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LOUISIANA'S PRESCRIPTION DRUG EXPERIMENT: A MODEL FOR THE NATION?

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P R O C E E D I N G S

MS. SHEINER: Hi is this on, yes it's on. Okay, hello everyone and welcome to Brookings. My name is Louise Sheiner. I'm the Policy Director of the Hutchins Center on Fiscal and Monitory Policy here at Brookings and along with my colleagues from the USC Brookings Schaeffer Initiative for Health Policy, I'm so pleased to welcome you today to talk about innovations in prescription drug policy.

So it seems that you can't go a day without reading about the problems of affordability with prescription drug prices, and about all the various plans to address them, and then how difficult they are to actually get enacted and get through, and all the challenges they face. Today we're actually going to talk about the experience in Louisiana where they've actually managed to put a plan in place to improve affordability and access to treatment for Hep C.

I'm really looking forward to this afternoon. I think its going to be incredibly interesting. Let me just tell you about what we're going to do. We're going to start the afternoon off with a presentation by Neeraj Sood who's the Professor of Public Policy at USC, who's going to provide us with really, some basic background on the fundamental idea underlying the Louisiana approach, and the Louisiana experiment.

We will then move on to a discussion with Rebekah Gee, Secretary of the Louisiana Department of Health who was instrumental in getting this plan actually put into place. And she'll talk about what challenges she faced in trying to do this and what challenges she thinks she faces in the future as well.

We'll then bring in some other experts to talk about the broader question about whether or not this model they've done should be thought of as a model for other states, other drugs; sort of, how far can we take this model. And then we're going to end the day with a conversation with Wendell Primus who is the Senior Policy Advisor to Nancy Pelosi and he's going to talk about the issue of prescription drugs from a Federal perspective.

So, I think it's going to be a great afternoon. I thank you all for being here, and I'm going to lead off to Neeraj. Thank you.

MR. SOOD: Louise, thank you for the introduction and thanks to Brookings for organizing this event.

So, my journey into Hep C and subscription models started in 2015 when I was invited to be part of a consensus committee for the National Academies of Sciences, and the charge of the committee was to come up with a national strategy to eliminate viral hepatitis, which is both Hep B, and Hep C, from the U.S.

When I was on this committee, one of the first presentations we had, or one of the first facts we learned was that every year about 20 thousand people in the U.S. die from hepatitis C and to just give context for this, this is more than the combined death toll of 60 other infectious diseases that are tracked by the CDC.

If you compare this to 9/11, this is six times the death toll from 9/11. This is a stark fact that 20 thousand people are dying every year from this disease, and you could still understand this fact, but we also know that there's a cure available for this disease. So that's the second fact that motivated me, which was that in 2014 there was a cure, which if you take a pill for 12 weeks you no longer have Hep C.

The third fact was that the most vulnerable people, so people in Medicaid, only less than 300 people in Medicaid, in the country like the U.S., had access to these cures. If you look at the prison population, the statistics were even more dire. 1 in 100 people in prisons, even though it's a captive audience, it's a population where you treat them, you're going to prevent many more secondary infections, so it makes public health sense to treat this population, yet only 1 in 100 people in prisons with Hep C were being given this cure.

So, these three facts motivated the committee to do something about this problem. What the committee found was that if you treat 90 percent of the people who have Hep C with these cures, we can essentially eliminate Hep C as a public health problem. So

if you treat 90 percent then we no longer have to worry about this problem for generations to come.

And the question, the charge, for us was: that sounds great, but how are we going to afford this? How are we going to manage to treat 80/90 percent of the population so that we can eliminate this? Because, at current prices that would have been billions, and billions, and billions of dollars of spending which you could see the prisons could not afford, the Medicaid program could not afford, and so on.

So, the National Academy's report was the first one that actually recommended subscription model for Hep C. But this model was at the Federal level, or at the National level, so there were three key points about the model.

The first was, we wanted to make sure that this was a voluntary transaction between manufacturers of Hep C cures and the Federal government because we were worried about the incentives for innovation. So, a simple solution would be to just ignore patents on these drugs, but that would mean we would not get future cures.

We wanted to make sure we were preserving incentives for innovation and that's why the voluntary transaction was an important part of this recommendation.

The second part was that the way the model works is, the Federal government gives a lump sum payment to one pharmaceutical firm that is making this cure. And in return for this lump sum payment, the pharmaceutical firm pushes the price of the drug to, essentially, zero.

Basically, what we're doing is, we are giving you the incentive for innovation up front, but in return, pharmaceutical firm is guaranteeing access. So, price is no longer a barrier for treatment. That was kind of the basic idea.

Since I'm, you know, a Professor of Public Policy or Economics, I love graphs, I love graphs; I'm going to show you some graphs to kind of, again, show how the logic of this works. But, when we came up with this recommendation, at the same time, Rebekah and Rena, who are going to be panelists, they were on a panel committee, which

was about making medicines affordable. And I remember, they heard about this idea and they asked me to present the idea to this committee, and I've never seen a government official so excited about economics (laughter).

Rebekah was just like; I'm going to do this! This is fantastic! And she had been motivated by the same facts. So, she'd been trying to figure this out probably even earlier than I'd been trying to figure this out. And when she saw this, she thought, this could break the political impasse, or kind of figure – like, this seemed to be the solution that would make different parties happy, and different stakeholders happy.

That's in somewhere where my work stopped, and Rebekah and Rena and the rest of their team's work began; which was to kind of take this idea, convert it into a solution that would actually work in the real world. Especially, a solution that would work at the state level, and not just at the Federal level.

So, at the same time about a year later I published a paper showing the outlines of how this Federal solution might work at the state level, and I published a policy brief at the Brookings institution outlining some of the challenges that might be faced.

Now, lets go to the idea. If you think about – you know, economists, again, love demand/supply, so this is a demand curve. On the Y axis you have the price of the drug, and on the X axis you have the patient population that's treated.

If you set a low price, you can treat – sorry, the pointer doesn't work – but, you can see if you set a low price, you can treat a lot of patients. That's shown by the Value Q star. You can treat a lot of patients, but the problem is that the reward for innovation is too low. The shaded area tells you how much money pharmaceutical firms would make, and that's too low.

If you choose a high price – and remember, it's pharmaceutical firms who are setting the price; so, they choose a high price because that leads to higher profits, right? So, remember, they are choosing a high price because they want more profits, not because they want to limit access to the drugs.

A side effect of high prices is that access to drugs is limited. So, at a high price, you move up the demand curve and instead of treating Q-Star patients, you're treating a much smaller number of patients.

So, the basic idea here is: look, lets give these profits up front to the pharmaceutical firm, and in return, lets remove price as a barrier; so, in return let's make the price, essentially, zero, right?

With this model you, kind of, preserve the incentives of innovation; you are giving profits to pharmaceutical firms up front, but you're also at the same time, dramatically improving access because now price is not a barrier. So how would this work?

Let's take a Hep C example. Suppose there's a state that's treating about six thousand Medicaid patients, and there are three pharmaceutical firms who have a cure for Hep C and who are competing, and let's assume – I don't know what the negotiated price is, so this is just a hypothetical price – let's assume the price is $40,000. Let's assume firm A, or drug A has majority of the market, so they treat about 4,000 patients, and the other two firms treat about 1,000 patients.

From a state or Federal perspective, so if you are a Medicaid program, the total cost of the program to you is about 240 million dollars, under the status quo. This is what you're spending for treating 6,000 patients.

So, the way the deal would work is, you would go to one of these firms; so, you would have competition between these firms, and suppose you negotiate a deal at 200 million. I don't know whether it's going to be 200 million, or maybe even lesser than that, but let's assume the deal is at 200 million.

What happens with this deal is, once you give a pharmaceutical firm 200 million, let's say we gave it to firm A, the firm that was making 160 million, that firm promises to make the treatment free of cost after they've got their 200 million. From the firm's perspective, they're winning. In the prior market they were making 160 million and now they're going to make 200 million. The firm that actually made the deal is a winner in this

market.

The state is also a winner because the state was spending 240 million, and instead of that, now they're going to spend 200 million. And, patients are also winners because now the drug is free; this price is no longer a barrier to access, once you've paid the 200 million. So, you've solved the problem for the state, you've solved the problem for patients, and you've solved the problem for the firm that won the deal.

The other two firms that didn't win the deal, are out of the market in the state, and now what are they going to do? They're going to compete, and they are going to make sure they get the deal. So maybe the price is not even 200 million, it could be lesser than that.

The key thing, the way this works is, because you have competition, that can drive down the price, right? And the second thing is, once you've made an upfront payment and the price is zero, price is no longer a barrier to access.

A lot of people have said, "Oh, subscription model, Volume-Based discounts, it's kind of all the same thing." And what I'm trying to show in this chart is that it's not the same thing. So, I've kind of put up three different models, one is like a Pure Subscription model from an economics textbook; which is you would pay a fixed upfront fee, and in return for the fee, you get an unlimited supply at zero cost.

Then there's a Modified Subscription model where you're paying a fixed price for the drug up to a cap. Once the cap is reached, the drug is free.

And the third is Volume-Based discount, which is if you buy a 100 units, you pay price X; if you buy more than 100, the price falls a little bit more, if you buy a thousand, the price falls more, but the price always stays positive, there is some positive number.

Only the Pure Subscription model requires an upfront payment, and only in the Pure Subscription model, the marginal cost of treating an additional patient is zero. So, in the Modified Subscription model, it's positive up until the time you reach a cap, and after you reach the cap it is actually zero. For a discount model, it's never zero. Every additional

patient is going to cost the state money.

In a Modified Subscription, only after you've hit the cap, every additional patient is free, and in the Pure Subscription, once you've made the upfront payment you have every additional patient is going to be free.

So, the implication of this is, if you look at this now from the manufacturer's point of view, what's happening is in the Pure Subscription model the manufacturer is guaranteed a fixed revenue that no matter what, after the deal is made, they are going to make a fixed amount of money. They would prefer a fixed upfront payment, rather than some uncertainty about how much money they would make. It depends upon whether the states are going to follow through or not. Given that they are going to be willing to give higher discounts, if you take away the risk for them.

That's why it will be the model which will have the lowest cost for eliminating Hep C, and then you can kind of argue that the Modified Subscription model would be in the middle, and the Volume-Based discounts would be at the end.

The other way to think about this is, let's think about the cost to the state with the status quo. If you've made a deal where you've already given money to the pharmaceutical firm upfront, the cost of the status quo is really high because you've paid money and if you don't treat additional people, you've, in some sense, lost all of that money.

In the Modified Subscription model, the cost is somewhere in the middle because you haven't made that upfront payment, but you still have an incentive to scale up frequent because you want to reach the cap and then beyond the cap, the treatment is going to be free. And in the Volume-Based model there is, in some sense, the cost of the status quo is zero, you don't treat people, you don't pay any additional money.

So, in some sense, which is the model which has the biggest commitment to elimination? The Pure Subscription models. And which is the model which can eliminate Hep C at the lowest cost? The Pure Subscription model.

Now let's think about whether this model will work in other markets. Can it

work in other states? Yes. But, can we replicate Rebekah in other states, I don't know (laughter). So, it really depends upon – and I think this is important because this is very innovative, and you need true leadership to actually implement this. You also need a partnership with CMS, and the third important thing is price is not the only barrier to expanding treatment.

So, even if you make the price zero, you still need to figure out how are you going to test everyone, link them to care, make sure they adhere to therapy, and that's no small task.

And finally, this is kind of a minor point, that once you've made the deal, you want to steer the man towards the preferred drug. So, now the company's that are not part of the deal, they are going to try every way to make sure the patients are treated with their drug and not the company that made the deal. So, you need to, kind of, manage utilization of the drug towards the preferred drug.

Can this work in a non-Medicaid market? It cannot with the current laws because what will happen is, this will change the Medicaid best price. So, if United made a deal, what will happen is United will pay upfront to a company and after that the price of the drug is going to be zero, and Medicaid best price would say, all Medicaid programs should also get the price to be equal to zero.

Can this work for other drugs? It can work, as long as three conditions hold. The first is that there is an access problem. We saw for Hep C there was a big access problem that even people with insurance could not afford this drug, and there were a lot of people who didn't have access to this drug.

The second is, the scope for model has it as minimal, which basically means, if you put the price of this drug at zero, would this encourage inappropriate use? So, if you make the price of a Hep C cure zero, people are not just going to take pills because, oh, it's fun to take these pills, right? So, you want a treatment where even if the price is zero, only people who need the treatment are getting the treatment.

And the third condition is, for this deal to be affordable you want competition between firms. One example of where all these conditions are, kind of, met, is insulin. It's been in the news, insulin prices are rising; a lot of people cannot afford insulin at these higher prices, and there are several firms competing in the market for insulin.

I have just two policy recommendations. One is, make it easier for states to implement ideally the Pure Subscription model. And this might need to regulations because it might need a CMS waiver or new laws, I don't know how that would work, I'm not a lawyer; or, maybe just set up like, provide technical resources to do this.

And the second is, change Medicaid best price rules to make an exception for Subscription models so this can happen in the private side. Thank you (applause).

MS. SHEINER: I'd like to introduce Secretary Gee. Thank you so much for being here, we are really honored that you joined us.

So, as Neeraj said, he had an idea for academics, and you turned it into an actual policy, and you had to actually make it work. So, can we just start off with what is it that you did, all right. So, what is the innovation that you are now undergoing.

MS. GEE: Sure, and before we start, I just want to thank the Brookings Institute for having us today. I am most certain that this is probably the first ever session called Louisiana Innovation here at Brookings (laughter). It is wonderful.

I also want to recognize my boss, Governor John Bel Edwards, who through the Medicaid expansion, made it possible for us to think about these types of things. When we think about eliminating a public health challenge, if you don't have healthcare coverage for individuals then you don't even have a conversation about it.

So, it was the Medicaid expansion in January of '16, which was his first executive order, that started this conversation, and him saying to me, "Rebekah, you have two jobs, one is to expand Medicaid; and two is to make people healthier."

And, of course, we have the best food in the country – I don't think you can argue with that (laughter), so as a result we have some health issues. We have significant

challenges; in many of our indicators we're 50th of most unwell, although some of the happiest people in the country, if you look at BRFSS and CDC surveys.

And so, I want to get into why? Why did we do this? Drug prices have vexed me for some time. I'm an obstetrician and had previously run a birth outcomes initiative to try to reduce infant mortality, and the one drug that is able to do that is 1700 hydroxyprogesterone. It went from $9.00 to $900 while I was trying to do my work, and the drug price, frankly, made it impossible. We did everything; created a national quality measure, relieved every barrier to access and it was simply the price was simply in the way.

So, starting in this role, although I'm not a hepatologist, unlike Senator Cassidy who's been our partner, but the first month on the job I got two letters; one was from CMS saying, "You should provide more drugs for Hep C." And the other was from Advocate saying, "You should provide more drugs for Hep C." And yet we had a 2 billion dollar deficit.

The previous Administration had left our budget in shambles. We were looking at, could be continue to cover nursing homes, pharmaceuticals are an optional program under Medicaid, there were draconian cuts that we faced, including to Higher-Ed and K-12, and so more Hep C drug was simply not possible, or much a more higher spend that it was simply not possible.

So, we aim to come up with a new way of doing it and the pitch was always this, it was never about just a slightly better price, or a better deal. It was that here we are in this country -- I think Neeraj so beautifully illustrated this -- with a disease that kills tens of thousands of people. It is the leading infectious disease killer of our time. And through, in large part, the innovations of Americans, our research institutions, we have a cure, and it's unacceptable that in this day and age we cannot provide it and we have people suffering, bleeding internally, and dying unnecessarily because of the price; just simply unacceptable.

And so we set out to solve it, and frankly, we were agnostic to the solution as long as we were able to provide individuals with access and the Governor supported me and my team, and I think that's very important. As we started this journey early in 2016,

many states were not willing to join because there was fear of change, and of how the pharmaceutical lobby would relate to this type of thing.

And so what we did achieve last month, and what started last week, which was wonderful to see, and we've already treated hundreds of patients who have been waiting, is the Modified Subscription model. To some affect, one of the things we navigated was that there really wasn't an understanding of Medicaid policy as you looked at applying this to a state context, and one of the challenges we have as states is that we have – as you know, Medicare is a Federal program, really mostly federally run, Medicaid is a state and Federal partnership and if you've seen one Medicaid program, you've seen one Medicaid program; but everything we do by and large has a Federal component to it. And so everything we do has to be under state plan.

We are not able to just write a check to a pharmaceutical company because there is no vehicle for us to do that and get our Federal match. And so we had to find a way around it.

What we realized -- and I do want to recognize the Trump Administration for their help -- is that working through Neeraj's idea, and that of Senator Cassidy, and Peter Bach, and others – you know, of course there were many other ideas over the course of the three years that we tried; we realized that way that you could get around the best price considerations that Neeraj outlined, if you enter into a supplemental rebate agreement and if an entity is a 340B entity. And so that's what we realized and --

MS. SHEINER: Can you tell us what's a 340B is?

MS. GEE: 340B is a discount pharmaceutical pricing program that was created to allow safety net institutions to have revenue stream to allow vulnerable individuals to be covered, and so many federally qualified health centers have used it. There's been a national debate about hospitals using it and are entities benefitting really most appropriate.

But we realize that there were these exceptions to what is important, because what we knew was that a state like Louisiana, a state of 4.6 million people, that no

pharmaceutical company would give us a deal that would then impact their entire national price. So we had to get around those considerations but we also had timing as an issue.

We started this in June of ’16 and I’m now 100 in Secretary years. I've been in this job nearly four years, and we didn’t have time to do -– as we discovered – as we went through all of these hoops -- we didn’t have time for a waiver. And so we looked at what could be do under existing policy.

So what we have now is a Modified Subscription model. We’re up to a cap, which is at or about what we spent last year for Medicaid and corrections. We will then get unlimited drug and then we will be able to eliminate this infectious disease and focus on more difficult challenges.

So we’re really proud of that and last week we started; patients are not getting drugs, some mother last week who had to go through two pregnancies with hepatitis C worry about whether she would give it to her babies, worry about whether she would die from this disease. You know, 60 percent of people who have Hep C have liver disease. One in five get sclerosis. 1 in 20 get cancer, so it’s a very scary thing to have to live with and we've seen hope for the first time in many, many people who've waited years.

And so, all of this has been worth it, and we’re excited to be able to offer that now, as of last week. And then in corrections, not just for Medicaid but in corrections. We think about 30 percent of people with Hep C will pass through a prison during their lifetime. About 95 percent will get out and if we aim to eliminate this disease we can't ignore then. And so we’re really, really proud to be the first state to be able to offer this unlimited access to individuals who are incarcerated.

MS. SHEINER: That sounds fantastic and it sounds, oh well, you just do the rebate and it sounds easy, like, oh, okay, now we know how to do it. From what I hear, it was not easy.

Who did you have to ask permission from and who did you have to convince, and what arguments did you face, and how was that?

MS. Gee: It took three years.

MS. SHEINER: Yeah.

MS. GEE: A little more than three years because we started June 16th. First of all, the Governor, to have his support and to have the support of my team. We were told no at least 50 times from a variety of people; whether it was the industry, or policy makers, or individuals at the CBC, or, you know, a variety of reasons because it had never been done before. Now it looks like it was an easy thing.

MS. SHEINER: (Laughter).

MS. GEE: And it seems intuitive, but it was not. And I think another important thing that Neeraj brought up is over the course of our journey it became a competitive market.

MS. SHEINER: Mm hmm.

MS. GEE: And so there then it became an economic impetus to enter into this kind of agreement. But the first thing we did is outline the tradeoffs. And I don't know if Josh Sharfstein is here, he was one of the early partners. But Peter Bach, who I knew from the Health Service Board at the National Academy, I called him up one day and said, you know, we talked about his abacus and how he'd showed tradeoffs, particularly demonstrated them in cancer, and asked him if he and his team could demonstrate those for state budgets.

So we mapped out the Louisiana budget and demonstrated that it would cost us 760 million dollars, at the prices at that time, to eliminate Hep C just for Medicaid alone, and that that would be more than our K-12 budget, our prisoner budget, and all administrative functions of government combined. And that there really are **real** tradeoffs.

We have to balance our budgets every year. As states we can't print money or borrow from China; we have to balance our budget. So that means when costs go up in healthcare, they go down in Higher-Ed, and we thought that was important because the national discussion at that time in '16 was about what a great value this is, and arguably it is

a great value.

There are so many drugs that don't work, that provide marginal benefit, and here is the first cure for a virus that I know of in human history. This was a tremendous innovation, but one in which was inaccessible to, you know, as Neeraj said, less than 3 percent of Medicaid and less than 1 percent of prisoners.

We said, although this is laudable, it's a great drug, we can't afford it. And there are economists – Rena who's going to be next – we were on this panel, and there was a gentleman from MIT there saying, "Well, just mortgage it, it's like a Tesla, you don't pay for it all in one year." And I was laughing, and I said, "Louisiana is never going to be able to afford a Tesla," (laughter). You know, maybe a Honda but we're not a Tesla state (laughter).

We're the lowest income state, 42 percent of our people live below 200 percent of poverty, we don't have paid family leave, we don't have universal Pre-K, we don't have other things that are meaningful, so we're just not in a position to pay the price that it was.

We then asked the question -- and Josh Sharfstein and his team at Hopkins helped us -- well, what about Federal Patent Law 1498, this is a 1910 law, most notably has been used for night vision goggles. So, if there's a technology or innovation that's been shown to improve the safety or health of the American public, the U.S. Government can fairly appropriate the patent holder and then use that technology. Now we brought this up; could this be used for Hep C?

MS. SHEINER: Yeah.

MS. GEE: And we had a conference, and overwhelmingly there was support for it, in people that came --

MS. SHEINER: (Laughter), yeah.

MS. GEE: But certainly, the pharmaceutical industry was less than enthusiastic.

MS. SHEINER: Mm hmm.

MS. GEE: So, then we said, “Okay, well if you don’t like this, status quo is unacceptable to us; what else?” and so, one day I got a call from a man named John Arnold, and it was a totally out of the blue cold call. And the Laura John Arnold Foundation is a foundation that supports innovation in pharmaceutical pricing, and he said, “Rebekah, how can I help you.” And I said, “Well, I think I need an offensive line, John.”

I think that Louisiana, to be the only state asking this question, asking for a different framework, we need a different equation to solve because we won't solve the equation how it is, we need other governors. And I happened to be at NJA at a meeting for Health Policy folks and said, “Well, why don’t we fund the NJA to bring other governors along.”

And so, it was through that that we brought 10 other governors along, it was bipartisan, there was Charlie Baker, Jay Inslee from Washington state; and so they joined us, and we asked the pharmaceutical industry, “Okay, you don’t like 1498. What would work?” Okay, it can't be the status quo, it can't be a mortgage, it can't be the same price, what would work?

We also asked Pares what would work and then our teams convened, and by that point Neeraj and his team were putting their recommendations for it, and that became a very attractive option because it really should be a win-win.

These pills cost dollars to make, the folks are incarcerated. There is never going to be enough money, because incarcerated people are funded totally by state dollars --

MS. SHEINER: Mm hmm.

MS. GEE: To cure everyone in prisons, nor was there going to be unlimited money in Medicaid to treat, so why not this win-win where pharmaceutical companies could have this guaranteed revenue, and yet a state could solve a public health challenge.

And so, we started to socialize that, but even that idea, as much as it seems like an inevitability, took about two years to really push forward, and it was in partnership

with Senator Cassidy, who is a hepatologist. In fact, he's only one of two hepatologists in Baton Rouge, our capital city.

MS. SHEINER: Oh.

MS. GEE: So one of the other pieces of the story is that we've had to think about how we think about treating and testing differently and Alex Billioux is here with me who heads up our Office of Public Health, and has been extraordinary in that regard, thinking through that. So we had Senator Cassidy, we had the Trump Administration, and others, and then solely over negotiations this became a viable option.

Now, last year in September we released an RFI asking folks what they thought of this idea, and there was a lot of support, Pharma was supportive, Gilead was supportive, Abbey was supportive. And then after that we did an SFO, or a Solicitation for Offers, and asked the companies to come to us with their proposals and it was only Asegua Pharmaceuticals, who is a subsidiary of Gilead, that had a real subscription model, or the Modified -- actually what they initially envisioned it as was a subscription model but we couldn't do because I can't write a check to a company, and we then negotiated it as a Modified Subscription model.

You know, I want to recognize that company because they were courageous to be the first company in the nation to enter into this. There is some risk, and we are really delighted to have started this last Monday.

MS. SHEINER: Yeah, that's fantastic.

MS. GEE: Yeah.

MS. SHEINER: So, talking about the tradeoffs, sort of, in terms of making the case, was that -- I mean, to me, it seems like that might be making the case to the public but also to Pharma, which is to say, it's a negotiation, we're not kidding here, we're actually not going to buy more.

MS. GEE: Mm hmm.

MS. SHEINER: Right, because we can't. Whereas the case about, it's

really a worthwhile investment, well you actually have some unique -- you know, the balanced budget requirements, that make that, “so what?” in some sense to you guys. It may be a great investment, but we still can't -- you know, maybe we should be able to afford it, but we can't.

So, was that the kind of stuff that convinced them to go along, was it mostly the fact about the competition that Neeraj was talking about, that this was a way of getting the market; what do you think their considerations were that made them decide to take that risk.

MS. GEE: I don't know if I’ll ever know.

MS. SHEINER: (Laughter).

MS. GEE: But we amassed that the smartest people, who I call the Pharmaceutical Avengers, I mean, the smartest most competent, creative people in this country helped us, with no renumeration. I mean, John Grober, Rena Conti, Josh Sharfstein; people spent hundreds of hours, calls every week helping us just because this is the right thing to do.

I mean, there are very few things in your career -- in my career, I think I’ll be able to say, certainly the Medicaid expansion was one of them -- but I truly save lives. Just to see the look on that mother’s eyes made it worth it and made it worth it for people who don’t even live in Louisiana, to help us.

We had the national best, Neeraj, I mean, we looked at every idea and we were also intrepid; we were not going to take “No.”

MS. SHEINER: (Laughter).

MS. GEE: I mean, as long as I had the ability to have this role and to fight for the people of my state, and my Governor, we were not going to take “No.” We were going to fix this problem. And so I think they got tired of us, too.

MS. SHEINER: (Laughter).

MS. GEE: (Laughter), but you know, I do think, again, I think there are

people like Gregg Alton who has been an advocate for patients. I think Gilead has been, in the space of trying to solve these issues of access globally. Typically, though, these solutions have been applied to other countries, right? So we look at Egypt and India, although in Louisiana, often, our economy looks like a developing country, and our health challenges mirror those of some developing countries, those solutions have not been applied to the U.S., but I think it was all of those things that was, having a company be willing, having the brightest minds in the country, having stubbornness --

MS. SHEINER: Mmm.

MS. GEE: You know, if we had given up the first time we heard “no”, that would have been in 2016; so, I think it’s a variety of things, but I know we’ll hear from Asegua next, so.

MS. SHEINER: Yeah.

MS. GEE: We’ll see what they’ll say.

MS. SHEINER: And, in terms of the challenges of getting through CMS.

MS. GEE: Yes.

MS. SHEINER: What was that partnership like, did they say no at first, too, and how did that come about?

MS. GEE: Yeah, I mean, CMS is fantastic. I just can't say enough. You were working with them now on a model to help spread this through CMMI and Adam Bolard to look at other states, because there is now a lot of interest.

Their pharmaceutical team got down and dirty with us, rolled up their sleeves, and tried to look at what the solution was, and were very constructive. So I just can't say enough about how great they were. And also, understanding that we were in a rush, right?

MS. SHEINER: Mm hmm.

MS. GEE: Every patient who gets sick, or dies, or gets sclerosis, or cancer, while we are trying to figure this out, is a failure. So, we always had that pressure, not just

about political timeframes, because my Governor is up for reelection this year, but, kind of, the moral imperative to get this solved. And so they were right in there with us and I think that some of the -- we don't need a waiver to do this. Okay, so I think that further states this is something you can do through a supplemental rebate agreement.

MS. SHEINER: Right.

MS. GEE: So I do think that figuring that out would definitely lead to other opportunities, not just for other states to do Hep C, but for other disease categories as well.

MS. SHEINER: Mm hmm.

MS. GEE: But I think, it should have been -- I think this should have been done earlier, but for whatever reason, we were the first state to think about this.

MS. SHEINER: And you chose Hep C because of that timing, because it was so important to do it quickly, or was Hep C a perfect case for this, or like, why Hep C?

MS. GEE: It's the leading infectious disease killer in the U.S. It kills more people than the 60 infectious diseases below it kills, combined, and we have a treatment; and this is an epidemic also. We've had, in some communities throughout the country, hundreds of percentage increase points in the number of infections. We have younger people getting infected.

It is, arguably, the most important public health issue dealing with pharmaceutical. Now, we're certainly concerned about prices when it comes to treating syphilis and prematurity and so on, but they're just so many people that have this, and so many of them are untreated.

And the other challenge that we had during this journey, frankly, was, to be successful to elimination, we are going to have to find and treat tens of thousands of people.

MS. SHEINER: Mm hmm.

MS. GEE: But we couldn't do that until we had this agreement, because we didn't want to give people false hope, right? So, we didn't want to go out there and say, "Oh, get tested, get treated, gonna get your meds," and then all of a sudden it fell through. We

couldn't do that, so it's been a challenge on the public health strategy side, while we plan the drug pricing strategy.

MS. SHEINER: So, how popular is this in Louisiana? Do people know about it? Is it more popular for Medicaid population than the prisons? Is that any issue at all, or, like, what are the politics of this?

MS. GEE: I mean, these are vulnerable populations. This is a disease that impacts vulnerable populations and our journey has been to really address this. And the individuals who are incarcerated were always central to our thinking, and I think that's one thing that also distinguishes Louisiana.

Until my Governor came into office, we were the number one, the highest rate of incarcerated people in the U.S. Now we are number 2, or 3.

MS. SHEINER: Mm hmm.

MS. GEE: So, this is a really important issue for us, and I do think having Senator Cassidy, who is a hepatologist, be supportive was helpful. People understand that the long-term costs of this are tremendous, both in terms of costs to the Medicaid program, as well as costs to society. And also, people support the fact that, if we know that 95 percent of people who are incarcerated will reenter, we want them to reenter healthy and ready to work, able to work.

And so, you know, it's not -- I think it is very -- I don't have a poll --

MS. SHEINER: Yeah.

MS. GEE: But certainly, we've had a lot of support, public support, in Louisiana for it.

MS. SHEINER: You just treated your first patients, just last week, you said?

MS. GEE: Last week.

MS. SHEINER: Last week, so now looking forward -- it sounds like you've got the hard part done; you've got the price down, so you have the ability to treat, right? You have the supply side; what are the challenges that you face going forward to make this

actually successful.

MS. GEE: I have two hepatologists in my capital city, one of them is our lead clinician, Gia, and the other is Senator Cassidy. So, if you think about the current system, which is really, a resource constrained system where we have to document organ damage before treatment, because the cost is so high, it would be an impossibility to achieve our goals. But we're going to have to do this in a totally different way.

We're looking at a renaissance in Louisiana. What can be done differently? We're doing everything from working with IBM to think about, how do you create social capital, and even do microfinance around, if you get treated, and you get someone else treated, and that person treats somebody else, can we figure out an economy for that.

We're looking at, how do we work with CVS or Wal-Mart and get people treated through a pharmacist. Can I write, similar to what I did three years ago with Narcan --

MS. SHEINER: Mm hmm.

MS. GEE: A statewide doctor-guise prescription for Epclusa --

MS. SHEINER: Ah.

MS. GEE: You know, where through a modified relationship with a pharmacist, nurse practitioner, or so on, you can be prescribed a cure for Hep C. We've also been working -- and a month ago we brought in every viral hepatologist who would come, who's a national expert, to look at a modified algorithm for treatment.

Now, the algorithms are very complex because again, they are focused on resource constraint, and organ damage. This one is extremely simplified, and has been informed by the VA, by UCSF, by Hopkins and others, so we can simplify.

Last week, also, we've been doing state-wide education of every doctor in the state, looking at, can you get a discount on your malpractice if you do the Hep C; education, for continuing medical education. So, we're going to have to think outside the box, because what we have now are very few people who understand how to treat this

because the focus has been on, you have to get a biopsy, or you have to show that you have a fibrosis score, you have to demonstrate complexity to be treated. Now, the goal is to treat everybody with this virus.

MS. SHEINER: Yeah.

MS. GEE: So, it will take work, and Alex Billioux is one of the best in the country. And also, again, what's happening for us, which has been wonderful, is folks like John and Laura Arnold have stepped forward to help us. We're working with experts at Hopkins, Risha Irvin, and others who have looked at, how do you use telemedicine, and other vehicles that are non-traditional for this disease, and we're excited about that part.

MS. SHEINER: What fraction of people with Hep C know they have it, do you think?

MS. GEE: So, in our state we have about 90 thousand people who have viral positives. How many of those know they have it, I don't know. I don't know that I have that number. In Medicaid alone it's about 37,000.

MS. SHEINER: And this is the population that -- so, has the Medicaid expansion changed the way these people already interact with the health system? Or do they all have doctors, or is that going to be even just pulling them into the health system and can you think of, sort of, once you do that, other positive effects coming from that?

MS. GEE: Yeah. I mean, we've already done a great job getting people into primary care. We exceed national averages on access to care, primary care. We have a tremendous network of federally qualified health centers. Some of that was born out of Katrina and the need to rebuild medical infrastructure.

And so, we have done fairly well with access, but we're going to have to get even more creative. I think that the idea is, look under every rock, think outside the box, figure out how to engage people. But the other issue is that people have felt -- and as we've been on this journey, we have seen -- in fact, one of the women who was in the picture with me the other day, was fired from her job after that picture came out in the paper when it said

she had Hep C.

And so those are the kinds of things when you look at stigma, I mean, we're going to have to deal with stigma and certainly, if something is totally curable, there should be no stigma, but that's part of what we need to address and get to people where they are.

If we were to focus simply on getting people into the four walls of our clinics and our hospitals, we're going to fail. We have to go to where they are and these are people who are traditionally, many of them don't trust the healthcare system, haven't had good experiences. So, it's about going to -- you know, we legalized needle exchange several years ago, in this Administration; so it's about interacting with those programs, and building trust with communities, and as we do that getting rid of the stigma associated with this disease.

MS. SHEINER: Yes, it's fascinating. Okay, so we have a few minutes for some questions from the audience. We have a mic that will come around. Right behind you.

SPEAKER: Hi, thank you so much for --

MS. SHEINER: Hi, yourself thanks.

SPEAKER: Hi I'm Hari, I work with AMA. Thank you so much for talking about this model for treating Hep C. I'm actually a medical student so it's pretty cool to hear about the new models to actually give access to the cure. What I was wondering about was, how long does the subscription, I guess, contract, last with the pharmaceutical company. Is it, kind of, into perpetuity?

MS. GEE: It's a five-year agreement.

SPEAKER: Okay.

MS. GEE: And I'm glad -- as a medical student, I applaud you being here.

SPEAKER: Hi there, Lauren Canary, I'm formally with the CBC and had the chance to visit you in November, I believe, and Alex. Now with National Viral Hepatitis Roundtable -- and I'm glad you brought up stigma, because it's a huge concern for a lot of

patients; and I just wondered if other states were looking to this model, and states who have previously had restrictions around treatment, based on sobriety, liver fibrosis, what can those states be doing to message patients that they are welcome now, that there will be less stigma, and that they are ready to prioritize their treatment?

MS. GEE: We're going to try to make it cool to have Hep C (laughter). You know, I mean, not that we want you to get it, but you know, if you have it, great, let's just deal with it (laughter). I don't know, it's about talking about it, it's about people seeing people who have Hep C, and they look like all of us and that it's okay.

I think, again, you have to have unrestricted access to, I think, to have that message. I think when people have to wait until they have end organ damage, that's part of the stigma, right, because people, by the time they find out they have Hep C, and they're getting treated, they're sick. And so, it's all of it.

I've had other countries reach out to me. In fact, there was an article last week about England looking at this for antibiotics.

SPEAKER: Yeah, I saw that.

MS. GEE: And so, we expect this to -- I mean, again, it would be successful -- success, for us, is replication. We want everyone to be cured in the U.S. I think the next real opportunity here is addiction medicine. Why doesn't everyone in every state in this country get treated for their addictions so they don't leave and have a 30+ times higher rate of dying because they take the same dose of opioid when they come back into communities without any treatment.

So, I think the possibilities here are unlimited. I don't know that we have the bandwidth to do it all right now, but we do hope it spreads, and we're happy. I think we're absolutely willing to work with other states, and the best way to reduce stigma is for people to speak out --

MS. SHEINER: Mm hmm.

MS. GEE: And for us to give them a voice, and also, that it's curable. So

there is no reason for stigma.

MS. SHEINER: Yes.

SPEAKER: Hi, thank you very much, my name is Adam Elshaug. I'm a professor of Health Policy from the University of Sydney, and I'm a visiting fellow here at Brookings. So, Australia started this Modified Subscription model in March 2016 with Gilead as our partner there. Two and a half years out, we've successfully (inaudible) treatment on 1 in 3 Hep C carriers, with a 95 percent success rate. So, we're aiming to eradicate completely Hep C from Australia by 2026.

Although, there's a lower diminishing march of returns, as you've pointed out, every new patient is harder to find. Can you reflect on how you go about setting the cost, if you think about it as a cost per initiated treatment, or per patient? And just to put a teaser in there, it's been said that Australia is paying $8,000 U.S. dollars per patient.

MS. GEE: And I apologize, I didn't recognize Australia. Australia proceeded us; it's a little bit different model, but similar idea, and Australia should be applauded for pioneering this.

I can't tell you exactly what our price is per unit, but what I can say is this: our goal, which we achieved, was to spend at or about our annual spend. So that's what we did. It's already a win. It's a short, intermediate and long-term win. So, what we've locked in is about or at our spend last year, and so that allows us to reduce inflation over time, as well as, over time, reduce those long-term costs.

The challenge for us, though, is most of the time people are on Medicare when they have those costs. Although one of the steps in our journey was to go to CMMI, or even go to the Veterans' Administration and say, "listen, these folks are going to be your patients one day." If we cure them, can you give us money now (laughter). And it was just too complicated.

But the idea was not for the pharmaceuticals to lose money, I mean to maintain at or about what they are making, but for us to have the ability to cure. And our

goal -- and this is Alex's goal, so it's his responsibility if we fail (laughter), 80 percent treatment.

But I mean -- what Australia did is great, but we are hoping to do better (laughter). And so, we are going to have to do everything that you did and more (laughter). And for that, again, we're looking to innovative technologies, working with IBM; one of their five innovation centers in North America is in Louisiana -- actually, two of them are in Louisiana, and we are really looking outside the box to try to see how to reach people in different ways.

And so, it's a big challenge. It's an audacious goal. We'll be successful if we don't treat 80 percent of people --

MS. SHEINER: Yeah.

MS. GEE: But that's our goal, and why not have an audacious goal.

MS. SHEINER: Yeah. All right, well, we're going to have more time for questions after the next panel, but we're out of time for this. Thank you so much, this was delightful.

MS. GEE: Thank you so much (applause).

MS. SHEINER: And so, you can stay in your chair (laughter). I have to leave.

MR. FIEDLER: Great. Well, we've already heard from Secretary Gee and from Neeraj, so I just want to briefly introduce the two new faces on the stage before we get started on this panel. So, sitting to Secretary Gee's left, I guess, you're right if you're out in the audience, we have Rekha Ramesh who is Executive Director for Public Policy at Gilead Sciences and can give us a perspective of how Gilead approached its engagement with the state of Louisiana. And then sitting to Rekha's left we have Rena Conti who is the Associate Professor of Markets, Public Policy, and Law at the Questrom School of Business, Boston University. She works on a range of questions related to drug pricing policy, but in particular advised the state of Louisiana on implementation and student evaluation of its initiative.

So, Rekha, we just heard from Secretary Gee so I want to start with you and get your perspective on how Gilead approached its engagement with the state and what the important -- the most important considerations for the company were.

MS. RAMESH: Absolutely. Thank you everybody. I want to start by -- on behalf of the Zekla Therapeutics and Gilead, thanking the state of Louisiana for their extraordinary leadership and commitment here. And to express our excitement to partner in this exciting public health opportunity. As Secretary Gee mentioned, the first patients have received treatment in Louisiana and my colleagues on the ground, a few of which are here today have talked about how both providers and health plans have opened restrictions and treated patients. And that's a very, very exciting thing to be a part of.

So, I'll start first with the broader considerations in terms of the environment in which Hep C has evolved. And then I'll talk specifically about Louisiana. And I think Dr. Gee has mentioned some of the particulars there, and talk about where we landed. And I think, Neeraj, to your point on this modified subscription model. Gilead for a while has been very committed to meeting governments and pairs where they are, and finding new ways to partner on innovative solutions for patients. We understand with Hepatitis C that these are populations especially in medicating corrections that face disproportionate prevalence as well as access to care -- quality care issues. And so, it's very important to find that middle ground on behalf of us and the state.

We've also learned from embarking on the Hep C journey that it is a journey. And as pairs have opened access and started treating patients that there's a curve to how this happens. And in the first few years, there is a budget impact which is associated with curing. After which there is a plateau and there is a decrease in number of patients. So, that rise and fall, due to the limitations that governments face in a one-year budget cycle is very difficult to absorb. And even though prices have come down with competition as has been referenced, that budget impact -- and I use those words very specifically -- is still a very important piece of this. At the same time all this is happening, we have greater access

-- we're showing there are a number of abstracts and research studies show that elimination is possible when you open access. And the more patients you reach, and the more patients you treat, you are able to eradicate the disease.

So, moving to Louisiana. The key parameters here are we have a partner in the state that has been extremely committed to the goal of eliminating disease within medicating corrections over a five-year period. And access was previously limited in the state, so now we are embarking on this journey together. We've talked about the prevalence being high, especially in these populations. And the state was able to be at, potentially or potentially slightly incrementally increase their spending due to Medicaid expansion where the state is drawing down on an enhanced federal match that results from Medicaid expansion.

Let me move now to this novel payment arrangement. Part of the consideration here to your question was, how do we provide predictable expenditure for the state and spread the budget impact over time? And that's kind of where we started with this, and how we thought about this in responding to the SFO that you mentioned. While still providing an incentive for the state to want to continue finding patients and curing patients over a five-year period. So, that's why we partnered with an authorized generic version of Gilead's EPCLUSA.

And then it took considerable effort to get here and to implement this model. I think this is the first of its kind. It's being implemented under the current constraints of the system, so there is an expenditure cap -- an expenditure cap, and after that the state receives free drug on an annual basis. We believe in what Louisiana is doing, and this does pose a bit of risk on behalf of the company. But we were -- we've tried to mitigate that obviously, as we've had conversations.

I'll end by saying that for years we've been working directly with governments around the world, in the U.S. to find solutions that work. So, we're excited about this and we look forward to continuing to partner as different models arise.

MR. FIEDLER: Great. So, I think one of the goals for the rest of the panel is to broaden out and think about how do we use these types of tools in other settings? Before we do that, I want to sort of focus in on what's the key insight here and what's new. So, obviously -- and Neeraj, I think you touched on this in your opening remarks, that the general idea of volume based pricing, or volume based discounts, or what have you is not a new one. So, I think one question is, what's distinctive about Louisiana's -- what Louisiana is doing here relative to what's come before? I think it would also be interesting, are there commonalities between what Louisiana has done and what other states have done in the past that might not meet the eye, but are important to think about when generalizing these ideas?

MR. SOOD: So, I think the two distinctive things that Louisiana is doing, or in general in the modified subscription model or a subscription model tries to do is, one that there is a commitment to treat a certain number of people. So, the discussions between the state and the pharmaceutical firm have been that we are committed to treating a certain number of people. And that makes the pharmaceutical firm more confident that they will expect a certain amount of revenue in the future. And that helps negotiate the price down to something that is affordable.

I think the second distinctive thing is that beyond the cap there is no -- price is no longer a barrier to access. So, in a volume based discount model, there is always a positive price that you need to pay for a drug when you are treating an incremental patient. And in this model, beyond a certain limit, that price is zero. And that really creates the incentive for the state to invest in testing, and treatment, and linkage to care because they know that there will not be an additional expense for the drug beyond that.

MS. GEE: I just wanted to add one thing.

MR. SOOD: Please.

MS. GEE: I think one thing that's very unique to our model too, and part of it as we reflect is why -- Secretary Le Blanc who is the Secretary of Corrections, and I work

very closely together. And I do think this is the first example of a Secretary of Health working directly with a Secretary of Corrections on a public health issue at this level. And I think he and I have such a great relationship because we've spent so much time in a situation room or command center because in our first year of the governor's leadership, 85 percent of our parishes or counties had weather events. And so, we've worked very closely together all along and I also think that's an innovative part. And this focus on population as a whole, not just Medicaid solutions but broader public health solutions that involve corrections is fairly novel and one that I'm not familiar with in other states.

MS. RAMESH: I have an addition as well --

MR. SOOD: Yes, please.

MS. RAMESH: Which is, I think the other really important thing here to appreciate is that we do modified prescription type purchasing for other types of medical care goods. But those are largely in the preventive sense. So, those are things that are effective, and that are intended to prevent people from becoming ill. So, for example, we do a sort of modified subscription for certain types of vaccines that are scheduled. What is really the other piece that's novel here is that this is a treatment and it provides a cure. The goal of public policy here is actually to improve public health, not to minimize expenditures in this case. And here we have a state working with the Federal Government and the private parties to enter into a voluntary agreement, not a required agreement, or a mandated agreement to solve this to expand access.

MR. FIEDLER: So, we've been focused so far on the specific case of Hepatitis C in Louisiana. So, is this a set of strategies that could be useful in other settings, and what might those other settings be? In particular, what characteristics do you think other settings where these tools might be useful tend to have? Rena, do you want to start?

MS. CONTI: Yeah. Sure. So, really just to pick up on that point, which is, this is a cure and secondarily, it affects a population that is under insured. And so, just to put a finer point on this, we are living in an unprecedented time in American medicine. The

cures are coming faster than before, and in prior generations. And we are looking at new treatments that are not only going to convert deadly diseases into chronic illnesses, but are going to cure them. Not only for people who are elderly, but for now, for young people, for children, for adolescents, and also for the working age population.

The financing of cures and things that truly are effective is generally left to the Federal Government for which there is no annualized budget. The Federal Government can expand budgets in order to provide access to things that really do work for the elderly population because of the way it's financed. The state and even, I think, many employer based insurance programs, they don't have the luxury of wanting to expand out budgets in perpetuity and just have premiums rise or have the taxpayer foot the bill. Instead they really do have to balance budgets, and they really do need to figure to where that money is going to come from. Whether it's going to be through taxation or through cutting services in other ways. So, if you think about it from that lens, what we're talking about are diseases that are affecting younger people, and people who are largely insured either by the state or by employers that may provide actually, pretty skimpy coverage. And so, there happen to be a lot of treatments, or a lot of diseases out there right now that are being targeted by pharmaceutical companies that have those type of characteristics. So, for example, hemophilia, sickle cell, certain types of mental illnesses for which, really it's the state, or it's employer based insurance that is going to be the payer there, and for which they're going to have to find ways to improve people's health and provide access, both to address current illness, but also to forestall other economic implications which are not being able to work, not being able to take care of your family if you can't actually get access to these treatments that are coming.

MS. GEE: Just also, the incarcerated population. Because the incarcerated populations are covered by state general fund dollars and those tradeoffs are imminent, when those decisions are made, the public generally is not going to be favorable to making tradeoffs to K through 12 to treat everyone in jail with X or Y. And so I do think -- and

companies aren't going -- there isn't a big -- there is not a lot of loss. These pills cost, generally, dollars to make. So, to treat people in jail -- and so I think this applies to many conditions in jail, whether it's cancer or addiction, but also just to remember as you said so eloquently, that Medicaid covers certain populations and we have to think about the fact that we cover in Louisiana, 60 percent of the kids and about that number of our pregnant women. And so any disease or condition that affects -- and nationally those number hover around 50 percent, and so any disease or condition that affects those populations has higher constraints in terms of being able to mortgage or come up with more money for. And so, these types of models could be very applicable to childhood cancer cures, rheumatoid arthritis, sickle cell, and so on.

MS. CONTI: And I do think that any condition for which the option of not treating is really distasteful, either because we're really talking about young kids dying, or young kids not being able to work and be productive members of society, it's going to be very difficult to say no in the normal way in which we're doing this. We're going to have to find other ways.

MR. SOOD: So, Matt, if you kind of just think of the economics of this, you can argue that a subscription model -- so let's assume that we can do subscription models, not just in Medicaid and corrections, but also in private insurance markets. Then one can argue that the subscription model is better than leaner pricing. And it's well established because of two reasons. That with leaner pricing you have the incentives for innovation, but leaner pricing creates what economists call dead weight loss from monopoly pricing, which is the higher prices mean there is an access problem. That people who should be buying the treatment are not able to afford to buy it.

So, in that sense, this model is applicable to all drugs. But if you say let's -- how do we start to think about where to implement it first, then I would say we need three conditions. One is, we need to pick drugs where this dead weight loss is the highest, or in other words, where the access problem is the highest. And that's why Hep C was such a

great example because we solved the access problem for Hep C. The second thing is, we need to pick drugs where reducing the price of the drug will not lead to inappropriate use. So, there could be other drugs where you make the copay equal zero, and maybe it leads to overprescribing of say antipsychotics that we don't want. Or overprescribing of drugs for ADHD, and we don't want that. So, we've got to make sure that we limit it to drugs where even if the price is zero, only people who actually need -- clinically need the drug are getting it. And the third thing is, this model solves the access problem, but it only solves the affordability problem if there is competition. So, if there is no competition, the upfront payment that you will pay for a break through therapy is still going to cost you billions and billions of dollars. Right? Because you have a monopoly and there is no other competition. So, this problem -- the affordability problem is only solved when there is competition. So, I would say that is kind of the third condition. That we want drugs where there is competition. If there is no competition, this is not -- it will solve the access problem, but not the affordability problem.

MS. CONTI: So, I actually slightly disagree with Neeraj here. So, I don't think that competition is a binding criteria. I think instead, what is the binding criteria is a willingness by the pharmaceutical companies to want to engage and to really care about access here. So, one could argue that we're in a special case because it's a competitive space, but I would say instead really, what is special here is that again, there's no mandate. There's no requirement. These are -- this is a private company that has -- that deeply cares about patient access partnering with a state that has the same objective. And so, I don't -- I think that there are many innovator companies that are particularly innovating for these type of conditions for which restraining access is going to be untenable. Not just because they want to profit maximize, but because again, delivering on the promise of treatment is truly what they are doing, as much as the state needs to come up with finding ways to access and pay for it.

MS. GEE: And I agree with Rena in disagreeing with Neeraj -- sorry -- in

that there are two other conditions and that I think one -- and I see one's a primus with the threat of regulation or policy change, and for public outcry are two other tools. It's not just competition. So, let's say we had a childhood cancer cure. I'm the mother of five. Let's say it cost a bajillion dollars. The public would not -- it would not -- the public would not stand for that. There would be regulations. That's the other tool. Competition is an independent tool, but I do think there are legislators who can enforce it.

MR. SOOD: No, I agree. But the thing is, and you can see this with the Hep C example, when there was only one drug on the market, the price was very different than when there were multiple similar drugs on the market. Did suddenly pharmaceutical firms become more altruistic? And said, oh we really care about people? No. It was the competition that drove down the prices. And so, I think that's a four star principal in economics that the more competition you have, the more -- the cheaper it is, or more affordable a drug is going to be.

MS. RAMESH: I would argue, competition helps the company be generous, or be motivated. But it's not the only thing. Public pressure, private pressure from the parents of kids who are suffering, and from the kids, and from the young adults who are suffering also creates pressure in a voluntary system as both parties have to respond.

MR. FIEDLER: Okay. So, I think to summarize this discussion. Definitely can solve the access problem without competition. Disagreement on whether competition is necessary for this to be a useful model to get savings for the state. So, moving on. Suppose we all agree. We've got a drug and a state where this type of model makes sense. What are states interested in in implementing that type of model? What can they learn from Louisiana's experience? What were the most important challenges Louisiana had to overcome, that if you were talking to a policymaker in that state, Secretary, you would communicate to them?

MS. GEE: I think, partly it was important to have a laser focus on this issue and keep at it. So, if you want to change something, it's not easy. And to not get

discouraged. I think this notion of bipartisan effort, having Senator Cassidy, my governor John Bel Edwards, the only Deep South democratic governor, having -- bringing in CMS early, I think was important for us. We did not want to get 90 percent down the path and then our federal partner said, hell no we don't like this idea. So, making sure that very early on -- they're not allowed to bless things in a certain way, but they certainly were allowed to guide us and work with us. I think, working with the advocacy community there were multiple times along our journey that there were threats of lawsuits. And really bringing them along to say, we're here to help solve this problem. Let's work together. Because lawsuits are a crude tool for change. What we're looking at is true innovation and reform. And I think also bringing them along to help us with our strategy. And then I think asking -- you know what else humbles me is there was nobody that I asked for help including Rena, and Neeraj, and Josh, or Alex, who said no. I mean, I think that -- don't underestimate the resources that you might not be aware of in your state. It might not be your own state Medicaid budget. It might be a private foundation like the John and Laura Arnold Foundation, but resources will come. If you have the right idea, and it's compelling and meaningful, then resources will come.

MR. SOOD: Just one other thing that it took Rebekah two and a half years after she said, I think this is a good idea to actually implement it. And I feel like, in some sense going forward in the future, it should not take other states two and a half years to implement a good idea. So, I don't know what it takes -- how can we shorten the time window? When I talk to states, a lot of them don't want to do anything because they're just daunted by the timeline. They're like, if it's going to take two years, I'm not going to be in office. Let's move on, do something that is a quicker win. So, I think we need -- I don't know what it is, but we need something that makes it easier for other states to now actually do it. Instead of taking two and a half years, they can implement this in three months. And maybe Rekha, and Rebekah, and Rena have ideas for how to do that faster.

MS. CONTI: Well, I would also say I don't necessarily think there is a one

size fits all solution on the state side. I mean, I think what works for Louisiana may not work for another state. And so, I think assessing what states need and what the right model might be is a first step. And engaging in that conversation versus, is this the model for everyone?

MS. RAMESH: I would -- so I think one of the things that I've definitely learned is that one could come up with ideal ways of solving this problem that really are fundamentally a challenge to the way in which the current system works. So, Medicaid best price, 340B drug discounts, these are realities that are actually the architecture of creating -- of drug pricing and drug access in the United States. And so thinking about -- okay, if we're not going to blow up best price, and we're not going to fundamentally alter the 340B program, how do we actually get around or how do we actually live within those boundaries to create access opportunities? I think those structures are serious, and they're real, and needed to be overcome. I would say it was really exciting to see the policymakers, both the state but also the Federal Government think very creatively given those structures.

MS. GEE: I think one thing too is that it is very hard as a state policy leader to know what's going on in other states. And so there are all kinds of efforts whether it's the Milbank Memorial Fund. We now have a secretary's monthly call where we share, but those things are relatively new, so that sharing state to state has been very difficult. Whereas Medicare, there's a national database, there's central policy. Medicaid, often has challenges there. There are places like Oregon Health Sciences University that help collate best practice and share, but it's generally fairly hard. And so, there are definitely -- there is a greater need I think than what we currently have to spread that type of innovation, and have a policy manual for other states. And so, I know CMMI tries to do that, but it's kind of a crude tool. I think certainly that's something that could be explored.

MS. RAMESH: And I think as you embark on this journey and study the metrics, and figure out what's working, and you're able to really then advise with some data and information in terms of how it's going. And what worked and what didn't. I mean, I think that's very important in the implementation science piece of this. We're really at the

beginning. So, I think those best practices are also a lot that we can all learn from.

MS. GEE: Yeah. Definitely.

MR. FIEDLER: So, just to follow up on this discussion a little bit, I mean it's been alluded that two and half years from conception to implementation. If another state were to want to do this, do you think the timeline is still that two and a half years? Or because the pathway that Louisiana has forged here, that in fact, there is a much clearer path from point A to point B than there once was? Secretary Gee?

MS. GEE: There's states that are doing -- I mean, Washington State has followed, other states are looking. I don't think so. I mean we have a waiver. Now, there's model draft waiver language -- I mean there's, not a waiver, but there's -- CMS approved our state plan to enter into this agreement. We did not need a waiver. Sorry for that miss -- but yes, so all of that has been done. There's a lot of discussion nationwide about transparency. Now, we are not able to be transparent about the price, and so that's a challenge. But on the other hand, I think a lot of the work has been done and could be spread. It should be a lot easier. And if it takes that long, I'd wonder why.

MS. RAMESH: And again, the architecture of the two pulls of you need to do something -- you need to deal with Medicaid best price, and you need to deal with 340B, and those things stand. What's the pathway forward given that has now been exercised by this state and will likely be exercised by others?

MR. SOOD: And I think in the long run we need to remove those barriers. So, everyone understands that Medicaid best price is a barrier to these kinds of models. And we need new public policy or new regulations to say that, let's allow a waiver from the Medicaid best price for these kind of new innovative models. And maybe do it not wholesale, maybe for certain classes of drugs and so on. But I think the time is now to kind of not just work within the constraints we have but to start to dismantle some of these constraints and see if we can come up with a better way to price drugs. For example, if innovation continues to happen the way it is happening, what would happen if you have a

cure for Alzheimer's disease? Or what would happen if you have a cure for diabetes? Our current pricing model doesn't work. That if you have a cure for Alzheimer's or diabetes, you'll have the same -- in fact, a much worse problem. That I can guarantee right now that with current pricing that there is no way they'll be able to treat 80 percent of the people who need the drug for Alzheimer's or 80 percent of the people who need the drug for diabetes because their prevalence is way higher than Hep C. So, if you -- even if you do value based pricing, you're not going to get there. So, we need these new models, and the only way we can implement them on a larger scale is to start breaking down these constraints.

MS. GEE: Well, I certainly do think that Medicaid should get the best price. And so, and that once we talk about that a little bit, but I'm not sure that that's the first thing I would try to address because we found a way to get around it. I mean, 340B covered entity supplemental rebate agreement, we were able to do this without a waiver. And that could be done today by 49 other states, if they wanted to. Although I think it's complex, obviously. And so, we need to make sure that as we -- I call it the whack a mole, you don't want to whack the mole and it pops up somewhere else and creates unintended consequences. And so I don't want -- right now I don't want you to get rid of Medicaid best price because it helps me afford drugs. And so, I think that would have to go along with a whole set of drug pricing reforms that would be understanding of the continued need to incentivize innovation because again in this situation we're talking about a Hepatitis C cure, which has a very high value. And so, you don't want to say, okay that was the other consideration as we did -- as we went along this journey is that we don't want to incentivize future cures by saying, okay as soon as you come up with a cure you're going to have your profits -- so that's why I think this was such a delicate dance.

MR. SOOD: And I think what I --

MS. CONTI: I -- Sorry.

MR. SOOD: So, what I'm advocating for is not getting rid of Medicaid best price, but if there is an innovative deal then that deal is accepted from Medicaid best price

regulations. Because I agree that there is a role for Medicaid best price regulations for a lot of drugs, but if someone is trying to innovate and make a deal that is going to expand access, that deal should be out of the -- the constraint should not be that the deal could not happen because it implicates Medicaid best price.

MS. CONTI: So, maybe. I mean, I would say that again, living within the current structures, there's lots of room to do innovation. And there's also lots of room to take the current structures and just expand on them. And just kind of rethink them. And so, I think there's a lot of interest in alternative payment models. Many of them -- much of that interest is on -- is for drugs that don't really work that well. And so in that setting, we don't necessarily need to reinvent the wheel, or blow up Medicaid best price. Instead, we just have to think harder about how we're using our resources for providing access to those treatments. I think the really novel thing here is, here's a cure. And the current structures allow for innovation and access for a cure.

MR. FIEDLER: And I was probably remiss, but for those in the audience, Rena can you just give us two sentences on what Medicaid best price is. Just to bring this conversation back.

MS. CONTI: Sure. So, it's a federal regulation that essentially creates an entitlement to the states that the states will get a supplemental rebate. States are entitled to the best price for any given drug that they cover. And there's a statutory rebate attached to that which Congress sets, but then there are supplemental rebates that the states can get that the states can negotiate on top of.

MR. FIEDLER: And so it has to be the best price that the manufacturer has given to any other payer for that drug, in general.

MS. CONTI: With some exceptions. Yes.

MR. FIEDLER: With exceptions. And a key exception came into play here.

MS. CONTI: Which is 340.

MR. FIEDLER: So, we've been sort of going round and round. Debates

over drug pricing often come back to this sort of tradeoff of high prices can impede access, but they also potentially create an incentive for innovation. So, the potential advantage of subscription models is they can sidestep that tension to some degree. They expand access while preserving manufacturer revenue. Is that enough to get to where we should be on prescription drug policy? These sorts of win-win policies. Or do we need to be thinking about policies that would also affect manufacturer revenue in some way?

MR. SOOD: So, I think these kinds of policies are a good start. That they help, as you said, sidestep the tradeoff to some degree. The other thing is, three years ago, I presented at this same stage where we were talking about the pharmaceutical supply chain, which is it's not just manufacturers, but there are PBMs, wholesalers, retailers, pharmacies, who are also involved in that business. And what we showed was that out of every $100 in drug spending, about 40 goes to the middle man or people in the supply chain, and 60 reaches the pharmaceutical firm. So, I think there is a lot of room for efficiency within that supply chain, which is also monopolistic. So, there are three wholesalers that control 85 percent of the market, three PBMs that control 70 percent of the market. So, I think we need to look not just at pharmaceutical firms to get the savings, but also in other parts of the supply chain. But yeah, there are certain drugs where the price doesn't justify their value, and there you want to argue that you want to look for saving directly from the manufacturer.

MS. RAMESH: And the supply chain is broken for certain populations. When we look at -- I'm an obstetrician, and when we look at drugs developed to treat pregnant women's conditions or even our understanding of how pharmaceuticals are impacted by a pregnancy, the understanding is minimal. And the research is inadequate. Similarly for something like sickle cell disease, something that's incredibly disabling and painful, the research on that condition doesn't match the important nature or the public health toll that that disease takes. Or you can talk about contraceptives. I mean, the IUD was developed in the 70s, and arguably there hasn't been significant innovation in the area

of contraceptives commensurate with the global need for issues dealing with population.

So, I think there are huge market failures. Victoria Hale who was on the committee with us has tried to solve those -- diseases in developing countries like leishmaniosis, that just there is not a for-profit motive. There was a Zika vaccine. The Secretary of Health for a state that has inundation of water and may have mosquito borne illnesses like Zika -- this was developed by the U.S. government, was given to Santa Fe and then they decided not to produce it. So, when we have market failures like that -- when something is not going to be profitable, how does the U.S. in the interest of its people step in and affect the supply chain? I think that's a really important consideration.

Secondarily, as an OB, I'm trying to get penicillin for someone for their syphilis. It should not cost $2,000. Period, end of story. It should not. So, that is something where I think there is a market failure and we need to step in. I think it's a case -- I wouldn't say there is a broad scale solution here because you're looking at innovation, but something like penicillin should not be unaffordable, should not be out reach. And something like 17 hydroxyprogesterone, something that prevents prematurity should not be initially $1,700. Now, I don't know $900, when it really costs $9. And it's not really innovative because it's been around for decades. So, think those are things that I'm concerned of. Are things that are population health problems, public health problems, public health challenges that we're not solving because we rely on a for profit mechanism as our pipeline. And that mechanism is important and reliable for certain things. Common conditions. Things like hypertension, diabetes arguably, but for other things like sickle cell disease, contraceptives, pregnancy related conditions, arguably it's not so much.

And so, there's not a one size fits all, and we need to have real discussions about these things because there are -- I also -- just finally, drug shortages. We look at certain areas where we just run out because there is not a sustained supply, or necessarily regulation and/or enough visibility on the national supply chains for things that are very important. And so that's another market failure that needs to be addressed and has to do

with the economics of pharmaceuticals.

MR. FIEDLER: Rebekah or Rena, do you want to jump in on this one?

MS. CONTI: So, I think that what we're seeing are two things. The first is that there is a lot of people who make money off the purchasing sale of drugs that have nothing to do with being innovation -- or innovative drivers. And for those entities, reforming that system, whether it be pharmacies, hospitals, physician offices, PBMs, I think that that makes a lot of sense, and it isn't about innovation. Then there's all the drugs that are really incremental in terms of what they're providing to patients' health or to population health. And there we have a lot of incentives already that actually create -- actually pull those into being, and if anything perhaps we've overdone it in some areas like cancer. And then there are true cures or things that truly transform people's lives either in terms of their ability to be well and take care of their families, or that are real cures. And there I think our system still provides under incentives for treatment. And thinking harder about financing incentives, thinking harder about other types of ways that we can incent companies to actually want to create cures, and get the financing to do it, all the way through the system needs some more work as well.

MR. FIEDLER: Very good, Rebekah, and I think we'll get some questions from the audience.

MS. GEE: Yeah, no, I think there were a lot of great ideas thrown out. I mean the only thing I would say is, I think there is an issue around prioritization of what's really high value, what is the value it provides. Not only to patients but to public health. And again I bring it back to this particular situation. You know, Louisiana is trying to eliminate a disease, right. It's an -- it's a noble goal. And it's ambitious.

And I think when you have a tool, a technology that can do that and you come together, I think that's a very powerful thing, right. And so there are high value technologies out there, drugs, whatever it may be, and there are also things that may not produce certain types of value. Not everything can be a cure. I also want to assert that

word, right.

MS. CONTI: Absolutely. It is the ultimate goal of a lot of companies but it's -- we're not there yet. So, I would just say that.

MR. FIEDLER: Great. Great. All right. We've got a few minutes left for questions from the audience. So, we have some microphones coming around. And gentleman here.

MR. SPITZ: Yes, hi, Dr. Gee, congratulations on your --

MR. FIEDLER: Please introduce yourself --

-- Successful --

MR. FIEDLER: Can you introduce yourself before you --

MR. SPITZ: Oh my name is Steven Spitz. Congratulations on your successful negotiation on the part of the State of Louisiana with the pharmaceutical company. There was another person from the State of Louisiana named Billy Tauzin, who put in a little sentence Medicare Part D that Medicare, the largest purchaser of prescription drugs in the country, cannot negotiate drug prices with the drug companies. And I'd the panelists to address that issue.

MR. FIEDLER: So, Medicare can negotiate drug prices.

MS. GEE: Yeah.

MR. FIEDLER: Can you address that?

MS. GEE: Yeah it's difficult. I mean Mr. Tauzin, the only American in history to be the whip for both the Democrats and the Republicans, had a major role in creating the pharmaceutical lobby. That regulation makes it very difficult because the bottom line is we file -- Medicaid follows Medicare policy. Once Medicare signs a rebate agreement, we must cover it. It doesn't matter what the price is.

Now, we have tools like pharmaceutical PBMs, who can then negotiate placement on formularies or tier certain things. But we cannot say no. And in any negotiation the ability to say now is very important. If you talk to somebody like Peter

Sands, whose been very active in Britain, who has NICE, National Institute for Clinical Effectiveness, he has said to me that it only takes one in 30 or 50 times to say no, and you don't say no to everything, but just the ability to say no has -- he thinks has dropped their prices by oh 25 percent, let's say.

So, I do think it's important to be able to say no to low value things, to things that have marginal benefit, things that don't offer a better health or cures, or don't make meaningful public health impact. And we currently do not have that ability.

MR. SOOD: So, there's actually I think a couple of years ago both me and Rena wrote a point counterpoint on this for a journal called Journal of Policy Analysis and Management. That I was arguing that we should not allow Medicare to negotiate drug prices, and Rena was arguing for negotiation.

So, the reason why I don't want Medicare to negotiate drug prices, or why I argued for that cases, because we already do. So, it's not that we are not negotiating drug prices. PBMs do negotiate drug prices on behalf of health plans. These are the Part D plans that provide prescription drug insurance.

And the second thing is going to Rebekah's point, which is the way to negotiate is to say no. That's what gets you lower prices. So, the question is, who has a better ability to say no? Someone who -- like suppose you say no to a drug company that's based in Ohio. What's going to happen? What if the one patient who could benefit from that drug doesn't get the benefit from the drug?

So, it's not easy to say that the government can negotiate drug prices and the government will do a better job negotiating rather than a PPM. And that's the reason because the government might have a tough time saying no. Because of different political considerations and pressures.

You could argue that the government can lower prices by just setting them. But then it comes to this tradeoff between innovation and access. And I think there are better ways of kind of preserving that tradeoff and still getting access.

MR. FIEDLER: All right, I think --

MS. GEE: So, do you --

MR. FIEDLER: Sorry.

MR. SOOD: You were trying to --

MR. GEE: Neeraj and I have been arguing forever on that. No. I mean I think bottom line is that for the drugs for which there is very limited or no competition and there will be no competition in the future because they are very small market drugs, the government doesn't actually have any ability to say no, and we risk bankrupting ourselves or just start tradeoffs that really do actually impede people's access to important things.

And so having a stick, and really an additional stick, we have some sticks already to actually get prices into a reasonable range. Particularly not for drugs that are covered under Part D or are oral drugs. But really the drugs that are injectable or infusible into patients, we have no meaningful ability to say no now. And we have no meaningful ability to get those prices down. Those prices are now in the order of $1 million for a launch pricing of these new drugs. And we're going to keep on going.

MR. FIEDLER: All right.

MS. GEE: So, we need some tool to help.

MR. FIEDLER: All right. So, I think we'll have to let that be the last one, but there's no doubt that there's a lot more to talk about with drug pricing and there will be many more discussions in years to come. I want to hand the floor over now to David Wessel, for a conversation with these and related issues with Wendell Primus, the Senior Political Office. Thank you very much to the panelists.

MR. WESSEL: Thank you very much. That was a fascinating discussion and I'm really glad to have Wendell Primus here. I definitely enjoyed the fact that when Rebekah Gee used the word regulation she looked right at you. I don't know what that was all about.

Wendell Primus was actually born in El Dora, Iowa, which I looked up today.

As of the 2010 Census it had a population of 2,732. So, I don't want anybody to think that despite his long career in Washington, that Wendell is actually an insider the beltway guy. However, he did go first work for Congress in 1975, so I don't know if any of that Iowa stuff has worn off yet.

Wendell's had many jobs on the Hill. Chief Economist of Ways and Means. He did a stint at the Department of Health and Human Services in the Clinton Administration, and actually left in protest when President Clinton signed the Welfare Reform Bill. He spent some time at the Center on Budget and Policy Priorities.

But most recently, and relevant to this discussion, he's the Chief Health Advisor to Speaker Nancy Pelosi. He was there during the ACA when the ACA was passed, making common cause with Rob Emanuel, or sometimes arguing with Rob Emanuel. Which doesn't distinguish you from many other people in Washington. But he's particularly involved in this big question of what do we do about prescription drug crisis which seems to be one that there is bipartisan agreement that there's a problem.

So, Wendell, I think what would be useful for us if we could start talking a little bit about the Louisiana thing and then we can broaden it up. So, has Louisiana shown us the way for something that (a) other states can do, or (b) as the National Academy suggested, the Federal Government should do for all states?

MR. PRIMUS: I think what Rebekah Gee and other -- and her team has done is truly exciting. And there's much to commend it, trying to get Hep C and that infectious disease under control. But it's one state; it's one drug company; and it took a lot of time a very talented people to get to where they're at.

I think that same result could be achieved much more efficiently and effectively if the Secretary had that authority --

MR. WESSEL: Secretary of Health as Human Services?

MR. PRIMUA: Yes, the Secretary here in Washington, DC, because I think Rena was right, we're going to see a whole avalanche of new drugs on the market that are

going to challenge state budgets. Sickle cell maybe being one of them. Where you have many people on the Medicaid program with that particular disease, the cure or the treat -- making it a chronic condition is going to be very expensive. That's a horrible disease.

And so I think there may be some tradeoff here, where the drug company gets the assurance that every person on the Medicaid program that is in clinical need of the drug gets access to that drug. And then in return there is a much deeper price discount than we get today. And then the implications for the budgets in Louisiana and Mississippi and elsewhere, might be for those, again, a few drugs with again very high spending. You could think maybe a higher FMap or something like that.

So, I think --

MR. WESSEL: The FMap is the Federal share of Medicaid?

MR. PRIMUS: Yeah. So, that the Federal Government, again on these very expensive drugs, where we then guaranteed that everybody on the Medicaid program gets it. And that did not happen. That did not happen with Sovaldi. Even though I could argue that is what the Medicaid laws says today.

States put up barriers, because sometimes the budget constraints to that in the states varied a lot in how much access the recipient population really had to Sovaldi. And I think we're going to see several more drugs like that come down the pike in the very near future.

MR. WESSEL: So, does the Secretary of Health and Human Services currently have the authority to do what you just suggested?

MR. PRIMUS: No, that's -- that is the problem. You know, I think President Trump and his team really do want to lower drug prices. But they don't have the authority. I mean it came up in the question just now, there is this prohibition in, at least Medicare, from negotiating. And even the authorities that the Secretary is using to do the “Part B” International Price Index thing is authority that was granted to him by the ACA, which they're trying to take away, ironically, in the Texas case that was just recently heard in Louisiana or

New Orleans.

MR. WESSEL: I don't think there's any irony left in this one, I'm sorry Wendell. So, at the beginning of the year you were publicly expressed optimism that the Congress could reach some agreement with the Trump White House to do something on prescription drugs. Not everybody in the Democratic caucus appreciated that sentiment. So, it's been several months. Do you think there's a chance of the House of Representatives passing a bill that President Trump would agree to?

MR. PRIMUS: Yes, I'm still very optimistic that that can happen. We've been working on this problem as a team, the community -- committee staff and I, and several outside experts. So, we were almost ready to roll something out and then we thought it better that, given the August recess, and I remember August 2009. And I think pharma, if we don't arm our new members, particularly with the arguments that pharma is going to advance, that it was much better that we wait until September. We could also --

MR. WESSEL: Remind people what happened in August 2009.

MR. PRIMUS: August 2009 there was a rebellion against the ACA that had just been reported out of all three committees on the House. Now, I'm not saying that would happen again exactly like that. But there is no doubt in my mind that pharma will argue very hard against drug negotiation of the kind we're talking about.

And I think by early September, it takes time to write the legislation well, it takes time for the Office of the Actuary and the Congressional Budget Office to score it. And I think we're better -- much better off that when this proposal is rolled out, that we have a very good defense of it That it's very clear to the public, and that we have outside validators and the people who do the scoring of this legislation that they will have been given time to actually create the official scores.

MR. WESSEL: And can you give us just the general principles or outlines of what you've been thinking about?

MR. PRIMUS: Yes, there is some information that's already been in the

public sector. And I think it's not just removing the noninterference clause; it's making sure that the Secretary is given clear authority and a clear mandate to do negotiation. I think the next thing is, that's very important, is that Secretary be given clear instructions.

I think for drugs that have been on the market for a long period of time that are without competition, one should be able to push the price down where, again, all the research and development costs have been recovered many times over. That you should be able to push the price down much closer, probably not all the way, but to the marginal cost.

And the marginal, I mean, the drug industry is very interesting here. The marginal cost of producing the drug is probably like one, two, three percent of the list price. The first drug, the first pill if you will, make cost literally $2 billion, $2.8 billion. So, you've got to recover that R&D. So, I think the clear instructions are, make sure that the drug companies get rewarded for innovation, for cures, but that for drugs where you've already recovered all the R&D, that that price should be pushed well below international prices.

And the drug companies can still make money, if their marginal cost is let's say, if you give them 30 percent of the list price, they still will make substantial monies on every drug that's -- So, we want a clear mandate to create innovation and cures, but where they already recovered it, we want to have substantial price reductions.

And then I think the other thing that's critical here is you've got to give the tools to the Secretary to do that. And buy a tool, I don't think the American public will tolerate saying no. That if you don't sell the drug -- if the drug company doesn't accept the price, there's no sale. I don't think that's going to fly here. By a tool I think you can talk about, what I'll call a noncompliance fee, you can call it a tax, or some kind related to sales. So, that's the tool.

And then I think the other thing you've got to be very concerned about, is stopping gaming. And by that I mean the price that's developed out of this process. I fear that if you don't think about the gaming that pharma might engage with, so let's say you

lower the price for the public beneficiaries, Medicare and Medicaid, I think they would raise prices on commercial.

So, I think one important aspect of this is to make sure that whatever the price is that comes out of this process applies to all payers. I think the Federal Government has the authority and the constitutional ability to do that. I think another thing is making sure that other drugs in a company's portfolio doesn't go up to compensate so you could handle that may be by inflation, rebates, et cetera

So, I think those things are all part of the process here. So, you have a clear mandate, clear instructions, the tools, and the ability to stop gaming.

MR. WESSEL: So, you'll give the Secretary the authority to negotiate, effectively, prices on drugs, I want to get to which drugs in a minute, for Medicare and Medicaid, both. And then you will have provisions to make sure that the drug companies don't recoup the -- don't raise prices on those drugs to private insurers, or on other drugs. So, there --

MR. PRIMUS: That's right.

MR. WESSEL: -- will be quite a bit of oversight and regulation there. That is correct. And is this going to apply to -- you refer to drugs that have been on the market for a long time that don't have any competition? Is that the whole university going to cover?

MR. PRIMUS: Yeah I think, again, it's not going to be drugs, orphan drugs, for example. It's going to be our -- not necessarily our most expensive but where our aggregate expenditures are the highest. And just to give you an example, 25 drugs in the Part D program are 23 percent of net Part D spending, 250 drugs in the Parts B and D out of about 8,000 or 9,000 drugs comprise 56 percent of Parts B and D drug spending.

So, again, there's the very small drugs without competition that are really burdening government expenditures significantly. And I think if you can lower those prices, without hurting innovation, the country will be ahead, along with the requirement that those who are in clinical need of that drug actually get the drug.

MR. WESSEL: And how do you make sure that happens?

MR. PRIMUS: Well, I explained a little bit on the Medicaid side.

MR. WESSEL: Right.

MR. PRIMUS: I mean on -- and then I think what we also want to engage in is, my expectation is, that this will save the government substantial sums of money. And then the members can decide that they could take those savings, lower the out of pocket, there is right now no out of pocket limit in Part D, for example. And so we could lower -- we could establish an out of pocket limit in Part D, lower cost sharing if you will, and bring that down enormously, so that our public beneficiaries would benefit twice, if you will. They get lower prices, plus, they get a much better Part D program.

MR. WESSEL: Okay so let's talk a little bit about the policy because -- so first, is the left wing of the Democratic Party in the house comfortable with this?

MR. PRIMUS: Yes and no. I've talked to many of our progressives in the caucus. I think again when the details of this are known, when they see the scores, I'm very comfortable that they will accept it. I worry just as much about the moderates and the messages that we'll hear from pharma that says, oh you're hurting innovation, you're going to stop cures, and all of that. So --

MR. WESSEL: What's your answer to that one, the innovation thing?

MR. PRIMUS: Well, I think there we want, again, those clear instructions for the Secretary to make sure that innovation is rewarded. That they can recover their research and development cost, et cetera And we may also, I mean again, these are decisions the members will make, we could put some money into NCATS, which is the --

MR. WESSEL: What's NCATS?

MR. PRIMUS: -- Institute at the National Institutes of Health that worries about investments in orphan drugs. I mean, there clearly are market failures here, not only in pricing, et cetera, but there's also some drugs for which the number of people in America with that disease, or even worldwide with that disease, causes a drug companies not to do

the right amount of investment in that particular disease, just because the end is not big enough.

MR. WESSEL: And what about the Senate?

MR. PRIMUS: Well, I've had some experience with that.

MR. WESSEL: Some of it favorable, actually.

MR. PRIMUS: I mean they're -- in 2015, I think the conventional wisdom in this town was we were not going to do an FDR fix. In fact, I think if you look -- asked any lobbyist --

MR. WESSEL: Said doctor --

MR. PRIMUS: That was a doctor fix yes.

MR. WESSEL: Doctor fees for Medicare.

MR. PRIMUS: Right. And then Speaker Boehner and the Democratic Leader, Nancy Pelosi, got together and said, we're going to do a deal. And I had the privilege of negotiating that with one of Boehner's key health persons. And it passed the House overwhelmingly 397 to something. And as a result of that mandate, when you get something out of the House with a very high vote, the Senate is somewhat forced to.

And I think, again, this all depends on a lot of things that will happen. But again, I think if the Democrats unveil this, and the Administration says they like it, you could see this passing the House overwhelmingly. And then who knows what happens in the Senate?

MR. WESSEL: Have you been talking to the Senate? Do they know what you're doing?

MR. PRIMUS: People have some idea.

MR. WESSEL: Okay. And what about, are you comfortable with the plan? Are you -- well comfortable is not the right word? Do you expect the Administration to support the plan that you have outlined here?

MR. PRIMUS: I know the press says that I've been negotiating with the

Administration. That is absolutely not true. You know, we have kept the Administration somewhat informed about what we're doing, et cetera. And my hope is, because I do truly believe that the staff of the Trump Administration do want to cut prices. And the problem is, as I've told them many times, they do not have the authority. And without the authority and the tools, they cannot get there.

And so I think it requires the Congress to act. And hopefully the Democrats can coalesce around this when it's rolled out in September, both our left and our moderates. And that the Administration will see the wisdom of that and come on board and support it. And we'll see what happens.

MR. WESSEL: Do you think this will get through Congress this calendar year?

MR. PRIMUS: I think if we really want to get it done, it behooves us to get it done before the election year.

MR. WESSEL: Right.

MR. PRIMUS: And again, I think there is -- there can be some clear benefits from lowering drug prices and reinvesting them and making the Part D program substantially better off.

MR. WESSEL: Wendell, what do you say to the Democrats who basically don't want to ever give President Trump a win on anything? Because they think it will handicap them and 2020 race? What's your response to that, which I'm sure you've heard at least once?

MR. PRIMUS: Well, one is that's above my pay grade. And the Speaker is very clear. The Democrats ran on this in 2018. She is very clear that this is a table issue.

MR. WESSEL: It's a table issue.

MR. PRIMUS: Kitchen table that's -- thank you, kitchen table issue. She wants lower drug prices for the American public. And I've been educated under Tom Foley and Dan Rostenkowski, and now Nancy Pelosi. I think, if you see the opportunity for getting

legislation done, you take advantage of that opportunity without compromising your principles. And we'll see if that opportunity exists. But I have no doubt that the person that I work for really wants to lower drug prices for the American Fed bill.

MR. WESSEL: And I, yeah interesting. Let me ask you about two other issues quickly before we go to the audience. So, as you mentioned, the Fifth Circuit is hearing this ACA case in which the question is having lowered the penalty for not having insurance to zero, does that mean that it's no longer a tax? And does that mean, it's unconstitutional? And does that mean, the whole ACA is going to be thrown out by the courts? So, what's the state -- what do you think is the state of play there? And what happens if the court rules against the ACA in that case?

MR. PRIMUS: Well, I think one it would be very unfortunate, and it would disrupt the lives of millions of Americans of those with pre-existing conditions would have a lot to fear. You know, the Medicaid expansions would be ruled unconstitutional. The age 26. I mean there are so many things that would happen as a result of taking the penalty, which still does exist, but it goes down to zero, that this is just a very weak, extremely weak case.

And conservative people have written Amicus briefs in this case saying they do not understand this. So, I think it will get obviously, if the Fifth Circuit rules the wrong way, it will get appealed to the Supreme Court. I have confidence in the Chief Justice, he's ruled on this before, but we'll see. I mean, it would cause a lot of undue anguish.

And the thing that when the Republicans took that penalty to zero, they made lots of statements on the Senate floor and elsewhere, saying we only take it to zero, we do not intend in any way, shape or form, that this should hurt people with pre-existing conditions.

So, just it's hard for me to believe that something that has been the law of the land since March of 2010, would now be ruled unconstitutional, because the Congress took a penalty to zero when they did not intend that anything else in that law should change.

It's just very hard for me to believe that an activist, conservative court would make -- would do that to the American people.

MR. WESSEL: And finally, you're in the midst of, not you, well maybe you, I don't know, the Speaker's in the midst of negotiations with the White House about a deal on the caps on annually appropriated spending and the debt ceiling. The press is that we're kind of getting closer, but we're not quite there yet. How close are we?

MR. PRIMUS: I was hoping I could even talk about it here. But we are not quite there. Yes, I think we're very close. The numbers had been agreed to. There's still one or two things holding it up. But I still have a lot of confidence we're going to get there by the end of the week.

MR. WESSEL: The end of the week?

MR. PRIMUS: I mean past -- I mean --

MR. WESSEL: Passed the House?

MR. PRIMUS: Passed the House by the end of the week, because they're going home for the August -- the House is going home for the August recess, the Senate is still around for another week.

MR. WESSEL: And two weeks, I mean two years deal pending?

MR. PRIMUS: Yes. Yes and a two-year, two and a half year deal on the debt limit and the sequesters are gone, if everything works out appropriately.

MR. WESSEL: Great. All right. We have time for questions. And here's what I propose. I'm going to take maybe three questions and then Wendell can pick and choose which ones he answers. Why don't we start with the gentleman here? And then we'll go to the woman over here. If you would tell us please, who you are and what your affiliation is?

MR. ROSE: Herb Rose, retired. A quickie question. Part of your approach is to make sure that innovation is rewarded by covering research and development of these drugs. How willing do you think big pharma is too revealing the costs that they -- that is

spent on research and development?

MR. WESSEL: Thank you. Over here. Why don't you give the mic in the back to the woman back there? Yeah, go ahead.

MS. TORRES: Hi there. My name is Rachel Torres. I'm a reporter with Inside Health Policy. And my understanding of kind of your structure is that there's some sort of backstop with arbitration to these negotiations. My question is what entity would kind of oversee that or play the arbiter role?

MR. WESSEL: Thank you. And in the back.

MS. CANARY: Lauren Canary, National Viral Hepatitis Roundtable. I wonder if you could comment on whether or not you think that HHS or CMS should be doing more to penalize those state Medicaid programs that are continuing to place restrictions on treatment, to perhaps encourage them to follow Dr. Lee's position to eliminate Hepatitis C.

MR. WESSEL: Okay, so three questions Wendell. One, will the drug companies tell us what they spend on R&D, so we know whether they're getting rewarded? Two, is there a backstop arbitration, and if so who's the arbitrator? And third, should HHS or CMS do something to crack down on states that put limits on treatment, as was discussed? So, --

MR. PRIMUS: So, I think we're still working on a little bit of -- I think they're going to reluctantly give us information. I think that goes back giving the tool in terms of the non, what I'll call the noncompliance fee. And I think we want to give absolute assurances that when certain very confidential information is revealed that it remains confidential. But I do think government has a right to know how much R&D has been spent, et cetera So, I think, again, this tool that I'm talking about, which you'll see unveiled, will, and they're going to do it very reluctantly, I have no doubt. But I think it's got to be part of the process of negotiation.

In terms of the dispute resolution, I think it can be another government agency. You could think of the FDC, you could think of the Veterans department that

negotiates, et cetera. And I don't think very many cases would actually go to arbitration. I mean the idea would be to reach an agreement between the Secretary and the drug manufacturer.

And on that last case, I don't think I have enough information to give you a good answer. So, we can maybe talk afterwards.

MR. WESSEL: So, the idea is that if the drug company is -- refuses to come -- you can't come to terms, that the government has a stick. I thought after the ACA you would call it a noncompliance tax, but okay, a noncompliance fee, there's probably some reason you're calling it a fee. That that would the stick, that either you do this, or --

MR. PRIMUS: Yeah.

MR. WESSEL: -- we're going to take some money.

MR. PRIMUS: And it's going to be sufficiently high so that the drug company, again, it's a noncompliance, we want the drug company to comply, we want the drug company to negotiate, et cetera. So --

MR. WESSEL: Okay. Time for a couple more. There's a woman over here Owen.

MS. BRAND: So, you mentioned --

MR. WESSEL: Tell us who you are.

MS. BRAND: Hi, my name is Shawna Brand, from Stein Mitchell LLP. You mentioned older drugs and I'm taking that to mean maybe generics. And what I've seen is that when it comes to generics, the problem isn't necessarily pricing alone, but rather that generic companies exit the market when they see the price drop. So, how does -- is there a mechanism to stop that from happening, given that we understand that the prices continue to increase, or we see supply problems?

MR. WESSEL: Thanks. Is there another one? Okay you want to take that one Wendell?

MR. PRIMUS: Yeah, so the older drugs I'm talking about here still drugs

without competition? I mean, Humira, as I understand it, has been on the market for quite a while. It has 120 patents, plus. They still don't have competition, although some of that may be right. So, we're not talking about drugs that have generics or biosimilars. We're talking here about single source, branded named drugs that have no generics.

And that is where we're spending all the money. I mean, and again, the statistic I gave you where 56 percent of spending in Part B, and D are in just 250 drugs. So, I mean, you want to go negotiate where the money is. I mean, Willie Sutton robs banks because that's where the money is. So, that's, I think, the class of drugs that, where we, again, and it's the older drugs, where I think we can get the biggest discount.

I don't think necessarily for a new drug, a new launch, again, I'm not saying the launch prices are appropriate. But you do want the drugs to -- the manufacturers to recover their R&D, et cetera. But it's those older drugs where we should be able to drive the price, the older single source drugs, where we should be able to drive the price down a long ways, because they've already recovered their R&D on those kind of drugs.

MR. WESSEL: But there will be -- they're going to make less money, there's going to be less incentive. There's no doubt about that. You're saying that the government will essentially say you can recover your costs. We're going to continue new drugs; we're not going to -- so we still have some really expensive new drugs coming on the market. And they won't be covered by this?

MR. PRIMUS: Yeah, that will be pharma's argument. And again, I think they have an advantage relative to other technologies. One is they are sometimes building on the research -- the public research that has gone on NIH, et cetera, relative to let's say driverless cars, insurance reimburses 80, 90 percent of the cost of the drug. So, they are charging these high prices, because they can.

MR. WESSEL. Right.

MR. PRIMUS: And, again, I think both Republicans and Democrats are saying those prices are too high. You can look at some drugs that was in a publication out

of the morning consult I got this morning, where they've --- some drugs they spent $90 billion, the sales. And you know they've made tons of money.

And it's those drugs where we ought to be able to drive the prices down sufficiently. And I think, again, I'm all for competition, I'm trained as an economist. But when the drug companies have taken advantage of their patent exclusivity, and that's what needs to be corrected here.

MR. WESSEL: Okay. Well, I want to thank Wendell and thank the whole panel. And thank Rebekah Gee for doing something that allowed us to make history today, link the words Louisiana and innovation. I hope you will continue to innovate so we can do this again with something else.

And I want to particularly thank Wendell for coming down here and doing this. Wendell's one of the people on the Hill who, let's just say that if we computed his wages at an hourly rate, Bernie Sanders would be upset that you're not making at least $15 an hour. So, I don't think there's often enough credit given to the people like Wendell, on both sides of the aisle, who spend a lot of time working behind the scenes to make things better.

So, I particularly want to thank him, but also, the USC Brookings Schaeffer Center and my colleagues. So, please join me in thanking everybody. (Applause)

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