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A CONVERSATION WITH CMS ADMINISTRATOR SEEMA VERMA

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P R O C E E D I N G S

MR. SCHAEFFER: Good afternoon. My name is Leonard Schaeffer and I'm very pleased to welcome all of you to today's event which features a conversation about Medicare Part D with CMS Administrator Seema Verma. Our event is hosted by the Schaeffer Initiative in Health Policy, which is a collaboration between USC Schaeffer Center and Brookings. I am a trustee of both and I'm here to make sure that the name Schaeffer is up there at least 50 times. (Laughter) And it is. We get lucky.

Today we'll have an opportunity to hear from the Administrator, followed by an interview of the Administrator by Dana Goldman, who is the head of the Schaeffer Center. There will be an opportunity for questions from the audience, and then there will be a panel of experts to discuss both the Administrator's remarks, and probably life and its meaning.

For those of you who tweet -- I can't believe I was asked to do this, but I was -- please note that our hashtag is #PartDPricing, as you can see on the screen. Yes, there it is. Okay, right above the word Schaeffer. (Laughter)

So I am very pleased to have the opportunity to introduce Administrator Verma today. We are very grateful to her for taking the time to meet with us. I have a vague understanding of the demands of her job. I was the Second Administrator. In those days it was called the Healthcare Financing Administration and it was my job to put Medicare and Medicaid together. That was a very interesting exercise. And, for the record, I have to note that when I left everything was perfect. (Laughter) Sorry about that. Administrator Verma is the 15th administrator and she's been in this position since March of 2017. She now oversees a $1 trillion budget, 26 percent of the entire federal budget, and she administers healthcare programs for over 130 million Americans.

During her career, Administrator Verma has held several posts that focus on health policy and operational design. Today's presentation though will focus on Medicare Part D, which provides prescription drug coverage to 43 million Americans, roughly double

the number that it covered when it was introduced in 2006. I think you know, or I hope you know, that the Administration has issued a series of recommendations in their blueprint for lower drug prices which advanced several pricing reforms through regulation, which will probably be mentioned today.

So please join me in welcoming CMS Administrator, Seema Verma.

(Applause)

MS. VERMA: Well, I can say between the Second Administrator and the 15th that things are not so perfect. (Laughter) It's a lot bigger though.

Well, good afternoon. Thank you for the introduction. It's a pleasure to be here today. I want to thank the Brookings Institute and the Schaeffer Center at the University of Southern California for hosting this discussion on such an important and timely topic. And I also appreciate all the publishing and the outstanding research and analysis on issues and health policy. You all serve a very critical function in the policy development process and I can tell you that I'm constantly emphasizing to my team the importance of staying on top of the latest work coming out of all the think tanks.

Several of our projects at CMS were aided by papers written by scholars at institutions like these. One paper that I wanted to highlight is the Schaeffer Center piece on the pharmaceutical distribution chain. I can tell you we learned a lot from it. But I am dying to know how many PhDs it took to map out the whole process. But, anyway, we really do appreciate all the analysis and all of your ideas on how to improve our healthcare system.

So we're here today to discuss an issue that many of you have worked on, strategies for lowering prescription drug prices. And it's no secret that this is a top priority for President Trump and Secretary Azar. The United States is the world's leader in biopharmaceutical innovation, but lifesaving medicines don't mean anything if patients can't afford them. And as Secretary Azar has said, there's little difference for a sick patient between a miracle cure that hasn't been discovered and one that is too expensive to use. And so if we take a step back from prescription drug related issues and look at our

healthcare system more broadly, we all know that costs are growing at an unsustainable rate. And as the CMS Administrator, I can tell you that I wake up every morning concerned about the trajectory of our Nation's healthcare spending. By 2026 $1 in every $5 spent in our economy will be spent on healthcare, and we all know we have to change this path because our country's future depends on it. And in order to do that we have to change how and how much we pay for prescription drugs.

In Medicare spending on prescription drugs is growing faster than spending in any other areas. In 2012 Medicare spent 17 percent of its total budget, or $109 billion, on prescription drugs. And four years later in 2016 this had increased to 23 percent or $174 billion. So lowering the cost of prescription drugs isn't just something that we would like to do, it's something that we must do in order to ensure the whole sustainability of our healthcare system.

New and innovative drugs are coming to market, which represents revolutionary advances in medical science, but also have very steep price tags. And it's wonderful news that there are hundreds of gene therapies in development. The CAR-T cancer therapies, however, that have reached the market have been priced at $373,000 and $475,000. And a new gene therapy for certain forms of blindness has been priced at $850,000.

President Trump has outlined the most sweeping set of policies to lower drug prices ever proposed by an Administration. And in the American Patients First blueprint, we have made our plans clear. The market for prescription drugs is complex, but the blueprint is focused on bringing the same principles of competition and choice that have worked in other markets to tackle challenges in this one. And it's no coincidence that the President's blueprint is organized around competition as a key pillar.

Generic drug competition in particular is critical. And CMS appreciates the outstanding work that the FDA has done under Scott Gottlieb's leadership to accelerate the approval of generic and biosimilar products. I always tell Scott, if you're doing your job, then

my job becomes a lot easier. And FDA has approved a record number of generic drugs, and this has had a major impact on CMS and really all payers. To take one example, FDA's recent approval of the first generic competitor to EpiPen was groundbreaking. And this approval is going to provide much needed competition for Medicare and Medicaid patients who rely on this lifesaving product. CMS's new drug dashboards show that collectively Medicare and Medicaid spent $501 million on EpiPens in 2016. And so generic competition should reduce the spend and generate savings for the programs and for states.

So while FDA has been accelerating the introduction of generic and biosimilar products, CMS has been acting in concert to modernize our payment policies to increase competition. Because at CMS, empowering patients and increasing choices are driving factors in virtually every area that we oversee. Because when patients have choices, cost and quality improve. And we often hear that Medicare should negotiate drug prices with manufacturers, and in response, I already point out that have negotiators, and these are the Part D plans which cover drugs that beneficiaries are picking up at pharmacies. And Part D has been a success because instead of a government bureaucracy making decisions for patients, the Part D program protects a patient's ability to choose a plan that's right for them. Beneficiaries know which drugs are covered in a particular plan, the premium, and the level of cost sharing. And the patient can choose the plan that meets their needs and make tradeoffs between costs and quality. They are making the decision, not the government.

Part D is a market based system and prescription drug plans are competing for beneficiaries. And in a market based system competitors must provide the highest quality at the lowest cost to attract customers. But when the government controls the process and only offers one option with no choices, the push to excel or go out of business is no longer there.

And so at a time when healthcare costs are rising, our Administration has proudly announced that Part D premiums decreased this year and we expect that they're

going to decrease again next year. And just as a side note, premiums for Medicare Advantage plans and plans on the exchanges are also projected to decline next year.

And as we look to the future of Part D, we must move to an even more dynamic and competitive market which will lower prices while protecting patient choice. CMS intends to give Part D plans more leverage in their negotiations and more flexibility in their benefit design so that they can continue to drive towards lower costs and higher quality for our beneficiaries. I want Part D plans to have every tool that plans in the commercial market have to lower costs, increase quality, and promote transparency, including at the point of prescribing. And we have seen innovative approaches emerge in the private sector to provide real time cost information to patients and providers.

And one area in which our Part D plans are more constrained is in their negotiating power for drugs that are in the "protected classes". These are therapeutic classes for which Part D plans have to cover essentially all available products. And this Administration is committed to ensuring that seniors have access to the medicines they need in all therapeutic classes, including in the protected classes. However, private plans are able to ensure access to drugs in these categories while also negotiating with drug manufacturers for the best deal. And today, there are more competitor drugs in these classes, including generic drugs, than there were when the protected class policy was created. And typical private market discounts for these drugs are in the 20-30 percent range, but the average discount across all protected classes and Medicare Part D is just 6 percent. So it's important to lower costs for all patients, including patients who need drugs in the protected classes.

And one of the successes of Part D plans has been their encouragement of generic drug utilization over the years. And most of you are aware that around 90 percent of prescriptions filled in America are for generic drugs -- a remarkable statistic. And earlier this year we finalized a rule that allows plans to substitute generic drugs for branded drugs more quickly on their formularies so that beneficiaries can access low cost generics as soon as

they're approved. Because when it comes to empowering Part D plans to encourage generic utilization, CMS is not leaving any stones unturned in looking for ways to save money for our beneficiaries.

In 2016 Part D beneficiaries spent over $1.1 billion in out-of-pocket expenses for branded drugs that had comparable generics. And so clearly there are savings for patients being left on the table. And to this end, CMS issued a memo to Part D plans this summer explaining the tools that they have available and the expectation that CMS has to ensure that beneficiaries are getting the best deal. And while the memo reminded Plans for their current authority in this area, we recognize that additional barriers stand in the way of fully encouraging generic utilization, so stay tuned for more from us on that issue.

But we haven't stopped there. Other policy changes I want to highlight today include removing what was called the "meaningful difference requirement", which restricted plans from offering more choices to seniors. CMS removed that requirement and saw an uptick in the number of Part D plans by over 15 percent this year. And we've also introduced flexibility that Part D plans will be able to leverage in the future. So currently if a Part D plan includes a particular drug on its formulary, the Plan must cover that drug for every FDA approved indication or patient condition, even if there are other drugs that are more effective for a given indication. So the requirement to cover drugs for all indications discourages Part D plans from including more drugs on their formularies. And so we announced that starting in 2020 plans can tailor their formularies so that they can cover drugs by indication. And this policy will provide beneficiaries with more drug choices as plans will be able to cover the most appropriate drug for every condition. And we announced the change this year so that plans have time to incorporate this flexibility into their negotiations with manufacturers prior to the 2020 plan year.

And Part D plans have done a great job in keeping premiums low. However, while plans can be a powerful negotiator, sometimes it's the case that a plan's

incentives are not completely aligned with the patient's. And one practice that some plans have used, which I find completely unacceptable, was the imposition of gag clauses. And so over the summer we sent a letter to Part D plans explaining that any form of gag clause is contrary to CMS's efforts to promote transparency and lower drug prices. And thanks to President Trump and bipartisan leadership in congress, gag clauses are now illegal. And I was honored last week to be at the White House for the signing of two Bills to end the practice. And pharmacists can now help their patients find the best deal on prescription drugs.

The drumbeat continues. Earlier this week CMS proposed to require that prescription drug manufacturers post their list prices for drugs covered in Medicare or Medicaid in direct to consumer TV ads, because patients often pay their cost sharing or deductible off of a drug's list price, and so therefore this requirement would inject greater transparency into prices that manufacturers set.

This week's announcement and the legislation on gag clauses demonstrate President Trump and Secretary Azar's commitment to pull back the curtain on the system of drug pricing. This is a commitment that's been ongoing and earlier this year we released a redesigned version of our drug spending dashboards, which include year-over-year information on drug prices and for the first time highlight which manufacturers have been increasing their prices. The pharmaceutical industry took a small step this week to increase transparency by committing to develop their own platform to provide pricing. However, the disclosure of prices in television ads is needed to ensure that patients have all of the relevant information when they're learning about a medication.

So far I've focused primarily on Part D because of the hashtag there and that's the market for drugs that patients pick up at the pharmacy, but I'd like to turn our attention to Part B. So maybe we could get a new hashtag for Part B. I do see a big B up there, so I think we're okay. In Part B though Medicare spends about $28 billion paying for providers for medicines for drugs that are patient administered, such as infusions. So the

story is much different here. We pay Part B providers for drugs at an amount equal to the average price the drug sells for, plus a percentage based add-on fee. And there's no negotiation. Medicare merely accepts the average sales price and patients have to pay their co-insurance off of that price as well. And that sales price is often higher in America than it is in other countries and other countries are not paying an appropriate share of the necessary research and development to bring innovative drugs to the market. And instead they are free riding off of U.S. consumers and tax payers. And this is in part why our spending on healthcare is so much higher than spending in other countries. And to make matters worse, the payment model in Part B creates a perverse incentive for manufacturers to set higher prices and for providers to pick drugs that are more expensive. And so while the system may have made sense when it was designed, in today's world with some therapies costs over a half a million dollars, just taking the average sales price and then adding an additional amount on top really just doesn't make sense.

And we also don't see the full benefits of competition in Part B because some drugs within a therapeutic class actually have their competitor in Part D. Because there are separate programs, the drugs don't have the opportunity to compete against each other. CMS recently took a historic step to address some of these issues in Part B with respect to Medicare Advantage plans. CMS gave MA plans the option of applying step therapy for Part B drugs, which make up around $12 billion of MA plan spending per year. And so this means starting in 2019 MA plans will be able to ensure that patients are receiving their most preferred drug therapy first and progress to other therapies only if necessary. So, for example, plans may ensure that a beneficiary began with treatment with a biosimilar before progressing to a more costly biologic only if the biosimilar is ineffective.

And for the very first time this will create competition and negotiation for Part B drugs and strengthen the position of MA plans as they work to lower prices for beneficiaries. And we've taken careful effort to make sure that patients are protected under this policy. So step therapy can only be applied to new prescriptions and patients always

have the right to appeal, and at least half of the savings must be shared with patients through incentive programs. And these incentive programs must be coupled with care coordination services, including implementing medication adherence strategies for beneficiaries. So patients will have time to decide whether to participate in a plan that takes advantage of this new flexibility and they can switch their plan if they don't like it through the end of March of 2019 if they change their mind.

So some Medicare Advantage plans also offer a Part D benefit, and so CMS's new policy will enable these plans to implement step therapy across B and Part D. And so for the first time competitor drugs will be on a level playing field and patients will receive the best medicine, whether it's physician administered or patient administered, and hopefully at a lower price.

The initiatives that I've outlined today will impact drugs with competitors. And while we can strengthen competition and negotiation for situations with multiple drugs, there are times when competition doesn't exist, especially for new drugs that enter the market. CMS will need other approaches. Treatment and cures are coming to market today that doctors could not have imagined a generation ago. Many of these treatments are for orphan diseases, and some new therapies are one time treatments that cure diseases altogether. And as I said earlier, the price tags for these drugs are exceeding $300,000, $400,000, and even $800,000. And I think we can see those price tags go up to $1 million and $2 million. So paying for these drugs based on an average sales price plus an add on really just doesn't make sense.

We need to modernize our payment systems to consider the new era of innovation. New payment arrangements are needed and could take various forms. They may include paying for a drug over time only if the patient achieves certain clinical outcomes, or paying for a drug through a shared savings approach based on the drug's impact on the patient's total cost of care, or paying for a drug under a subscription approach, with an upfront fee in exchange for as many doses of the drug that are as clinically

necessary. So when drugs are as expensive as some of the new gene therapies are, we must absolutely hold manufacturers accountable for achieving outcomes.

The President's blueprint was released on May the 11th and we have been taking swift action since then. It's been very, very busy. But this is just a start and there is more to come. There are additional steps that we will be taking in Part D in the near-term to strengthen negotiations and get a better deal for beneficiaries. Prescription drug pricing is a very complex issue to navigate and, clearly, there are many issues to unpack and address. And I want to thank all of you again for your work in helping us to pinpoint problems and develop solutions. Together we can modernize our payment systems to ensure sustainability, encourage access, and foster competition, which will lead to lower prices. And that way all Americans will benefit from 21st century advancements in biomedicine.

Thank you. (Applause)

MR. GOLDMAN: Thank you, Administrator Verma, for those very thoughtful and substantive remarks. I think you really pointed out the importance of formulary policy for both solving access issues and also putting some downward pressure on prices.

I want to talk about some other topics, if you don't mind. And I'd like to start with price transparency. You mentioned the signing of the prohibition against gag clauses which allow patients to know exactly what they're paying when they get to the pharmacy. I've been studying health policy for about 30 years and one of the problems we've always had is that we don't have a clear understanding of who's actually paying what and what's driving price increases and what should be done to reduce them. So I'm going to advocate for a researcher gag clause and ask you -- well, actually that went the wrong way. People might view that -- but what can be done in terms of improving price transparency so we really understand what people are paying?

MS. VERMA: Well, let me just say I think that price transparency is a major issue in our healthcare system, not just for drug pricing but just at large. I mean if we look at everything that's gone on in the last 10 years, right. We've had so many changes, we've

pretty much regulated everybody. Our Administration is putting out pages and pages of regulations. And one of the things that we haven't done in our healthcare system is activate probably the most powerful force that we have, which is the consumer and the patient. And so I think that price transparency might be the piece that really helps turn the page for us in terms of controlling healthcare spending. So we're taking a lot of effort around transparency. Just this year we asked hospitals to post their pricing on line. That's one piece that we've done. Later on this year we're going to have some cost comparison tools so that patients can look at costs between surgery centers and also the hospital. And so really the drug pricing piece is just another part of this. We did the piece around the gag clauses to make sure that people have an understanding of what options they may have. You know, often times you can get the drug cheaper than what you're plan is offering the price for.

And then the other area, you know, is the stuff that we've put out on line. We had our drug pricing dashboard, which I think is helpful. But this week's action I think was particularly important because while the dashboards are important, and I think pharma made a small step in that area as well, but when people are learning about the drug it's important that they understand the price. And we've heard a lot of discussion of well, you know, the price isn't exactly what they're going to pay. But it gives them some sense of a ballpark, and people do pay their deductibles off the list price and they do pay their co-insurance off the list price.

So we're going to always continue to push for transparency. I think that's probably how we move forward on bending the cost-growth curve in all of healthcare.

MR. GOLDMAN: Yes, I couldn't agree more. I want to also talk about the supply chain. And one of the points you made, and I think it bears repeating, is that one of the reasons for the success of the Part D program has been that we're at 90 percent use of generics. And that has really allowed premiums to stay lower than they were originally forecast. And PBMs played a big role in that. On the other hand, today we have three PBMs that account for about 85 percent of the market. And a lot of the rebates are acting

like hidden discounts. They're invisible to consumers and you're making progress there. But they are also moving patients more quickly into the catastrophic range in Part D. So I'm wondering, what can be done in terms of -- what are the policy options in terms of both offering patients some relief in the catastrophic and also what can be done to solve this push towards people into an area where the federal government bears more responsibility?

MS. VERMA: I think this is a great example of where Part D can perhaps be updated or modernized. I think that when this was originally developed, developed that catastrophic phase to encourage insurers and Part D plans to participate in having that catastrophic phase, essentially put that risk on the government. But now I think we're sort of in a different era. We have a better sense of what drugs costs have been, there's a little bit more predictability, and I think we're at a point now where it would be better I think for Part D plans to manage that portion of the benefit as well. That way we can bring competition and negotiation to that piece as well. And I think the way it's set up now, there's sort of perverse incentive to move people to that catastrophic phase, to not take on the risk.

So, as you know, with the President's budget this year we proposed essentially to allow that change and to also cap what beneficiaries would pay in the catastrophic phase. So hopefully we'll have some changes in congress, but if not I think that's an area that we're looking at what we can do with our existing authorities.

MR. GOLDMAN: That's excellent. And I think it's important for people to understand that at the time of passage of Part D there was concern that insurers wouldn't play. And so you really need a different -- you need to provide some reinsurance and risk, but, as you point out, the market is quite healthy and we have lots of plans that are playing here. And so the role of the government as a reinsurer is not as important anymore.

You also mentioned Part B, and feel free anyone who wants to tweet to use that hashtag. Medicare is, as you pointed out, spending almost $30 billion a year there a lot of this is concentrated in oncology, ophthalmology, and rheumatology. And so you've made these policy changes that have given Medicare advantage some tools. And I'm just curious,

what's been the response to the plans to this change in policy? Have they been supportive? Are they pushing towards even more extreme I would say or different competitive bidding models, for example, to try and change the way we administer physician administered drugs?

MS. VERMA: Well, I think the response that we've gotten is very positive, because I think the plans are -- this is something that they're excited to do largely because they're doing this on the commercial side. This is the way that the rest of the industry works and they haven't had the opportunity to do this in Part B. And I think that this gives them the opportunity to manage this a little bit better. And, ultimately, that's going to lower cost for their beneficiaries. And it's going to put them in a position where they're able to negotiate a little bit more with manufacturers. And we haven't had that in Part B.

I think Part B I feel like has been sort of untouched. You know, talk about the need for modernization. I mean this is where I think going forward, when these new drugs are coming out and we're looking at all of these price tags, there's no way the system can support this in its current structure. So we're looking at some of the changes that we've done with MA, but I think there's a lot more work to do on Part B.

MR. GOLDMAN: Yes, agreed. And, finally, you were talking about cures and you talked about rare diseases and very -- you mentioned some scary numbers. But often those are small patient populations. But I think one of the interesting things in terms of biomedical innovation is that we may be working towards the prospect of cures for very prevalent illnesses. And we saw a sense for that with Hepatitis C when we developed direct acting antivirals which actually had a 99 percent cure rate for the disease. And in 2015 CMS sent a letter to state Medicaid programs noting to make sure that they were paying for these cures for the population. And this affected a very disenfranchised population of IV drug users and such. But I think CMS also kept pressure on manufacturers, expressing concerns about access and affordability.

You mentioned some possible solutions, licensing, paying over time, and

such. Do you think that's going to be enough here? Do you think we have the right incentives to develop cures rather than treatments?

MS. VERMA: Well, I think we need to do something in this particular area because, of course, you want to encourage innovation, especially for those particular areas of diseases where there are so few people. The Hepatitis example I think, you know, there's a lot to draw from there. I mean I think you saw when there was competition the price went down. But in particular I think it was a very interesting test case or case study for what happens with state government. So if you're state government, your budget is on a one or two year budget cycle and all the sudden this new drug comes out and you have to pay for it. And they don't have the capacity in terms -- they don't have that flexibility in terms of their budget, they don't get to run a deficit.

So that being said, they have to sort of figure out, what are we doing to do. And, you know, it works well -- the system I think works well in Medicaid because they do have some required rebates, when the cost of the drug is so high -- and that's where I think they really struggle. As I talk to states across the Nation, it's really these new high cost drugs. And so I think we're moving to a new era when you think about how we're paying for these. You know, there's no magic or silver bullet in terms of how we're going to pay for these drugs. And the whole area of value based pricing is very new. You know, there's a lot of complicated issues there in terms of if you are doing a value based contract where you say, okay, you don't have to pay for the drug if it doesn't work, well then the drug is zero. And when you're trying to do things like Medicaid best pricing, you're reporting around that, everything kind of gets convoluted. And so that's something that we're looking at within the agency as well is what kind of changes do we need to make from a regulatory standpoint to encourage these types, or at least allow these types of value payment models to at least occur. I don't know that it's a panacea, I don't think it works for every single type of drug, but I think some of these high cost drugs that are coming to market, I think the idea of tying outcomes is also -- it sounds really good, but that's going to be very complicated. You know,

how do you make sure you can track the patient, for what period of time, how do you gather the data, and what is that clinical indication that you're looking for. Sometimes it can be very simple, is the person alive or not. But sometimes it's a lot more complex than that.

So what we want to do is make sure that we are allowing for this type of innovation and payment models. So you're going to see some more work from us on that to at least create the opportunities for other payers to be able to engage in these types of payment arrangements.

MR. GOLDMAN: Well, that's great news because it means full employment for health economists for years to come. (Laughter) So I know you're pressed for time and you have meetings, but we have time for one or two questions from the audience. And if you could wait for a microphone to come around. Is there someone with a microphone? Yes, why don't we start up here. And if you could introduce yourself and ask your question and avoid soliloquies.

MR. KLEIN: Okay. Dan Klein, the PAN Foundation. So it's great that you're taking the approach of maybe capping Part D out-of-pocket costs.

MS. VERMA: I think some people are having trouble hearing you.

MR. GOLDMAN: Yes, speak loudly.

MR. KLEIN: Okay, I'll speaker louder. Dan Klein, the PAN Foundation. So capping out-of-pocket costs and putting downward pressure on prices is great, but we see a lot of patients with serious illness in Medicare Part D who can't get to the catastrophic threshold, that the costs up front are really an insurmountable barrier. So what's CMS doing to look at spreading those costs more evenly throughout the benefit year or lowering those costs for people with serious illness?

MR. GOLDMAN: Thank you. That was a brief question, and clear.

MS. VERMA: I think that across the across the board -- I mean when we're -- as we're kind of coming up with our strategy the idea is to really focus on the patient and their out-of-pocket expenses. And so every policy that we're coming up with really does

focus on well how is that going to impact their out-of-pocket spend. And some of the things that we've talked about and even asked for comment on were things like how do we deal with rebates. Should we require that those rebates be passed onto the patient at point of sale so that they can have lower out-of-pocket expenses? But what we find that there's a yin and a yang. If you that, yes, you may lower out-of-pocket expenses for some patients, especially those that have a lot of serious illnesses and very expensive medications, but you also may increase the premiums for the Part D program for everybody.

So, you know, our foremost principle is try to lower out-of-pocket expenses, try to lower drug costs for seniors and all of our beneficiaries. But it is very complicated because sometimes those are tradeoffs between premiums and out-of-pocket expenses.

MR. GOLDMAN: But I would add that one of your recommendations, which is to make sure plans don't have incentives to move people to the catastrophic cap, might actually help in that regard.

MS. VERMA: Exactly. And that's why we're so interested in doing some more work around the catastrophic.

MR. GOLDMAN: Yes, a question right here.

MR. FLORKO: Hi, Nick Florko with STAT. So a new Medicare rule landed yesterday at OMB with the title "index price concession model", and I was wondering if you could get us any clues as to what that might deal with given the cryptic title. (Laughter)

MS. VERMA: Well, as a matter of -- I think it's a legal issue that we cannot comment on proposed rules. So I would say just use your wild imagination on that. (Laughter)

MR. GOLDMAN: Yes, we have one in the back here. No one is giving the microphone to the people I point to (laughter), so anyone who would like to ask a question who has the microphone, please proceed.

MR. BLAKE: Rick Blake, Strategic Health Resources. We do a lot of work with biotechs, particularly in the area of HIV. And for state Medicaid, even if the drug is FDA

approved, we found that states are hesitant to actually use the drug that's approved versus one that's -- well, it's not -- prior approval is part of the issue. So CMS has been less than assertive in terms of working with state Medicaids on drugs like this. What more can you do is the question?

MS. VERMA: Well, we continue to work with states, but we also respect the fact that states are managing their Medicaid programs. And so we can always reiterate to them what the requirements are. But states have used, you know, as one of their tools to managing healthcare costs -- just like we're talking about with MA, prior authorizations, step therapy, and those types of things to manage costs and to ultimately keep down costs for the program.

I think one of the things to point out, though, is that in all of those cases, you know, patients -- I think we also look to make sure that patients have the opportunity to appeal those decisions. Even some of the work that we just did allowing the MA plans to incorporate step therapy, one of the things that we said there was can't be for medications that the patient is already taking. So if it's a new drug, they can move forward with it, but if it's something the patient has already been on, they couldn't make changes there. And also to make sure that the patients have that ability to appeal.

MR. GOLDMAN: And this is just one of the fundamental tensions that you talked about, which is at the end of the day we all want unfettered access to everything, but on the other hand, we do have concern about costs and being able to use those tools. And how we balance those is a policy question. And, again, health economists are happy to work on that.

We have one last question here.

MS. HANSEN: I don't have a microphone.

MR. GOLDMAN: Hold on for the microphone. Thank you.

MS. HANSEN: Jan Hansen from Genentech. Thank you for speaking with us today. I have a two-part question. One is what was the biggest surprise you faced when

you took the role with CMS? Second, what is the thing you'll be most proud of? The accomplishment you most want to achieve in the role?

MS. VERMA: Wow, I didn't think about that when I got here. You know, I think that I come from the private sector and I consider myself a problem solver. I will be given difficult things, things that I may not know anything about, and I feel like I'm always able to figure out solutions. But it is the government, and there is an incredible process of review and bureaucracy and the speed in which things go I think has always been something that I have found challenging. So even with the Medicare program it's these payment rules and they go out once a year and it's sort of like if you don't hit that at that time, you know, you have to wait an entire year. So I think it's just the speed in which things move. I'm an impatient person.

I think in terms of accomplishments, like I said, when I wake up in the morning I do think about the cost of the entire healthcare system and that it's not sustainable. And so I'm trying to spend my time and my focus on things that are really going to improve the sustainability of the program. So it's things like we've made a lot of effort around interoperability or site-neutral payments. And to be honest with you, I'm trying to tackle issues that may not be popular, may not make me very popular, but at the end of the day we want to do something that's going to advance the healthcare system and sustain it.

I will also say that I'm trying to look at big issues, right. So drug pricing or we talk about the future of Medicaid spending. But I also want to impact the experience that each and every person has when they go to the doctor's office. And so that's why we're focusing on things like price transparency, like making sure that people have their healthcare record, and making sure that people understand quality information. So we're trying to do things at a big level, at a macro level, and also at a micro level.

Thank you.

MR. GOLDMAN: I thought that you were going to say that the hardest part was filling Leonard Schaeffer's shoes, because he left everything perfect. (Laughter)

MS. VERMA: He left it in great shape.

MR. GOLDMAN: But I want to thank you for taking the time.

MS. VERMA: A pleasure.

MR. GOLDMAN: I know you're very busy and you have a lot of policy challenges and we appreciate your efforts on everyone's behalf.

Thank you.

MS. VERMA: Thank you so much. (Applause)

MR. GOLDMAN: Thank you Administrator Verma. Now I'm going to turn it over to Kavita Patel, who is a Non Resident Fellow here at Brookings, and we'll have a panel discussion. She'll introduce the speakers.

MS. PATEL: I'll say Leonard Schaeffer one more time just to get it in there, and also I thank Leonard and Dana for that, and the Administrator, who is off to undoubtedly do more. I think hopefully today's conversation gave us a lot to think about. I'll sit down -- oh, there is room for me. I'm so used to command and control -- ooh, and a teleprompter too. There we go. I'll do it all from here.

So let me go ahead and introduce the panel. I'm not going to read -- I won't do justice if I try to read their bios, but I will at least just kind of tell us who you're looking at from your left all the way to your right. And the goal is to also just get some kind of opening thoughts, a little bit of question, and then, as Dana successfully modeled, to get non soliloquy questions from the audience, and maybe some interaction, and especially kind of -- I think the panelists would agree with me, there was a lot of food for thought there.

So all the way to your left is Dr. Geoffrey Joyce, who is the Chair of Health Policy at USC, the Director of Health Policy at the Schaeffer Center for Health Policy and Economics, and someone I knew way back in the day from our time at Rand. And so he's had quite a few roles around some of the things that I think the Administrator was mentioning for education around Part D. So maybe when you get into that we can talk about that a little bit more.

Next to him, Dr. Stacie Dusetzina, who is an Associate Professor at UNC and also has an illustrious title, The Ingram Associate Professor of Cancer Research. Did I say UNC? I'm sorry, I insulted all of Vanderbilt by doing that. Weren't you at UNC?

MS. DUSETZINA: I was, yes.

MS. PATEL: Okay. I'm not completely losing my mind -- Vanderbilt University Medical Center. Apologies. And also has just from background a body of work that kind of not only touches on the effects of pricing for cancer patients, but also looks more broadly at kind of health policy levers to impact that.

And then right next to her, my friend, Dr. Sam Nussbaum, who has been a Senior Fellow at the Schaeffer Center and I have had the privilege of working with when he was at his role at Anthem as the Chief Medical Officer. And I think, Sam, it was on this stage two or three years ago where we were talking at Hep C and talking about the cost of kind of the drugs in the pipeline, as well as those that were commercially available with kind of this conundrum around affordability and optionality.

We're each just kind of going to go through some opening thoughts and comments. And I love that at Brookings it's about independence, impact, transparency, all sorts of things. Full transparency, we did not have access to the Administrator's remarks; so we had some inkling of what was going to happen, but none of us had had like a prepared script on what she was going to do. And I would just like to say that it was refreshing to hear topics like protected classes -- I mean some of these things are slightly thought of we don't have quite the detail on it yet and for those of you that haven't been following the day-to-day plays at OMB, the kind of proposed Part D rule that people are waiting for has not been released yet. But there were hints, protected classes, some of the changes on the catastrophic side, out-of-pocket. Things that I would say that someone like myself who worked on the Hill when the MMA was passed, we would like to see this benefit program being modernized and she alluded to it.

Sam, do you mind starting and just given us some opening impressions,

thoughts, and any other perspectives? And we'll just go through the panel and then do some questions.

MR. NUSSBAUM: Thanks, Kavita. And it's wonderful to be with all of you. And you were right, we talked about the cost of a cure. And today it's increasingly about the cost of breathtaking new therapies, the cost of cures, because when we step back -- and I want to respond very specifically to the really I think innovative, powerful, far reaching ideas that were expressed by Administrator Verma, but if we just step back and look at the time in which we are living, where we have such breakthrough science, the opportunities for immuno-oncology and CAR-T therapy and gene therapy, and treatments that seen a decade ago we could never have envisioned. So we have seen the fruits really of 20 years of fundamental science playing out in terms of these new therapies. But as we heard, the costs are extraordinary. And I remember in fact two years ago when I was representing Anthem on the stage I mentioned that the total cost of drugs in the medical and pharmacy benefit to Anthem was close to 25 percent. And people thought that was extraordinary. Now we see we're approaching 23 percent for Medicare.

So we can't sustain this, but we also have to be mindful that there are offsets to these extraordinary drug costs, and that is that we can have better quality of life, longevity, less hospitalization. But I want to comment specifically about three domains that the Administrator talked about.

The first I'd like to bring forward, some of the themes that we experiences on the commercial private plans and how those might impact Medicare Part D and Part B. And I think I want to hark back to the fact that health plans have had a lot of flexibility on formulary designs. And the flexibility enabled plans, such as Anthem and other commercial payers, to basically create formularies that have one or two of the most popular brand of drugs in a class, all the rest generics. And we were able to deliver to the market savings between 15 and 20 percent if those plans were chosen. So just by formulary decisions you can see that there can be significant cost savings.

Secondly is the whole arena of prior authorization, of utilization management, of tools that by their very nature sound perhaps not compelling. They may not be compelling to patients who might see this as more limited access. But used in the right way, prior authorization and these other tools can actually guide some of the most effective therapies to follow guidelines and clinical data that's generated both in real world evidence as well as through academic studies. And that can guide more effective therapy for patients so that we don't have in cancer, for example, the 15 to 25 percent of care that is not following evidence and may not lead to the best outcomes.

So if we do these approaches as is proposed, we need to be sure that patients have access to speedy review, that guidelines are meeting scientific standards, that there are a whole host of safeguards that are introduced.

The third area that I would like to comment on, and I think it's one that again can be compelling, is the whole model that the Administrator talked about toward the end, of value based payments. And it's not going to be for every drug in every class, but for these extremely costly therapies there will be value in figuring out the clinical offsets and not only using qualities and cost effectiveness, which are time honored, but using other approaches. In fact, some, Dana, that you've been a leader in thinking through, but sort of whether it's workplace productivity, it's value of hope, all of these other models that can find their way into true approaches that make a difference.

Just to close these first comments, several years ago it was proposed that value based payments become more and more part of the landscape, the foundation of our healthcare system. And we know that the private sector and CMS, HHS work together and set goals of 30 percent by 2016, 50 percent by this year, 2018. But what is lacking are the same strategies in the drug space. Those have to be included. And part of the way to begin to get there is to, as a specific policy opportunity, is to consider Part D drugs in terms of the population health payments, the value based payments, to include as we are including Part B drugs in the total frame of either MIPS or alternative payment models.

So at the end of this we will have a system that not only can measure value, but a system that will link reimbursement to value and very much do it in a way that stimulates innovation. This is the area where the U.S. leads and we must continue to bring new lifesaving, life changing therapies to consumers in the U.S.

Thank you.

MS. PATEL: Great. Thank you, Sam.

Stacie, your thoughts? And I just want to say at the outset, it's okay, I would assume and hope we probably have some overlapping kind of thoughts, so in my mind that's actually good if we can reinforce or have different kind of viewpoints.

So, your thoughts?

MS. DUSETZINA: Sure. So I will start by saying that I probably spend an unhealthy amount of my own time thinking about Medicare Part D, so I'm really excited to be here as part of this group.

So one of the things I spend a lot of time thinking about is access for patients. And I think a couple of things really struck me as part of the Administrator's comments. You know, she started out saying Medicare Part D is a success. And I think that that is largely true unless you happen to be one of the Americans who needs a very expensive drug. And so one of the first questions to the Administrator really hit on this point. Well, the people who need these very expensive therapies like cancer therapies, like those for rheumatoid arthritis or multiple sclerosis, they do face very high out-of-pocket costs when they're trying to fill drugs on Medicare Part D, and they wouldn't really see the same benefits of things like passing along rebates because they don't really get them to the same level as you would if you were in a more competitive area. So we have sort of the perfect storm of coverage and lack of rebates around those protected classes that make them really unaffordable for patients.

While some of the proposals that were put forward in the blueprint, like capping out-of-pocket costs for seniors once they hit the catastrophic phase, you know, that

requires a lot of money up front to get there. And I think that the question that was raised about trying to spread that payment over the course of the year to make things more affordable for patients, to allow patients to start a drug, is an important question and one where I think the Administration could do more.

Prior work as shown, especially for people with orally administered cancer drugs that there's a very high rate of people leaving those drugs behind at the pharmacy. And these aren't really optional treatments for people at that stage. So I think it's something really important to keep an eye on.

One other thing that I'd like to comment on -- and I won't kind of keep the comments too long, I want there to be time for other discussion -- is around this issue of step therapy, again, thinking about access questions for patients. I think it's really intriguing. When they first brought this up I thought well, that's a really interesting idea to think about introducing competition across Part B and Part D because we don't typically think about it that way. And if you can start to get more competition maybe you can lower spending. But I wonder a lot about what would happen to patients out-of-pocket spending requirements and whether patients would be harmed in that situation. The reason is, is that for Part B most patients have supplemental insurance that helps them with their out-of-pocket costs. So if you fill a Part B drug or you have a physician administer a drug to you, most Americans have that covered. If you're filling it on Part D, and let's say it's a cancer therapy, you would have a very high out-of-pocket cost. So if you're step therapy pushes you to a Part D drug the out-of-pocket cost implications could be that it harms patients.

So I think with this sort of really progressive thinking along the lines of improving competition, we also have to do that thinking about what is the downstream impact on patients. We want those prices to be lower, we want to really keep premiums from growing too high, but we also need to protect patients who need expensive therapies.

So I will stop with that.

MS. PATEL: Great. Geoffrey?

MR. JOYCE: Okay. Following up on Stacie, I do think we're going to talk about how do we improve Part D. And I think broadly it is a success from a government perspective. If you look back at projections in 2003, costs are much lower, beneficiary satisfaction is high. Dana alluded to there was real concern the industry wouldn't participate, and they've participated in groves. So we're talking about improving and modernizing a program that's been largely successful -- not that it doesn't have flaws.

And I can't believe I'm saying this, but the Administration should be commended for taking some bold steps towards reforming Part D and drug pricing more generally. Some of the things are logical. For example, there were just design flaws in the program. The donut hole was not a smart idea, it was a political compromise. So then we said, okay, how do we make the donut hole more affordable -- let's put in manufacturer rebates or discounts in the donut hole. But very cleverly then that counted towards your out-of-pocket expenditures, which then pushed you into the catastrophic. So we have things like that that really don't make sense that I think the Administration has proposed that are logical reforms.

Other Part D reforms, everyone is quite aware there is a growing gap between the list price of a drug and its actual discounted or net price to consumers or to the Plan. But those rebates are being generated on expensive drugs taken by sick people and they go to lower premiums for both sick and healthy people overall. And so both in the commercial sector and in Medicare Part D there's been a movement towards maybe having pass through pricing or rebate pass through so that the people who purchase those high cost, high rebate drugs actually benefit at the point of sale. We're actually modeling that in Part D right now and looking at how that will change the distribution of spending for the beneficiary, for the plan, for Medicare, and how it changes sort of people's flow through the coverage phases.

Out-of-pocket maximums seem to be a fairly -- I would put an out-of-pocket maximum in general, I might even put an out-of-pocket maximum on a per prescription to

protect. But I do think we do have safeguards in Part D, we do have low income subsidies. And so typically those who qualify do have some protection, albeit we can improve the system on the margin.

But there are other issues that are coming up on the forefront, the troop limit that gets you into catastrophic goes up by 30 percent 2020, manufacturer rebates go to 70 percent in the donut hole in 2019. So we need to make changes sooner rather than later to modernize Medicare.

Then there are a few other issues I think more broadly that we have to think about. The ACA expanded Medicaid coverage, and it increased the mandated rebates in Medicaid. And so when you squeeze manufacturer revenues in one area they tend to raise prices in other domains. The 340b program is a perfect example of a very well intended program to lower and make drugs more affordable for lower income populations. It is almost akin to rent control, making housing more affordable for low income folks. But over time these programs expand and they tend to subsidize middle and higher income folks, which is what the 340b program does. But what the does is by lowering manufacturer revenues for certain populations, it tends to raise prices in other domains. And I think we have to think more broadly about reform.

And I guess I'll take on broader step back. I think some of the dysfunction of Medicate Part D is not Part D's fault, it's just how this industry functions and how we pay for drugs in the supply chain that we have. Generally speaking, I think we want a thriving innovative pharmaceutical industry and we tend to forget that. But when we think about advances in medical care of the past two decades, most of them have been in drug therapy. So we want innovation and that -- you know, prices do generate innovation. Higher prices to incentivize innovation. So we want to be careful of how we regulate prices. But having said that, economists tend to look at who's innovating and who's taking risks, and that's largely manufacturers. And I think too much of the cost of drugs are being absorbed in the supply chain. And there's been talk, I think, the largest culprit in the supply chain are the PBMs. I

think their value added is modest and I think if you were to say, for example, they were covered under ERISA, the Employee Retirement Income Security Act, were if Fidelity manages your retirement plan they have to act in the best interest of you and your plan. We don't see that on the drug side. And if PBMs were covered under that it would change a lot of the dysfunction in this market, spread pricing, rebates, all sorts of perverse incentives of pushing a brand of drug over a generic drug. All of those are based on the financial incentives that are built into the system.

And so I think there's some broad issues that I think are bigger issues for both the commercial and Part D and I think the Administration's outlined some very constructive and doable things to improve Part D.

MS. PATEL: Let me start -- folks are getting interested in starting questions. I think we do have maybe one or two microphones, so maybe raise your hand so we at least know where to point a microphone if you're interested in asking a question.

Let me ask Sam. I'll start and have a different question for each one of you. Sam, you mentioned kind of the need to integrate more around direct kind of consciousness around Part D or even prescription drugs or even physician administered drugs more directly into alternative payment models. There is currently kind of at least one alternative payment model in the Medicare program around oncology. Interestingly enough it's a total cost of care model in oncology that we're learning from kind of early readouts from that model it's actually really a drug model because so much of oncology spend is on the kind of Part B and a growing percentage on the Part D side. Some of the hiccups in that model have been around timely data, having some kind of model that integrates into the delivery system at point of prescribing information around cost consciousness, et cetera.

Do you have from kind of your experience and vantage point -- you mentioned prior auth, UM. I will say, you know, you and I are physicians, I cringe a little when I hear prior auth and UM because it doesn't necessarily to me lend itself to things that make my life easier -- not that that's the goal. So can you thread that needle a little bit, Sam,

and try to maybe -- let's say you were running CMS and you were thinking about APMs that did this a little more aggressively, what would you do? And what would you do to maybe offer I would say a modernization of kind of the traditional PA UM strategy, which as we have like maybe three PBMs nowadays and vendors that are also consolidating under those organizations. It's only a handful of entities that are offering these programs, by the way.

I know that's a very loaded question.

MR. NUSSBAUM: But you've made such important points in your question. The first is -- and I acknowledge that prior authorizations, step therapies, all of these connote limiting care and limiting freedom of evidence. But if we in fact go to professional organizations and use clinical guidelines, clinical paths, and have those paths actually meet a whole set of criteria that are patient centered, that are responsive to best practices, to side effects, to a number of scientific and clinical endpoints, I think we can begin to get there. And what we did at Anthem, for example, as just one model, is we knew that -- again what we'll call Part B drugs or drugs in the medical benefit for commercial plans -- that the ASP mark up was a perverse incentive. The Administrator mentioned that, you know, that. And believe me, it was not 6 percent as it was for CMS.

MS. PATEL: It's a lot higher. (Laughing)

MR. NUSSBAUM: But it was much higher on the commercial side -- much higher. So what we did is we said how do we democratize payment. And so we said if physicians, oncologists in this program, followed clinical evidence and guidelines developed by their peers -- and that could be if the therapy was incredibly expensive, but the best evidence, or less costly, that we would pay the oncologist in addition to their ASP, but we would pay a care management fee. So we would try to democratize payment by taking away that perverse incentive of just prescribing the most expensive chemotherapy and replacing it with a patient centered scientifically based therapy. That's an example that could be used. And when you look at the total cost of care, it could even be more impactful because you would choose therapies that would be less complicated that would lead to

longer-term responses. And it would even over time -- when we think of CAR-T therapies, perhaps the answer is to use CAR-T therapies earlier, maybe even before autologous bone marrow transplants where we know we have costs in the hundreds of thousands of dollars.

So that's the piece that I think wasn't really highly emphasized, although there was mention of it, is that we are spending hundreds of thousands for therapies that don't have the sustained impact. And I think these approaches can get us there.

So that's I think part of an answer. But what we do know is that for state Medicaid programs, for gene therapies for children, others, we need to figure out how to best and effectively use these therapies and have physicians and science guide this.

MS. PATEL: Present the guidelines. Stacie, building on actually -- again I think Dana pointed out kind of the obvious, that oncology, ophthalmology, rheumatology, at this time those are some of the dominant specialty areas, not to say that we won't potentially see innovations in other clinical areas, but those tend to be the most associated, not just in Part B and D, but in general with kind of serious illness and accessibility. Sam mentioned CAR-T and some of the kind of nuances around -- or complexities around reimbursement.

Feel free to comment on that. But then I also wanted to touch on you mentioned kind of the patients. Something I was curious about, one could argue -- I've argued -- we might even want to move away from co-insurance to kind of co-pay copayments, just because when you're a patient you understand and you can wrap your brain around co-pays, something that in the commercial sector you're traditionally kind of acculturated to. Co-insurance -- I don't even know what that means. So offer, if you will, any commentary around where we need to evolve in our payment for some of the therapies like CAR-T, and then also just curious about co-insurance as a model in Part D.

MS. DUSETZINA: Sure. So for the co-insurance part -- I'll start with that. You know, I fully agree with you. It's really interesting when you think about trying to tell someone how much they might pay for a treatment and then having to explain to them, well, it depends on how many other drugs you've already filled and if you haven't, you know, your

first fill is going to be high and then it will be less once you hit the catastrophic phase, and if you're the gap -- you know, it's like literally month to month your expenses can change. So even telling somebody kind of the average amount you would expect to pay out-of-pocket over the course of a year, you know, that may be helpful but it doesn't really reflect what they'd pay at a specific visit.

So I think co-insurance is a very challenging thing for patients. And, as the Administrator pointed out, you know, list price is relevant when we're paying co-insurance. So you don't benefit from those rebates or discounts that are in the supply chain and kind of flowing back to the Part D plans. So I think as much as we could disconnect what patients pay from the list price, from having a percentage based costs, that would be really helpful for providing some form of stability.

You know, the downside of that is we have a lot of very expensive drugs that aren't helpful in the same ways. We talk a lot about the innovative cures, the really high value treatments, but we have a lot of very low value treatments with high price tags. And so we need to really be able to use our levers around incentivizing patients to use the drugs that are high value. So maybe co-insurance has a role for some of these more expensive, but not very high value treatments.

As far as CAR-T and thinking about other therapies, the payment issues there are sort of really forcing us into a new area of thinking about how drugs or innovative products are covered. It's been interesting to see this roll out and then also hearing across different payers what they're trying to do to manage the financial loss in some cases. The fact that if you are treated with CAR-T as an inpatient and you're a Medicare beneficiary, your hospital is likely going to be losing a lot of money in that situation on your treatment. They get paid less than the total amount of the drug. If you get the drug on the outpatient side or if you're treated in that way and you're a Medicare beneficiary the hospital might actually make some money on that. To be determined. But the fact that there's different reimbursement levels based on whether you're inpatient or outpatient, even under Medicare,

it just makes it very confusing. And I think it's confusing for everyone right now -- hospitals, the people trying to treat patients, and patients across various insurers. The rules are kind of just being set as we go.

MS. PATEL: And I think the industry is still -- it's not as if we're done with where CAR-T is going. There are community based trials, so aside from even kind of hospital administered -- I mean there is going to be a future very near where it will be kind of a community administered treatment, which is going to change the scale or potential applicability in a very different way.

So, Geoffrey, you mentioned kind of pass throughs, out-of-pocket max, and then kind of hinted -- there have been -- just curious about whether some kind of change to the low income subsidy, kind of the LIS program raising eligibility, other kind of options or tweaks on those levers might be applicable.

And then something I didn't hear anybody mention, interesting given light of the blueprint, which I thought the Administrator might even mention and she didn't -- CAP, the Competitive Acquisition Program, kind of one of my favorites that was a big dud back in the early 2000s but has been resurrected. And certainly the Administration put out kind of a request for information that lent some notionality to not only resuming or resurrecting this program, but effectively modernizing it. And do you see that as having any promise, or do you see the absence of talking about that as a sign that, you know, we've learned, we're one and done? So, just curious.

MR. JOYCE: Quickly, on the LIS side, I mean think obviously we want to make drugs affordable and it's obviously a vulnerable population, typically the low income eligible and the duals. So I think we don't want to impose any sort of significant cost sharing burden, but we do want --

MS. PATEL: No, we'd make it fit -- we actually -- you know, should we change the eligibility to make it --

MR. JOYCE: Well, I think we can maybe steer -- for example, generic uses

much lower in the LIS population, there's no incentive to go generic versus a brand in some cases, from just a personal individual consumer perspective.

MS. PATEL: Right.

MR. JOYCE: So I think there are things we can do to try and incentivize them to make better choices or lower --

MS. PATEL: I'm a Democrat, so we want to raise eligibility as much as possible. (Laughter)

MR. JOYCE: Oh, you want more eligibility?

MS. PATEL: I want more people to be on -- let me make that more clear.

MR. JOYCE: Okay.

MS. PATEL: I'm a Democrat. (Laughter) We want to make it more -- I was just curious because there's an argument to be made that kind of the seniors of 2003, that there's different economic pressures.

MR. JOYCE: Again, I'm very sensitive to patient out-of-pocket costs, but at the time a lot of these drugs are very effective therapy and we don't complain about paying --

MS. PATEL: Right, okay.

MR. JOYCE: -- to go to the doctor and go other things, and many healthcare services that are very ineffective. So the idea that we have to pay something for drugs I don't think is abhorrent and I don't think it's controversial. We want to protect people who can't afford it, and how we do that --

MS. PATEL: Right. How we do that is the --

MR. JOYCE: I think we can do that a little better and I think out-of-pocket maximums for a year, out-of-pocket limits per prescription, perhaps, so people don't get to the pharmacy and walk away without the script.

MS. PATEL: With nothing, mm-hmm.

MR. JOYCE: Those are logical things to do.

As far as Part B and CAP, I think any type of competitive bidding type process in Part B would be welcome. I think if you look at DME, Durable Medical Equipment, that was fairly successful. And, again, we did have a bad experience in the past, but I don't think movement towards a more competitive market, which is I think what the Administrator talked about, is something that -- it's hard to argue against.

MS. PATEL: Oh, we have lots of hands. Let's get a microphone because we've got webcast -- let's start with this gentleman on my right and then over here in the front, the second row, and then I'll get you in the back, sir, yes.

MR. MILLER: Thanks, Kavita. Are they mic-ing up somebody again?

MS. PATEL: Can we hear you? Yes, go ahead.

MR. MILLER: Mike Miller; I'm a physician doing health policy for about 30 years now. And I want to come back to something that Geoffrey said about higher prices being an incentive for innovation. I've done a lot of work now with patients groups in a variety of ways, and personally as a patient it's sort of the concept of I want to have high prices for drugs for a disease that I'm going to have in the future so that there's going to be in innovation in that area. But when I get that disease I want things to be lower prices.

So can you guys talk about some of these concepts, CAP and all these other things, what they would do for incentives for innovation around, you know, a certain population, a certain disease area, if it's just in Medicare, if it's in Medicaid, if it's 340b? Because I think that's a complicated concept. It came up here at a Brookings event back in February and we talked about it in terms of closing the donut hole and the incentives that it had for companies to dramatically raise their list prices for Medicare Part D drugs.

MS. PATEL: Right. Okay, great. Who wants to -- Geoffrey?

MR. JOYCE: Sure, I'll start. Obviously we want innovation. And I think obviously there's plenty of empirical evidence in the academic literature and others that a higher profitability in an area will lead to more R & D. We see lots of R & D in areas like Alzheimer's disease versus Malaria and TB where the loss of life is maybe greater in one

versus another. So we know sort of the lure of richer markets and profitability is going to attract more capital and more R & D.

Like you say, we can lower prices today and that will benefit today's consumers at the cost of future innovation and maybe the people in the next generation. So we have to be careful. And I think we can just do this intelligently by saying let's foster an innovative environment and we're going to make drugs that we think are value oriented, that are worth it, affordable to patients. Out-of-pocket maximums, cap on pricing per script, for example, is an easy way to make it accessible, with subsidies for low income folks.

So I don't think they're mutually exclusive, I don't think you can have one without the other, but we have to do it intelligently.

MS. PATEL: Stacie or Sam?

MS. DUSETZINA: Yes. I guess one just general reaction to that is I hear that question a lot or I hear that concept a lot, thinking about where we're rewarding innovation. And I was part of a panel at the beginning of the year and we had someone representing venture capital, which was kind of new for us at this nerdy academic conference. But they said something really interesting and important, they said money doesn't care about public health. And it was really interesting to think about this concept of getting the innovation and rewarding innovation, but then having that money all flow to solve the same problems because there's a reward. And I think in some ways we're starting to see that happen a lot in oncology. There are thousands of trials for the same type of drug to meet the same target population. And you're like eventually you're going to run out of people who even can be in the trials because so many people want to get a product onto the market.

So I think one question that we really have to wrestle with is how do we get innovation in the right places so that we're not just repeating the same drug because there looks like a good market for it, but we actually have the innovation and the money kind of rewarding sort of the public health good. And I don't think we're anywhere close to doing

that at the moment.

MR. NUSSBAUM: And just very quickly, I think that no one would be critical of our lack of innovation today. I mean in fact there is so much innovation it's -- to Stacie's point -- how do we find models to even test these new therapies. But what is critical -- and we really haven't talked about this -- we've made assumptions that the current pricing structure of drugs basically remains the same and we're looking at models of copayment and access, but think about innovation also means more efficient ways of doing gene therapy, more efficient ways of preparing cells. Scott Gottlieb has talked a lot about and is promoting new study designs, basket trials.

So I think there are many ways along the innovation path where efficiency can both speed development and drive lower overall cost of therapies.

MS. PATEL: Perfect. Go ahead.

MS. FRIEDEN: Hi, Joyce Frieden with MedPage Today. We've talked a lot about the effect of these high drug prices on patients, but what about their effects on physicians in the Part B program who might have to pay for some of the drugs in advance before they can administer them? Because I have heard stories about people having to get loans in order to do that. And are any of the solutions being looked at address that?

MS. PATEL: Who wants to --

MR. NUSSBAUM: I think that a lot of your question is provocative because most people are looking at the physician income and when they look at oncologists and see that 30-40 percent of their revenue is generated by markups on drugs or, again, rheumatologists. But your point I think is really being addressed in the market. More and more specialty pharmaceuticals are being distributed through different channels, and even health plans. And potentially in the future CMS would look at those channels where the cost is being borne by the specialty distributor. It's more control over the cost, more control over the right clinical setting for the drugs, and it takes the burden of acquiring those drugs off the physician. But it must be replaced as -- Kavita's question was by something else. It can't

just be any NM code, it has to be a care coordination, care management, and overall cost of care code.

MS. PATEL: And I would say the more you're seeing consolidation in the oncology industry, as well as some of these others, the less you have -- you're starting to see more physicians that actually don't want to do buy and bill anymore. And you're starting to see a willingness to say I will come in in a kind of a salaried arrangement or something that has less of this risk. Because they don't want to keep their practice under water. And so I think it's going to be a very interesting time if a CAP type of program that could have some provider facing aspect could be successful. I think you'll see oncologists and other types of specialists that are saying I don't necessarily want to be responsible for holding the drug and holding the supply and keeping kind of all of those things that used to be not only profitable, but to be fair, were convenient for both the doctor and the patient. We call them physician administered drugs because they were done in my office, they were done here. And I think we're just changing how we think about that now.

So, Geoffrey?

MR. JOYCE: Just a quick anecdote related to that. I was at the oncology meetings a few weeks ago and a physician oncologist stood up and said when I was in private practice we had a third-party vendor who would tell us and provide the prices, real time prices for all of the oncology drugs so we could compare them to what we were going to get reimbursed. And so we would see what our margin was on every drug and we would prescribe according to margin. He goes, I'm so relieved to be in a hospital now where I don't have to do that.

MS. PATEL: I mean that's not how a physician -- I mean no matter -- there's this inflection point where you -- even making that much money, it's just people do not necessarily want that. And especially now that they're inundated -- oncology when I was training, you know, you had a handful of drugs. Gleevec was the newest greatest drug we ever had and now it's just dwarfed by -- name any of the checkpoint inhibitors, immune

therapy. I mean it's mindboggling. So it's not easy for care providers either.

In the back and then right next to him, and then we'll be done. Both the gentleman.

MR. BLAKE: Rich Blake, Strategic Health Resources again. I mean we're talking about innovation as if it were just a word. It's not. There's a dollar sign attached to it. And we work with more a dozen biotech firms which have innovative drugs in their particular therapeutic areas. So at the end of the day the logjam -- and 78 percent of all the new drugs are developed by small to mid-size biotechs. There's no real incentives for large pharmaceutical firms to want to develop new drugs. Why? Why would they want to? They're already making billions of dollars on the existing drugs whether they're the best therapeutics or not.

So at the middle of the day, we have to remove the logjam, the regulatory and the venture capital logjam, for these small biotechs to develop. Most of these small firms are in -- our clients may be stage 2B. If they get to stage 3, which is highly unlikely, it's very lucky because you're talking about hundreds of billions of dollars along each of the clinical trial pathways.

MS. PATEL: All right, Rick, get to the question.

MR. BLAKE: No, but the point is then how do we change the system so that the therapeutics that need to be out there get out there rather than have a Raiders of the Lost Ark, where you have the things schlepped away and put away in a stockroom somewhere? That's the question.

MS. PATEL: Okay. I feel like that is a very weighty question.

MR. JOYCE: I mean you're right. In a sense large pharma manufacturers are now basically licensing or venture capital funding smaller labs, partly because they weren't very successful. Developing a new drug is hard. And when a Gleevec comes on the market it raises the bar. You've got to be better than Gleevec. And so drug development is risky and difficult. And I think you're absolutely right, it's small and mid-sized

companies that are developing new molecules and then being licensed or purchased by large pharma and shepherded through the regulatory process, the clinical trials, and they market it.

MR. BLAKE: Or they're killing it.

MR. JOYCE: I don't think they're killing good efficacious drugs.

MS. PATEL: Molecules sit on the shelf and nobody uses them. Right. I mean I think that's the way we kill things, it's we didn't find a use or can't -- complexity of enrolling in a trial, right. And so then it's not -- to Stacie's point, I mean finding patients is not easy, and so it's challenging financially even if you get through. That's why you're at 2B, right.

So I think that's where Scott Gottlieb has really stepped up to say what can we do to cut through some of that. But then you've got to have some sort of reimbursement or commercialization strategy, which is something Scott can't do in some ways.

All right. I think that was next to -- yes, you get the last word, my friend.

MR. SMITH: Thank you. Richard Smith, independent consultant. A question for Dr. Nussbaum. So you emphasized the positive aspects of using prior authorization step therapy and the like, and it triggered a thought that when a manufacturer brings a drug to patients, have to get FDA approval, and that's based on an extensive body of evidence, you know, with step therapy, with prior authorization, and other techniques, you know, tiering and so forth, you know, we have a system in which there isn't anything approaching that level of oversight. There are a few process standards here and there, but very little oversight, very few real standards, very little evidence about how they operate. A recent Health Fairs article identified step therapy sometimes requiring five steps through to a step drug. That was an outlier, but they found examples.

So my question for you is if we're going to throw in with these strategies as a principle way of managing, what's the accountability, what are the standards with teeth, how do we know that they're working, you know, what's the -- kind of what is the deal with

society to know that this is actually being deployed in a way that's at all useful or positive.

MR. NUSSBAUM: That's a really important point. Number one, start with professional expertise. Number two, based on clinical data, increasing real world evidence. The one thing about health plans that all generally do is approve off label use if, in fact, there is evidence behind that, if there's follow on studies. That's really important. So, again, the science being number two.

And number three, a series of safeguards. You know, there are safeguards. Every company has their own internal review, and particularly in oncology, you know, we had, and I know others have exceptions process where clinician to clinician would review issues and make decisions. But also there are processes at the state level and beyond that would allow appeals to peer groups. So I think there's evidence that there can be a very well developed process in place that guides effective therapy, state of the art care, but limits in some way the ineffective care.

Now remember, the reason these are done is in part is to have a more limited repertoire in your formularies, in part, so that that can lead to greater rebating. So that's the immediate -- one immediate impact. I think it can be done well. And what we have today, though, are large compendia we've not used -- and I know this hasn't been raised -- but we've not used PCORI in a way that maybe many of us initially thought it would be intended. This is really where PCORI could be stepping in and guiding us as we look at the next decade for PCORI.

So there are many approaches that we could all talk about that can be effective here.

MS. PATEL: All right. So any last thoughts? You get your chance. So join me in thanking an excellent panel. (Applause) See you next time.

Thank you.

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