mr. Secretary, it's nice to see you. There is no issue that I hear more about in my town hall meetings than drug prices, and it is a mystery to everybody in America why the government can't negotiate these prices in Medicare, and I know there's some proposals in the Blueprint around that.

During your hearing in the Finance Committee when you were asked about whether the government should negotiate prices for naloxone, the opioid overdose antidote, you were open to the idea, and you said there's nothing at all wrong with the government directly negotiating when we're the purchaser for value. I completely agree with that sentiment and just wonder why that shouldn't be the line of thought that we apply to all drugs, particularly with respect to Medicare negotiations.

Why not go all the way to fulfill the President's promise on this subject?

Secretary AZAR. Again, the President has fulfilled his promise by introducing for the first time ever negotiation to Part B and actually fixing and improving negotiation in D. But the issue you raise is should I sit there and actually directly be the one to negotiate rather than using these pharmacy benefit managers that currently do that work and actually enhancing that work for them to do better.

As Peter Orszag said when he was the Congressional Budget Office head and President Obama's OMB Director, there's only one way that that could possibly lead to better discounts, and that would be if for all of our seniors, we had a single formulary with uniform national decision of covering this drug and not covering that drug. No choice, no opt out, no options for seniors. So if I decided that I didn't like to be on this drug or that drug, and you needed that drug, you know where you go? The UK, France, Germany, somewhere else, but not America. We would take away that choice.

We believe we can get the same type of rebates, the same type of discounts by better negotiation using these private sector entities. That is their job. They do this. We need to unleash them, and what happens then is the patient is at the center. The patient can pick. This plan has negotiated this formulary. This plan has negotiated that formulary. Which one works best for me? I, the senior, am in the driver's seat instead of the government making those one-size-fits-all choices for me. So that's why we've chosen that approach for now.

Senator BENNET. One thing about those one-size-fits-all places is that drugs are a lot cheaper there than they are here.

Secretary AZAR. Well, that's because they have no choice. God help you if you get cancer in the United Kingdom. You don't have choice or access to the most modern oncology and cancer therapies. You'll be coming to America to get your treatment if you have the money to be able to get here.

Senator BENNET. The Blueprint also proposes moving some drugs that are currently part of Medicare Part B to Medicare Part D, as you've testified. And just for people who are listening, Medicare Part B covers drugs that are administered in a doctor's office or other outpatient setting, many of which are infusion drugs related to cancer treatments.

Last month, Avalere Health released a study that I'm sure you saw on the difference in out-of-pocket costs under Part D versus Part B. They found that in 2016, the out-of-pocket costs for beneficiaries who received new cancer therapy infusion drugs were an average of 33 percent higher for beneficiaries who had the drugs covered under Part D compared to those who had them covered under Part B.

I guess my question is are you aware of that, and what's the plan to not have this, either inadvertently or in some other way, end up with people charged more as a result of the transition.

Secretary AZAR. You raise an important point, and that's exactly why we want to tread very carefully here on the move of drugs from B to D or introducing tactics from D into B. The key is we need to get negotiation. Right now, we're paying a stiffer price for these drugs, no discounting. We ought to be able to get 20 percent to 40 percent discounting, as we do in Part D, on those drugs. That's \$30 billion of spend.

If we took all the savings we'd get from that kind of negotiating in Part B, that would leave money that we could figure out any out-of-pocket, cost sharing, Medigap coverage, et cetera, issues. That's why we want to try this through a demonstration, figure out how to make this work, make it work for patients, make it work for the Treasury, work with you on that, and, hopefully, figure this out so Congress could then effectively legislate in the space of how we can get the best deals and negotiate in Part B.

A valid concern, and we want to work with you on making sure that our seniors are protected and that it works.

Senator BENNET. Okay. Well, we look forward to working with you on that.

I would, just by way of closing, Mr. Chairman, say that I think one of the roots of all this, however one wants to look at it, whatever the policy choices are one wants to make—there is a complete lack of transparency in this industry, and it's not just drugs but everything in healthcare, and unless people can actually understand what stuff costs, not just what they're charged, not the list price, not what they had to fight with their insurance company about, but what stuff actually costs, we're going to have a hard time making progress.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Bennet.

I thank the Senators for being succinct.

Senator Collins.

Senator COLLINS. Thank you, Mr. Chairman.

Mr. Secretary, just to build on what my colleague just said, this system is opaque, and the incentives are frequently perverse in drug pricing. Pharmacy benefit managers, for example, are often hired by insurers to negotiate on their behalf with pharmaceutical companies. But the fact is that the PBMs make more money if they are paid a percentage of a higher list price.

The problem is that the pharmaceutical companies know that the PBMs are going to control whether or not their drug is listed on the formulary of the health insurance plan. So doesn't that give PBMs enormous leverage and create an incentive for higher list prices?

Secretary AZAR. Senator, thank you for that, and that is exactly, I think, what this Committee saw when you had the heads of the pharmacy benefit managers, distributors, everyone in the channel, and they all were here pointing fingers at each other. Now, let's start first—the drug companies have their list prices. So, first, they're accountable for setting their prices. But there are very important financial incentives that make that work, and one of them is the PBMs benefit from higher list prices because of how these arrangements work. It's rather a startling and perverse system that has evolved over time, and that's why this Blueprint suggests the comprehensive tackling and restructuring of the drug channel, nothing short of that.

Senator COLLINS. I was very pleased this morning to hear you endorse the prohibition on gag clauses on pharmacists, which actually prevent them from telling a consumer, unless the consumer asks, of whether or not they'd be better off not using their insurance and paying for a prescription drug out-of-pocket. I was behind a couple at the pharmacy counter recently who found out that their co-pay was \$111 and said, "We can't afford that," and walked away.

I asked the pharmacist, "Does this happen often?" And he told me every single day, and that really troubles me.

It was pharmacists who brought to my attention the fact that these gag clauses exist. I know that CMS Administrator Verma has issued a letter telling plans that the agency will no longer tolerate gag clauses in Medicare drug plans. But that leaves out the plans on the exchanges and other health plans.

Are you planning to take similar action? And don't you think we really ought to pass legislation that Senator Casey and I have introduced to apply to the Affordable Healthcare plans and that Senator Stabenow and I have introduced to apply to Medicare and Medicaid so that we can put this in law?

Secretary AZAR. We agree with you. I appreciate—you were the one who raised this to my attention during the confirmation process, and we find this unconscionable. So we will look forward to working with you and other Senators on legislation that would across the spectrum deal with the issue of these gag clauses and getting it to stop, because we think the patient should have the right to know what their out-of-pockets are and what their lower cost alternatives are.

Senator COLLINS. Most patients are not going to assume that if they don't use their insurance, they'll get a better price.

Secretary AZAR. Right. So it would seem—to the average person, it's not intuitive.

Senator COLLINS. Right. I'm also very concerned about the problems of gaming the patent system through strategies such as patent thickets and evergreening. When we talked on the telephone recently, you mentioned that our country's annual spending on just one drug, Humira, is the equivalent to the cost of an aircraft carrier. And we found, particularly with rheumatoid arthritis drugs, that evergreening is going on, and that, in fact, there's been payments so that biosimilars that are much less expensive generics are available in Europe come this October, but they're not available to our citizens.

How can we solve this problem? Is legislation needed?

Secretary AZAR. Certainly, legislation to stop that 180-day swatting—

The CHAIRMAN. Mr. Secretary, to be fair, I'm going to have to ask you to do that in writing.

Secretary AZAR. Of course.

The CHAIRMAN. Thank you, Senator Collins. I'm sorry to cut everyone off, but I want to—

Senator COLLINS. Thank you. I understand.

The CHAIRMAN. Senator Warren.

Senator WARREN. Thank you, Mr. Chairman.

Secretary Azar, I'll get right to the point. You and President Trump say that you want to get tough on drug companies. So do I. Let's start with the President's promise. On May 30th, the President said that in reaction to the release of the Drug Pricing Blueprint, drug companies would be, quote, "announcing voluntary massive drops in prices within 2 weeks." That was 2 weeks ago tomorrow.

Now, the same day that the President made that statement, Senator Smith and I sent letters to the top 10 drug manufacturers to see how many had lowered prices in response to the Blueprint, and all 10 of them have now responded. Zero out of 10 said that they had lowered any prices, zero out of 10 gave any indication that they plan to do so, and, in fact, one out of 10 said prices are going to go up later this year.

Maybe you can clear this up for us.

Secretary Azar, which drug companies will be voluntarily lowering their prices massively, for which drugs, and how much money will the American people save as a result?

Secretary AZAR. There are actually several drug companies that are looking at substantial and material decreases of drug prices in competitive classes and actually competing with each other and looking to do that, and, frankly, at this point, the biggest challenge is working—

Senator WARREN. Let me stop you here. Let me just ask you there—you said they're looking at it.

Secretary AZAR. Well, the reason is they're working right now with the pharmacy benefit managers and distributors. The challenge—this is the perversion of the system we're talking about.

Senator WARREN. In other words, the President's promise that we would see massive decreases in 2 weeks hasn't happened and

there's no—you don't have anyone lined up who's actually going to decrease drug prices.

Secretary AZAR. What they're trying to do is work to ensure they're not discriminated against. Oddly, the fear is that they would be discriminated against for decreasing their price.

Senator WARREN. Was that true when the President made the promise?

Secretary AZAR. They're working to ensure they're not discriminated against for lowering their prices. You should focus, if I would suggest, on the PBMs and distributors who might say to these do not decrease your price.

Senator WARREN. Mr. Azar, I'm simply focusing exactly where the President told us to focus. He said there would be massive decreases in prices within 2 weeks. It's been 2 weeks, and there have been no decreases and an indication of increases. Mr. Secretary, you said you wanted to get tough on drug companies, but under your approach, it seems that the drug companies can just keep charging people more and more. The only thing you've done is set it up so maybe if a drug company reduces a price, you can give them a cheap PR moment and then let them jack up prices later.

But let me look, since we're under time pressure, at the President's other big promise, the one he made over and over during the campaign that several of my colleagues on both sides have referred to, and that is that he was going to, quote, "negotiate like crazy over drug prices." I don't see that in this plan. Instead, the President proposes moving patients from getting their drugs through Medicare Part B, where co-pays are capped at 20 percent, to getting their drugs through Part D, where co-pays can go as high as 40 percent.

Secretary Azar, if a so-called negotiation ends up in raising Medicare drug prices, it's not a negotiation at all. It's just a bad deal for seniors. So here's my question about this negotiation. Can you guarantee that no Medicare beneficiary will pay higher drug prices as a result of your plan to change drug coverage under Medicare?

Secretary AZAR. It seems to me that your perspective is we should be happy with the status quo with Part B where we pay \$30 billion for drugs and pay the list price with no discount whatsoever.

Senator WARREN. No, it's not. I'm asking—Secretary Azar, it's a pretty straightforward question, a yes or no.

Secretary AZAR. We're challenging the status quo and you're not.

Senator WARREN. I just need a yes or no. Can you guarantee that no Medicare beneficiary will pay higher drug prices as a result of your plan to change coverage under Medicare?

Secretary AZAR. As I said to Senator Bennet, the whole point of our working with Congress on looking at how we might introduce competition and negotiation to Part B is to deal with these very complex questions, and, of course, we want the beneficiary at the center. We want to make sure that they have choice. We want to make sure that their medical needs are met by introducing modern techniques of formulary management and pathways for them.

Senator WARREN. That sounds like a runaround to the yes or no question. Can you—

Secretary AZAR. It's we're going to work on it, and at some—

Senator WARREN. Then you're going to work on it, and maybe some beneficiaries will end up paying more? Is that what you're saying, Secretary Azar? That's not going to be good for those—

Secretary AZAR. As I said to Senator Bennet, if we can bring 20 percent to 40 percent reduction in Part B, that would be so much money in savings that we should be able to figure out how to ensure the protection of beneficiaries through this process.

Senator WARREN. Secretary Azar, what we're talking about is moving people to a plan that has a higher co-pay, and I've asked the question now three times, and you've given me no answer at all. You cannot guarantee that there will not be Medicare beneficiaries who will be paying more.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Warren.

Senator Cassidy.

Senator CASSIDY. Actually, Secretary Azar, what I heard is that if you effectively work with Congress, we can keep Medicare beneficiaries from paying more, but we save taxpayers \$30 billion and make the system more sustainable. So that's what I heard from you. I'm not going to—I have 5 minutes. So I agree totally with Senator Bennet. He and I and others are working on a price transparency initiative. Clearly, you're after transparency.

Now, one thing, when you spoke about rebates, and you pointedly said you may have the authority within Part D—what about the commercial system?

Secretary AZAR. Within rebates, we actually have the anti-kick-back statute, which is where the rebate safe harbor exists that allows this—that created this whole rebate system to start with. How far that reaches beyond government programs and whether that could apply in purely commercial private pay systems would be—we need to study that—

Senator CASSIDY. If you can let us know, because that's where Congress would want to step in.

Secretary AZAR. Yes, and that's why I told the Chairman we would welcome Congress in this important area.

Senator CASSIDY. Next, you had mentioned as well—and people have been concerned how quickly will consumers begin to see lower drug costs. It seems that that is predicated on how quickly you can get out a rule forbidding gag clauses. That will be when we begin to see lower costs at the counter.

Secretary AZAR. That's certainly one element.

Senator CASSIDY. When do you think you'll have out that rule?

Secretary AZAR. We've already sent a notice out to the Part D drug plans telling them that we do not expect to see any drug clauses. We find them intolerable in the Part D drug programs. So, frankly, that should be taking place immediately, already. If anyone is being subject to a gag clause, if there's a pharmacist being subject, I ask you to please let CMS know immediately.

Senator CASSIDY. You also mentioned that you want folks to know the cost of a drug before they go to the pharmacy. There's a recent consumer report about the cash price of drugs, not Medicare, but the cash price, varying in one case for a generic from \$44 to \$700, but you only found out when you knocked on the door of the pharmacy.

By what means are you suggesting that they will push—will this publicizing of drug prices by the pharmacy include the cash price, and by what means will you do that, and do you need our help to execute?

Secretary AZAR. On this type of transparency at both the point of sale at the pharmacy as well as—I would like to see this at the point of prescribing so that when the doctor actually decides, they could advise you, the patient, for this drug you'll pay this much out-of-pocket when you go to this pharmacy, but there are these alternative drugs that I could write if that—

Senator CASSIDY. But what about the cash price?

Secretary AZAR. I think we need Congress—that is that out-of-pocket cash price. That should be knowable, and that is an area where we really could—

Senator CASSIDY. But, theoretically, cash price, though, would not be under the legislation of an insurance company. That would be someone uninsured.

Secretary AZAR. For the folks who are just paying without insurance on that. Well, that one, I'd want to work with you on. I've been most focused on those who are insured and knowing what your out-of-pocket expenses are under your plan. That's an area we'd love to work with Congress on. It would be a huge benefit to patients in the system if we could design a system where the doctor knows when writing that prescription—

Senator CASSIDY. Let me stop—my office has just recently posted a bill, a white paper on how to lower costs. One thing as we think of—and my colleague, Senator Collins, did such good work on this—the Martin Shkreli of the world, who get a single drug and then they raise the price dramatically. Now, you could go to Great Britain and get the same drug and bring it back, but that's currently not allowed except under exceptional circumstances.

One proposal that we proposed in our white paper is that since the FDA has a memorandum of understanding with their EU equivalent, that if one certifies a plant in India as having good manufacturing practices, the other agency will agree with it. What if we extend that to if both agencies have a secure supply chain, that a wholesaler could go to Great Britain and buy a generic drug if we're down to one producer here who, using monopoly power, is jacking up the price? What would you think about that?

Secretary AZAR. That should be on the table, and I'd love to work with Commissioner Gottlieb and the Congress on that. If we could wire the systems together to allow a generic drug that expedited approval through FDA in those kinds of circumstances—

Senator CASSIDY. Well, this is not an expedited approval—

Secretary AZAR. We might actually—with a generic, we might actually be able to construct an expedited approval so we don't even do any violence to our approval system and get that in. That's one issue Commissioner Gottlieb could focus on.

Senator CASSIDY. Well, I'm speaking of, say, doxycycline, a pill which I'm told now costs \$13.50. It's out there for 50 years. It should cost 50 cents.

Secretary AZAR. Exactly.

Senator CASSIDY. If we know it's being produced in India, coming to the U.S. and Great Britain, why can't a wholesaler just go to

Great Britain, if there's only one importer—this is not re-importation. This is importation.

Secretary AZAR. I'm happy to work and be open minded here on coming up with a solution.

Senator CASSIDY. I'm out of time. Lots of questions I will submit for the record. Thank you.

The CHAIRMAN. Thank you, Senator Cassidy.

Senator Kaine.

Senator KAINE. Thank you, Mr. Chairman.

Thank you, Mr. Secretary. Like all my colleagues, I hear from my families across the Commonwealth about how high prices affect their lives. One in four Americans who take prescription drugs have difficulty affording them. Let me read a letter that I got from a guy named Andrew Ventnor who lives in Great Falls. He wanted to share his story.

Quote, "In the United States, Gleevec, a drug that effectively cures several forms of leukemia, costs approximately \$159 to manufacture for a year's dose. In the United States, there's no available generic, and the brand name drug's market cost is \$146,000 a year, \$159 to make it, \$146,000 a year. This is not a drug that consumers can simply choose not to take. To be blunt, they will quite literally die of cancer.

"My father is being treated for CML, one of the leukemias that is effectively curable by Gleevec. The cost of this drug is a major financial burden on our family. Many who are not as fortunate as my family have been forced to choose between having Gleevec and keeping their homes. This is, to me, an absolutely unacceptable exploitation of extremely vulnerable Americans who have quite literally no other options to get this lifesaving treatment without searching for loopholes in the law or outright breaking it.

"Preventing this exploitation is something every American can agree on, an issue that has lives in the balance. I know these are trying divided times, but this issue is one that I hope all in Congress and the Nation as a whole may come together on."

Studies that indicated that the cost of manufacturing Gleevec costs \$159 a year also pointed out that the cost of Gleevec, the price charged to those in the UK, is \$31,000, and the price for a generic to Gleevec in Brazil is \$8,000.

I read President Trump's announcement, your own interviews about his announcement, and your testimony today, and here's something that fascinates me. The Administration has been blaming high drug prices on other nations, many of which have the ability to negotiate lower drug prices. In his speech announcing the Blueprint, President Trump said it's time to end the global free-loading once and for all. Americans will not be cheated any longer and especially not be cheated by foreign countries.

In an interview, you said foreign countries should be paying more of their fair share, and you indicated the same thing in your written testimony today. I'm just going to assert this. I think blaming our allies for Americans paying those kinds of prices is ridiculous. I'm going to call this the blame Canada argument. And to your question to us earlier about whether we would want you to have negotiated pricing ability, I'm going to say, Mr. Secretary, I

would love for you to have that power. You know this industry very well.

There's a very standard form of contracting in commercial settings of best price contract, where you enter into a contract and you say with somebody, "I'm going to buy, and I want your best price. I have a big market. You will want to do business with me, and I want your best price."

In commercial settings, people do best price contracts all the time.

I would like to give you, if you do not already have it, the ability to go to the manufacturer of Gleevec and say, "I have the biggest and the most important market in the world, and I will pay you your best price." If the best price that they have is the \$31,000 that they're charging UK citizens, well, we want \$31,000 here, not \$146,000.

Why should I not be able to give you that instruction, and why should you not be able to go out and negotiate on those terms just like people in commercial settings negotiate in that way every day?

Secretary AZAR. I've actually looked a lot and thought a lot about this issue of best price, slash, most favored nation status where we would say, "Give us the best price you give to developed countries." So it's on the table. I've looked at it.

I don't think it would be effective, to be very honest, because what would happen is we would say that. They make most of their profit, the bulk of it, here in the United States, the drug companies, and what they would do is they'd pull out of the countries that are setting that reference price.

We see that even within Europe, with parallel trade and reference pricing within Europe. That's why drugs are often not launched in certain countries like the UK or Germany, and those people just don't ever get those drugs—

Senator Kaine. I'm just going to put a parenthetical—they make most of their profit here in this country.

Secretary AZAR. They do, indeed. They do, indeed.

Senator Kaine. Right. So now can we—

Secretary AZAR. We pay too much, and they pay too little.

Senator Kaine. Here's an idea.

Secretary AZAR. But it's superficially appealing, but I don't know that it really would work, and we might end up paying more for the drug.

Senator Kaine. Here's an idea. You have thought about it. You're not sure it would work to ask companies to treat the U.S. the same way they treat UK citizens. How about a pilot project? How about pick Gleevec and about five cancer drugs and say, "Well, I don't think it'll work, but we haven't tried it." Why don't we try it? Why don't we pick a couple of drugs and try it, give you that power, get a most favored nation or a best price contract, and let's test whether it works or not, and help a lot of Americans who are suffering through high drug costs as we try?

The CHAIRMAN. Could you please answer that in writing, Mr. Secretary?

Secretary AZAR. Certainly.

The CHAIRMAN. Thank you, Senator Kaine.

Senator Burr.

Senator BURR. Thank you, Mr. Chairman.

Mr. Secretary, welcome. Mr. Secretary, would you agree with this statement, that the policy challenge that we have in this Committee and in this country is how to balance competition, price, with innovation, cures?

Secretary AZAR. I would completely agree, and I would just add and with the patient sitting at the center.

Senator BURR. We have on the Committee passed numerous fast-track initiatives, drugs, devices, so that we could introduce these into the marketplace quicker. Do you agree that the length of patent life divided by the cost of R and D is sort of a starting point for a company to determine a price?

Secretary AZAR. It is that, absolutely. The shorter the patent life, the shorter the exclusivity, the higher the price will end up being to recover cost as well as to make a profit and a return on investment.

Senator BURR. If under our intellectual property laws, which we're not debating today, we give a company a longer period of exclusivity, you're saying the price comes down.

Secretary AZAR. I wish it would. I wish it would. It will certainly go up the shorter it is. I wish it would go down the longer it is. It's some of the perversions, as Senator Collins raised in our discussion, about the system favoring higher list prices but greater rebate and discounting.

Senator BURR. But you would agree if you begin to address—and I've said to you in the past—when you talk about list price, I've said, "What is that?" It's a made up number, and if you were here 20 years ago when we were debating this same issue, it was AWP plus six, and this plus that and this minus that.

Would you agree that accelerating the approval time presents us with the opportunity to put downward pressure on drug pricing?

Secretary AZAR. Oh, that's absolutely and demonstrable. Even the highest profile drug, Sovaldi, which is the Hep-C drug that cost billions to the system, there was a competitor to that within a year that drove discounting to over 50 percent to where we pay less in the U.S. than Europeans pay for those drugs, the Hep-C drugs. Competition works. The faster we can approve drugs and get more drugs on the market, the lower the prices we're going to pay here in the U.S., absolutely.

Senator BURR. When can the American people expect an architectural change at FDA that really gets out of a 20th century model and gets into a 21st century model that meets the expectations of what technology provides us to innovate today?

Secretary AZAR. It's an important challenge. I don't know if you've seen the announcement Commissioner Gottlieb made very recently about reorganizing the Office of New Drugs and how we can streamline the review of drugs procedures as well as the expectations on sponsors, but very happy to work with you on that. I agree that we need to keep holding FDA to be up to date with the most recent science and statistics and methodologies to get drugs out there for patients and increase competition and reduce costs. I totally agree with you.

Senator BURR. When the clinical treatment is off of a technological platform, which is the future—it may be tomorrow, it may

be next year. It's certainly going to be 5 years down the road—is there any value from the debate we're currently having as to how you apply that to that type of world where you've got a technology platform and you're treating a genetic imperfection and five different cancers off of the same platform? Or are we just having this debate for today and not for the future?

Secretary AZAR. We're trying to have it for tomorrow. Fortunately, the future is now in many respects, the regenerative medicine, for instance, cell-based therapies, cell manipulation and actual cell splicing. We're in that era right now and working on that, and that is the future the next decades ahead.

Senator BURR. Mr. Secretary, how do you put a value? How do you value fairly something that didn't exist?

Secretary AZAR. Well, that's where I count on the marketplace, the patient in the center, with major insurance companies negotiating on their behalf and competing to create as powerful a competitive market as possible. That, for me, is—

Senator BURR. But that doesn't exist today, does it?

Secretary AZAR. That's what our Blueprint is aiming to create, is a more competitive system around drug pricing and drug availability with the patient at the center.

Senator BURR. Well, I'm grateful for the President's proposal. I'm skeptical as to whether we can accomplish all of it, because I think in part of it, it's policy, and this Committee has always tackled it. We tackle it vigorously.

Part of it's culture. Part of it's culture within government. I don't believe there's an architecture of government today, whether it's in HHS or anywhere else, that can handle technology with the speed that it's going to come at us. And if we believe that that's the case in DOD, let me say to my colleagues it's going to be 10 times the pace in healthcare, and we've got to get ready for it and set that architecture.

Thank you.

The CHAIRMAN. Thank you, Senator Burr.

Senator HASSAN.

Senator HASSAN. Well, thank you, Mr. Chairman and Ranking Member Murray.

Mr. Secretary, thank you so much for being here today.

I'd like to ask, Mr. Chairman, for unanimous consent for the entry into the record of a copy that 19 of us Senators wrote to the President in October 2017, asking that the President follow the recommendation of his opioid commission to give the Secretary of Health and Human Services the authority to negotiate the price of naloxone.

I don't need a response to it now, Mr. Secretary, but I would appreciate a response for the record on what steps the Department has taken to investigate this recommendation by the President's own commission, because, as you know, naloxone prices have been skyrocketing, and it is definitely hampering our first responders with regard to the opioid crisis.

The CHAIRMAN. So ordered.

Senator HASSAN. Thank you.

Senator HASSAN. Mr. Secretary, in November, Senator Durbin and I introduced a bill with a number of others in the Democratic

Caucus called the Drug Price Transparency and Communication Act to require under the FDA's authority that direct-to-consumer drug advertisements disclose the cost of the drug. In my view, this represents an important step toward transparency, and despite this Administration's silence when the bill was introduced, I'm really glad you are now looking into this idea.

But what authority do you think HHS and FDA have to require drug companies to disclose prices in direct-to-consumer ads? Don't you need Congress to give you this authority?

Secretary AZAR. It would certainly—I would always appreciate congressional authority to back me up on that, because I undoubtedly will be sued. But I believe as part of the fair balance in ads, it's an important piece of information that consumers are entitled to. Along with cost benefit, I think it's part of the cost.

Senator HASSAN. If your working group at the Department determines that you can't do this administratively, will you commit to requesting such authority from Congress?

Secretary AZAR. Absolutely, and, in fact, I'm happy even concurrently to be working with Congress if Congress wanted to move forward on that now.

Senator HASSAN. All right. Excellent. So while disclosing prices in ads is important, in my view, there's also a much larger problem—and we talked a little bit about this last week when we had a phone call—the fact that we have direct-to-consumer drug ads to begin with, and that we give drug companies a big tax break for them, even though they increase costs that patients have to pay.

To me, this is a basic fairness issue. We shouldn't be giving drug companies tax breaks on the billions of dollars they spend on advertising, advertising that hikes up costs for consumers while Americans struggle to afford the rising cost of lifesaving medications.

If this Administration is actually serious about addressing drug pricing, I'd encourage you and the whole Administration to go even further on the direct-to-consumer issue and work with Congress on ending these outrageous tax breaks and, frankly, getting rid of these ads all together. So I'd appreciate the chance to continue to discuss these issues with you. I will tell you that when I suggest to constituents that we don't have these drug ads to begin with, they are overwhelmingly in favor of it.

I want to turn to a different topic now. This Administration has released its Blueprint, and it says it wants to lower prescription drug costs. As you and I have discussed, I don't think the Blueprint accomplishes what it sets out to do. But not even a month after releasing the Blueprint, the Trump Administration told a Federal court that it would not defend the provision in the Affordable Care Act that protects people with preexisting conditions. This Administration is, frankly, talking out of both sides of its mouth.

If the ACA's preexisting conditions protections disappear because the Trump Administration is putting politics over people and refusing to defend these very popular provisions in the ACA, then many Americans who need health insurance won't be able to get it, meaning they won't have insurance to help them afford their medications. This, Mr. Secretary, is like some kind of sick joke. The Administration is trying to pull the wool over the American people's

eyes by paying lip service to affordable prescription drugs in their do-little Blueprint, all while gutting protections for preexisting conditions which will obviously make drugs less affordable for patients who lose their coverage.

Given that the ACA's preexisting conditions protections are critical for consumers' access to affordable prescription drugs, yes or no, will you encourage the Trump Administration to change its position and defend the preexisting conditions protections in the Affordable Care Act?

Secretary AZAR. The position articulated by the Attorney General is a constitutional and legal position, not a policy position. But we share the view of working to ensure that individuals with preexisting conditions can have access to affordable health insurance. The President has always shared that. We look forward to working with Congress under all circumstances toward achieving that.

Senator HASSAN. Excuse me. Then the President should instruct his Attorney General and the Department of Justice to do what they are obligated to do, which is to defend the Affordable Care Act, by the way, provisions of which, such as this one, the American people overwhelmingly support.

Finally, I will just add my concerns to those that Senator Murray expressed about the separation of children from their parents at our border. First of all, some of the folks whose children are being taken away from them are coming to our country to seek asylum. So your characterization of them all being here illegally is inaccurate, to say the least. I also—

Secretary AZAR. It's actually not. If you present at a legal border crossing with an asylum claim, you will not be arrested and you will not have your child taken from you. These are individuals crossing illegally into our country and being arrested. That's a fact.

Senator HASSAN. Well, that is different from what some of us are understanding from firsthand reports on the border.

Second, as a member of the Homeland Security Committee, I had the opportunity to talk to your Department members, and I'm very concerned that they don't have any protocols for reaching out to states when they are sending these children who have been separated from their parents or arrive here without parents to different states. States have an entire child welfare organization set up. They have procedures, and they should be partners with all of you. It is very concerning that the Department has not prioritized the welfare of these children the way it should, and we will continue to ask you to take much more aggressive action to ensure that that happens.

Thank you, and I'm sorry for going over, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Hassan.

Senator Isakson.

Senator ISAKSON. Thank you, Chairman Alexander.

Welcome, Secretary Azar. I appreciate you being here today. In fact, at the end of last year, I asked you in your confirmation hearing if you'd come back after 6 months and report to us on this issue of drug pricing, and I'm happy to see that you've done so. I appreciate what you've said about it, and I also appreciate the points that have been raised by many of the Members.

I think that Senator Bennet was right on target in talking about the confusion in the pricing of pharmaceutical services and, in fact, all healthcare services. I still to this day can't understand an insurance statement on my healthcare to beat the band. I can't understand half the things that are going on, and I think there is an absence of transparency in the whole process that's almost transactional in its absence so that you go from one to another trying to find something else, and then you've got to go back and start all over again at the beginning.

With that said, I appreciate you coming here. I'm glad the President has spoken out on the issue of drug pricing. It's not going to go away, because it's entirely too expensive, and there are some big problems. One of them I want to talk about right now is a personal experience I recently had.

Do you know what Batten disease is?

Secretary AZAR. I'm afraid I don't, Senator.

Senator ISAKSON. It's a very rare disease that only occurs in children. It's 100 percent fatal. Usually, the individual will live from six to 12 years, and, basically, all the basic bodily functions disappear. I mean, they generally waste away. It's a horrible disease.

My daughter's best friend, who married a number of years ago when my daughter did—their second child ended up having Batten disease, and she has dedicated her life to trying to find a cure, like all of us do when we get some dreaded disease or incurable disease. But she did so well. She found two doctors at Boston Children's Hospital. They were working on a gene therapy concept where they would be able to use gene therapy to get the part of the brain that needed attention—and I'm not using the right medical terms—to respond and had gotten approval from the agency to have a field trial if they could raise the money, and she volunteered for her child to go through the field test, so her child is going to be the first person ever tested with this technique of gene therapy at Boston Medical and is under testing now.

The cost to do that is \$1.7 million, and that's with a lot of charitable support and help to get that done. It raises the question that I think begs all of us that rising costs of designer drugs, biologics, the new techniques like gene therapy is making the new products that come out to treat maybe only a select few diseases but are potential cures for some of those future incurable diseases are totally unaffordable.

Is there any work being done anywhere in the depths of your agency to come up with a mechanism where we can incentivize the development of new drugs and find a way to ameliorate the impact of the dramatic cost at the beginning so we can spread it enough to where the cost is somewhat affordable for the average American family? Is anybody in your agency actually thinking about that?

Secretary AZAR. We are, but I actually think this is an issue we need to work with Congress on. This is a broader issue of curative therapies and lifetime therapies that can be for a very small population and quite expensive, and our insurance system, which is really meant for small molecule pills, is not built for these types of therapies, and it challenges our system greatly and hurts individuals. So we need to work together to try to find solutions for these lifetime therapies and how those are financed and handled.

Senator ISAKSON. I certainly don't have the answer, but I know the problem is desperate, and we need to do whatever we can to start developing, and then we need to encourage it.

One other thing I want to say, too, is that I was pleased that President Trump mentioned speeding up the approval process for over-the-counter drugs in his Rose Garden statement on pharmaceutical costs. I was pleased with Bob Casey to sponsor the Monograph Reform bill, which we passed in this Committee a couple of months ago, which I think is going to be a contributor to lowering costs. Would you agree with that, and do you support that getting to the President?

Secretary AZAR. I very much support the OTC process and reform and enhancing the number of cheaper OTC drugs for consumers, absolutely.

Senator ISAKSON. Thank you, Mr. Secretary.

The CHAIRMAN. Thank you, Senator Isakson.

Senator Smith.

Senator SMITH. Thank you, Chairman Alexander and Ranking Member Murray, and thank you very much for being here today.

Secretary Azar, you previously served as Deputy Secretary of HHS when the agency was implementing Medicare Part D. I believe that is when the express prohibition against negotiating lower prices was put into place. And then, also, I know you served in the private sector, Eli Lilly. I also come out of the private sector myself—one of the biggest drug companies in the world.

One thing that I've noticed is that in the time that you were at Eli Lilly, insulin prices increased dramatically. I think, in fact, one of your insulin products saw a price increase of about 325 percent between 2010 and 2015. Is that right?

Secretary AZAR. I don't have the data on that. But drug prices, insulin prices and all drug prices, have gone up quite substantially. That's the problem we're dealing with today, to try to reverse the—

Senator SMITH. I'll make sure that we send you that data, because I think it's really relevant here and relevant to my constituents.

After coming out of the pharmaceutical industry—and also, as I understand it, the lead White House staffer on this also came out of the pharmaceutical industry—we have this proposal here which we are being asked to believe is a bold plan to lower drug costs. But I'm skeptical about this for a lot of reasons.

One, in particular, is that right after the President's speech and the release of the drug plan, pharmaceutical stocks soared. The Wall Street Journal posted an article saying Trump's plan to cut drug prices leaves the industry relieved. The Investor's Business Daily wrote "biopharma stocks fly as Trump's speech seen as more bark than bite."

Secretary Azar, can you explain that? Why would stock prices go up if this plan was going to take a meaningful bite—meaningful reform?

Secretary AZAR. If I could predict the stock market, I would be Warren Buffet. All 11 S&P sectors went up that day. So it's unclear what happened that day in terms of the stock market.

But let me be really clear. If you're a drug company, a PBM, or a distributor, or anyone else in this channel, and you think you're untouched, not going to be touched, and aren't going to have to completely change your business model, you cannot read, you cannot listen. This will change. We are tackling this, and we have a firm commitment to do so.

Senator SMITH. Well, you know, I have an MBA. I don't think you have to have an MBA to know that when stock prices go up, it's usually because investors think that their profits are going to go up, and it just causes me real concern.

Another question—and this is getting to something that I'm very concerned about. Do you know how much the pharmaceutical industry has spent on lobbying just since the Trump Administration took office in January?

Secretary AZAR. Well, they spend hundreds of millions of dollars a year, every year, whether President Obama is president or any other president. That is what they do, and I say save your money, because I'm being really clear publicly—

Senator SMITH. Three hundred and sixty million dollars.

Secretary AZAR. What we're going to do is really clear. Save your money on lobbyists, because there's no secret what we're about.

Senator SMITH. The challenge that I have, Secretary, is that my constituents look at this. They look at stock prices going up, they look at lobbying costs, and they feel like the drug companies and not people are at the center of this problem that we have and at the center also of what's been proposed. I feel like we need significant accountability right now.

I want to just tell you one story, Mr. Secretary, about a Minnesotan named Nicole. Her son named Alec passed away last year because he couldn't afford his insulin. He went off of his parents' insurance, and he rationed his insulin. Nobody realized he was doing it until it was too late. The price of insulin was going to be roughly, according to his mom, 80 percent of his take home salary.

In the 1960's, insulin was cheaper than shampoo, but that's not the case now. I mean, I say this because I feel so strongly that we need immediate action to address this, and my colleagues and I have been working on solutions to do this, including, as Senator Kaine and others have talked about, allowing negotiations, allowing Medicare to negotiate prices, more price competition for generics and biosimilars—end some of this anti-competitive behavior that allows for collusion around pricing and pated delay.

I know there's some mention of this in the President's proposal, and I have a bill with others to advance that. I'd love to have some Republican support for this bill—and better information for consumers and providers so they know about effectiveness and price. I want to work with you on this, but I am deeply concerned about the lack of accountability in the system as a whole and also in the President's proposals, and I think we really need more.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Smith.

Senator Paul.

Senator PAUL. Thank you for coming today, and I appreciate your enthusiasm toward trying to fix these problems that are admittedly very complicated and longstanding. I think both sides

have talked some about the rebate system and it being opaque and nobody quite understands it and nobody can figure out the thousands of different prices that we have out there, and some have talked about maybe legislatively should we just ban rebates or should we do it through the anti-kickback statutes.

I guess my question is that some of this—Dr. Gottlieb wrote many years ago and other folks have written and said that the 1996 lawsuit by the pharmacies against big pharma got rid of the discount system, and so a way of getting around the rebate system is not a natural occurrence in the marketplace. It's getting around a court case that prevented discounts, which are a market phenomenon.

My question is: If we either ban rebates and don't allow discounts, could we be worse off? And I guess that's a question of whether we do it regulatory or through legislation. Could we be worse off by banning rebates if we don't allow discounts?

Secretary AZAR. What we would do is allow fixed price discounting so that the contracts—and they're actually in Part D. There's at least one PBM that does this, where they frame them not as a percent of list price but just here's what we'll pay for your drug, and having that be a fixed price. So I think we need to—

Senator PAUL. Based on volume, people can still—

Secretary AZAR. Absolutely, because otherwise it'll cost more money for patients in the system. We have to allow that negotiation and discounting, absolutely, Senator. You're right.

Senator PAUL. I guess the question—since big pharma was involved with a settlement, and they're still, I guess, bound by that settlement, you could look at the anti-kickback statutes in a regulatory fashion for either Part D or for everyone. But can you, through regulation, actually change a legal settlement?

Secretary AZAR. I don't mean to differ with Commissioner Gottlieb's former statements, but the genesis of the rebate system is the rebate safe harbor, and I don't believe that anything in that gets in our way.

Senator PAUL. Just legislation or regulation.

Secretary AZAR. I believe by regulation we could get at it, but we would welcome working with Congress for greater clarity and a thoughtful democratic process also.

Senator PAUL. There's another piece of legislation—there's a lot floating around on how to try to fix bits and pieces of all this—called the CREATES Act, and this addresses the issue where big pharma is using a system called the risk evaluation and mitigation strategies to sort of not turn over samples. We could fix that legislatively. Is there also a regulatory way that you could look at that as well?

Secretary AZAR. There is, and that's exactly the kind of gaming that we've been talking about getting after. So we've already announced—Commissioner Gottlieb announced that companies that have been accused of gaming the REMS system by generic companies to block that. We've put out—I think it was last week—two guidances making clear how these REMS, the risk management programs, cannot and should not be interpreted to stand in the way of sample availability to generic and biosimilar companies. So very supportive there.

Senator PAUL. Because in some ways, the regulatory way, if you're allowed to do it, might be better. You know, big pharma complains, oh, we're just going to have all these lawsuits, and they've got lots of lawyers. They may well resist the CREATES Act, even if it were to pass. The regulatory way might even be better if we just prevent big pharma from gaming the system through the REMS, which I don't think it was intended to be used that way—

Secretary AZAR. No, it wasn't.

Senator PAUL.—and it's being used that way, and, really, most people are saying it doesn't have anything to do with safety. So I'd appreciate it if you'll look at that, and, also, I'm with you on the anti-kickback. I'm just not—I still think some of that comes from that settlement, and we have to decide—people want discounts for Medicare. We want to use our bulk purchasing somehow to get discounts, but we have to acknowledge that discounts are a function of the marketplace. So if we were to allow association health plans and—I work at McDonald's, but my McDonald's is now part of 15 million people that are a group, I'm going to get a discount.

Secretary AZAR. Get a better deal.

Senator PAUL. Yes, and so what it does is it drives people to join groups. Right now, you get those discounts if you work for a large corporation. Your health insurance is good stuff and a cheaper price, and your drugs typically are, too. If we can individuals into that, we go a long way toward fixing the problem of a guy who—or a woman who works for themselves and the prices are going through the roof.

I think there are ways to do that, and the Trump Administration is coming out with a rule very soon on association health plans, so I'm hoping that will also help not only with insurance for individuals, but also help with drug pricing.

Thank you.

The CHAIRMAN. Thank you, Senator Paul.

Senator Jones.

Senator JONES. Thank you, Mr. Chairman.

Thank you, Mr. Secretary for being here and also for the call the other day. I know it was not the topic of this conversation today, but I appreciate your discussion with me on the wage index, which is just drastically affecting Alabama and is one of my top priorities, and I look forward to continuing to work with you on that.

Mr. Secretary, one of the advantages of kind of being last or close to it in these is you get to hear some really great questions, but don't always get to the answers. I'd like to go back real quick to what Senator Kaine was talking about, about the best pricing and the fact that we've got European countries that are lower. We're paying a lot more. And the question which he asked at the end, which you didn't get a chance to answer, is why not do a pilot program? There's a lot of this in this plan, which I agree.

One of the things I've seen in my short time here is just the inertia, that it takes so long for anything to happen in Congress or the Federal Government. Why not during this time when we're talking about rebates and all of these things—why not do a pilot program on the drug that Senator Kaine asked you about so that we can see the actual instead of just listening to stakeholders, wring their

hands about it. Let's get out there and do some work and see what we can do. How would that work?

Secretary AZAR. I'm happy to look at that idea. The issue that I didn't get to talk fully with Senator Kaine about there is if the companies pull out—let's take a drug, and if they pull out of Europe and Canada, say, as a result, because then there's no reference price to set it with, they'll lose the profit they do make there, and they'll continue to jack up their price here. So perversely, we can end up paying more for the drug, and then the Europeans could try to use tools like socialist compulsory licensing to actually expropriate the product and get the product even cheaper.

Oddly, we could move to a world where they pay even less than they're currently underpaying, and we end up getting stuck with paying even more for patient access. But I'm happy to talk with you all about that and think if there's solutions there.

Senator JONES. I mean, the operative word there is could. The opposite is also true. This all could work really well for the United States. So I guess the point is why don't we give it a real-world trial instead of talking theoretical and listening to the academics and the bureaucrats in the department talk about the theoretically possible. Take one or two and let's see what in the real world works and what doesn't. Why can't we do that?

Secretary AZAR. I'm happy to talk with you about that. The big issue is if we were to try something there, does it actually create a problem for patients here in the United States in terms of access or create a precedent that in the international community we would have hung over our head for the rest of time. That's the worry.

Senator JONES. Of course, if it does, we can always stop it and say it didn't work. I know a lot of times, we're reluctant to admit we're wrong, but we could just stop it. Right?

Secretary AZAR. If it hasn't done irreparable harm. That's one of the issues I'd want to work with you on.

Senator JONES. Fair enough. Senator Murray was also talking about the companies that game the system and trying to file lawsuits and getting changed, and we didn't get a chance to talk about that. It was a minute and a half long question that I won't repeat. But I would like to talk about what can be done right now to stop the gaming of the system by these companies so that we can get these generic drugs to market faster. What can you do? What would you like to see us do really quickly?

Secretary AZAR. One of the things Congress could do right away would be to pass the proposal in the budget on ending the 180-day gaming that generic companies, often in collusion with big pharma on the branded side—they sit on their right to have the first 6 months as a generic exclusive to them. If they don't launch, the clock never starts, and so we want the authority to, once another generic is available to be approved, let that clock start running and roll. That would take legislation, but I'd love to work with you on that.

For us, we're going after the REMS programs, as I just told Senator Paul, these risk management programs that are used as a phony shield by drug companies to keep away from access to samples. We're administratively going after that, and if—open door. If

there are examples of branded companies evergreening patents and practices—I'm not—we are not the head of IP, but I want to know about those, know your diagnosis, and be able to work with the folks in Congress or in the Administration around this to see if we can tackle any instances of gaming that you all are aware of that we can work together on. We want to tackle those together.

Senator JONES. Right. A lot of these prescription drug plans—your plan asks a lot of questions, and you're seeking feedback. What's going to happen after the 60-day period? How soon can we expect you to start, after a study, implementing some of these proposals?

Secretary AZAR. We're actually working on several already even while we ask for input. We want to get that input. We want to make sure that—listen, I think that there's a healthy benefit to us having an open dialog when impacting such a major segment of our economy and patients at the center. It is very complex. As much as I know, I don't want to make missteps here that could harm patients or patient access.

That's why I want to be—my style—I hope you've seen it in our interactions—is to try to be open-minded, thoughtful, and get as much input as possible. So, frankly, the asking of questions reflects my personal style of approaching this, but then we are going to be moving as quickly, as humanly—and from the legal perspective, regulatory—possible to drive ahead on any of these agenda items.

Senator JONES. Thank you, Mr. Secretary. I would say real quickly I've also had an opportunity to meet with Dr. Gottlieb and appreciate that he is also being very aggressive in this, and I appreciate that.

The CHAIRMAN. Thank you, Senator Jones.

Senator Young.

Senator YOUNG. Thank you, Secretary Azar. I appreciate your presence here today and your thoughtfulness as you've responded to so many wide-ranging questions. There's been quite a bit of emphasis here today, and I think appropriately, on how the U.S. spends more for prescription drugs than other industrialized countries. I'd like to ask you a series of questions. My expectation is they'll require short responses, and then I have another topic I'd like to turn to, and I'm just going to give you the floor on that.

With respect to the first question on foreign pricing versus U.S. pricing, Europe and other wealthy countries—they set their drug prices by governments as opposed to pharmaceutical companies. Is that correct?

Secretary AZAR. That's correct, and then there's no choice for the patient. They're not at all at the center of that decision making. That's correct.

Senator YOUNG. Do you agree that every time one country demands a lower benchmark or reference price, it leads to a lower reference price used by other countries?

Secretary AZAR. It does, and that's why pharma companies are very careful about which countries they will launch their drugs in or not launch in because of those systems.

Senator YOUNG. Are U.S. patients and innovators, Mr. Secretary, shouldering the burden for financing medical advances around the world?

Secretary AZAR. We pay too much and they pay too little, absolutely.

Senator YOUNG. Do you think we could or should use trade agreements to help level the playing field with foreign countries?

Secretary AZAR. We absolutely believe we should be using our trade agreements to get them to pay more, even as we have our job to pay less.

Senator YOUNG. Okay. Now the broad question. Mr. Secretary, what can payers and employers be doing now to lower drug prices?

Secretary AZAR. I mentioned to Senator Warren, we've had several drug companies come in who want to execute substantial, material reductions in their drug prices. They are finding hurdles from pharmacy benefit managers and distributors that I think will get worked out—I really do—but they're based on list price, where they might say, well, if you decrease your list price, I will take you off formulary, compared to your competitor who will have a higher list price where I will make more money. I find that unconscionable. I would hope that if that were to—if we were to find ourselves in that situation that the CEOs of those companies would find themselves sitting in this chair rather quickly to explain themselves.

I think employers and payer customers of PBMs, those pharmacy benefit managers, should be asking their PBMs right now, "Have you received any commitments of lower list prices, and what have you done? Why have you not passed those on to us, and are you pushing back on drug companies, saying that you would actually prefer higher list drug prices?" I think the employers and the plans can do that.

There's a player in this market that's these benefit consultants. The way this works is they pitch on the big employers, the big companies, these health benefit plans that guarantee a flow of rebates. It's not based on the lowest net price. It's based on a cash-flow of rebates. And I think that system will work its way out. I think that the first couple of drug companies that reduce price, this whole system will flip on its head and have to be redone. I think as adults, they'll figure that out.

But right now, that's the biggest hurdle holding things back. It's going to break. Somebody's going to do it, and if I were a drug company executive, I wouldn't want to be beaten by my competitor over that line, because the first to do—the first companies to do this are going to win.

Senator YOUNG. Continuing with the topic of rebates, there's been a lot of discussion about the role rebates play in drug pricing in this hearing. I understand some manufacturers engage in a contracting practice called the rebate wall. A rebate wall occurs when an established manufacturer with significant market share uses rebates and discounts to block formulary access to competitor products. In the most egregious cases, a manufacturer with established product volume across multiple therapeutic areas will threaten to cut discounts and rebates to a PBM if its product is not the preferred agent within a class.

Mr. Azar, is HHS aware of rebate walls, and if yes, what types of actions would HHS consider to limit the use of rebate walls?

Secretary AZAR. We are and I am very much aware of these rebate walls that can prevent competition and new entrance into the system. That is yet again a reason why I think we need to get at this question of rebates in the PBM world. These are drug companies. I don't like that practice. I think it's using their market power in a way that is not appropriate. So I want to make sure we're looking at that. I think Congress certainly could look at that question as part of this whole initiative.

That's where Senator Isakson's question about indication-based pricing can be helpful, because sometimes that's a company that has a drug with many indications, and they use it as leverage over drugs that have a single indication.

Senator YOUNG. Thank you.

The CHAIRMAN. Thank you, Senator Young.

Senator Casey.

Senator CASEY. Thank you, Mr. Chairman and Ranking Member.

Thank you, Mr. Secretary. I know you've been through a number of these issues in the course of the hearing, but I want to raise one that I'm not sure we talked about directly, the question of price clarity. As you know—and I believe this is not addressed in the Blueprint—when someone goes to fill a prescription for the first time, they often don't have a sense of their own cost, their out-of-pocket cost, and often the physician has no easy way to check when they're writing the prescription. The consumer obviously doesn't know the price of the drug and whether it's subject to any kind of co-insurance or co-pay.

Without this information, providers might write a prescription for a particular drug that the patient can't afford, even if there's a cheaper alternative. That may lead to the patient not, in fact, getting the prescription they need. So my question is: Outside of the context of Medicare, Medicaid, what specific proposal in the Administration's Blueprint would have the most immediate impact on out-of-pocket cost transparency for consumers in the commercial market?

Secretary AZAR. I'm so glad you raised that. We 100 percent agree about the need for patient transparency on out-of-pocket expense both at the point of prescribing and when you go to the pharmacy. One of the things we raised in the Blueprint is we'd like to get to a system where when you're with your doctor, you actually have the right to be told what your out-of-pocket would be for the drug that that doctor is writing as well as for competing products.

That comes into play—for me, it's—I run HHS. This is Medicare where I have that power to regulate more. I'm happy to work with Congress more broadly on anything that would impact the commercial sector here in terms of the patient's right to transparency and knowledge at the point of sale.

You can have a doctor who's writing a Part B drug, which is an infusion drug, and have an infusion clinic in their office and, obviously, making money from that. But the patient would pay less out-of-pocket if they wrote a Part D drug that they got at the pharmacy and self-administered, and the patient doesn't know that. I think that's fundamentally unfair, and the patient ought to be in the driver's seat and have that information.

I think you've raised a very important issue. It's in the Blueprint. We want to work—it's very complex to solve. We want to work with you on that.

Senator CASEY. Is it your belief that that would require specific statutory change?

Secretary AZAR. I think that a more broad solution here would, in fact, benefit from Congress acting, certainly anything that would reach the private sector and not interactions with the Medicare program, yes.

Senator CASEY. Certainly we'd look forward to working with you and the Administration on that.

Secretary AZAR. Thank you.

Senator CASEY. I think it's so fundamental to people's lives now when they get hammered by a cost that they had no notice about or no information on.

The last thing—I know we're wrapping up, but I'll just conclude with this, more in the form of a statement than a question. I hope that you and the Administration would rethink what the position was in litigation last week with regard to preexisting conditions. I don't know of any American who wants to go back to those days when you could be denied coverage or treatment because of a pre-existing condition.

I hope it's your position that we're going to ensure that going forward, no matter what, no matter who's in power, no matter who is in charge of HHS, or no matter who is in the Administration, that we can have that guarantee that any American with a pre-existing condition will be given the protections that they have in the Affordable Care Act. I think if that's not the position of the Administration, I think the opposition from people like me will be unyielding, and I think that's true of folks in both parties.

I hope you take that back to the Administration if they don't—have not heard that message already, and I hope that would be your position and that of the Administration.

Secretary AZAR. We do believe in finding solutions on the issue of preexisting conditions and affordable insurance for individuals with it. So we look forward to working with you regardless of the litigation, but if there are any legislative packages that would say alternatives to the Affordable Care Act, modifications to the Affordable Care Act—we share the goal of affordable access to insurance for individuals with preexisting conditions.

Senator CASEY. Well, I know we're done, but I just hope you take it off the table and say you're going to guarantee it.

Thank you.

The CHAIRMAN. Thank you, Senator Casey.

Senator Baldwin.

Senator BALDWIN. Thank you, Mr. Chairman and Ranking Member.

I want to talk about real transparency. I think the evidence is pretty clear that brand name drug corporations continue to jack up the cost of prescription drug prices. In fact, HHS's own inspector general recently found that even though seniors used fewer brand name drugs over 5 years, Medicare spending using taxpayer dollars on branded drugs increased by more than 62 percent because of increasing manufacturer prices.

Your recent prescription drug pricing plan promises to lower prices and even says the word, transparency, frequently throughout the Blueprint. At a recent hearing, you promised me that this plan would hold drug makers accountable for these price increases, but I haven't been able to find where your plan actually does this, where it holds drug corporations accountable to explain why they continue to raise drug prices. As you know, this is exactly what my bipartisan Fair Drug Pricing Act would do.

I'm puzzled why you failed to include the Fair Drug Pricing Act within this Blueprint going forward, because it would require companies to disclose and explain price hikes. Do you support the Fair Drug Pricing Act?

Secretary AZAR. We don't have an Administration position on that particular piece of legislation but are working with you. I just, in fact, responded to a request today, as the hearing was about to start, around that to your office.

We actually—on the issue of drug pricing and list pricing and holding them accountable, that's exactly why we want to in Part B put an inflation penalty on increases of drug pricing in Part B that would actually create for the first time ever a penalty for increasing your price in Part B for drugs, and we want to remove the cap that was put in the Affordable Care Act on the inflation penalty for drugs in Part D—so real financial penalties on price increases.

We actually are committed around this, and on transparency, we're happy to keep working with you on efforts to bring greater transparency. We've done the CMS dashboard, which for the first time ever had increases in it.

Senator BALDWIN. We've talked about this in this hearing so far, the Medicare dashboard and the prices being revealed in direct-to-consumer advertising, but those do nothing to require companies to show or explain why they are increasing their prices.

I want to ask an additional question. Before I do, I want to just associate myself with the many Senators who have raised the issue of the Trump position on litigation regarding coverage for people with preexisting conditions. I can think of nothing more anxiety provoking and harmful to the people that I represent.

I also want to associate myself with Senators who requested additional information of why there's no focus on naloxone and Trump's own opioid commission recommending that you have the authority to negotiate over that. This is costing taxpayers in my state through the roof because we want to make sure that every first responder has opioid overdose reversal drugs.

But the question I want to ask in my remaining time relates to this transparency issue and a topic that we haven't talked about really yet. Over the last decade, the number of pharmaceutical company executives among the top 500 highest paid in the United States has steadily increased, as has the portion of their total compensation received in the form of stock, now at 84 percent. Drug corporations have announced more than \$50 billion in stock buy-backs since partisan tax legislation became law last year, enriching executives as prescription drug prices continue to rise.

I have legislation, the Reward Work Act, that would put a stop to this by banning these corporate stock buy-backs in most contexts

and giving workers a voice in how corporate profits are spent. I would note that recently, the S&P 500 pharmaceutical corporations have spent 99 percent of net profits on dividends or stock buy-backs.

Do you think it is wrong that pharmaceutical corporations are using money from the corporate tax breaks to buy back their own stock and enrich their executives and wealthy stockholders while families in Wisconsin—

The CHAIRMAN. Thank you, Senator—

Senator BALDWIN. I'll finish the question—in Wisconsin continue to face increasing prescription drug prices?

The CHAIRMAN. Mr. Secretary, as we have with other Senators, if you could reply to the Senator in writing, we would appreciate that.

The CHAIRMAN. Thank you, Senator Baldwin.

Senator Sanders.

Senator SANDERS. Thank you, Mr. Chairman, and my apologies for being here late. I had to be on the floor.

Thanks, Mr. Azar, for being with us. Mr. Azar, as I understand it, about one out of five people in this country, unbelievably, cannot afford the medicine their doctors prescribe to them. Have you guys done a study yet as to how many thousands of people die each year because we pay by far the highest prices in the world for prescription drugs? Would you guess 5,000, 10,000 people die?

Secretary AZAR. I haven't seen a study on that question, but we all agree that drug prices are too high and out-of-pocket expenses are too high.

Senator SANDERS. If you do a study for me, and if—my guess would be that if we get letters—and I'm sure every Senator does—from people who are struggling with cancer among other life threatening diseases, they can't afford the medicine. I would guess that thousands of people die each year. Do you think that's something you might want to look at?

Secretary AZAR. I don't think it would change our commitment to fix this issue. We are firmly—

Senator SANDERS. It wouldn't? Thousands of people are—

Secretary AZAR. Because we—

Senator SANDERS. You are firmly—Okay.

Secretary AZAR. Because we are firmly committed to do something about pricing—

Senator SANDERS. Oh, I know you are.

Secretary AZAR.—and out-of-pocket costs—

Senator SANDERS. Oh, I know you are firmly—

Secretary AZAR.—and nothing will change the firmness of that commitment.

Senator SANDERS. I know how firmly convinced you are to lower prices, and maybe you could tell us why it is that major drug after major drug in the United States is a fraction of the cost in Canada or in Europe. Do you really think, as the President does, that raising prices on people abroad is going to help working people in this country afford the medicine they desperately need?

Secretary AZAR. Actually, that would be a misstatement of the President's proposal, which is that we need to decrease what we pay here and they need to increase their share of what they pay.

They're not necessarily directly tied—we have our own obligation to change our programs and our work to ensure we pay less—

Senator SANDERS. Why would the people of Canada, who pay the second highest prices in the world for drugs, or the people of Europe, want to pay more? My guess is that they would want to pay less, especially when in the last 5 years, the five most successful drug companies in the world made \$50 billion in profit, and, as Senator Baldwin said, they pay their CEOs exorbitant prices. So I would ask you that maybe we should learn something from countries around the world that are negotiating drug prices and lowering prices rather than demanding that countries around the world pay higher prices, which, by the way, I don't think they would.

I don't have a lot of time, so let me just ask you another question. During his campaign for president, President Trump, now President Trump, made a lot of statements to the American people which turned out to be lies. He didn't keep his word on those promises. He told the American people during his campaign that he would allow consumers access to, quote, "imported, safe, and dependable drugs from overseas," end of quote. This is an issue that has had bipartisan support for a whole lot of years right here.

You have Canada 50 miles away from where I live. We have free trade all over the world. Trump, during the campaign, said he wanted to support importation of safe FDA-approved drugs from abroad. Why has he changed his mind on that, do you think?

Secretary AZAR. He hasn't changed his mind at all, and as you even said, he supports—we support, if it could be done safely. We will never jeopardize American patients' safety—

Senator SANDERS. Well, that's what every administration has—of course, we all—

Secretary AZAR. Democrat and Republican have—

Senator SANDERS. You're absolutely correct, and maybe that has something to do with the fact that over the last 20 years, the pharmaceutical industry has put \$4 billion into lobbying and campaign contributions, which, as you indicate, has hit both political parties. The bottom line is you do not believe—tell me that you do not believe that we can import safe, lower cost prescription drugs from Canada.

Secretary AZAR. One would have to actually wire the safe—and the Canadian system has a safe Canadian drug distribution system internally for Canadians. You would have to wire that system into the American safe drug distribution system without any leakage or opportunity for invasion into that. I've actually even addressed this with the Canadian health minister. The Canadians and others would have very little interest to do that, because the minute you do that and we import, the supply would get cutoff and Canadians will be without drugs because we'll suck up all their drugs.

Senator SANDERS. Well, I just have a hard time—you're going to go out to lunch, and I guess you can have some salad, and maybe the lettuce comes from Mexico. I always have a hard time understanding how we can "safely," quote, unquote, import fish, poultry from all over the world, yet somehow from a highly developed country on our border, we cannot figure out a way to bring those products back into this country.

The President also told us during his campaign that he would have Medicare, not the private sector, negotiate for lower drug prices. As you know, the Veterans Administration pays the lowest prices in the country for prescription drugs. Medicare pays a lot more. Why did the President go back on that promise as well to negotiate—have the Federal Government—Medicare negotiate drug prices?

Secretary AZAR. The VA is a very unique system. In fact, 74 percent of our veterans have supplemental drug coverage. So it really requires looking at that imbalance. It's quite a unique system that's not necessarily applicable to our seniors.

Senator SANDERS. Thank you.

The CHAIRMAN. Thank you, Senator Sanders.

Senator Murray, would you have any closing comments or questions?

Senator MURRAY. Well, I recognize, Mr. Secretary, that you need to go. But I just want to thank you for being here today to talk about this.

I do have to say again, reviewing this Blueprint, I am disappointed. President Trump abandoned his campaign promise to negotiate lower prices through Medicare. That idea would have a real impact to lower drug prices for patients, and I'm going to keep pushing it. I know many others will.

But at the end of the day, we need a really serious plan. It has to bring drug prices lower than our patients and families actually see. I know you're now seeking comments from stakeholders. I'm interested to hear what they have to say, but it is time for action. We know what the major problems are: companies setting high list prices, no negotiating authority in Medicare Part D, and patents taken out solely to build legal fortresses around products to thwart competition for decades.

I want you to know Democrats are at the table. We take this issue extremely serious. We have a lot of ideas. We're going to keep talking about them, and I hope the Administration is serious about listening to our ideas and incorporating them.

Finally, I do want to add my voice to those who expressed their concerns about defending critical protections for women and patients with preexisting conditions in Federal court. I was astonished that the Administration is not doing that. Millions of Americans are counting on their ability to buy insurance when they have a preexisting condition. This is about cost. It's about access. It's about family security. Millions of Americans stood up over the last year and a half and said, "Don't take this away." So I just add my voice and say I'm appalled that the Administration has decided not to defend this, and I hope that they reconsider, and I hope you take that message back.

The CHAIRMAN. Thank you, Senator Murray.

Mr. Secretary, I thank you for coming. I think the Senators have been vigorous and succinct, which is unusual for—the latter part is unusual for Senators, and I thank Senator Murray for helping do that.

You are, in my opinion, a very knowledgeable secretary of a very complex and difficult department. I think it helps to have a secretary who is so thoroughly versed on the issues. I believe your

Blueprint is promising, even though you heard from our Committee that we're a Committee with many different points of view and sometimes very different points of view among ourselves.

There are a number of items in your Blueprint that Democratic Members of this Committee have advanced and a number that Republican Members have advanced. Senator Enzi likes to say that sometimes we can focus on the 80 percent we agree on and leave the 20 percent for another day, and I think Senator Murray and I have shown we're able to do that, even on difficult issues. So we'll continue our discussion on drug prices with you.

You've talked about gag clauses. The issue of rebates could be very important, blocking generic drugs, how list prices seem to benefit everybody but the consumer, more negotiating in some cases. Perhaps there are some areas that we can agree on in the Committee, which would get us off to a first-step fast start on helping to deal with reducing drug prices. I'll talk with Senator Murray about that, and we'll see if that's possible. In the meantime, we'll work with you and the Department toward the goal of making drug prices lower for American consumers.

The hearing record will remain open for 10 days. Members may submit additional information for the record within that time if they would like. The HELP Committee will meet again on Tuesday, June 19, at 10 a.m. on the 340 drug pricing program.

Thank you for being here today. The Committee will stand adjourned.

[Whereupon, at 12:01 p.m., the hearing was adjourned.]