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THE COMPLEX WEB OF PRESCRIPTION DRUG PRICES, PART III: EXAMINING AGENCY EFFORTS TO FURTHER COMPETITION AND INCREASE AFFORDABILITY

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BEFORE THE

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THE COMPLEX WEB OF PRESCRIPTION DRUG PRICES, PART III: EXAMINING AGENCY EFFORTS TO FURTHER COMPETITION AND INCREASE AFFORDABILITY

WEDNESDAY, JUNE 19, 2019

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, DC.

The Committee met, pursuant to notice, at 9 a.m., in Room 562, Dirksen Senate Office Building, Hon. Susan M. Collins, Chairman of the Committee, presiding.

Present: Senators Collins, Tim Scott, McSally, Braun, Rick Scott, Casey, Blumenthal, and Jones.

Also present: Senator Shaheen.

OPENING STATEMENT OF SENATOR SUSAN M. COLLINS, CHAIRMAN

The CHAIRMAN. The Committee will come to order.

Good morning. Today we are holding the third in our current series of hearings on the complex web of prescription drug prices. We will feature witnesses from the Food and Drug Administration, better known as the FDA, the Centers for Medicare and Medicaid Services, CMS, and the Office of the Inspector General at the Department of Health and Human Services.

Since 2015, our Committee has held eight hearings on drug pricing and the issue that I believe bridges the partisan divide. According to the Kaiser Family Foundation, nearly 7 in 10 Americans say that lowering prescription drug prices should be a top priority for Congress. As those who have followed our Committee's work on drug pricing know, we have highlighted example after example of patients who feel powerless when confronted with sky-high drug costs, and go to extraordinary lengths to cover the costs of their medications.

In the interest of time this morning, I am only going to list one of those examples, but I will be putting others into the record as part of my full opening statement.

At last year's hearing on the spike in insulin costs, we learned how rebates and the complicated supply chain create pricing distortions, particularly for those with high-deductible health plans.

We heard from Paul Grant, a father of four, who lives in New Gloucester, Maine, who discovered 1 day that the cost of a 90-day supply of insulin for his 13-year-old son with type 1 diabetes had

tripled overnight to more than $900. He had to resort to importing much lower-cost insulin from Canada, with no help from his insurance company.

This is typical of stories that we have heard from across the country, and the American people are clamoring for action.

While much more needs to be done, we have met with some successes. Following this Committee's year-long investigation into dramatic price spikes, in decades-old prescription drugs, I co-authorized a bipartisan bill with former Senator Claire McCaskill, to promote more competition from lower-priced but equally effective generic drugs. This bill was signed into law in 2017 and it appears to be showing results. To date, FDA has granted more than 100 application requests under this new pathway, with five approvals.

In 2018, I authored another bipartisan bill banning pharmacy gag clauses, contract provisions that prevent pharmacists from informing consumers how to get the lowest price for their prescriptions. It became law, and a recent study published by the Journal of American Medical Association suggests that banning gag clauses could help Americans save money in nearly 1 out of 4 prescription transactions.

Throughout our deliberations, I have emphasized that we want to keep strong incentives for innovation, so that companies continue to invest in research and development and take the risks necessary to develop innovative drugs, but we must do more to ensure that these essential medicines are more affordable, that their prices are more transparent, and that their competitors are not blocked once their patents have expired by gaining of the patent system.

While past hearings have focused on the root causes behind escalating prices, today we will focus on some potential solutions. The timing is fortuitous, as House and Senate Committees are acting on a variety of proposals, including our bill to prevent patent gaming strategies and other approaches that delay generic or biosimilar competition, legislation to establish more price transparency, and measures to address out-of-pocket costs under Medicare Part D.

Members of this Committee have been working hard on a number of promising ideas. I have introduced, along with Senator Tim Kaine, the Biological Transparency Act that would require companies to publicly disclose the web of patents that protect their biologics, making it easier for competitors to evaluate and plan for the development of generic versions, as well as to discourage late-filed patents.

I am pleased that on this Committee, Senators Braun and Hawley are co-sponsors, as well as Senators Kaine, Portman, Shaheen, Stabenow, Paul, and Murkowski, who serve on other committee. Ranking Member Casey and I have partnered on legislation that he has introduced to codify the CMS drug pricing dashboards, to provide consumers with more information about out-of-pocket costs. Senator Rick Scott and I are working on legislation that creates a data base of drug prices and aggregate manufacturer rebates, as well as justifications for any price increases.

One thing is certain: our drug pricing system is opaque and rife with misaligned incentives. In order to untangle patients from this complex web and bring them the relief they need without damp-

ening R&D that produces life-saving new drugs, we need to work together, and that has been the spirit of this Committee.

I am now pleased to turn to the Ranking Member, Senator Casey, for his opening remarks.

OPENING STATEMENT OF SENATOR ROBERT P. CASEY, JR., RANKING MEMBER

Senator CASEY. Chairman Collins, thank you very much for holding this hearing on the rising cost of prescription drugs. We hear about it all the time, all across the country.

With current prices, Americans are being asked to pay for their prescription drugs. Many find themselves asking, how can I make ends meet? Over and over again they ask themselves that question. That is because the rising cost of prescription drugs is not in isolation. It is part of a larger challenge many Americans face.

With flat wages over many years, and high costs, the cost of prescription drugs is like a bag of rocks on the shoulders of most families. The other heavy bags of rocks on those same shoulders are the cost of child care, the cost of health care, the cost of college, and that is just to name a few.

People are paying more for child care costs, and that is crushing for many families. Just as they are starting a family, that bag of rocks is dropped on their back. Then, as someone who is trying to make life better for the next generation through higher education, the cost of college increases. That is another bag of rocks. Third, just as someone is about to enter their golden years and have a secure retirement, or they hope for a secure retirement, the cost of prescription drugs skyrockets.

These costs, to say the least, can be crushing. That is what we heard from Barbara Cisek from Rural Ridge, Pennsylvania, and other witnesses from across the country who testified before this Committee earlier this year. The need to make prescription drugs more affordable has never been more urgent.

We will have a chance to highlight proposals under consideration in Congress, including one that Chairman Collins and I are working on, to bring greater transparency to drug pricing through the Medicare and Medicaid prescription drug dashboards.

I hope we will have a chance to discuss one of my key priorities, a policy supported by 95 percent of the American people, which is to finally—finally—allow Medicare to directly negotiate the price of prescription drugs. While we hear a litany of Medicare proposals made by the Administration today, I note that not a single one of those proposals, so far, permit Medicare to use its full purchasing power to bring down the cost of prescription drugs.

Indeed, it's our sacred responsibility to our aging loved ones, as well as our children and their children, that they are not forced to shoulder the crushing bag of rocks that prescription drug costs have become.

I want to thank the Chairman again for scheduling this hearing about the rising cost of prescription drugs, and I look forward, as I know we all do, to getting some solutions signed into law. Thank you.

The CHAIRMAN. Thank you very much, Senator Casey. I want to welcome Senator Jones and Senator Scott to the hearing as well.

Our first witness today will be Demetrios Kouzoukas, the Principal Deputy Administrator and Director of the Center for Medicare, at the Center for Medicare and Medicaid Services. He will discuss the proposals within the Administration drug pricing blueprint.

Next we will hear from a familiar witness to our Committee deliberations over the years, Dr. Janet Woodcock, Director of the Center for Drug Evaluation and Research at the FDA. Dr. Woodcock first joined the Center in 1994, and in 2015 was appointed to be Acting Director of its Office on Pharmaceutical Quality. Her testimony today will focus on actions the FDA has taken to improve competition in the biosimilar and generic drug marketplaces.

Finally, we will hear from Vicki Robinson, the Senior Counselor for Policy at the Department of Health and Human Services, Office of the Inspector General. She will discuss the Administration's proposed rebate rule and specifically the anti-kickback statute.

I want to thank you for joining us and I also want to welcome Senator Shaheen, who while not officially a member of this Committee, is the co-chair of the Diabetes Caucus with me, and has been extremely active in this area, and we have worked together, particularly on the insulin pricing issue, so we are delighted to have her as an honorary member of the Aging Committee today.

Mr. Kouzoukas, we will start with you.

STATEMENT OF DEMETRIOS KOUZOUKAS, PRINCIPAL DEPUTY ADMINISTRATOR AND DIRECTOR OF THE CENTER FOR MEDICARE, CENTER FOR MEDICARE AND MEDICAID SERVICES, WASHINGTON, D.C.

Mr. KOUZOUKAS. Thank you, Chairman Collins.

The CHAIRMAN. I am going to ask you to turn your mic on.

Mr. KOUZOUKAS. There we go. Thank you very much, Chairman Collins, Ranking Member Casey, and other honorable members of this Committee. Thank you very much for the invitation to talk with you today about the critical issue of lowering prescription drug prices in the United States.

I am honored to be here on behalf of the Centers for Medicare and Medicaid Services, where I serve as Principal Deputy Administrator and Director of the Center for Medicare. Thank you, as well, to my esteemed colleagues from the Department. It is an honor to be here alongside them as well.

Prescription drugs are an important part of health care, as we all know. Patients with diseases that scarcely a decade ago had any treatment options now have access to cures that allow them to lead their best lives. However, patients opportunities to access these drugs are ultimately undermined by numerous distortions which can drive the price of these drugs beyond the reach of patients who need them most. This Administration has been diligently working to root out these distortions and correct disincentives to ensure that true competition allows patients to access the drugs at competitive prices.

Earlier this year, the President's Fiscal Year 2020 budget laid out a range of proposals for lowering prescription drug prices, including through reforms to Medicare. Many of the proposals buildupon the President's blueprint, as you called it, that is, the "American Patients First Blueprint to Lower Drug Prices and Re-

duce Out-of-Pocket Costs," released in May 2018. This blueprint constitutes the most aggressive and comprehensive plan of action for decreasing drug prices released by any administration ever. It lays out dozens of possible ways that HHS, including Congress and CMS, can together address this vital issue.

We are already seeing results from the Administration's efforts to lower drug prices. In 2018, drug prices experienced their single largest decline in 46 years. We also know there is more work to be done, and CMS is committed to doing our part to lower prescription drug prices.

Medicare policies can have a wide-reaching impact on health care spending, including prescription drug costs. That is why we are taking steps to unleash innovation, empower patients, and increase transparency across the program.

I would like to take a moment to draw your attention some of the proposals in the President's Fiscal Year 202020 budget request. These are of particularly interest, I hope, to the Committee. There is an opportunity for us to work together.

The President's proposed budget request for Fiscal Year 2020 includes a comprehensive Medicare Part D structural reform package that would lower prescription drug prices in several ways, including by maximizing the incentives for plans to manage benefits and provide beneficiaries with better protection against catastrophic costs through a maximum out-of-pocket cost.

I also want to highlight a few things CMS has already done. Just last month, for example, CMS finalized improvements to Medicare Advantage and Part D, which provides seniors with medical and prescription drug coverage through competing private plans. The policies we finalized will enhance transparency by giving patients greater information on the cost of prescription drugs.

The final rule includes a requirement that Part D plans implement one or more real-time benefit tools, so prescribers can discuss out-of-pocket costs for prescription drugs with patients at the time a prescription is written, in the physician office. By empowering patients with more information on the cost of their prescription drugs, our rule will help ensure that pharmaceutical companies have to compete on the basis of prices for patients.

We are also pleased with the increased transparency that has come about as a result of CMS' drug spending dashboards. These dashboards reflect CMS' efforts to support innovative, data-driven insights to improve the quality, accessibility, and affordability of prescription drugs. The dashboards focus on average spending and change in average spending per dosage unit to allow the public to understand trends in drug spending.

Additionally, CMS is undertaking a comprehensive redesign of the Medicare Plan Finder. We are working to improve the usability of the Plan Finder based on feedback we have been collecting from stakeholders, and we look forward to continuing our collaborations as we move forward with our efforts to modernize this important tool.

Some of the other efforts we have already undertaken and are working on to bring down drug prices include giving patients the opportunity to select from competing plans with a selection of physician-administered drugs more tailored to them, so as to drive bet-

ter deals; putting patients in the driver's seat by helping them engage with plans on the medications they are taking, and what can be done to ensure that the combinations of drugs they are taking are low cost and do not produce negative effects; encouraging biosimilar innovations, by giving each biosimilar its own billing code and lowering biosimilar copays for low-income beneficiaries in Part D; increasing price transparency by presenting data on CMS' average spending per drug dose, and other data insights, and otherwise ensuring that patients know the cost of their drug before they see the doctor or visit the pharmacy; allowing patients to communicate freely with their doctor or pharmacy about the cost of their drug.

While CMS has taken these and many other actions to implement the President's American Patient First Blueprint to combat dramatically rising prescription drug prices, we know we have more to do. As we continue our important work in this area, and hopefully our collaborations with Congress, we remain committed to finding ways to promote innovation and patient empowerment in our programs by facilitating transparency and competition.

We look forward to working with this Committee, our Federal partners, and most of all, with patients, as we continue to evaluate and implement the most effective ways to approach these issues.

Again, thank you for the invitation to speak with you today. I look forward to answering your questions.

The CHAIRMAN. Thank you very much.

Dr. Woodcock, welcome.

STATEMENT OF JANET WOODCOCK, M.D., DIRECTOR OF THE CENTER FOR DRUG EVALUATION AND RESEARCH, FOOD AND DRUG ADMINISTRATION, SILVER SPRING, MARYLAND

Dr. WOODCOCK. Thank you, Madam Chairman, Ranking Member, and members of the Committee. I am very happy to be able to talk to you about this important issue today.

As you know, FDA does not have a direct role in drug pricing, but we play a major role by driving down prices through competition, and the best example of that is our generic drug program, which has really been empowered since Congress passed the Generic Drug User Fee Program, which is now in its second iteration.

Last year, 2018, FDA approved over 1,000 generic drugs. That is a lot of competition, and each year previous had been a record. That was a record and each year previous had been a record, so we are really getting generic drugs out there.

Of these last year, 10 percent were first generic approval, so that is the first time competition had been introduced for this molecules, and 12 percent were for complex generics, where there has been a lot of trouble getting competition for complex products. Perhaps they have an auto-injector, they have a device associated with them, or they have some other complexity, so we are making a lot of progress there.

We can do more. In 2017, we launched the Drug Competition Action Plan for Generics, and that had a whole menu of activities that we were going to do to try and streamline the process, reducing gaming, and get as many generic products that would be legally appropriate out onto the market.

We are taking many steps to promote more competition for complex generics, including helping the companies with developing their drugs. In February alone, we issued 74 product-specific draft guidances, and these guidances were like a cookbook of what you need to do to get a particular generic onto the market, and they explain our expectations of what needs to be done.

We also posted the inaugural list of off-patent, off-exclusivity drugs without an approved generic in June 2017, so that gives industry sight into what is available for competition, where there is no competition at the moment.

In February, we issued draft guidance on the Competitive Generic Therapies Program, that Senator Collins mentioned. My understanding is by now we have designated almost 200, and we are up to around 10 that we have approved. The new guidance on the Complex Generics Program provides robust information on how drug developers can apply for this designation and when they might be eligible for exclusivity based on it.

We are also identifying abuses of the system that can impede competition and doing our part to fix them. We really applaud congressional efforts to remove barriers to drug development and appreciate the work on the CREATES Act, that is looking at access to samples, because generic competitors need access to sample from the innovators in order to make the copies and demonstrate that they are equivalent.

There are several proposals in the 2020 budget from the President that also target possible gaming, including statutory improvements to our citizen petitions process, amending the existing 180-day forfeiture provisions to limit gaming in that space, and prevention of 180-day exclusivity parking, we call it, where companies can get exclusivity and then never launch it.

The way the statute works now—remember, I am not a lawyer—is that you have to market to make that clock start running, and if you make an agreement or something and you do not market then that can go on. You have never launched and the clock never runs.

We look forward to working with your staff on these measures, and we are continuing to coordinate with the Federal Trade Commission, who is a vital partner, in working on anti-competitive issues.

Also, we are building a strong framework for biosimilar competition, which is something that has not been present until Congress passed a statute allowing the pathway. That is really key to facilitating greater innovation and competition in the biologics marketplace.

Biologics are costly. They account for almost 40 percent of the total prescription drug spend and about 70 percent of the growth in spending between 2010 to 2015, and so since 2010, when Congress enacted the Biologics Price Competition and Innovation Act, creating a pathway, we have approved 20 biosimilars, and we hope more are on the way, and there is a robust pathway for more biosimilars to come.

The President's budget recommends a legislative proposal to encourage biosimilar development and innovation and reduced gaming in that space.

In closing, there are a lot of efforts that can be done to reduce gaming, to streamline processes, and to get as much competition on the market as possible, and we believe all these efforts will help to reduce the cost of drugs overall.

Thank you.

The CHAIRMAN. Thank you very much, Doctor.

Ms. Robinson.

STATEMENT OF VICKI L. ROBINSON, SENIOR COUNSELOR FOR POLICY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, WASHINGTON, D.C.

Ms. ROBINSON. Good morning, Chairman Collins, Ranking Member Casey, and other distinguished members of this Committee. Thank you for the invitation to testify about the Department's recent proposed rule, which is one part of the Department's strategy to lower prices and reduce prescription costs for beneficiaries.

We are in active rulemaking, my testimony today is limited to what is in the proposed rule. It is not intended to predict what might be in the final rule.

This morning I want to cover three areas. First, the proposed goals for the rule; second, how the proposed rule meets those goals; and third, the public comments on the proposed rule.

Let me begin with the goals. The Department intends for the proposed rule to help lower drug prices and reduce prescription drug costs for beneficiaries. The proposed rule also aims to improve transparency for beneficiaries about the prices they pay. In addition, the proposed rule aims to address the problem that rebates may be skewing decisions about the placement of drugs on formularies, that is, on the list of drugs covered by the beneficiary's plan.

Today, under the rebate system, manufacturers typically negotiate rebates with insurance companies and pharmacy benefit managers. The rebates reduce the net cost of drugs for the insurance companies, but the rebate does not necessarily help the beneficiary, because it does not reduce what he or she pays at the pharmacy counter.

The proposed rule is intended to shift this dynamic and help move from a system of rebates to one of up-front discounts that lower costs to beneficiaries when they fill their prescription.

Second, let me explain what the proposed rule would do to meet these goals. Currently, the safe harbor regulations under the Federal anti-kickback statute, protect discounts and other reductions in price, including rebates that meet specified conditions.

The proposed rule would make the following changes. It would remove existing discount safe harbor protection for rebates and reductions in price of prescription drugs given by manufacturers to Part D plans and Medicaid managed care organizations. Next, it would add new safe harbor protections for point-of-sale discounts that are completely applied to the price of the prescription drug at the time the pharmacy dispenses it to the beneficiary. Further, the proposal would add new safe harbor protection for manufacturers to pay pharmacy benefit managers fixed fair market value fees for services they provide to the manufacturer.

My written testimony and the proposed rule spell out additional details about these changes.

I will close with observations about the public comments. The proposed rule contains analyses of the potential impact on beneficiaries, plans, and others, by CMS' Office of the Actuary and to independent actuarial firms. We received a range of comments about these analyses.

In addition, we solicited public comments about many other aspects of the proposed rule. In total, we have received and reviewed about 26,000 public comments from a broad spectrum of stakeholders. We received many thoughtful comments and appreciate the engagement of the public in this rulemaking. Comments addressed a range of important topics, from legal issues to policy goals to practical implementation concerns, and comments expressed strong support for lowering drug costs for beneficiaries.

OIG is working with the Department on this rulemaking and a final rule is currently pending review at the Office of Management and Budget.

Thank you again for the opportunity to appear today, and I would be happy to take questions.

The CHAIRMAN. Thank you very much for your work in this area and your testimony.

Dr. Woodcock, I am going to start with you. You mentioned in your testimony that biologics account for about 40 percent of all prescription drug spending, so obviously this category is one that we need to take a close look at, and biologics are very important drugs to an awful lot of people.

Former Commissioner Gottlieb has said that if all the biosimilars that have been already approved by the FDA were successfully marketed in the United States in a timely fashion, based on the information on the experiences of European countries, Americans would have saved more than $4.5 billion in 2017.

Humira is my poster child for what has happened in this area, and it shows what is wrong with the current system. Humira is an extremely valuable drug for rheumatoid arthritis, psoriasis, and other ailments, and it has been on the market in the European Union since October, while the American people, incredibly, must wait until 2023 before the less-expensive biosimilar is available, as a result of AbbVie's anti-competitive patent strategy, so that is 20 years after the drug was first introduced, and that is why I have introduced legislation, and we have worked very closely with the FDA aimed at curbing patent abuses. Everybody wants a period of exclusivity, but it seems to me when that expires the biosimilars should be able to go forward.

First of all, does the FDA support the provision of listing, in the Purple Book, all of the patents that a company has to make it easier for the biosimilar to figure out a path forward when the patent has expired?

Dr. WOODCOCK. We are very happy to work with you. The listing would be somewhat burdensome for the FDA, although we would presumably simply play a ministerial role in allowing the companies to list.

I think the root cause problem, though, is the adjudication of whether the patents are legal and whether they block the bio-

similar product, and for what amount of time, and that really pertains to our patent system and protection of intellectual property, so how far should that go?

We have had discussions with the Patent Office about this, because if these are valid patents and they are felt to pertain to the biosimilar then they will block availability for potentially many years after exclusivity has expired and a tentative approval has been granted by the FDA.

I think this is a complicated issue, and we are really eager to work with your staff on this issue, because it is blocking availability, and the question is what is the root cause here and how can we untangle this?

The CHAIRMAN. You have previously testified that the FDA has done 150 referrals to the Federal Trade Commission to take a look at anti-competitive processes without much success. Last May, FDA began publishing a list of inquiries received from generic drug developers who report having trouble accessing testing samples they need. The CREATES Act would help with that, which I have co-sponsored and you mentioned in your testimony.

The question for me is, the FTC ought to be taking action when it sees anticompetitive practices preventing generics from getting to the market—paper delay is another outrageous example. Now that the FDA has had a year of experience with this new initiative, is the FTC becoming more aggressive in handling these complaints?

Dr. WOODCOCK. We are really not privy to the FTC actions, so we have referred all of these on our list to the FTC for their evaluation, but the further steps I would refer you to the FTC to, you know, get more complete information. We don't have that.

The CHAIRMAN. Well, my time has expired so I am going to yield to the Ranking Member, but I would say there is something wrong with the process if there is not feedback from the FTC to the FDA on whether or not they have taken action on a referral from the FDA, so it seems to me maybe that is another area for legislation.

Senator CASEY. I want to thank the Chairman. I want to thank our panel for being here. I want to focus my first round of questions on Mr. Kouzoukas. I appreciate you being here. You represent the Administration, and I have got a couple of things I want to say about why we are here and how this relates to some larger debates we are having.

We are having a debate about how to get the cost of prescription drug prices down, especially out-of-pocket costs. In the midst of all that, this Administration on health care, when you consider the actions taken against the Affordable Care Act and against Medicaid, it can only be described as sabotage/decimate, to both programs, both the ACA and Medicaid. Over and over again, attempts to undermine both programs, in terms of supporting a lawsuit, in terms of the budget proposals, in terms of efforts to repeal, in terms of giving states waivers, which will undermine these efforts even further, so my point on raising this is simply that these actions are undermining what I think are actually bipartisan efforts to get prescription drug prices down, number one, and number two is, it is having an effect. We were told, as of January—this is a story from Vox dated January 23, "Under Trump, the number of uninsured

Americans has gone up by 7 million." It refers to Gallup data—7 million people. Other sources say it is in the millions, at least.

While we are doing all this, we are undermining any effort to lower the cost of prescription drugs, because of actions taken against both the Affordable Care Act and Medicaid.

We have sent a letter to President Trump where we say, in the opening of the letter, "The coverage individuals receive through Medicaid and the Affordable Care Act provides protection against extreme out-of-pocket costs on the medications they need in order to remain healthy." All these efforts we have undertaken, whether it is filling the donut hole for seniors so their prescription drug costs go down, whether it is coverage for others who are not seniors but they have the protection of health care or the protection of Medicaid or the Affordable Care Act, all of that is undermined, so even if we take steps that are constructive on prescription drugs, all of that is undermined.

Madam Chairman, I would ask that both a letter dated June 19th, to the President, on this issue of the connection between actions on health care and prescription drugs be made part of the record. That is number one, and number two, I would ask that a June 11th letter that we sent to the president on the official poverty measure, another effort which, over time, which we say in the letter, will undermine several programs. The official poverty measure is used by Department of Health and Human Services to annually issue poverty guidelines and thresholds.

I would ask that both letters be made part of the record.

The CHAIRMAN. Without objection.

Senator CASEY. I would ask, and I am almost out of time and I will get back to it, but I would ask this question. What have you done when you and your team are developing and then proposing ways to get prescription drug costs down? What have you done, what has the Administration done to assess the impact that their efforts on Medicaid and the Affordable Care Act, what have you done to make an assessment of how one impacts the other? How can we get prescription drug prices down when we have the Affordable Care Act being attacked morning, noon, and night, and the Medicaid program being the subject of what I would call decimation, because of what the Administration is doing?

I give you the rest of the time that I have.

Mr. KOUZOUKAS. Thank you, Senator, and I appreciate the opportunity to hear you out today in person as well as in the correspondence and the dialog I know with which you regularly engage the agency in.

I would like to focus a bit on some of the shared—areas of agreement that I think I heard in your question, and I see an area of shared goals here, about access to care and high-quality care, and using competition, really, as the way to get there. I also heard a focus on out-of-pocket costs, and that is very much at the centerpiece—at the center of many of our proposals.

I also heard some reference to bipartisan efforts and constructive discussions, and I am heartened, despite—I understand you have a number of other areas with which you disagree with some of our actions, but I also hear you acknowledging, and perhaps it is an

opening and an opportunity for us to work together on these bipartisan efforts and constructive discussions.

I assure you that as we work on these efforts, internally and externally, we are collaborating, both within the agency and across the Department, to address not only prescription drug prices but access to care, more generally, and that we are also looking forward to engaging in continuing that constructive dialog with you, other members of this Committee, and the Congress.

Senator CASEY. Well, I would ask again. Did you assess the actions taken by the Administration with regard to ACA and Medicaid, the larger actions that have been ongoing since the beginning? Did you make an assessment of the impact of those actions on your efforts to reduce the cost of prescription drugs? Yes or no.

Mr. KOUZOUKAS. We believe that our efforts to reduce the cost of prescription drugs rely on a variety of authorities that we have, and we are confident and excited about the opportunity to continue to take action that has brought down prices, as they have, and I will——

Senator CASEY. That is great. That is great, but I want to know, did you make that assessment?

Mr. KOUZOUKAS. We are working together every day, both within the agency and with Congress to assess the best path forward, and the opportunity, I think, here is for us to work together to ensure that to the extent we do not have authorities——

Senator CASEY. Okay. I am over time, but until I hear otherwise I am assuming the answer to my question is no.

Thank you, Madam Chair.

The CHAIRMAN. Senator McSally.

Senator MCSALLY. Thank you, Madam Chair. I appreciate your continued leadership on this really important issue. I apologize I missed your verbal testimony. I was meeting with a number of my constituents from Arizona.

I have done a 15-county tour in my first 90 days in the Senate, and the cost of prescription drugs has been a top issue for my constituents, regardless of their age, of their situation, economically, as seniors, young people, small business owners, you name it. This is a top-of-mind issue for Arizona families.

For example, my office recently heard from a woman from Lake Havasu who suffers from rheumatoid arthritis, so some days she cannot even use her hands or walk. Her prescription costs are approximately $5,000 a month, which is obviously too much for most people to afford or for her to afford. She has decided she can no longer fill these prescriptions and continues to go without the medicine that she needs. She says she carries on with a good attitude but this is really unacceptable that we are leaving patients with no choice but to stop taking the medications.

We have seen reports, earlier this year, that 3 out of 10 adults report not filling their prescriptions, that they are left at the pharmacy, even when they show up and see what the out-of-pocket cost is going to be, and again, throughout my State I hear stories like this over and over and over again.

Mr. Kouzoukas—is that how you pronounce your name? No. Come on. Tell me. Kouzoukas. Okay. In your testimony you State that under Medicare's Part D new rule would be a requirement

that real-time benefit tools that are capable of providing patients with real-time information for their out-of-pocket costs for prescription drugs would be available at the time the prescription is written.

I mean, this is, again, the vision, right, that when the doctor says, "Where should I send the prescription?"—that you are able to pull out an app and you are able to kind of look through it and go, "I want to go here," and it is based on you understanding what your costs are going to be and where you are going to get it filled.

I know these are complex issues, but this is where we need to be going. Can you get into further detail on some of the tools and how they would be implemented for that real-time information, and will the rule ensure pharmacies have the right to also disclose lower cash costs?

Mr. KOUZOUKAS. I am so delighted, Senator, that you asked me about that. This is one of those kind of unnoticed items, perhaps, at times, that is a subtle action, but it is part of a bigger picture, part of a comprehensive strategy, of course, as I have mentioned, but it also is a real part, and that is because it goes to that very conversation that the doctor and the patient are having, at the very point where the patient is deciding what it is that they need, and working with their doctor, and at that moment—and I think we have all been in that moment—where you get handed a prescription by the doctor, and I guess——

Senator MCSALLY. Or they say, "Where should I send it?"

Mr. KOUZOUKAS. Indeed. Now it is electronic.

Senator MCSALLY. Yes.

Mr. KOUZOUKAS. You kind of wonder, in the back of your head, well, how much is this going to cost me? Is it even covered? It feels—like you will sometimes as your doctor and the doctor doesn't know, and what this requirement is, in Part D, is that the plans have a system whereby the doctor can access it through their EHR—at least one EHR has to be compatible with this kind of tool—and identify at that point, what are the formulary alternatives?

It is even really critical that it is happening with the doctor's consultation, because then they can clinically discern what kind of medicine is really a kind of alternative, and that is going to really, I feel, change the dialog at that most basic interaction, and it has great promise.

Senator MCSALLY. I totally agree. I mean, this is where we need to go. In everything else in our life you are able to have information and then you can make choices and you can do what is best for you, and so, you know, this is America. Why can't we have this tool available now? Like how do you see this being implemented? The data is out there. The information is out there. What is it going to take to make this happen?

Mr. KOUZOUKAS. Well, first of all, I think the support of the Congress as we move forward here, has been important, and I appreciate the opportunity to hear from you and others who recognize the importance of this kind of change, so that is particularly helpful.

I will also say that having put it forward, the regulation as we have, we did it in a way that recognized that this is not something

that can easily happen overnight, but we pushed very hard to put an aggressive timeline on this.

What we would like to see is this kind of technology develop in a way that is truly interaction, and so it does not exist in a silo for only one kind of EHR or one particular plan.

Senator MCSALLY. Right.

Mr. KOUZOUKAS. What we are hoping and expecting is that there will be standard that is developed by the industry, and there is a process by which these standards are developed, and we expect our actions are going to really precipitate the development and issuance of that standard so that it is not just—so that the tool is available in all of the EHRs for all of the doctors, in all of the patient rooms, and then it spreads even beyond Medicare, obviously.

Senator MCSALLY. Exactly, and that is the vision, again. Again, this should not be that difficult, even though this is a complex issue. The information is out there. We have smart people who can develop these tools, and it should not just be for Medicare. People should be able to have that conversation with their doctor, know what their costs are going to be, to include their cash costs, and then be able to make those decisions as to where to send a prescription and know what it is going to cost them and their family.

I look forward to continuing to work with you on this, because we really need to make this happen.

Mr. KOUZOUKAS. Thank you very much.

Senator MCSALLY. All right. Thanks. I am out of time.

The CHAIRMAN. Senator Jones.

Senator JONES. Thank you, Madam Chairman and thanks to all the witnesses for being here today.

Dr. Kouzoukas, I would like to talk just a minute. One of the biggest things I think that we have seen with the Administration right now is the new rebate rule that is out there, which would change the way discounts are spread, across the board.

How would you anticipate that this rule is going to affect the overall price of premiums, and is there going to be a tradeoff for folks with lower drug costs but higher premiums? How will you anticipate the long-term benefit being?

Mr. KOUZOUKAS. Thank you, Senator, for the opportunity to address that particular question. It is an important one with respect to the rebate rule. I know that Ms. Robinson may be able to provide some additional details regarding the mechanics of how the rule works, in terms of its connection to premiums.

I will say this, in terms of how it impacts the program and the Part D plans, and when they set their premiums, that what we expect and hope for here is the same kind of dynamic that you get when you go in to buy a car, and if you have had this experience lately—and I have had perhaps the fortunate or unfortunate experience of doing this recently—the salesman is talking about buying some mats, getting the rustproofing, the financing from the dealer, and so on, and imagine if they gave you the price for the package deal but they never can tell you how much the car is going to cost, if you just buy the car.

Ultimately, what we are talking about here is changing the dynamic through the mechanics of the rebate rule, that Ms. Robinson summarized for us, to a situation where when you go into the car

dealership, when those plans and the manufacturers negotiate against each other and create the kinds of competition we think is fundamentally necessary to lowering drug prices, that they are going to be negotiating over the price of the car, not over the rust-proofing, and not over the finance deal, and not over these other things, and the mats, and that is the kind of dynamic we are looking to create, and we think that is going to result in lower cost-sharing, ultimately result in better negotiations, and also result in lower premiums. That is precisely what we are looking for.

Senator JONES. Right, but you believe that the lower premiums, it will result in enough lower premiums to—you know, that we are not just going to, you know, lower the cost of the drugs but raise the cost of premiums to where the consumer does not have an effect. You think it is going to affect both?

Mr. KOUZOUKAS. Our view is that ultimately these better negotiations are going to result in all of these positive effects, and that is the spirit with which we undertook this. Obviously, it is a rule-making so we have a lot of comments to consider, from the OIG perspective, but in terms of the impact on Part D and its program, that is what we are expecting and hoping for as this plays out.

Senator JONES. Okay. Well, I may come back to Ms. Robinson on that in a minute.

The other thing, I would like to go back to something that Senator Casey said in his opening statement. It does seem—and it does not seem to me that the Administration has any real interest in allowing Medicare, which is the biggest purchaser, I think, of drugs these days, to be able to negotiate these prices, and I am curious as to why there seems to be that resistance. As Senator Casey said, we do not see anything coming out.

There are a lot of things, and I want to commend the Administration for their work on this, and I think there are a lot of good things that are coming out, but with Medicare, it would seem like that that is the biggest player in the market, that they could really have a huge effect by negotiating drug prices, and I would like for you to address that.

Mr. KOUZOUKAS. Senator, I think that what I hear in your question is really a focus on negotiation, and the question you are raising, obviously, is who should have those negotiations, but there is clearly an agreement that negotiation and competition are the best path forward, and I am delighted to hear that.

Our concern, really, is that as we engage in looking at all the various options for how we can lower drug prices, that we do so in a way that promotes access to innovation as well as negotiation, and that the negotiations are ones that are conducted in the most vigorous possible way.

What we have seen is that the negotiations that are conducted by PBMs, the people who do this for a living, have resulted in tremendous amounts of competition. We think that there are opportunities to improve that, obviously, given the nature of the other activities we have been doing, but those kinds of negotiations have been quite intense and are likely to produce the right outcomes.

I will also say that also present in our minds, as we consider this situation, is the conclusions drawn by Congress' own budget office, that in order for some kinds of negotiations to play out and

achieve—even have the hope of achieving a lower drug price, what ultimately would be required is for the leverage in that negotiation to be driven by the government making a decision about what kinds of drugs people will have access to, and we think that as we look at that current landscape and evaluate the range of alternatives, that giving patients the opportunity to select amongst competing plans in order to achieve the best—who, themselves, are negotiating deals with the manufacturers, is a way to preserve access and get those lower prices through negotiation.

Senator JONES. Thank you. Thank you, Madam Chairman.

The CHAIRMAN. Thank you very much. Senator Shaheen.

Senator SHAHEEN. Thank you, Madam Chairman. I very much appreciate your willingness and Senator Casey's willingness to let me participate in this hearing. As Senator Collins mentioned, she and I co-chair the Diabetes Caucus and we have heard dramatic concerns from people with type 1 and type 2 diabetes across this country about the rising costs of insulin prices.

In Medicare patients alone, annual out-of-pocket costs for insulin have more than quadrupled since 2007, and it is not just seniors, as we all know. The skyrocketing cost of insulin is a matter of life and death for diabetic patients of all agents. Many of those patients have tried to ration their insulin because they cannot afford its high cost.

In New Hampshire, and I am true it is true in Maine and probably Pennsylvania, we have many of our citizens who are going to Canada to buy insulin because they can buy it cheaper in Canada.

Mr. Kouzoukas, what is CMS doing to reduce the sky-high costs of insulin, not just by holding insulin manufacturers accountable but also pharmacy benefit managers accountable for how these costs have risen?

Mr. KOUZOUKAS. Senator, I am glad you gave me an opportunity to talk about this. I will say that diabetes, in particular—and it is great to see you here and have an opportunity to talk about this, to recognize your interest in it, because diabetes is a disaster that affects so many Americans and so many Medicare beneficiaries, and while it affects so many people, I can tell you that it also seems to affect every person in a different way. Every person finds a way to their own treatment journey.

Senator SHAHEEN. I am sorry to interrupt, but I would just point out that for those people who have type 1, they must have insulin or they die, so the idea that there is an alternative treatment to having insulin is just not accurate.

Mr. KOUZOUKAS. Senator, I hope that is not what you got, the impression I was saying. What I was hoping to, perhaps inarticulately, suggest is that the type of insulin, the method of delivery, the way that they handle their dosing, their own management is really something that is an individualized journey for many diabetes patients, and I know that from family members that have diabetes and suffer from it, but I have seen that up close.

I think our work in the diabetes space has really been focused on recognizing exactly that, and certainly drug pricing is a big part of it. It is the most key part because of the role insulin plays. I will also point out that we have also undertaken a number of efforts to ensure access to a broad variety of different kinds of insulin deliv-

ery devices and other mechanisms by which people can access and make sure that they have the insulin they need or monitor their daily levels and the like, and that is also a critical piece of this.

Our work—and I think that this is a good opportunity perhaps to highlight, in diabetes, the opportunity that the rebate offers, for example, because it is a competitive space with a lot of rebates, so that is one area where we would expect to see, you know, a significant change or impact in terms of benefits to beneficiaries, paying the cost share.

Senator SHAHEEN. Do you have any data that shows any changes as the result of what you are proposing on the rebate rule?

Mr. KOUZOUKAS. I think that we can certainly try to work with you to identify what kinds of data you are interested in. We have a lot of data, and a lot of it is out in the proposed rule, but we can also identify what else your data interests are, for sure.

Senator SHAHEEN. Well, I guess it would be—I assume the Committee—I certainly would be interested in how it is going to reduce the costs of insulin and make it more accessible for those people who need it.

Mr. KOUZOUKAS. Indeed, and we share your interest in that. I think that—and that is really just one part of a comprehensive strategy, so we will be delighted to work with you on that.

Senator SHAHEEN. Thank you.

Dr. Woodcock, I am going to go back to the point that Senator Collins made and that you were confirming when you talked about the importance of approving biosimilars to provide competition for biologics, because that has been where the real increases in costs have been in recent years, and my recollection is that the legislation that set up a method for approving biosimilars was part of the Affordable Care Act when it was passed. Can you tell me if the effort to strike down the Affordable Care Act will also strike down that pathway for biosimilars?

Dr. WOODCOCK. Well, I am not a lawyer, but my understanding of the law is that there are many ifs in this. It would depend on all sorts of things about the ruling, what the ruling was, so I can't predict.

Senator SHAHEEN. We do not know what the impact would be.

Dr. WOODCOCK. Yes, I do not know. I cannot predict.

Senator SHAHEEN. It is possible that like many of the other aspects of the Affordable Care Act it will strike that down as well.

Dr. WOODCOCK. I do not know.

Senator SHAHEEN. Thank you, Madam Chair.

The CHAIRMAN. Thank you, Senator.

Before I call on Senator Braun I just want to add a comment to what Senator Shaheen said to Mr. Kouzoukas, and that is insulin has been around since 1921, and when we hear from constituents who are now seeing the price having increased by, on average, 240 percent over the past decade, I realize there are different kinds of insulin but that is just an outrage, and I am going to followup on the suggestion that the Senator from New Hampshire made on asking you, in writing, to give to us more of an explanation of how the rebate rule would have a positive effect on that. I personally believe it would, but I want to get that from you, so perhaps we can followup on that.

Senator BRAUN. Thank you, Madam Chair and Ranking Member Casey. I am on the Health Committee as well and had basically this same discussion yesterday. Every time I get involved in one of these discussions I want to make sure that the industry is aware, and that is from health insurance to pharma to hospitals and even the people that make their living in the business, doctors and nurses, with the exception of the latter, where I think they are caught in a swirl just like in big agriculture, we increasingly have huge corporations that dominate, you know, the landscape. At least in agriculture there is transparency and farmers know what they are buying and paying for.

In health care, when I tackled this issue as a CEO of a company 10 years ago, and I look at this, efforts to further competition and increase affordability, there is no other industry that I am aware of, especially one has large as health care, that needs the nudging that we are trying to give here on aging and in the Health Committee. I would like to put all the CEOs on notice that now control the dynamic in health care, that have delivered the product that we are all grappling with, that we know has excellent features to it, where we do things really well in this country when it comes to health care but it just costs too much, and hidden behind, universally, opaqueness, not embracing competition, like all the rest of us do in running our businesses in other sectors of the economy. Thank goodness we are taking this on as a real issue.

Until, I do not know that we here will accomplish what needs to happen quickly enough to stave off, you know, what may be solved through some type of crisis down the road, but I am at least glad we are taking about it.

Focusing in on PBM rebates, Senator Romney and I have got a bill that does something similar to what Alex Azar is putting out as a ruling, you know, for Medicare and Medicaid. My analysis of PBM rebates is why do you have a middleman involved, number one. I do not know of one other supply chain, in any other industry, that has a middle man that is hired to determine how margin gets divvied up to get it through the supply chain. That is archaic. It is not needs. That should ideally be done by the people that make the product, big pharma, and the distributors, and the dealers, the pharmacists.

The only part of that network that looks to me like it is functioning would be at the pharmacy level, where, in most domains, you have still got lots of choices. It gets murky and confusing when you look at the distributors, and especially the people that make it.

I size up PBM rebates as around $150 billion a year, of which $85 billion of it, most of the rebate, gets eaten up by the costs and the profits of a middleman that is unneeded.

Whoever would like to respond to it, do we need PBMs? Do you think if we shed light and transparency on it that this can get solved, and drugs can get priced at a reasonable level without the need of an artificial middleman that exists in no other supply chain? Anybody that wants to tackle it.

Mr. KOUZOUKAS. I can start sir.

Senator BRAUN. Thank you.

Mr. KOUZOUKAS. Thank you, Senator, for that. The question about PBMs and their role, I think the answer, from my perspective, really is that we need to ensure that there is competition in a market, and that may or may not include PBMs. It does not necessarily have to. The ultimate question should be, though—the answer should really lie and be driven—we should get to the answer by looking to consumers and competition to lead us to the right path, and I think you have identified, in your question, very much some of the concerns we have about how the system that has grown up around prescription drugs and Part D, perhaps unintentionally in many ways, as creating its own kind of perverse incentives. It is not an example we think, necessarily, of the market driving to a conclusion and ordering itself in a way that your business is accustomed to, before you got here.

What we seek to do, within the confines of the government program—it is obviously a government program that we are administering here and the Congress has given us the task to run—how do we make sure that there is as much market competition so that that gets us to the right answer, and that is what we are looking for, and as to your legislation, we are always interested and willing to work with you and others on potential legislative approaches as well.

Senator BRAUN. Thank you. I am out of time. If there is another round of questions I would have one, in especially addressing the consumer component, where I think it has been an atrophied health care user that has been, you know, not participating in his or her own well-being as part of what drives most other markets as well. I will save that for a second round, if we have it.

Thank you.

The CHAIRMAN. Thank you, Senator.

Senator BLUMENTHAL. Thanks, Madam Chair, and thanks for holding this hearing. Thank you all for being here.

There is no disagreement that drug prices are too high. There is no shortage of proposals to deal with it. I have offered a number of them myself, the CURE High Drug Prices Act that would compel pharmaceutical drug companies to lower their prices if they are found to be engaging in price gouging.

Another is the Affordable Prescriptions for Patients Act, which I introduced along with Senator Cornyn, that would take action against egregious patent abuses like product hopping and patent thickening. These terms have probably little meaning to most Americans but they raise the prices of prescription drug prices, as probably you know, and other tactics are similar anti-competitive.

But I want to come back to the price of insulin, because here is a very simple drug. As Senator Collins observes, it has been around for decades, almost a century. There is nothing novel about it. It is not a wonder drug, and the prices continue to increase. We are not talking about a plateau. The prices are continuing to rise astronomically.

Mr. Kouzoukas, what are you going to do about it? Tell me in simple English what you think the causes are and what the remedies are that you would undertake?

Mr. KOUZOUKAS. Senator, I recognize, really, your long history and passion for consumers, and I think that the kinds of ap-

proaches that we are taking today I hope are ones that we have common ground on and share appeal—you have some shared appeal for, because they are really focused on consumers and the bottom-line impact on them.

I will say that a big part of that strategy is the proposed rule that is around rebates that ultimately——

Senator BLUMENTHAL. Will that solve it?

Mr. KOUZOUKAS. That is part of a multilayered——

Senator BLUMENTHAL. What else is necessary?

Mr. KOUZOUKAS. We also are working very hard to implement a number of changes in how the Part D program is administered, and have proposed a number of them to Congress.

I will give you a few examples. One is the model that we recently put out that provides an incentive or removes a disincentive, in some ways, for plans to maximize their negotiation in the catastrophic phase of the Part D program. That is one that we believe has promise to change the dynamic when it comes to a patient who has come to the very end of their very high-cost drug spending over the course of a year, and diabetics often have a lot of comorbid conditions so they are often going to be people who are going to be affected by the catastrophic phase of the Part D program.

We also have implemented the legislation that this Congress, and I know this Committee and many of you have been helpful in getting this legislation passed around gag clauses, to make sure that patients know that they can pay cash prices if they need to in a way that is lower than what they would have otherwise been charged as a result of some of the distortions in the pricing system.

Then I would also—I really, most of all, though, would really be remiss not to highlight that the entire package of the President's budget, it represents a multilayered approach to prescription drug prices. It is going to have, we think, the most promising opportunities to address the situation you described, and that it is one that, I think, that there are many elements of it that I know have a lot of bipartisan support, and so we are quite hopeful that we will have the opportunity to work with you and others to get to exactly that place.

I know Dr. Woodcock may have something to add there as well.

Senator BLUMENTHAL. Before you pass the microphone, so to speak, can you assure us that a year from now, when we are sitting here, and if you come back, that the prices of insulin will be lower?

Mr. KOUZOUKAS. We are working to assure that every day, and we are really delighted about changes that we have already seen, a corner start to turn, and we are working every day to make sure that exactly that happens—a year from now, a month from now, every day, and any day.

Senator BLUMENTHAL. Would you favor Medicare negotiation of drug prices?

Mr. KOUZOUKAS. We think Medicare, Senator, does negotiate for drug prices. It does it in a way that brings about really effective negotiations. It drives down prices and it also ensures access to broad types of drugs.

Senator BLUMENTHAL. You think it is doing enough now to negotiate?

Mr. KOUZOUKAS. We think that there are opportunities to improve the negotiation and that we have definitely worked to create new levers and new opportunities for negotiation to maximize that, and we are also——

Senator BLUMENTHAL. Do you support legislation to increase the authority to negotiate?

Mr. KOUZOUKAS. We would be certainly interested to understand a little bit more about what you have in mind, but we are always interested in ways to maximize negotiations.

Senator BLUMENTHAL. I am out of time. I know Dr. Woodcock may have had another response.

The CHAIRMAN. Dr. Woodcock, why don't you respond and then we will move on.

Dr. WOODCOCK. Certainly. Insulin has been regulated as a drug, not a biologic, although it is a protein hormone, and Congress put in place deeming next March. They will be deemed—insulins will be deemed to biologics that will open them up to biosimilar competition. We have, again, a robust pipeline of interests in biosimilars for various insulins, because although they are—it is an old molecule, there are many delivery systems and modifications to insulin that have made them easier for diabetics to manage their blood sugar effectively, so there are a variety of products out there and they will be eligible for biosimilar competition come March, after they are transferred as biologics.

Senator BLUMENTHAL. Thanks, Dr. Woodcock. Thank you, Madam Chair.

The CHAIRMAN. You are welcome, Senator.

Ms. Robinson, in your written testimony you mentioned that the President's proposed budget request includes a provision that would increase competition by reducing average sales price base payments when a drug manufacturer takes anti-competitive action.

An example of that is pay-for-delay. What exactly would the rule do to prevent pay-for-delay agreements?

Ms. ROBINSON. Senator, I think that may be from one of my colleagues' actual written testimony. I will say that this rule really focuses on the rebate stream of payments and the discounts. It does not address the pay-for-delay issue that you are mentioning, and I apologize.

The CHAIRMAN. If was not your testimony, then I have a feeling it was Mr. Kouzoukas' testimony, so could you answer that question for me? What specifically does the President's proposal do to prevent these kinds of anti-competitive behaviors like pay-for-delay?

Mr. KOUZOUKAS. Chairman Collins, the President's proposal—and I will say as with all the things in the budget, it is part of a comprehensive package, so it is one part among many that we think need to be considered in concert. It would essentially reduce payment for innovator drugs when the ASP—from ASP plus 6 to ASP minus 33 percent, when a manufacturer files a pay-for-delay agreement or takes another anti-competitive action.

Now the details, as with many budget proposals, are ones that we believe that we would be delighted to have an opportunity to work with Congress on to fill in, but the basic notion and the gist is that we think that the ASP mechanism is one that provides an

opportunity to address this kind of anti-competitive behavior that you and others have identified as a concern.

The CHAIRMAN. You would use the reimbursement system, essentially, that is available under the Medicare system to penalize a company that pays a generic not to come to market. Is that correct?

Mr. KOUZOUKAS. Chairman Collins, I do not know if I would use the word "penalize." It is perhaps to—

The CHAIRMAN. Well I hope if we are going to average sales price plus 6 to average sales price minus 30 percent, or whatever it was that you said, I think most companies would view that as a penalty.

Mr. KOUZOUKAS. I understand, Chairman Collins.

The CHAIRMAN. I am not against it. Believe me. I think pay-for-delay is outrageous.

Mr. KOUZOUKAS. I think our view might be that we are pricing appropriate to what we think is a dynamic that is great in the marketplace, and that if it is going to be a situation where the ASP is essentially undermined by the anti-competitive action that we should recognize that in our pricing, but certainly I imagine some might view that differently.

The CHAIRMAN. Let me move on to another issue. At our previous hearings we heard from patients who have monthly drug costs that are completely unpredictable and can range significantly, depending on their benefit design, where they are in reaching their deductible, or where their spending places them in the Part D stages. Others who take extraordinarily expensive drugs go through the benefit stages very quickly.

One witness who was diagnosed with multiple melanoma 3 years ago testified that she went in and out of the donut hole in January, paying $4,950 for the first month and then $640 every 28 days for the rest of the year for the drug that she needed. She had refinance her home to afford the cost of her medication.

My question to you is this. What is the best way to reform the catastrophic benefit so that it helps patients without creating any perverse incentives in our drug pricing system?

Mr. KOUZOUKAS. Chairman Collins, first I would like to note that I empathize with the letters and the testimony that you have heard. Really, these are the kinds of stories that we get every day as well, and it is very much a big part of why we do what we do and are working so hard to address this prescription drug dynamic.

The catastrophic phase is an important piece of this because the people who are most affected, sort of the worst situations are the ones who have the high drug costs, and that puts them into the catastrophic phase.

I will say that we are testing, in our Part D modernization model right now, a change whereby prescription drug plans have an opportunity to come in and offer a—give an incentive, if you will, in order to get even bigger discounts in the catastrophic phase, and to do that in a way that will drive better negotiation.

I will also say that in our budget proposal, as one part among several, we have a protection for maximum out-of-pocket costs as well, and we think that what is important——

The CHAIRMAN. That is lower than current law?

Mr. KOUZOUKAS. Indeed. In Part D there is not currently an out-of-pocket maximum.

The CHAIRMAN. Well, there is a matching system that comes into play.

Mr. KOUZOUKAS. Of course, Chairman Collins, and so it is broader than current law in terms of the proposal, and I will say in terms of the incentives it creates—which I think is an important part of this, and I recognize that you are pointing out some of these tradeoffs. Every policy that we make here, in this kind of program, there are going to be these tradeoffs, and that is why the budget proposal is part of a package. There are other things in that package that will essentially work in concert to ensure that we have both negotiation and access, and that we address any distortions or misincentives.

The CHAIRMAN. Senator Casey.

Senator CASEY. Thanks. Ms. Robinson, I will start with you. I wanted to refer to a Pennsylvania report. This is from 2018, and the auditor general of the State uncovered a troubling practice of spread pricing by our state's pharmacy benefit managers in allowing private companies to profit at the expense of State Medicaid programs and taxpayers. This report found that in 2017, three such middlemen got millions in profits from Pennsylvania's Medicaid program by using spread pricing tactics. Medicaid, as I think you would agree, we all agree, is not a program for which private companies should be permitted to skim off the top in order to pad company profits or the wallets of CEOs.

The Office of Inspector General received a letter from the Finance Committee leadership, written by Chairman Grassley and Ranking Member Wyden, in April of this year, urging additional, "transparency and oversight," into these spread pricing practices that were cited in Pennsylvania.

Can you comment on the status of this request at the HHS OIG?

Ms. ROBINSON. Yes, I can, Senator Casey, and I appreciate the interest in our work. We have that inquiry and we are in the process of thinking about what new work we would do in this area to look at spread pricing in Medicaid, you describe. We have a team of experts actually doing some research, including they have reviewed the Pennsylvania State auditor's report that you mentioned and a variety of other things, so we are in the early stages of looking at what work we would do there. We would be happy, first off, to meet with you or your staff to hear more about your interests, and certainly happy to keep you apprised as that work develops.

Senator CASEY. Thanks. Any sense of the timing on this?

Ms. ROBINSON. I am sorry. I do not have any sense of timing right now.

Senator CASEY. I was hoping I could report back to the committee.

Ms. ROBINSON. I would be happy to followup after, if I can, on that.

Senator CASEY. We will, and thank you very much.

Mr. Kouzoukas, I have one fact check but also, I think, an area of agreement. You mentioned in your opening about the cost reduction of prescription drug prices, and I think what you are referencing is something the President said in the State of the Union.

The Associated Press quoted the President as saying, "As a result of my Administration's efforts in 2018, drug prices experienced their single largest decline in 46 years." You made reference to that in your opening.

I just wanted to point out what the Associated Press found. They found, "The Consumer Price Index for prescription drugs shows a 0.6 percent reduction in prices in December 2018 when compared with December 2017," and that I think that is the reference the President is making.

However, the same index showed a 1.6 percent increase when comparing the full 12 months of 2018 compared with the entire previous year, so I hope the Administration will clarify that that reference he makes and that you have made is a December-to-December comparison as opposed to a year-to-year.

I think there is an area of agreement here when it comes to drug spending dashboards. As you know, Chairman Collins and I have introduced a bill to codify and strengthen the Medicare/Medicaid prescription drug spending dashboards. This was started by the Obama administration to shine a light on how much the Federal Government spends on prescription drugs. The Trump administration expanded the tool to show what thousands of prescription drug costs taxpayers, and the need for transparency is obvious, I think, and this is one area where we can make some progress and do it in a bipartisan way.

I just wanted to ask you about your sense of the value of these dashboards, and tell us, if anything, what the administration hopes to do about it—to strengthen it, I should say.

Mr. KOUZOUKAS. Thank you, Senator. As you noted, we have been hard at work to expand the dashboards and we view it as really an opportunity, one part of many, to build a bipartisan approach, and all of these efforts are ones that we expect will sort of accumulate and will buildupon themselves. It is something that has been a priority for the Administration, is to make sure that we provide an expanded opportunity for people to get access to this kind of information, and it certainly is potentially useful to beneficiaries and patients as well, but it is also really important for some of the other stakeholders and other parts of the industry where, if we are not going to get the kind of transparency through a market, as Senator Braun had indicated earlier, then bringing this transparency through the data that we have access to, and so we are always working to identify ways to even further enhance what we are already doing. We are interested in hearing from you and others on the Committee on how we can do that even more intensely, but we are excited about the opportunity that the dashboards present and are grateful for the support.

Senator CASEY. Thanks very much, Madam Chair.

The CHAIRMAN. Thank you.

Senator MCSALLY. Thank you, Madam Chair, and my next question is for Dr. Woodcock. You talked about the importance of biosimilars in your testimony. We know that it is a crucial tool for so many patients, but earlier this year it was released that those specialty drugs are taken by a relatively small share of Part D enrollees. Spending on the drugs has increased and accounts for more than 20 percent of Part D spending.

The FDA is continually approving biosimilars but fewer than half are actually showing up on the market, so I share your concern about a large portion of these being approved and never making it to patients, so I was wondering if you could elaborate on what you think is holding that up and what else we could do to get these approved biosimilars to patients so that they can use them.

Dr. WOODCOCK. We are not totally sure because we do not have total visibility into what companies do after we would approve a biosimilar. We are aware that some of these are caught up in patent disputes, though, and as was discussed earlier, patents can run much longer than any exclusivity and fights over those can delay availability for a long time, but we are not fully clear on the different reasons that these drugs do not reach the market. In fact, when we approve generic drugs, often they are not launched in the United States, even after we have approved them, and the reasons are business reasons and they are not shared with us.

Senator MCSALLY. Is there anything else that we can do, or you can do, in order to better understand, other than the very significant patent discussions that we have had about, you know, really allowing competition to truly be there once the patent has expired and to stop the abuses of patents? Is there anything else that can be done?

Dr. WOODCOCK. We hold meetings with the industry to try elicit an understanding of these things, and we will continue to do that. My impression, though, is that the patent issues are the most pressing right now, and probably the most responsible for the failure to launch these. It is very expensive to develop a biosimilar, unlike, say, a generic, and that is a lot of investment and then not to seek the market. There have to be substantive reasons.

Senator MCSALLY. Great. Thank you. Mr. Kouzoukas, any other perspectives on that issue?

Mr. KOUZOUKAS. Of course. Thank you, Senator. The question of how we can encourage greater biosimilar innovation and adoption is one that we work collaboratively with the FDA on. Clearly it starts with what the FDA's work is, in terms of getting an approval process, and the tremendous work they have done to create a new biosimilars pathway has been a big part of this, and it would not be even possible to have this conversation without it.

In terms of what happens once that drug gets to market, that is where the Medicare program often can play a big influence. We are pleased that we have taken a few really important steps already to encourage greater biosimilar innovation adoption.

One is that we changed the way that we assign separate codes for biosimilar payment. It sounds like a rather obscure change, I suppose, but really it is quite important, because the way that biosimilars had been previously paid for and priced in Part B of Medicare is that they essentially were all lumped in together, and that did not encourage additional innovators to come into the market, so we think that was an important step and we are really excited about seeing it play out over the long term. It will not be an overnight kind of thing because investors have to line up behind putting that kind of infrastructure in place, as Dr. Woodcock pointed out.

We also made some changes to the way that we—cost-share, that we oversee cost-sharing for low-income beneficiaries when they take a biosimilar. We essentially changed the rule so that a biosimilar is treated as a generic for those low-income beneficiaries. That is a good part of the market and so it is important there that that kind of change continue to play itself out, and then we also have, with respect to biosimilars, a budget proposal that would eliminate cost-sharing for generics and biosimilars. It is part, again, of a larger package that needs to be viewed in concert, but we would be delighted to have the opportunity to work with Congress on passing that, and that is just really a thumbnail sketch.

Senator MCSALLY. Great. Thank you. I appreciate it.

Thank you, Madam Chair.

The CHAIRMAN. Thank you.

Senator JONES. Thank you, Madam Chairman. Ms. Robinson, I would like to give you an opportunity to talk about the rebate rule a little bit and followup on the question I asked Mr. Kouzoukas about kind of the tradeoffs between potential rising premiums and a lower cost. Can you just—I know you are limited on somewhat of what you can say, but do you have any thoughts about that?

Ms. ROBINSON. Thank you, Senator, for the question. I think what I can draw from is what is in the proposed rule, some of the modeling that was done by the actuaries, looking at this rule. It is difficult to know and to quantify accurately what the effects are going to be. There is a lot of uncertainty. It is a very complex industry and a complex rule, but what some of that modeling shows is that overall, on average, beneficiaries would have net reduction in out-of-pocket costs, the combination of premiums and what you pay at the counter, as a result of this rule, but the results would very much be different for different beneficiaries, so they did model increases in premiums but also decreases in out-of-pocket spending, particularly for sicker beneficiaries, beneficiaries that take high-cost drugs that are currently subject to rebates, and when you netted out the savings at the counter, net it out against the premiums, the modeling shows an overall savings, in general. There are actually multiple scenarios modeled here so it is a bit complicated. The premium estimate increases for 2020, for example, range from about $3.20 a month to $5.64 a month, per bene, per month, so it is a fairly complex scenario. We have solicited public comments on all of this modeling, and have all of those comments in front of us.

Senator JONES. Would you anticipate some kind of monitoring over the course—and let's assume this rule goes into effect—some type of monitoring to make sure that PBMs just do not, you know, say, well, you know, this is going to cost us profits so we are just going to artificially boost the premiums, you know, to keep our profits, you know, the PBM profits. Is there going to be a monitoring in place to monitor that?

Ms. ROBINSON. I think it is going to be incredibly important that the Department monitor what happens here. We want to be sure that these rules, if they are finalized, work the way they are intended to work, and if things go differently than intended, corrective actions and things can be done.

I think it is going to be incredibly important for the Department to monitor what happens if this rule is finalized.

Senator JONES. All right. Thank you.

Dr. Woodcock, we seem to still be seeing rising costs in even generic drugs over the last couple of years, so what do you see we can do to incentivize manufacturers to enter the generic market, encourage the competition, and will that drive down the prices by doing that or do we need to do something more?

Dr. WOODCOCK. The generic drug price rises often relate when there is a sole source, where there is no competition, and this is related to shortages. Why do we have markets where there is not really a market? There is one market entrant. Our Drug Shortage Task Force is really looking at this, to try and figure out the root causes of this distortion in the market, or market failure.

Obviously areas where robust competition, where we have four or five competitors offering the same drug, the prices of those drugs are very low, but where there is a single manufacturer making that drug, and it may be going in and out of shortage, that is where we see the prices going up.

Senator JONES. Okay. All right. That is all I have. Thank you, Madam Chairman.

The CHAIRMAN. Thank you.

Senator BRAUN. Thank you, Madam Chair. Ending on that point there, that is, again, very simple. When there is one supplier the price is going to go up. You know, we are nudging the industry with this conversation, and I am hopeful, like I said earlier, that they are going to get the message and help us out.

Let's assume we get the industry to be transparent and competitive. It's a big assumption. I want to turn where we ended up a while ago, the consumer. In my own plan, when I took this on 11 years ago, it was an atrophied health care consumer that would have described my average employee. You know, they, of course, were concerned about their premium contribution staying low. That is the really only thing out-of-pocket if you take care of yourself, but what I tried to tell them, and I need you to help me do some of the heavy lifting, there is no market that works well, even when it is transparent and competitive on the supply provider side, if you do not have an engaged consumer. Look how often you see people at the grocery store looking at their phone to save 20 cents on a $2 item. We do not have that currently in health care.

I created an atmosphere to where I told them I would hold their costs down in the future, which was an idea. I could not guarantee it but I did it. I had to change a behavior to get my employees, health care customers, eventually, engaged.

Do you think that is possible when health care has been so paternalistic, whether it is through Medicare, Medicaid, or employer-provided plans, where most individuals are only interested in how low their co-pay is, to avoid any skin in the game? I fixed it and it has worked. Do you think we can get the other side of the equation involved, that is the individual that uses health care, to help transparency out if, in fact, we get it?

Anyone that wants to comment on it.

Mr. KOUZOUKAS. Senator, I can start, for sure. You know, I am really excited to hear about your personal story of leadership within the commercial enterprise or business in terms of how to approach this together with employees, and I lament, really, that we

put you in a situation where you had to find your way to that, and so many employers, I think, we hear from, feel like they are struggling, swimming upstream against a system that is designed to make it harder and harder for them to get a better deal for their employees, and yet the employees rely on them for that health care.

To answer your question, I think just very directly, not only is it possible, it is necessary, and I believe, ultimately, inevitable, that ultimately what we are talking about here—and this is why our strategy just fundamentally relies on consumers and patients, what we are talking about are people making decisions for their own health care. They are the ones that are ultimately going to end up in the hospital, or not be in the hospital, or shorten their life, or being able to spend time with their loved ones or not, and so as we empower them, I have absolute faith that people want to live healthier lives. They want to live better lives. They want to live longer lives, and even sometimes if they are going to make some tradeoffs, they need to be in control, and when we give people that information, when we give them a taste and an ability to make those decisions for themselves, I think we are all going to have to run to get out of the way, because they are going to be checking their phones and doing everything else in health care, and demanding, really, the kinds of accountability and choice that they are accustomed to in the rest of the economy. All we need to do is really start getting out of their way.

Senator BRAUN. That is what we did in my company. Dr. Woodcock.

Dr. WOODCOCK. Well, we have proposed reform in our self-care part of drugs, which is the over-the-counter. We regulate maybe 100,000 different drugs that are offered to consumers for self-care, but that whole system is stuck in the 1970's, and we cannot have any innovation within that monograph system.

As a physician, I would say I think there is a generational issue here. My older patients often wanted "Doctor Knows Best," okay, but the rising generations really want to be active participants, and there is no better way for more minor conditions or certain conditions than to actually have safe and effective drugs available to you over the counter. You do not have to take off work, you do not have to make a doctor's appointment, you do not have to pay for parking, and you can select amongst options, but that has to be done so that it is safe and effective for the person to use that product, so we are very dedicated to self-care and the rising self-care industry, and we believe that the OTC reform—and, Senator Casey, thank you for your leadership—we believe that will help bring that about.

Senator BRAUN. Ms. Robinson, would you want to comment quickly?

Ms. ROBINSON. Yes. I do not know that we have a view on your exact question but I will say that in the Inspector General's Office we know we need to be prepared to oversee a health care system that is going to be more technologically driven, more consumer driven. It is going to be much more in that vein, and so we are preparing to be ready oversee that kind of health care system.

Senator BRAUN. In fact, I know from my own experiment, when you own your own well-being, and when you have skin in the game, and you make tools available, that are like pulling teeth to get available, it can work. You know, we have done it now 10 years running, so thank you for your comments.

The CHAIRMAN. Thank you, Senator.

I want to thank all of our witnesses today for your work in developing and advancing policies to lower the cost of prescription drugs for all Americans. Today we have examined Federal efforts to foster more competition, transparency, and increase affordability. I salute all of you for your efforts and it is important that they continue as the Senate and the House act in this area.

Committee members are going to have until Friday, June 28th, to submit questions for the record. I know that I have got a couple I want to submit.

Again, I want to thank our witnesses, Ranking Member, all the Committee members who participated, as well as our very hard-working staff.

I have to go to Appropriations for a mark-up on the supplemental appropriations bill, so if the Senator will excuse me for not being here for his final comments, I am going to turn the gavel over to you.

Senator CASEY. Wow.

The CHAIRMAN. I am little nervous about this, but I trust you. Thank you all for being here today.

Senator CASEY. Madam Chair, thank you very much for the hearing, and as you leave I will make sure the gavel goes back. I do want to thank the Chairman for calling this hearing and for giving us a chance to talk about this important issue. I want to thank our witnesses for being here, for your testimony, for the work you are doing on these important issues.

I will say, for the record, that I did not have a chance to—or I did not take the opportunity, I guess, to ask Dr. Woodcock a question, and I feel really badly about that, not only because she is so capable but she has an extra qualifier for today. She is a native of Blair County, Pennsylvania. She has got a Bucknell degree and a Penn State degree, or teaching?

Dr. WOODCOCK. Post-medical school, so teaching.

Senator CASEY. Teaching. I owe you one. Next time we will ask you every single question, but thanks for the testimony.

I think we can all agree, in a country as prosperous as ours, we must do better on this issue of lowering prescription drug costs. No family should be forced to carry what I called earlier the heavy bag of rocks of child care costs, the cost of college, and then, on top of all that, the heavy back of rocks called prescription drug costs, on their back. No family should have to endure that many costs, just to name a few.

We heard what the Administration is proposing to do about it and we are grateful the Administration is focused on this. We have discussed solutions that Members of Congress in both houses are working on. We have got to get those enacted into law. That is a whole other challenge.

We must do what 95 percent of Americans demand of us and pass a law that allows Medicare to negotiate drug prices. We must

not lose sight of the continued threats to the very programs like Medicaid and the Affordable Care Act, that I mentioned earlier in my question, that ensure families affordable access to needed medicines, and more, and I think that is a critical part of this debate. We cannot be focusing on lowering drug prices only and then forgetting about the supports for keeping those prices down that come through the Affordable Care Act and Medicaid.

We want to thank our witnesses, and with that, with my left hand, I will gavel us out. Thank you.

[Whereupon, at 10:39 a.m., the Committee was adjourned.]

APPENDIX

Prepared Witness Statements

STATEMENT OF

DEMETRIOS KOUZOUKAS,

PRINCIPAL DEPUTY ADMINISTRATOR, AND

DIRECTOR OF THE CENTER FOR MEDICARE

CENTERS FOR MEDICARE & MEDICAID SERVICES

ON

"THE COMPLEX WEB OF PRESCRIPTION DRUG PRICES, PART III: EXAMINING FEDERAL EFFORTS TO FOSTER COMPETITION AND INCREASE AFFORDABILITY"

BEFORE THE

U.S. SENATE SPECIAL COMMITTEE ON AGING

JUNE 19, 2019

U.S. Senate Special Committee on Aging

Chairman Collins, Ranking Member Casey, and members of the Committee, thank you for the invitation to discuss the Centers for Medicare & Medicaid Services' (CMS's) efforts to reduce prescription drug prices in Medicare. From day one of this Administration, President Trump has directed the Department of Health and Human Services (HHS) to make reducing drug prices a top priority, and CMS plays a critical role in these efforts.

Drugs are an important part of healthcare. Patients with diseases that scarcely a decade ago had no treatment potentially have access to cures that allow them to lead their best lives. However, patient opportunities to access these drugs are restrained by numerous distortions by a variety of factors, which can drive the price of these drugs beyond the reach of the patients who need them most. This Administration has been diligently working to root out these distortions in the interest of ensuring that patients have access to drugs at competitive prices.

Earlier this year, the President's Fiscal Year (FY) 2020 Budget laid out a range of proposals for lowering drug prices, including through reforms to Medicare. These proposals are consistent with the four key strategies for addressing challenges in the American drug market outlined in the "American Patients First Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs," released in May 2018 including improved competition, better negotiation, incentives for lower list prices, and lower out-of-pocket costs.[1] This blueprint constitutes the most aggressive plan of action for decreasing drug prices released by any administration ever. It, along with the FY 2020 Budget, appropriately promotes the objective of decreasing prices while maintaining our position as the world's leader in biopharmaceutical innovation and lays out dozens of possible ways that HHS—including CMS—and Congress can address this vital issue. HHS is executing on that strategy, and we are already seeing real results. Within the first 100 days since the blueprint was released, 15 drug companies reduced list prices, rolled back planned price increases, or committed to price freezes for the rest of 2018. In addition, there were 60 percent fewer brand-

[1] "American Patients First Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs," https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf

drug price increases and 54 percent more generic and brand-drug price decreases than the same period in 2017.[2]

However, we know there is more work to be done, and CMS is committed to doing our part to lower prescription drug prices. As the largest payer for health care in the U.S., Medicare policies can have a wide-reaching impact on health care spending, including prescription drug costs. That is why we are taking steps to reduce prescription drug prices by unleashing innovation and empowering patients through increased transparency across the program.

Unleashing Innovation

Modernizing Medicare Part D and Medicare Advantage

Last month, CMS finalized improvements to Medicare Advantage and Part D, which provide seniors with medical and prescription drug coverage through competing private insurance plans, in the "Modernizing Part D And Medicare Advantage To Lower Drug Prices and Out-of-Pocket Expenses" final rule.[3] The policies we finalized will enhance transparency by giving patients greater information on the cost of prescription drugs so they can compare options and demand value from pharmaceutical companies. Part D plans are the primary source of outpatient prescription drug coverage for 43.9 million Medicare beneficiaries.

In an effort to promote greater innovation in Part D, our final rule requires Part D plans, by January 1, 2021, to implement one or more real time benefit tools that are capable of providing prescribers with information through the prescriber's electronic health record or e-prescribing system so they can discuss out-of-pocket costs for prescription drugs with patients at the time a prescription is written. By empowering patients with more information on the cost of their prescription drugs at the point of prescribing, the rule will increase the likelihood that patients will fill their prescriptions and help ensure that pharmaceutical companies have to compete on the basis of price. After an implementation period, Part D plans would be required to provide

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[2] HHS, 100 Days of Action on the President's American Patients First Blueprint, https://www.hhs.gov/about/news/2018/08/20/100-days-of-action-on-the-presidents-american-patients-first-blueprint.html

[3] CMS, Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses, Final Rule, 84 Fed. Reg. 23832 (May 23, 2019), available at https://www.govinfo.gov/content/pkg/FR-2019-05-23/pdf/2019-10521.pdf.

access to at least one real time benefit tool that is capable of integrating with at least one prescriber's electronic prescribing (eRx) or electronic health record (EHR) system. CMS is encouraged that some plans are already offering these tools, but our policy will require all plans to provide prescribers with access to price information for different prescription drugs through this tool by 2021. Getting more information on out-of-pocket costs for prescription drugs to patients and their clinicians early in the process is critical, as there should be no surprises at the pharmacy counter.

In addition, based on guidance CMS issued in August, beginning this year, Medicare Advantage plans may use step therapy for Part B drugs as part of a patient centered care coordination program.[4] Step therapy can only be applied to new prescriptions or new administrations of Part B drugs and provides plans with the opportunity to encourage the utilization of a more affordable biosimilars before a patient progresses to a more costly biologic. Enrollees are entitled to request an exception from the plan's step therapy requirement in order to access a covered Part B drug. Medicare Advantage plans are now allowed to use consolidated step therapy programs for drugs covered under Parts B and D.

In our final rule, CMS issued a policy that further facilitates a Medicare Advantage plan's ability to negotiate prices for Part B physician-administered medicines by allowing the plan to institute step therapy when beneficiaries first start on the medicines.[5] By strengthening a plan's ability to negotiate with prescription drug companies, plans can deliver better value for a patient's medical needs. Many physician-administered medicines are biologics, which are some of the most expensive therapies in use today. Lower-cost biosimilars are coming to market to compete with biologics, and this policy is part of the Administration's broader strategy to foster innovation in biosimilars and to drive competition in the market for physician-administered drugs.

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[4] https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf
[5] https://www.govinfo.gov/content/pkg/FR-2019-05-23/pdf/2019-10521.pdf

Beginning in plan year 2020, CMS is also providing plans with the power to use indication-based formulary design and management as a new negotiation tool.[6] Currently, when a plan covers a drug for one FDA-approved indication, it has to cover all indications. This can mean that a more appropriate or more affordable drug may not be covered because the plan has already been required to cover a therapeutic alternative. Allowing indication-based management will mean more tailored choices for patients and more power for Part D plans to bring down drug prices.

Biosimilars

In 2018, an HHS report found that Medicare Part D plans spend $9 billion on brand-name drugs that have a generic alternative.[7] Choosing generics in these situations would mean $3 billion in total savings for Part D, including $1.1 billion in out-of-pocket savings for patients. In response to this report, CMS issued a memo to Part D plans reminding them of the tools they have available and the expectation CMS has to ensure that beneficiaries get the best deal.[8]

Similar to encouraging the uptake of generics, CMS is also looking to increase the availability of biosimilars to encourage competition with biologics. Many of the highest-cost medicines that Medicare pays for are biologics. Biosimilars have the potential to introduce competition and drive down costs for patients. However, right now, there are only a few biosimilars available in the U.S. To encourage growth, CMS finalized a policy in the CY 2018 Physician fee Schedule Final Rule that established separate Part B billing codes for each biosimilar product for a given biologic.[9] This change was designed to encourage companies to invest in bringing more biosimilars to market and would increase competition to reduce costs.

Reducing Out-of-Pocket Costs

The President's Proposed Budget request for FY 2020 includes a comprehensive Medicare Part D structural reform package that gives plan sponsors more incentives to manage benefits,

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[6] https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/Downloads/HPMS-Memos/Weekly/SysHPMS-Memo-2018-Aug-29th.pdf
[7] https://aspe.hhs.gov/system/files/pdf/259326/DP-Multisource-Brands-in-Part-D.pdf
[8] https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Weekly-Items/SysHPMS-Memo-2018-July-24th.html?DLPage=1&DLEntries=10&DLSort=1&DLSortDir=ascending
[9] https://www.govinfo.gov/content/pkg/FR-2017-11-15/pdf/2017-23953.pdf

provides beneficiaries with better protection against catastrophic costs, and encourages use of lower-cost drug alternatives.[10] A portion of this package would provide beneficiaries with more predictable annual drug expenses through the creation of a new out-of-pocket spending cap. Currently, the Part D benefit creates a perverse incentive structure for plans, wherein plans are incentivized to speed beneficiaries through the donut hole and into the catastrophic phase, where Medicare pays 80 percent of costs. Beneficiaries who reach the catastrophic phase continue to be responsible for five percent of their drug costs, which can be a substantial financial burden for those using high cost specialty drugs, such as those used to treat Hepatitis C. This proposal would: (1) increase Part D plan sponsors' risk in the catastrophic phase by increasing plan liability over four years from 15 percent to 80 percent; (2) decrease Medicare's reinsurance liability from 80 to 20 percent; and, (3) eliminate beneficiary coinsurance, creating a true out-of-pocket maximum in Part D for the first time in the program's history.

In addition, last year CMS issued a final Medicare Advantage and Medicare Part D rule to establish a lower copay for biosimilars that is equivalent to the lower copay required for generic drugs for low-income subsidy beneficiaries in Part D.[11] This will lower out-of-pocket costs for biosimilars for low-income beneficiaries, thereby incentivizing biosimilar use. President Trump's FY 2020 Budget goes even further, with a proposal to eliminate cost sharing altogether for generics and biosimilars for low-income beneficiaries.

Increasing Competition and Reducing Opportunities for Gaming

The President's FY 2020 Proposed Budget request also includes a provision that would increase competition by reducing average sales price-based payments when a drug manufacturer takes anti-competitive action. Currently, the majority of Part B drugs are paid at Average Sales Price (ASP) plus 6 percent. When an innovator product is under patent, the ASP is based on that drug's ASP alone, meaning that the manufacturer has complete power to set the price. Often,

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[10] Putting American Patients First: Lowering List Prices, Reducing Out-of-Pocket Costs, and Improving Negotiation and Competition, https://www.whitehouse.gov/wp-content/uploads/2019/03/FY20-Fact-Sheet_Lowering-Drug-Pricing-and-Payment_FINAL.pdf.

[11] CMS, Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program, Final Rule, 83 FR 16440 (April 16, 2018) available at: https://www.govinfo.gov/content/pkg/FR-2018-04-16/pdf/2018-07179.pdf

when a drug is about to go off patent, manufacturers will make an agreement with generic or biosimilar competitors to delay the launch of their product in exchange for some sort of payment, extending the time period during which the innovator product is available without competition. These agreements are known as "pay-for-delay" deals. Actions like the filing of pay-for-delay agreements slow the entry of generic competitors and keep drug prices higher for longer.

The proposal would reduce payment for innovator drugs from average sales price (ASP) plus 6 percent to ASP minus 33 percent when a manufacturer files a pay-for-delay agreement or takes another anti-competitive action. Once a competitor to the innovator product is commercially available, CMS would provide payment for both the innovator and competitor product at ASP plus 6 percent.

Part D Models at the Center for Medicare and Medicaid Innovation

On January 18, 2019, CMS's Center for Medicare and Medicaid Innovation ("Innovation Center"), which tests innovative payment and service delivery models to reduce expenditures and preserve or enhance the quality of care, announced a new payment model to enable Part D plans to better serve patients and help them achieve good health. The Part D Payment Modernization model will test the impact of a revised Part D program design and incentive alignment on overall Part D prescription drug spending and beneficiary out-of-pocket costs.[12] The model is open to eligible standalone Prescription Drug Plans (PDPs) and Medicare Advantage-Prescription Drug Plans (MA-PDs) that are approved to participate. Under the new model, which takes effect for the 2020 plan year, participating plans will take on greater risk for spending in the catastrophic phase of Part D, creating new incentives for plans, patients, and providers to choose drugs with lower list prices. Based on plan year performance, CMS will calculate a spending target for what governmental spending would have been without plans taking on this additional risk. Participating Part D plans will share in savings if they stay below the target but will be accountable for losses if they exceed the target.

The Innovation Center is also testing ways to improve Part D Medication Therapy Management (MTM) activities under the Enhanced MTM Model, which began on January 1, 2017, with a

[12] https://innovation.cms.gov/initiatives/part-d-payment-modernization-model/

five-year performance period. CMS is testing the model across five Part D regions with 22 participating plans administered by six Part D sponsors. Under this model, participating basic stand-alone Part D Prescription Drug Plans (PDPs) adopt innovative approaches to administering MTM activities in lieu of the standard Part D MTM program. The objectives for this model are for stand-alone PDP sponsors to identify and implement innovative strategies to optimize medication use and therapeutic outcomes, improve care coordination, strengthen system linkages, and maximize the effectiveness of Part D MTM expenditures. The Enhanced MTM Model offers a performance-based payment to participating prescription drug plans in a Part D region if their enrolled members' medical (Part A and B) expenses are reduced by at least 2 percent in a given plan year compared to a benchmark that simulated their performance if they were not in the model. For performance year 2017, the first performance year of the model, participants in the model spent approximately $325 million less than the anticipated spending benchmark across the 1.7 million beneficiaries enrolled in participating plans.[13]

Through the Innovation Center, CMS is examining still other ways to lower drug prices, including last year's advance notice of proposed rulemaking that solicited comments on a new way of paying for Part B drugs under an International Pricing Index (IPI) model.

Empowering Patients Through Increased Transparency

The "American Patients First Blueprint" described a new, more transparent drug pricing system that would lower high prescription drug prices and bring down out-of-pocket costs. At CMS, we are constantly looking for better ways to serve our beneficiaries and empower them with information they need to make the best health care decisions for themselves and their families. We have several complementary efforts underway to increase transparency on drug prices.

Prohibition on Gag Clauses in Pharmacy Contracts

In the "Modernizing Part D And Medicare Advantage To Lower Drug Prices and Out-of-Pocket Expenses" final rule issued last month, CMS implemented a provision in the Know the Lowest Price Act of 2018 (P.L. 115-262) to codify our existing prohibition of "gag clauses." Gag clauses

[13] CMS, Part D Enhanced Medication Therapy Management Model First year Performance Based Payment Results Fact Sheet, https://innovation.cms.gov/files/x/mtm-firstyrresults-fs.pdf.

are provisions in drug plan pharmacy contracts that restrict the ability of pharmacies to discuss with enrollees the availability of prescriptions at a cash price that is less than the amount the enrollee would be charged when obtaining the prescription through their insurance. Under the rule, Part D sponsors may not prohibit or penalize a pharmacy from disclosing a lower cash price to an enrollee. Ultimately, informing Medicare beneficiaries about lower cost alternatives will help Medicare beneficiaries save money on their prescription drugs costs.

Drug Spending Dashboards

CMS has also advanced price transparency through the release of interactive, web-based dashboards that present spending on prescription drugs for the Medicare Part B and Part D programs as well as Medicaid.[14] The dashboards reflect CMS' effort to support innovative data driven insights to improve quality, accessibility, and affordability of prescription drugs as well as empower patients and prescribers with information to take ownership of their health and ensure that patients have the flexibility and information to make choices as they seek care.

The dashboards focus on average spending per dosage unit and change in average spending per dosage unit over time in order to allow the public to understand trends in drug spending. The tools also display information for manufacturer(s) of the drugs as well consumer-friendly information of drug uses and clinical indications so patients and physicians can compare program spending for different medications for a given condition. This tool allows the public to see both spending and spending increases in Medicare and Medicaid on prescription drugs.

Plan Finder

As part of CMS's eMedicare multi-year initiative to improve Medicare service across its customer support channels, CMS is undertaking a comprehensive redesign of the Medicare Plan Finder this year. CMS is working to improve usability of the Plan Finder based on feedback we have been collecting from stakeholders and we look forward to continuing our collaborations as we move forward with our efforts to modernize this important tool.

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[14] https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/information-on-prescription-drugs/index.html

The updated Plan Finder will combine and update several tools on the current site to provide a comprehensive experience that offers additional decision support and clarity around prescription drug costs. The redesigned Plan Finder tool will be an important source for Medicare plan information and provide an updated platform and experience for Medicare beneficiaries, family members, caregivers, advocates, and healthcare providers with one central place to view, compare, and select Medicare Part D prescription drug and Medicare Advantage plans. The redesigned Plan Finder tool is expected to be released before the upcoming Medicare Open Enrollment Period.

Requiring Manufacturers to Disclose Drug Prices in Television Ads

To create better incentives for lower list prices, the blueprint considered requiring the inclusion of list prices in direct-to-consumer advertising. Less than a year later, CMS published a final rule to implement this policy.[15]

Price transparency is a necessary element of an efficient market that allows consumers to make informed decisions when presented with relevant information. However, for consumers of prescription drugs or biological products, including those whose drugs are covered through Medicare, the list price remains hard to find.

Our final rule, effective July 9, 2019, requires direct-to-consumer television advertisements for prescription pharmaceuticals covered by Medicare or Medicaid to include the list price, if that price is equal to or greater than $35 for a month's supply or the usual course of therapy. This final rule will provide consumers with more information to better position them as active and well-informed participants in their health care decision-making.

Moving Forward

While CMS has taken actions consistent with the President's "American Patient First Blueprint" to combat drastically rising prescription drug prices, we know we have more to do. As we continue our important work in this area, we remain committed to finding ways to promote innovation and patient empowerment in our programs by facilitating transparency and

[15] https://www.govinfo.gov/content/pkg/FR-2019-05-10/pdf/2019-09655.pdf

competition. We look forward to working with Congress and our Federal partners as well as providers, beneficiaries, plans, pharmaceutical companies, and other stakeholders as we continue to evaluate the most effective ways to approach these issues.

TESTIMONY

OF

JANET WOODCOCK, M.D.

DIRECTOR

CENTER FOR DRUG EVALUATION AND RESEARCH

FOOD AND DRUG ADMINISTRATION (FDA)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SPECIAL COMMITTEE ON AGING

UNITED STATES SENATE

JUNE 19, 2019

RELEASE ONLY UPON DELIVERY

Introduction

Good morning Chairman Collins, Ranking Member Casey, and Members of the Committee. Thank you for the opportunity to testify today and for this Committee's distinguished record of focusing attention on policies to expand access to life-saving medications.

Access to affordable medicine is a matter of life and death for many Americans. Yet, too many Americans are unable to afford life-saving therapies because of their high costs. As the Director of FDA's Center for Drug Evaluation and Research, I can tell you that my colleagues and I take this issue very seriously.

FDA doesn't have a direct role in how drugs are priced; however, we can play an indirect role in holding down prices by bringing efficiencies to the drug development and review process and by promoting robust competition for established drugs, both of which are of great importance to the Center. We are committed to expanding access to high-quality, safe and effective, affordable therapies.

Promoting Competition in Development of Drugs and Biologics

Congress took care to promote innovation and access when it created the framework for generic drug development more than three decades ago and established a biosimilars pathway twenty-five years later. At FDA, we're proud of our record under these laws of fostering generic and biosimilar competition to expand access, lower drug prices, and promote public health.

FDA has worked hard to encourage applicants to enter the market with safe and effective generic drugs after legal barriers to approval, such as patents and exclusivities, have lapsed or otherwise been addressed. As a result the United States has one of the most competitive generic markets in the world.

Under FDA's Drug Competition Action Plan (DCAP), launched in 2017, we're enhancing our efforts to promote greater patient access to more lower-cost options via robust competition. More recently, we announced a Biosimilars Action Plan (BAP) to advance biosimilar development and approval — and facilitate access to lower-cost biological products to treat a growing number of chronic and life-threatening conditions.

Under the DCAP, we are taking steps across three main areas: 1) streamlining the abbreviated new drug application review process, 2) facilitating development of "complex" generic products, and 3) working to close loopholes that allow brand-name drug companies to "game" FDA rules in ways that delay generic competition. We kicked off our efforts in July 2017 with a public meeting to solicit input on ways to promote innovation in drug development and accelerate the availability of lower cost drugs to the American public. The Agency carefully reviewed all the input received and is actively considering new initiatives to help advance competition.

Of course, the foundation of our efforts is our generics review program. We committed under the Generic Drug User Fee Act (GDUFA II) (as part of FDARA) to timelier generic drug application assessments and to enhancements to help reduce the average number of generic review cycles –

and we are delivering. In FY 2018, the first full year of GDUFA II, FDA granted 971 approvals, of those 781 were full approvals and 190 were "tentative" approvals, that is, applications that are ready for approval from a scientific perspective but cannot be fully approved due to existing patents or exclusivities. Nearly 10 percent of the FY 18 approvals were first generics with no generic competition – and 12 percent were for complex, often difficult-to-copy, generic versions of branded products. The latter includes the first generic version of EpiPen and EpiPen Jr (epinephrine injection USP) auto-injector. FDA anticipates this approval means patients living with severe allergies who require constant access to lifesaving epinephrine should have a lower-cost option.

For the full year, FDA approved a record number of generic drugs, including first generics, high-priority medications, and drugs meeting vital public health needs. FDA's record-setting year for new generic approvals in 2018 continues a trend. In 2017, FDA surpassed it generic approval rate for 2016, which was itself another record-setting year.

FDARA recognized that consumers see significant price reductions when multiple FDA-approved generics are available. Based on that principle, we updated our internal procedures to prioritize the review of certain generic applications with not more than three approved generic drugs for a reference listed drug for which there are no blocking patents or exclusivities.

Generic competition is thriving for many products, but some products, including complex generics, have limited competition. Developing a generic version of a complex drug can offer a high-value opportunity at a time when the generics industry is facing economic pressures from rising costs, supply chain consolidation, increased competition and declining reimbursement on many generic products. Since brand-name versions of complex drug products are often higher-priced than many other brand name drugs, efforts to encourage generic competition for complex products also offers outsized potential to increase patient access and lower drug spending.

In February, FDA issued 74 product-specific draft guidances to assist industry in developing generic drugs, including 22 new guidances and 52 revised guidances. Four of the new draft guidances and 45 of the revised draft guidances are for complex drug products, including 16 complex products that, to date, do not have approved generics. Once finalized, these draft guidances will explain our current thinking and expectations on how to develop specific generic drug products that are therapeutically equivalent to the brand name drug products, providing an efficient path for these products to receive regulatory approval.

Recognizing that ready access to comprehensive, accurate, and reliable information on drugs is essential, we posted the inaugural List of Off-Patent, Off-Exclusivity Drugs without an Approved Generic in June 2017, and have subsequently posted more detailed, updated versions every 6 months. The list enables generic sponsors to more easily identify drugs without an approved generic. We intend to expedite the review of any generic drug application for a product on this list to ensure that they come to market as expeditiously as possible. We are also considering how we can enhance the *Approved Drug Products with Therapeutic Equivalence Evaluations* – known as the Orange Book – and clarify Orange Book processes. We are encouraged by congressional interest in improving the utility of the Orange Book for users who rely on its information for drug development. We hope to work with the Senate should it

consider H.R. 1503, the "Orange Book Transparency Act of 2019." Separately, we are undertaking efforts of our own to solicit public comment on Orange Book use and potential enhancements, including a re-examination of which pharmaceutical patents should be listed in the Orange Book.

We know there are still many branded products on the market without generic competition – and we are helping to encourage development of safe and effective generic competition to these sole source drugs. Since being granted new authorities in FDARA, the agency has moved quickly to designate drugs as Competitive Generic Therapies (CGT). The designation provides incentives for industry to develop generics for drugs lacking competition.

In February, FDA issued draft guidance on Competitive Generic Therapies to help provide even greater clarity to industry about the CGT pathway. This new guidance provides robust information on how drug developers can apply for CGT designation and when they may be eligible for CGT exclusivity. FDA's implementation of this new pathway is an important part of our broader effort to foster generic competition and help address the high cost of drugs and improve patient access to important medicines.

In addition, we are identifying abuses of the system that can impede competition and are doing our part to fix them. For example, many generic developers have reported difficulty obtaining brand drug samples needed for generic drug development, including bioequivalence testing, delaying or entirely preventing their efforts to develop more affordable generic drugs. In May of last year, we published a list on FDA's website of branded products for which generic drug developers have reported difficulties in obtaining access to samples. We also published a draft guidance to provide FDA's proposed response to some of the Risk Evaluation and Mitigation Strategies (REMS) competitor negotiation practices that can delay the entry of generic drugs.

We applaud congressional efforts to remove barriers to drug development and appreciate Congress' work on the "Creating and Restoring Equal Access to Equivalent Samples Act" (the CREATES Act). A path to securing samples of brand drugs for the purpose of generic drug development should always be available. We look forward to continuing to work with Congress on this legislation with the shared goal of reducing any opportunity for gaming.

Several proposals in the FY 2020 budget also target possible gaming. We would like to see statutory improvements to our citizen petitions process. Specifically, FDA would like greater authority to summarily deny petitions submitted with the primary purpose of delaying approval of an application and to incentivize timely filing of petitions. We would also like to eliminate the mandatory 150-day response timeframe from the statute. Operationally, the mandatory response timeframe is no longer needed to avoid delay of approval of follow-on applications as FDA already works under the goal dates set for these applications separate from this mandatory 150-day period.

Two other legislative proposals encourage competition, but with a focus on the 180-day exclusivity available to first-filers. First, we propose that Congress amend one of the existing 180-day forfeiture provisions to limit the ability of first filers with deficient ANDAs to game the system to avoid forfeiture. Forfeiture occurs under this provision when an applicant fails to

receive tentative approval within 30 months, unless the failure to obtain tentative approval is caused by a change in or a review of the requirements for approval imposed after the application filing date. Currently, first applicants with deficient applications may benefit from this provision by avoiding forfeiture even though they have deficiencies in their application unrelated to any change in or review of the requirements for approval. The proposal would clarify that the exception to forfeiture will only apply if the change in or review of the requirements for approval was the sole cause of the applicant's failure to obtain tentative approval.

The second proposal would address situations we see on a recurring basis where, after patent and exclusivity issues with the innovator drug have been resolved, first filers "park" their 180-day exclusivity and do not seek final approval, thereby delaying marketing and blocking competition for periods beyond which Congress envisioned. We suggest statutory modifications to trigger the start of the 180-day clock when: (1) a subsequent filer is ready for approval and the only barrier to final approval of the subsequent filer's application is a first filer's eligibility for 180-day exclusivity; and (2) certain other conditions are met, including that the first filer is past the 30-month timeframe to receive tentative approval and that any statutory stay of approval for the first filer has expired or terminated. This proposal will help ensure that generic competition occurs in a timely manner and that first filers who are unable or unwilling to obtain approval in a timely fashion cannot delay approval of subsequent applications indefinitely.

We are continuing to coordinate with the Federal Trade Commission, a vital partner in our efforts to address anti-competitive behavior in the drugs and biologics marketplace. Although we remain concerned about pay-for-delay agreements due to their anticompetitive impact, we are also concerned about *any* agreement that delays competition in the drug or biologic markets.

At FDA we have a number of pathways available to companies to get products to market more quickly than under our standard review. We offer those pathways (such as fast track and breakthrough, and even expedited consideration of applications for drugs currently in or vulnerable to a drug shortage). Let me make clear that although FDA may approve a drug, a company is under no obligation to market it. This is no small point given the scrutiny of drug prices and competition, and I raise it to highlight a dynamic outside of FDA's framework.

Every day we work to ensure that medical products are safe and effective, and that consumers can have confidence in the products they use. As regulators, we are on the front lines of the tension between upholding our standards of safety and efficacy and concerns over patient accessibility. I can't tell you how many times I have heard heartbreaking stories of families struggling with severe diseases, some of which are terminal, and others which are chronic and require a lifetime of care and close monitoring. At FDA, we have access to the best science and research in the world, and we do our level best to facilitate getting life-changing therapies to patients. Efforts to bypass our rigorous standards have unforeseen consequences, and I am always mindful of those challenges. The lessons we have learned since the establishment of FDA have helped inform our current thinking, which has also kept pace with scientific innovation and development.

Building a Strong Framework for Biosimilars

Similarly, an efficient, predictable development and approval pathway for biosimilars is a key to facilitating greater competition and innovation in the biologics marketplace. Biologic medicines have become a crucial tool in the treatment of many serious and life-threatening diseases. Biologics, which are typically complex molecules produced by living cells, are increasingly the backbone of modern therapy. But biologics are costly: they account for almost 40 percent of total prescription drug spending and 70 percent of the growth in drug spending between 2010 to 2015.

Until recently, biologics lacked effective competition because there was no abbreviated pathway for bringing follow-on versions of biologics to market under the Public Health Service Act (PHS Act), similar to the generic pathway we have for small molecule drugs created under the 1984 Hatch Waxman amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act). In 2010, Congress enacted the Biologics Price Competition and Innovation Act (BPCI Act), creating a pathway for approval of biosimilar and interchangeable products. This opened biologics to effective competition, with the ultimate goal of providing more treatment options, increasing access to lifesaving medications, and potentially lowering health care costs.

Since that time, FDA has approved 19 biosimilars and interest in these products remains high, with over 75 development programs currently enrolled in FDA's Biosimilar Biological Product Development Program for 36 different reference products. However, although the development pipeline for biosimilars is robust, fewer than half of the biosimilars approved by FDA have gone to market. We are very concerned that a large portion of the biosimilars that have been demonstrated to meet FDA's robust scientific standards for approval are not yet available to patients. We've set out in recent months to clarify and expand upon policies that promote more competition when it comes to biosimilar products and to advance our overall framework that improves the efficiency of the biosimilar and interchangeable product development and approval process.

FDA announced its Biosimilars Action Plan (BAP) in July 2018, recognizing that this is a crucial time in the emergence of biosimilars and a more competitive market for biologics. Under the BAP, FDA is focusing its efforts on: advancing the science and policies to make the development of biosimilars more efficient; increasing the understanding of biosimilars; and acting against regulatory gaming that can deter or delay competition.

Not only are we making the biosimilar development and review process more efficient and predictable, under the BAP we are also taking new steps to communicate with patients, payors, and providers to improve the understanding of biosimilar and interchangeable products. Further, we will act where appropriate to deter gaming of FDA requirements that unfairly delays competition among biologics.

The President's budget recommends a legislative proposal to encourage biosimilar development and innovation – and reduce gaming. Statutory provisions that relate to monograph standards issued by the U.S. Pharmacopeia, which include standards for strength, quality, packaging and labeling, were originally drafted for non-biologic drug products, but currently also apply to

biological products, including biosimilars. These provisions do not provide the flexibility needed to support innovation in product and test development. The proposal is meant to ensure that FDA can continue to approve biologic products with innovative changes that meet FDA's rigorous, approval requirements but nevertheless fail to meet static, prescriptive monograph standards – that, in some cases, have been outdated for decades. USP standards cannot be updated quickly enough to facilitate timely approval of novel products and/or novel manufacturing practices. The proposal would amend the Public Health Service Act so it is clear that biological products do not have to meet monograph standards, which could delay or impede licensure of a biosimilar and create substantial uncertainty for biosimilar applicants.

We're taking new steps to implement Congress's direction that we transition approved applications for biological products approved as drugs under the FD&C Act to biologics licenses under the PHS Act, opening them up to biosimilar competition. This will enable – for the first time – products that are biosimilar to, or interchangeable with, these biological products to come to market. Once an interchangeable product is approved and available on the market, it can then be substituted for the reference product without the involvement of the prescriber, potentially leading to increased access and lower costs for patients.

This transition is particularly important for insulin. Diabetes takes a tremendous toll on Americans, both physically and economically. It remains the seventh leading cause of death in the U.S. and accounts for $330 billion in annual health care spending. Insulin list prices have been regularly increasing by double digits annually despite the presence of numerous approved insulin products on the market. These increases have raised serious concerns about the ability for many patients to access the insulin needed to survive.

We must ensure that everyone who needs insulin has access to it. Under the FD&C Act, it has been hard to bring a substitutable generic insulin to the market. We believe the biosimilar pathway should help usher in a new era of competition for these products that we hope will lead to lower prices and better access.

As we transition to this pathway, FDA has been working to implement the statutory transition provision in a manner that promotes clarity, minimizes burden, helps ensure stability for patients using currently marketed products, and facilitates the development of biosimilar and interchangeable products. FDA has issued final guidance on the transition that provides recommendations to biological product sponsors to facilitate alignment of product development plans with FDA's interpretation of this statutory provision. We believe that FDA's recommendations to sponsors and performance goal dates for applications have made it unlikely that there would be any pending applications originally submitted under the FD&C Act that would need to be submitted and reviewed under the PHS Act. The Agency is also taking steps to minimize disruption and to provide clarity and certainty to application holders who seek to make changes to their approved products close to the transition date.

We're also working now – in advance of the March 2020 transition – to provide advice to sponsors on development programs for proposed biosimilar and interchangeable insulin products and to build a solid regulatory foundation for the review and approval of these products. In December 2018, we took a suite of actions designed to advance the agency's biosimilar

framework and to provide clarity and predictability to manufacturers, and earlier this month we published a final guidance outlining considerations for demonstrating interchangeability.

We're already seeing robust activity among sponsors seeking to develop products that are biosimilar to or interchangeable with insulin. Recently, we held a public hearing to discuss access to affordable insulin products, as well as the scientific and regulatory issues related to the development and evaluation of biosimilar and interchangeable insulin products. Stakeholders provided valuable input on data and information needed to support a demonstration of biosimilarity or interchangeability for insulin, and what factors the Agency should consider when evaluating data and other information submitted by an applicant, including from analytical and clinical studies. Importantly, we're also seeking input directly from patients about their experience with insulin products to inform our approach to regulating biosimilar and interchangeable products.

We have also closely reviewed legislation that affects biologic products. In many ways, the research, development and manufacturing of these products differs from small molecules. At FDA, we are cognizant of the many differences between drugs and biologics. Any proposal that attempts to import requirements of drug products that do not squarely fit within the biologics space could disrupt approval and access to these products.

We appreciate the Chairman's efforts to promote robust competition for biologics by introducing S. 659, the "Biologic Patent Transparency Act" and we hope to continue our constructive dialogue with your office on this important subject. We share your goal of enhanced transparency and are committed to making improvements to the Purple Book (a reference providing information relating to licensed biologic products).

We continue to evaluate additional steps necessary to strike the appropriate balance between encouraging ongoing innovation and facilitating the robust competition that can reduce costs to patients. We are committed to ongoing enhancements to reduce the time, uncertainty and cost of generic and biosimilar product development.

Modernizing Regulatory Oversight of New Drugs

Developing new medical therapies requires a challenging scientific process and significant financial investment. FDA has an important role to play in providing efficient, predictable, and science-based oversight to help reduce the time and uncertainty of bringing new drugs and biologics to market and, therefore, reduce the corresponding cost of drug development – and we are doing so.

Important new authorities and resources provided by Congress in the FDA Reauthorization Act of 2017 (FDARA) and the 21st Century Cures Act are helping transform the way we support medical product development and innovation while maintaining FDA's gold standard for safety and effectiveness. FDA is modernizing our science-based framework for clinical trials and embracing flexible, transparent, and innovative approaches to regulate new categories of products.

A cornerstone of our efforts is interactive communications with sponsors, which enables them to develop clinical trial designs and approaches, navigate key milestones, and understand submission requirements. Meaningful dialogue reduces the need for additional review cycles which can add significant time and expense to drug development.

In 2018, we approved many new drugs never before marketed in the United States, known as "novel" drugs, along with a wide variety of approvals for new and innovative uses of drugs already on the market. Many of these new approvals will have a significant impact on improving—and indeed, saving—countless patients' lives. All were approved within Prescription Drug User Fee Act (PDUFA) review goal dates. Approximately two-thirds used one or more of FDA's expedited development and review programs. We continue our efforts to keep pace with the rapidly changing scientific landscape and are working to modernize our regulatory framework. One legislative clarification we have sought in our FY 2020 budget proposal would codify FDA's active moiety approach for new chemical entity exclusivity determinations. This statutory change would help resolve uncertainty regarding applicability of our regulations in light of recent caselaw developments.

FDA is committed to enhancing achievement of its core mission, which includes efforts to help ensure and improve the safety and effectiveness of over-the-counter (OTC) Monograph drugs. Self-care through the use of OTC drugs empowers consumers to choose therapies which work best for them. Americans use OTC drugs every day, and these products will become increasingly important as patients take greater control of their own health. Reforms of the existing system are needed to promote innovation and choice for patients and consumers while also improving FDA's ability to address urgent safety issues in a timely fashion and help ensure the safety and effectiveness of OTC products. A wide range of stakeholders has come together to support these reforms and we hope to continue to work with Congress on legislation to make them a reality.

Conclusion

I look forward to continuing to work with the Committee as we address the problem of high drug prices, provide greater access to lifesaving medical products, and ensure that the United States remains a leader in biomedical innovation.

I am happy to answer questions from the Committee.

Testimony Before the United States Senate Special Committee on Aging

"The Complex Web of Prescription Drug Prices, Part III: Examining Agency Efforts to Further Competition and Increase Affordability"

Testimony of:
Vicki L. Robinson
Senior Counselor for Policy

Office of Inspector General
Department of Health and Human Services

June 19, 2019

Dirksen Senate Office Building, Room 562

Chairman Collins, Ranking Member Casey, and other distinguished members of the Committee, I am Vicki L. Robinson, Senior Counselor for Policy at the Department of Health and Human Services (HHS), Office of Inspector General (OIG). Thank you for the invitation to testify today about the Department's recent proposed rule addressing rebates and other price reductions on prescription drugs.

Introduction

My testimony will describe the Department's proposal to change the safe harbor framework under the Federal anti-kickback statute as it applies to certain rebates and other price reductions on prescription pharmaceutical products from manufacturers to Part D plan sponsors and Medicaid managed care organizations (MCOs).[1]

Specifically, the proposed rule would:

1. remove existing protection from anti-kickback statute liability under the discount safe harbor (42 CFR 1001.952(h)) for rebates and other reductions in price on prescription drugs from a manufacturer to a Part D plan sponsor, Medicaid MCO, or pharmacy benefits manager (PBM) under contract with them;
2. add new safe harbor protection for point-of-sale discounts that are completely applied to the price of the prescription drug at the time the pharmacy dispenses it to the beneficiary; and
3. add new safe harbor protection for fixed fees paid by manufacturers to PBMs for services the PBMs perform for the manufacturers.

As stated in the proposed rule, the Secretary is concerned that existing rebate arrangements have proven to be ineffective at, and counterproductive to, putting downward pressure on drug prices and that rebates may be harming Federal healthcare programs by increasing list prices, preventing competition to lower drug prices, discouraging the use of lower-cost brand or generic drugs, and skewing formularies. The proposed rule further explains concerns about PBMs favoring drugs with higher rebates over drugs with lower costs and basing formulary decisions on rebate potential rather than the quality or effectiveness of the drug. The Department's goals for the proposed rule are to curb list price increases, reduce financial burden on beneficiaries, improve transparency, and reduce the risks associated with rebates inappropriately influencing formulary placement or inducing business payable by Medicare Part D or Medicaid.

Because we are in active rulemaking, my testimony is limited to what the Department proposed in the Notice of Proposed Rulemaking published in the *Federal Register* on February 6, 2019 (84 FR 2340) and the public comments we received in response. My testimony is not intended to predict, and should not be viewed or interpreted as predicting, what might be in a final rule. A final rule is currently pending review at the Office of Management and Budget.

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[1] Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees, 84 Fed. Reg. 2,340 (Feb. 6, 2019), *available at* https://www.govinfo.gov/content/pkg/FR-2019-02-06/pdf/2019-01026.pdf.

Legal Background

1. The Federal Anti-Kickback Statute and Safe Harbors

The Federal anti-kickback statute, section 1128B(b) of the Social Security Act, serves an important role in ensuring that medical decision-making is not improperly influenced by financial interests. Broadly speaking, the statute provides for criminal penalties for whoever knowingly and willfully offers, pays, solicits, or receives remuneration (generally, anything of value) to induce or reward the referral of business reimbursable under any of the Federal healthcare programs (as defined in section 1128B(f) of the Act). Among other things, the statute applies to remuneration offered or paid in return for arranging for or recommending the purchase of products.

The statute contains certain exceptions describing payment practices that are not violations of the law, including one that protects discounts or other reductions in price. Given the broad reach of the anti-kickback statute, Congress enacted legislation that required the Secretary to develop and promulgate regulations, the so-called safe harbor regulations, that would specify various payment and business practices that are not subject to sanctions under the anti-kickback statute, even though they may potentially be capable of inducing referrals of business for which payment may be made under a Federal healthcare program.[2] The safe harbor regulations are evolving rules intended to be updated periodically to reflect changing business practices and technologies in the healthcare industry. In crafting safe harbors, the Secretary may consider a variety of factors, including increases or decreases in access to healthcare services, increases or decreases in the cost to Federal healthcare programs, and increases or decreases in competition among healthcare providers.[3] Congress gave the responsibility for the development of safe harbors to the Secretary, and the Secretary has further delegated the authority to OIG.

Healthcare providers and others may voluntarily seek to comply with safe harbors so that they have the assurance that their business practices will not be subject to any anti-kickback statute enforcement action. The fact that a business practice does not fit in a safe harbor does not mean it is necessarily unlawful. Rather, it would be examined for compliance under the anti-kickback statute on the basis of its facts and circumstances, including the intent of the parties.

2. The Discount Safe Harbor

The original discount safe harbor regulation at 42 CFR 1001.952(h) was promulgated in 1991 and amended in 1999 and 2002.[4] The discount safe harbor recognizes that a price reduction is an

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[2] Specifically, section 1128B(b)(3) of the Act protects from the anti-kickback statute "any payment practice specified by the Secretary in regulations promulgated pursuant to section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987."

[3] See Section 205 of the Health Insurance Portability and Accountability Act of 1996.

[4] Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952 (July 29, 1991), *available at* https://oig.hhs.gov/fraud/docs/safeharborregulations/072991.htm; Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute 64 Fed. Reg. 63518 (Nov. 19, 1999), *available at* https://www.govinfo.gov/content/pkg/FR-1999-11-19/pdf/99-29989.pdf; Medicare and Federal Health

inducement to purchase a product and therefore implicates the anti-kickback statute. In its current form, the discount safe harbor—which is available broadly across the healthcare industry—protects discounts and other reductions in price to a buyer, including rebates, provided that all conditions of the safe harbor are satisfied.

Summary of the Proposed Rule

To address the Department's concerns with the current rebate system in the pharmaceutical supply chain, the Department proposed and solicited comments on revisions to the safe harbor regulations. The stated intent of the proposed rule is to eliminate rebates from manufacturers to plan sponsors under Part D, Medicaid MCOs, and PBMs operating on their behalf, and replace them with discounts that would benefit beneficiaries at the point of sale. In addition, the Department proposed a new safe harbor to protect certain fixed fees that pharmaceutical manufacturers pay to PBMs for certain services rendered to the manufacturers.

1. Proposed Amendment to the Discount Safe Harbor to Remove Protection for Discounts to Part D Plans and Medicaid MCOs

First, the Department proposed to amend the current discount safe harbor to exclude from the definition of "discount" at paragraph 1001.952(h)(5) all price reductions (including rebates) from manufacturers on prescription pharmaceutical products in connection with their sale to or purchase by plan sponsors under Medicare Part D, Medicaid MCOs, directly or through PBMs acting under contract with plan sponsors under Medicare Part D or Medicaid MCOs, unless the reduction in price is required by law (*e.g.*, rebates under the Medicaid Drug Rebate Program). This change would have the effect of removing safe harbor protection under the anti-kickback statute for these price reductions.[5] The proposed effective date of this change is January 1, 2020. The proposed rule solicited comments on the proposed exclusion and the proposed establishment of a new safe harbor for point-of-sale price reductions, including impact on beneficiaries, states, pharmacies, commercial markets, and others.

2. Proposed Safe Harbor for Point-of-Sale Reductions in Price for Prescription Pharmaceutical Products

Second, the Department proposed to add a new safe harbor at 42 CFR 1001.952(cc) to protect certain point-of-sale price reductions that benefit patients when they fill prescriptions at the pharmacy counter. Three proposed criteria would apply. The reduction in price would need to be set in advance in writing; the reduction in price could not be a rebate unless the full value of the reduction in price is provided to the dispensing pharmacy through a chargeback, or the rebate is required by law; and the reduction in price would need to be completely applied to the price the pharmacy charges to the beneficiary at the point of sale. The proposed rule solicited comments on how best to frame the new safe harbor to foster point-of-sale price reductions while minimizing any fraud or abuse risks to programs and patients.

Care Programs: Fraud and Abuse; Revisions and Technical Corrections, 67 Fed. Reg. 11928 (March 18, 2002), *available at* http://www.federalregister.com/Browse/AuxData/9F5C6DD8-FF39-4FB6-85C0-DBC24659C3B2.

[5] The proposed rule would not alter any rules or obligations under the Part D or Medicaid programs.

3. Proposed Safe Harbor for Pharmacy Benefit Manager Service Fees

Third, the Department proposed to add a new safe harbor at 42 CFR 1001.952(dd) specifically designed to protect certain fees a pharmaceutical manufacturer pays to a PBM. These fees would pay for services rendered by the PBM to the manufacturer that relate to the PBM's arrangements to provide pharmacy benefit management services to health plans. Among other conditions, protected fees would need to be fixed (*i.e.*, not based on a percentage of sales); be set out in advance in writing; be fair market value for the service rendered; and not be determined in a manner that takes into account the volume or value of referrals or business generated between the parties). The services rendered would be disclosed to plans. The proposed rule recognized the possibility that certain types of remuneration that manufacturers might pay to PBMs either would not implicate the anti-kickback statute or could be protected using another safe harbor. However, the proposed safe harbor would provide a pathway, specific to PBMs, to protect certain low risk service fee arrangements. The proposed rule solicited comments on the proposed criteria and specifically highlighted as goals for the proposed criteria the importance of furthering transparency and avoiding risks connected with waste, fraud, and abuse.

4. Estimated Impacts of the Proposed Regulation

As described more fully in the proposed rule, due to the complexity and uncertainly of stakeholder response, it is difficult to accurately quantify the potential benefit of the proposed regulation. The Department engaged the Centers for Medicare & Medicaid Services' (CMS's) Office of the Actuary (OACT) and two independent actuarial firms (Milliman and Wakely)[6] with experience working with Part D plan bid preparation to assess the potential effects on both premiums and out-of-pocket expenses. As described in the proposed rule, certain behavioral responses to the regulation by industry actors and beneficiaries would potentially affect benefit design, plan bids and, ultimately, beneficiary and government spending. The proposed rule presented six scenarios analyzed by OACT, Wakely, and Milliman. The scenarios made different assumptions about how plans might change benefit offerings or how manufacturers might change pricing processes.

Broadly speaking, the analyses show potential for beneficiaries, on average, to experience lower costs (combined premiums and out-of-pocket drug spending), although the impact on individual beneficiaries would vary greatly. Some beneficiaries, such as sicker beneficiaries with high drug costs, would see savings, while others would experience increases in out-of-pocket spending, such as increased plan premiums. Similarly, the analyses show variation in potential impact on Federal spending, with one scenario that assumed behavioral changes predicting potential decreased Federal spending, while other scenarios show substantial increases. The proposed rule solicited comments on the estimated impacts.

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[6] These analyses are *available at* https://aspe.hhs.gov/pdf-report/prescription-drug-pricing-aspe-resources-related-safe-harbor-rule.

Overview of Public Comments

The public comment period for the proposed rule closed on April 8, 2019. We received approximately 26,000 comments from a wide range of stakeholders, including PBMs, pharmaceutical manufacturers, Part D plan sponsors, pharmacies, wholesalers, Medicaid MCOs, states, consumers, and trade associations representing various individuals and entities. We received extensive, thoughtful comments, and we appreciate the engagement of the public in this rulemaking process. We have read, and are continuing to consider closely, all comments received. We are also coordinating closely with CMS, the HHS agency that administers the Part D and Medicaid MCO programs.

The comments address a broad range of topics and issues, from legal concerns to policy goals to practical implementation. Key themes in the public comments include:

- Beneficiary Out-of-Pocket Spending on Drugs. Comments reflected broad support across stakeholders for reducing beneficiaries' out-of-pocket spending on drugs.
- Formularies. Commenters made suggestions related to ensuring beneficiary access to drugs, raised concerns about plans using more restrictive formularies to keep premiums down, and supported eliminating rebates as an incentive for preferred formulary placement of brand name drugs over less costly, equally effective drugs (e.g., generics or biosimilar products).
- Implementation. Stakeholders raised both concerns about and support for the proposed implementation timeframe, as well as concerns about needed infrastructure to operationalize point-of-sale discounts and chargebacks.
- Additional Guidance. Commenters requested additional guidance and clarity regarding key terms and provisions, including how the chargeback process would work in the proposed point-of-sale price reductions safe harbor.
- Medicaid MCOs. Commenters requested we remove Medicaid MCOs from the amendments to the discount safe harbor given that most patients in these programs have nominal, if any, cost-sharing obligations.
- Impacts. Commenters offered feedback on the estimated impacts of the proposed rule on programs and beneficiaries.

Conclusion

I appreciate the opportunity to testify about the Department's proposed rule and would be happy to discuss the issues raised more fully after completion of the rulemaking process.

Since 1976, OIG has provided objective, independent, credible oversight to drive positive change for the Department of Health and Human Services' programs and the people they serve. OIG is at the forefront in preventing and detecting fraud, waste, and abuse in health and human services programs and, where necessary, enforcement to address violations of law. OIG carries out its mission through audits, evaluations, inspections, investigations, and legal actions in accordance with established professional standards.

OIG's past and current work speaks to the integrity and effectiveness of critically important benefits on which senior citizens depend and that taxpayers fund, such as prescription drugs, hospice, and nursing homes. OIG has a rich body of work focused on ensuring that HHS prescription drug programs work as intended. Protecting the integrity of prescription drug programs, fostering prudent payments for prescription drugs, and ensuring appropriate access to prescription drugs drive our efforts in this space. Our goal is to identify opportunities to limit the impact of high drug prices on Federal programs and senior citizens, while protecting access to medically necessary drugs. OIG will continue to work diligently to promote the effective and efficient operation and fiscal soundness of HHS's programs and to protect the health and welfare of the people they serve.

OIG greatly appreciates the support of this Committee for its oversight and program integrity work. Thank you again for the invitation to testify. I would be happy to take your questions.

Statements for the Record

United States Senate
WASHINGTON, DC 20510

June 11, 2019

President Trump
The White House
1600 Pennsylvania Avenue NW
Washington, DC 20500

Dear President Trump:

We write to express our opposition to your administration's numerous and ongoing efforts to undermine the health, well-being and quality of life of low-income Americans. You and your administration have already attempted to take away health care coverage by sabotaging the Affordable Care Act (ACA), to decimate Medicaid, to impose additional work requirements for Supplemental Nutrition Assistance Program (SNAP) benefits and to make draconian cuts to federal housing programs. Now, it appears your Office of Management and Budget (OMB) is poised to take another damaging step to undermine the economic security of our country's most at-risk citizens by proposing a change to how poverty is measured. The change would result in decreases in eligibility for vital assistance, less support for those in need and, ultimately, greater poverty and hardship for millions of children and families.

On May 7, 2019, OMB issued a request for comment on a potential change to how the federal government measures poverty in the United States.[1] Under the Official Poverty Measure (OPM), the poverty thresholds are calculated by the U.S. Census Bureau and updated each year to account for inflation. While the OPM is primarily used for statistical purposes, the Department of Health and Human Services (HHS) bases its annually issued poverty guidelines on the OPM thresholds. The poverty guidelines are in turn used to determine eligibility for a number of government programs, including Medicaid, the Children's Health Insurance Program (CHIP), the Maternal and Child Health Block Grant, the Community Service Block Grant, Head Start, the School Breakfast Program, HOME Investment Partnership and Community Development Block Grants, among others.[2]

The HHS poverty guidelines for 2019 are $25,750 for a family of four,[3] and there is evidence to suggest that even these guidelines are far too low and that they do not capture the true financial struggles of millions of Americans. This includes the 12.8 million children, 4.7 million seniors and 3.8 million individuals ages 18 to 64 with a disability who live below the current poverty line, as well as the millions of people living just above it.[4] These Americans and their families rely on the aforementioned

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[1] Federal Register 84 FR 19961, "Request for Comment on the Consumer Inflation Measures Produced by Federal Statistical Agencies" (May 7, 2019) Online at: https://www.federalregister.gov/documents/2019/05/07/2019-09106/request-for-comment-on-the-consumer-inflation-measures-produced-by-federal-statistical-agencies. Accessed May 8, 2019.
[2] Office of the Assistant Secretary for Planning and Evaluation, "Frequently Asked Questions Related to the Poverty Guidelines and Poverty." Online at: https://aspe.hhs.gov/frequently-asked-questions-related-poverty-guidelines-and-poverty; Karen Spar and Gene Falk, Congressional Research Service, "Federal Benefits and Services for People with Low Income: Overview of Spending Trends, FY2008-FY2015" (July 29, 2016). Online at: https://www.crs.gov/reports/pdf/R44574. Accessed May 8, 2019.
[3] Federal Register 84 FR 1167, "Annual Update of the HHS Poverty Guidelines." Online at: https://www.federalregister.gov/documents/2019/02/01/2019-00621/annual-update-of-the-hhs-poverty-guidelines. Accessed May 8, 2019.
[4] Kayla Fontenot, Jessica Semega and Melissa Kollar, United States Census Bureau, "Income and Poverty in the United States: 2017" (September, 2018). Online at https://www.census.gov/content/dam/Census/library/publications/2018/demo/p60-263.pdf.

programs, among many others, in order to survive. If anything, Congress and your administration should be doing *more* to lift them out of poverty. Every child should have the freedom to grow up in a safe, financially secure and healthy environment. Every senior should have the peace of mind that a secure retirement is achievable. Every person with a disability should be able to fully participate in all aspects of society.

However, instead of ensuring the OPM more fully captures the financial hardships of low-income Americans and helping programs better serve them, OMB is looking for ways to shrink the services these individuals can access. According to the May 7 Request for Comment, it appears that your administration would like to change the inflation measure currently used to set the OPM each year from the Consumer Price Index for All Urban Consumers (CPI-U) to the Chained Consumer Price Index for All Urban Consumers (C-CPI-U or 'chained CPI'). Making this change while failing to address the ways in which the current poverty line underestimates hardship could decrease the accuracy of the OPM. Further, because chained CPI shows *slower* inflation over time, fewer Americans would fall below the poverty line in the future, and programs that serve low- and moderate-income people would see major funding cuts.[5]

OMB itself acknowledges this when it says, "[C]hanges to the poverty thresholds, including how they are updated for inflation over time, may affect eligibility for programs that use the poverty guidelines."[6] Meanwhile, your 2017 tax law included hundreds of billions of dollars in giveaways to the wealthiest Americans, while over 50 million households making under $100,000 a year will see a tax increase or a tax cut of less than $9 a month this year. This OPM action only doubles down on these inequitable tax policies. Instead of giving $1.5 trillion in tax breaks to wealthy Americans and large, multi-national companies, you should be focusing on ensuring a safer, more equitable and more supportive foundation for low-income Americans, especially for our kids, seniors and people with disabilities.

While we would welcome a careful, well-researched and evidence-based discussion about how to measure poverty for statistical purposes, the OMB notice ignores many of the well-known limitations of the current measure; a 45-day comment period to consider these issues is woefully insufficient. Moreover, Congress has repeatedly enacted program eligibility standards based on the HHS guidelines, always assuming that these guidelines would continue to be updated using the current methodology. OMB should not unilaterally lower the guidelines and take health coverage and other basic assistance away from people Congress intended to have it, thereby increasing hardship for American children and families.

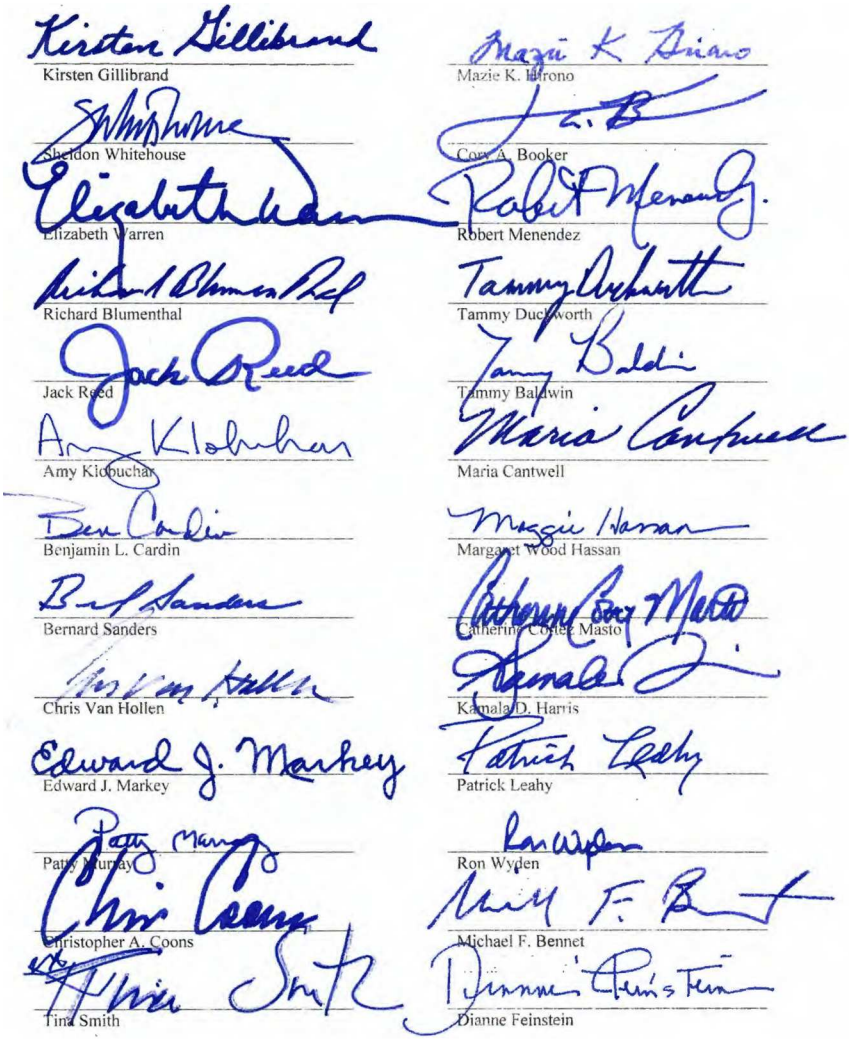
Sincerely,

Robert P. Casey, Jr.

Sherrod Brown

[5] Sharon Parrott, Center on Budget and Policy Priorities, "Trump Administration Floating Changes to Poverty Measure That Would Reduce or Eliminate Assistance to Millions of Lower-Income Americans" (May 7, 2019) Online at: https://www.cbpp.org/press/statements/trump-administration-floating-changes-to-poverty-measure-that-would-reduce-or. Accessed May 8, 2019.

[6] Federal Register 84 FR 19961 *supra*.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Kamala D. Harris
Edward J. Markey
Patrick Leahy
Patty Murray
Ron Wyden
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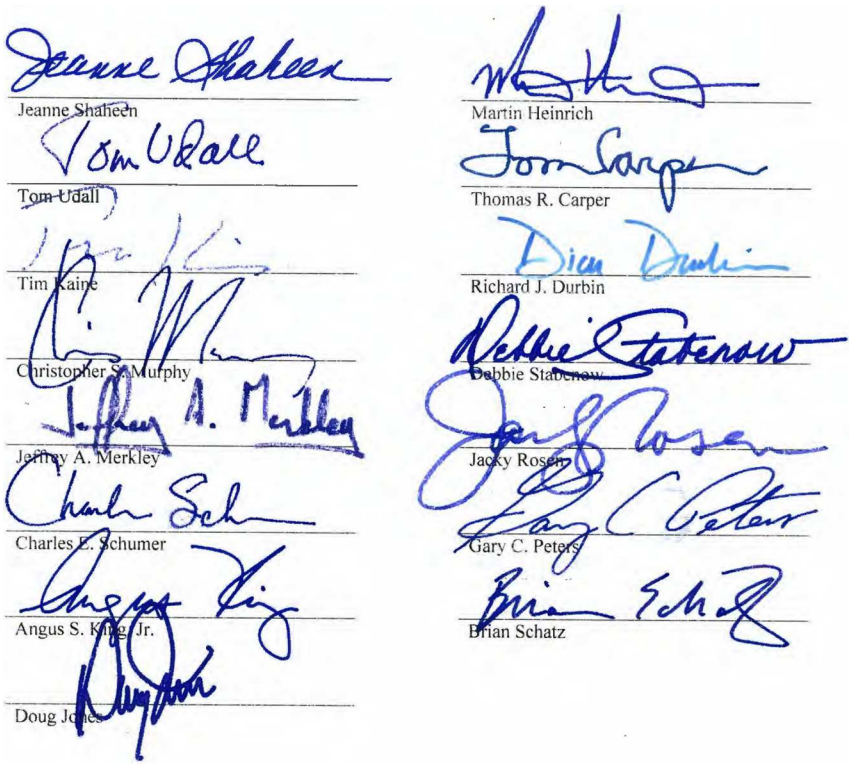
Jeanne Shaheen
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Christopher S. Murphy
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Jeffrey A. Merkley
Jacky Rosen
Charles E. Schumer
Gary C. Peters
Angus S. King, Jr.
Brian Schatz
Doug Jones

United States Senate
WASHINGTON, DC 20510

June 19, 2019

President Donald J. Trump
The White House
1600 Pennsylvania Ave, NW
Washington, DC 20500

Dear President Trump:

We write regarding concerns that your efforts to sabotage the health care coverage of millions of Americans will undermine our shared goal of lowering the price of prescription drugs. As you know, the coverage individuals receive through Medicaid and the Affordable Care Act provides protection against extreme out-of-pocket costs on the medications they need in order remain healthy. To that end, we urge you to cease all efforts to cap Medicaid or turn the program into a block grant and to ensure consumers benefit from the protections in the Affordable Care Act so that families are not forced to pay more for prescription drugs or potentially lose coverage entirely.

Medicaid plays a pivotal role in making sure our most vulnerable Americans have access to quality, affordable health care, including prescription drug coverage. Indeed, Medicaid covers the cost of prescription drugs for over 75 million seniors, people with disabilities, adults and children. As a result of the Affordable Care Act, individuals and families gained key consumer protections that guaranteed access to comprehensive coverage, including prescription medications. Medicaid and the Affordable Care Act are emblematic of who we are as a nation – reflecting what and who we value and the ideals we are willing to fight for.

Despite the public outcry in 2017 that prevented your Administration and Republicans in Congress from imposing caps on Medicaid and repealing the Affordable Care Act legislatively, your Administration remains steadfast in undermining these two programs. For example, your Administration is working with states behind closed doors to impose spending caps on Medicaid according to reports, and actively working with states to implement harmful work-requirements on those most in need. These secret negotiations have already caused people to lose coverage and threaten the coverage of millions more. Your Administration also expanded enrollment in short-term, limited duration health plans, "junk plans," in some cases for up to three years. These plans were only ever intended for short-term use and are not bound by the consumer protections required in the Affordable Care Act. As a result, individuals and families are signing up for health insurance thinking it provides comprehensive coverage when it does not. Worse yet, you have proposed using federal dollars to help consumers pay for these junk plans. Your support of *Texas v. United States* makes it clear that your fundamental intention is to upend our health care system in its entirety.

The actions by your Administration to sabotage, slash and undermine Medicaid and the Affordable Care Act have already resulted in higher out-of-pocket costs for individuals and families in need of prescription drugs to remain healthy. If these efforts continue, we fear that our shared goal of lowering the cost of prescription drugs will be for naught. We urge you to protect comprehensive health coverage through Medicaid and the Affordable Care Act for our nation's children, seniors, people with disabilities and families to make sure drugs are affordable for everyone.

Sincerely,

Robert P. Casey, Jr.
U.S. Senator

Tammy Baldwin
U.S. Senator

Chris Murphy
U.S. Senator

Sherrod Brown
U.S. Senator

Amy Klobuchar
U.S. Senator

Bernard Sanders
U.S. Senator

Catherine Cortez Masto
U.S. Senator

Edward J. Markey
U.S. Senator

Richard J. Durbin
U.S. Senator

Debbie Stabenow
U.S. Senator

Jeanne Shaheen
U.S. Senator

Margaret Wood Hassan
U.S. Senator

Elizabeth Warren
U.S. Senator

Kirsten Gillibrand
U.S. Senator

Sheldon Whitehouse
U.S. Senator

Richard Blumenthal
U.S. Senator

Jacky Rosen
U.S. Senator

Tammy Duckworth
U.S. Senator

Cc: The Honorable Alex Azar, Department of Health and Human Services

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