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REINING IN PRESCRIPTION DRUG PRICES

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## P R O C E E D I N G S

MS. SHEINER: Good morning everyone. I'm Louise Sheiner, policy director of the Hutchins Center on Fiscal and Monetary Policy. I'd like to thank you all for taking the time to come out to Brookings this morning to join us in this conversation about reigning in prescription drug prices. We're really excited about today's event and I hope you will find it informative and thought provoking as well.

One thing I have learned during our work putting together today's event is that issues involving prescription drug pricing are really complicated. Who knew, right? So, before we jump into the proposals about ways that we might reform drug pricing, I just wanted to give you a little background on the issue that we'll be talking about this morning. I also want to point you to our website. We have what we call, *The Hutchins Center Explains*, an explainer on prescription drug pricing that will go over some of the same issues that I'm talking about this morning.

So, drug spending in the United States. Retail drug spending, which is drug spending at pharmacies, was \$325 billion in 2015. That's about \$1000 per person and about 10 percent of total health spending. On top of this drug spending that we do at pharmacies, there was an additional roughly \$125 billion spent on pharmaceuticals that are administered in physicians' offices and hospitals. So, about \$450 billion altogether.

Now prescription drugs were not always such an important component of health spending. So, if you go back to 1980, for example, drug spending was only about 5 percent of total health spending and that has climbed over time and now it is about 10 percent and projections are for it to continue to climb, although slowly, over the next decade.

One of the things that happened as drug spending became a more important component of health spending and as health spending became more and more expensive, so the drug spending becoming more and more expensive, insurance markets changed. It used to be a lot of people did not have prescription coverage for drugs. But as drugs became something that actually presented a big financial risk to people, insurance began increasingly to cover it. For Medicare, up until 2006, Medicare didn't cover prescription drugs and in 2006 Part D was introduced.

So, if you look at what share of drug spending is out of pocket, when you go to pick up

your prescription, the amount you have to pay your co-pays, your co-insurance, you still have a deductible, what share of spending is paid for at the time that you pick up that prescription. In 1980, it was about 70 percent and it has fallen dramatically over time so that now the out of pocket share is something close to 15 percent. What does that mean? Well, it means people have more protection for drugs so that's good from the perspective of risk, but it also means that consumers are increasingly insensitive to the price of drugs when they decide whether or not to fill their order or when they talk to their physician about what drug to try. That will come up later today as something that sort of effects policies related to drug spending.

Like everything else in healthcare, we spend a lot more in the United States per person on drugs than other countries do. So, as I said, we spend around \$1000 per person in the United States. In Japan, Canada and Germany they are more like less than \$800 per person and if you go far to the right to Denmark, they're only spending \$325 per person. A lot of that is because we have high prices for drugs. Not all of it but a lot of it.

What are the basic economics of drug development. So, I think the biggest thing to remember is that there are large fixed costs to invent and test new drugs. So, you've got to invent the drug and that's a lot of R and D and then you have to pay for very extensive and very expensive testing to make sure that the drug works and that it's safe to get it through the FDA approval process and that's very expensive. When you start the process, you really have no idea if you're going to get much of a return on your investment. A lot of drugs fail before they get to all the stages. They fail all along the way. So, there's a huge uncertainty but the likely returns to R and D.

Now once the drug has reached the approval stage and you're ready to market it, in general, not for all drugs but in general, the marginal cost to produce the drug, what it actually costs you to put out another pill are low. So, what does that mean. It means it is an industry where most of the costs are fixed costs that have to be taken years before and without regulation, no one would want to invest in pharmaceutical R and D. Because if you invested and you had this new great drug and there was no protection, somebody else could just come in and undercut you, you'd get into a price war where you'd be pricing at marginal cost, you'd never recoup your investment.

So, the regulations that give drug companies market power are kind of interesting. So,

like all intellectual property, you can get a patent on an invention of a drug and patents last 20 years from the date of filing and that time is not even related to drugs, it is just very general. At the same time, a parallel path, the FDA provides something called exclusive marketing rights that also give you the exclusive right to market a particular drug and they give that for a certain length of period and that starts once they've approved a drug. Now, that length of exclusive marketing rights does depend on the type of drug and drugs in small markets, so called orphan drugs which you probably will hear more about today, are given longer rights so as to encourage innovation. Now after both your patent and your exclusive marketing rights expire, and it could be either one being the longest one, then generics can enter the market and then we have a more competitive environment. On average, brand name drugs have about 13 years of sales before a generic competitor enters the market.

There are a lot of tradeoffs when you're thinking about drug pricing policy. The tradeoffs between the incentives that you want for innovation between access issues which is you don't want really high prices that will make it hard for people to get the drugs and there is also an issue of fairness which is a little bit different and I'll explain. So, as I said, we need higher than normal profits and we need prices greater than marginal cost if we're going to encourage innovation. Pharmaceutical companies have to be able to recoup their investment. But high prices limit access to drugs, that's the tradeoff. They increase out of pocket costs and they also increase insurance premiums. And there's another wrinkle which, as I showed you before, high prices also make generous insurance necessary, but insurance also leads to too little price sensitivity on the part of consumers.

And then there is the issue of fairness which is different than the issues of access or innovation which are kind of efficiency considerations. Which is the monopoly power might allow drug companies to reap too much of the benefits of new drugs. So, take an example. Imagine there is a drug that costs \$500 to produce per drug. Once I can include all the costs I've talking about, sort of getting back your cost of innovation and a reasonable return on the projects that didn't work, \$500 is kind of a social value of producing the cost. But consumers value that drug at \$5000 dollars. That is a great innovation right, it costs \$500, it's worth \$5000 to consumers. Let's say that drug is priced at \$4900. If you looked at that drug, you'd say oh, it's \$4900 but it's \$5000 worth of benefit, it is still worth it, it is still something that consumers should buy, it's still a good deal for them but kind of just barely. So, they get

\$5000 of benefit, they're happy about that, but the drug is going to seem really, really expensive.

Meanwhile, most of that benefit, the difference between \$4900, the price they're charging, and \$500 the cost, goes to the drug manufacturer.

So, the question is whether or not there are tradeoffs here where we might even give up a little bit on the incentives for innovation in order get what some might feel is a fairer distribution of the social benefits from innovation.

What can be done. So, let me step back and tell you why we have this conference. Why did we think about asking people to write proposals. So, you all know that there have been a lot of stories in the press about branding drugs that are very valuable coming on, people value them but the prices are kind of shockingly high as well as the stories that seem really hard to explain about people like Martin Shkreli, buying up old drugs. They didn't do any of these innovations, they didn't bear any of those costs, and figure a way to use the system essentially, to jack up the prices like 600 percent or more. So, I think there's a lot of desire on the part of consumers and government to take steps to reign in drug prices. We thought, well if people are talking about doing something, this is a good time to ask the experts what can be done. In particular, what can we do that might reign in prices without unduly harming innovation.

So, we went and we said, okay let's just find really great authors to come up with their proposals of what they think is interesting and a good idea and they'd like to write about. Nobody came to us and said, the drug industry needs to be completely regulated, we need to set all prices, no one proposed things like that. All three of this morning proposals recognized the need for drug companies to retain significant market power and recognize the large benefits that as a society, we get from drug prices. They recognize the tradeoffs. But their proposals are sort of suggesting changes in areas where drug company market power might seem larger than a socially optimal that can be justified.

The authors are going to present their papers to you this morning, but frankly, they don't have that much time. So, they will give you, I'm sure, a very good summary of their papers but I really encourage you all to read the papers because they're wonderful and they're well written, we're really happy with them and they are available on our website, [brookings.edu/hutchinscenter](http://brookings.edu/hutchinscenter) and you can find the papers and I really encourage you to do so.

With that background, I know we're already to hear about the actual proposals and before

I turn it over to Paul Ginsburg who is director of the Center for Health Policy here at Brookings and our collaborator in this event. Let me just quickly go over this morning's agenda. So, as I said, each of our authors will present the proposal and there will be some limited time for question and answers. I will then come back and spend some time talking about the proposals and the broader issues that they present with a panel of experts who brings a lot of insights from the field, practical insights into these questions. And then finally, David Wessel, the director of the Hutchins Center, will talk about the politics of drug price reform with former congressman, Henry Waxman, who played such an important part in encouraging innovation in prescription drug pricing.

I'm really looking forward to this morning's program and I hope you are too. Again, thank you for coming and I'm going to give it to Paul.

MR. GINSBURG: I'm really pleased to introduce Richard Frank who is the Margaret T. Morris professor of health economics in the Department of Health Policy at Harvard Medical School. He's going to present the first paper. There is going to be a framework for negotiation of prices in Medicare Part D. And Richard Zeckhauser, his co-author, will be participating in the discussion.

MR. FRANK: Thank you. I'm delighted to be here and I'm going to take a few minutes and sketch out the ideas that Richard Zeckhauser and I have developed. What I'm going to do is first, I'm going to spend a couple of minutes just outlining the problems related to pricing and spending in Part D. Then I'm going to focus very specifically, on an area where we think there are particular distortions and inefficiencies which is what we call, market power under nearly complete insurance and we've given that situation the acronym, MISK, Monopoly Insurance Subsidized Consumption. That means market power where insurance is complete means focusing on the reinsurance section of Part D. After explaining why, we focused on that area, I'll outline specifically how we proposed that negotiation to take place and the framework within which that happens and then I'll make some concluding observations.

So, this is a graph of price indexes in Part D. And really the thing to note, is that top line is unique branded drugs. And what that shows you is that it is really those drugs that are pulling up the whole price index. So, it's that set of unique branded products that don't have a lot of competition that have rapidly accelerating prices and they are large enough so that they offset all that stuff from generics that are driving down prices.

This shows you what has happened to the reinsurance segment of Part D over the last ten or so years. So, in 2007, it was about 25 percent of all Part D spending was in that reinsurance segment. Today, it's over 56 percent. So, there's been more than a doubling in those ten years. It is really the combination of those things that are driving us to focus where we are.

So, let me just remind you what the reinsurance section looks like. It is what we call double insurance. Consumers are subsidized to the tune of 95 percent, that is they pay 5 percent out of pocket. Plans are subsidized to the tune of 85 percent. That is, that they're at risk for 15 percent and so, the government is picking up 80 percent. It turns out that about 65 percent of that reinsurance benefit, was paid out for high cost drugs according to the Office of the Inspector General. And by high cost drugs, we mean, drugs that cost at least \$1000 a month to take and to use.

When you put those things together, the graphs and the structure of the reinsurance program, it leads to rapid price increases. So, if you look at that doubling of this share that I just told you about, over 90 percent of that was due to price increases and not quantity increases. The number of people entering the reinsurance scheme as a percentage of the total enrolled population, has remained roughly constant over time. So, that really emphasizes the price driving. So, there are two types of incentive distortions that occur under these circumstances.

The first comes from just the fact that plans face very little risk. What that does is when you think about the subsidy combined with the possibility for rebates, combined with some of the allocation rules that are contained in Medicare Part D, there is an incentive for formulary placement that doesn't necessarily lead to the lowest cost drug being put in a favorable formulary position. What that means is that the incentives are set up so that what is low cost to society is not necessarily low cost to plans and therefore, you have a misalignment.

The second issue focuses on what Louise is talking about which is that combination of having market power granted through the patent system accompanied by almost complete insurance. And let me go into that. This is the obligatory nerdy part of the talk. So, if you look at the left hand side of the graph, that portrays a patent monopoly under conditions where there is no health insurance. So, that is the way the patent system is designed for almost every other good except for prescription drugs. What you see is an equilibrium profit maximizing combination of price and quantity of  $P_0$   $Q_0$  up there. Now,



layer on, and one of the things to notice about that is if you compare to the competitive part which is  $Q_c$  right there, what you see is one of the distortions that people are worried about that Louise mentioned is that the competitive quantity was quite a bit larger than what would happen under that monopoly price.

So, the good part of insurance is that it corrects that distortion and so you see that by the movement of the demand curve upward but you'll notice that the new quantity and the new price are much higher on both accounts and, in fact, the distortion might get over corrected and so there would be a distortion in the other direction. The price, it turns out, is much higher and it is much higher in a known fashion. It turns out that under reasonable assumptions, the distortion price is proportional to the copayment. So, in this case, the distortion of the insured price over the monopoly price is a factor of 20.

So, as Louise mentioned, any time you start talking about doing something about prices, you have to start worrying about profitability and research and development and the incentives there. So, there is strong evidence suggesting that positive relationship between profitability and new drugs at least in terms of number of new drugs and in terms of higher spending on R and D and there is good evidence on both. There is also evidence suggesting that that relationship is subject to diminishing returns and Fiona has produced some of that. More recent research has shown something else which is of the new drugs that are launched from that additional profitability, only a few of them are really truly novel drugs. So, as you read that literature, it is hard not to walk away with the sense that the signal of profitability and innovation is a very weak one. That you get more stuff but it isn't necessarily the best stuff.

So, what we propose to do, is we propose a very targeted and temporary approach to negotiated prices. Our target is those high cost drugs with market power selling in the reinsurance benefit. So, that is actually a fairly limited number of drugs but they count for a lot of money. They are limited in number which makes it practical to actually negotiate over them.

The second thing we do is we propose to constrain the government's ability to exercise monopsony power by requiring that economic profits, that prices can only be accepted if they, in a sense, guarantee economic profits which is that incentive to innovate. And what we do is we cover all drugs and therefore it is mandatory but we specify a default price which does two things. One, it keeps people from the industry at the negotiating table and it also allows us to pay on value and create a bonus scheme for drugs that really do a good job that helps us with that profitability value signal.

This is the second nerdy part of the program which is, these are the details of the pricing scheme. And really, the unit price has three components. The first is the default price, which I mentioned, which is set by the government. The two other pieces are the standard for performance. That is, we want to pay on performance and then the question is what is the standard for each therapeutic area that you want to set. What is that schedule that would allow payouts to occur. And then the third component is, what is the size of the bonus that you give for reaching different milestones. Those two would be subject to negotiation.

Now key here is how you set the default. We consider three possibilities. The first, was to mimic what is done in Europe which is to go out there, see what everybody else is doing, what all the other countries are doing and then set the standard that way. We dismissed that because we were uncomfortable with the potential distortions that creates in launch strategy. The second approach was to sort of do for prescription drugs what we do in most other parts of Medicare and what most of the rest of the world does in their insurance scheme which is to have sort of an ad hoc pricing scheme. We were uncomfortable with that as well. So, the third one was to set the default price as a portion of the typical cost of R and D and bring into market, a drug of a particular therapeutic type, say an arthritis drug or something like that.

So, under this scheme, the base price would be set but then the two other components would be subject to negotiation and negotiations would really focus on the paid for performance part of the pricing scheme and would be done in a prorated basis of volume.

So, let me wrap up by saying, for the most part, we don't touch a lot of Part D because, in fact, the market works pretty well and there isn't a particularly obvious alternative. What we do is we focus on the places where we think the incentives are most distorted and most subject to market failure and really put our attention on a scheme where we think you could make a correction that would enhance welfare and do so in a way that leaves enough incentive for innovation to continue the flow of good drugs and, in fact, send a more positive quality signal.

The negotiation structure creates incentives to bargain on one hand but also constrains the government's ability to exercise monopsony power and generates economic profits and expectations. From the numerical examples that are in the paper and ones we've explored, we believe that there are

meaningful savings here and rewards from this targeted approach and can be done in a way that preserves substantial incentives to innovate. That was, in a sense, that point that Louise made saying rather than giving all the surplus to the companies, let's split it up a little differently than we might typically do.

Finally, the negotiated arrangement, we can do variations on this theme. One important variation that we will continue to explore is a scheme where you negotiate the upfront payment dramatically based on performance and industry costs and then leave prices closer to marginal costs. That is still work to come and I'll stop there, thanks.

MR. GINSBURG: I'd like to introduce Richard Zeckhauser, the co-author of the paper from the Kennedy School at Harvard. Let me get started with a question for one of the authors about, what are your thoughts about how Medicare approach like that would affect private insurers payment for drugs?

MR. ZECKHAUSER: Well, first I think there are two things to talk about. One is the private insurers within Medicare Part D and the other is general. In Part D, I apologize to the American transportation system because I was late. Within the plan, I presume you mentioned the fact that in the reinsurance range, the pharmaceutical plans are heavily subsidized. So, they are going to behave an awful lot better because they're going to have incentives. It would be a wonderful system as somebody who is selling a product to get 80 percent subsidy from somebody else when you're providing your product. Think of what Wal Mart would be charging for its certain types of products. But Medicare really does play a major role in influencing everybody else. And a drug that we used to charge \$4000 a year for, we're now charging \$1000 a year for, will have ripples throughout the system. And there is no way, I mean, I don't think that water always reaches its own level because there is sort of bogs and pipes and so on and so forth but water sort of reaches its own level. So, I think that this program for what I would call, Richard that equal the MISES, I would call the MISES grant. And for the MISC drugs we're going to do an awful lot better and you're not going to be able to stand up in the world and say, we're charging \$4000 for this drug which Medicare Part D is paying us \$1000 for.

MR. GINSBURG: Thanks. Let me go to the audience for questions. Do you have a microphone? Okay the gentleman here.

QUESTIONER: What information do you need from industry about costs?

MR. ZECKHAUSER: You would need information from the industry. There is some out there. There is information from abroad. There is a variety of information out there but clearly some of it is private and you think that that might be there for a subject of negotiation. On the other hand, you want to make sure that it's not any one firm's cost you're looking at when you do this. So, you're doing it for the average in a therapeutic area so that would require some data gathering, data collection.

MR. FRANK: I'll just say, from a pure theory standpoint, what I would like to do with these four people who were producing drugs in an area, I'd like to ask each of them for their costs and sort of say, that cost is going to be given to your competitor and it is going to have no role in what you get reimbursed. That's a system which your little word that your competitors are going to get paid more than you are but I'm not suggesting that we use that system, I'm just suggesting that Richard is a very clever guy and I'm trying to put things in his mind.

MR. GINSBURG: Okay.

MR. ROSE: Herb Rose. You spoke briefly about novel drugs without defining what a novel drug is and how does a pharmaceutical company know what is going to be a novel drug until they've invested the time in developing it and testing it.

MR. FRANK: Well, first of all, the research that I was sighting used the FDA definition of novel. So, I didn't make that up and being a country economist I wouldn't know the biochemistry of it. I do think that companies only know that they're going for a novel drug after the fact is kind of incorrect. I think that going after a new mechanism of action versus an existing one is an important distinction and that's the way I would do it. It is a little bit like the Olympics, sometimes you run really fast and you get the gold medal, sometimes you get the bronze even though you were trying to get the gold but sometimes you're not even trying, you're just trying to finish.

MS. SILBER: Diane Silber. Can you explain the discrepancy between prices in the U.S. and other parts of the world from the same drug companies for the same drugs?

MR. FRANK: We don't negotiate is one big piece. We've delegated negotiation to prescription drug plans and sometimes they do very well when there is a lot of competition. But in the cases that we're focused on here, that's the place where you would see the biggest disjuncture between

our prices and any other prices.

MR. ZECKHAUSER: We don't negotiate. We're the world's major drug producer which gives us an incentive to pay more. Drugs are also more expensive in Japan and Switzerland which are major drug producing countries. And we have subsidies all over the place which makes the various participants less sensitive to the price of drugs than they otherwise would be.

MR. GINSBURG: There is a gentleman over there.

MR. STRIVER: Zach Striver from Knowledge Ecology International. You've drawn from prize fund approaches in terms of incentives for innovation. So, I'm wondering what your thoughts are on a full delinkage approach that would delink the price of drugs from the cost of research and development.

MR. FRANK: Well, Richard mentioned at the end of his talk, the possibility of giving you a big upfront payment and then having marginal costs pricing. There have been a variety of proposals on a lot of patents. The patent system is the second best solution. We want you to go out, you're the agent who has come up with some great IT patent. When you do, you're going to charge a lot of money for it and the proposal is that the federal government should give you \$5 million and then you would charge \$.50 which is what it costs to produce. Actually, there is more promise for that approach in drugs than there is in IT solutions because the government would be, as a major payor, would be saving money at the same time that it was paying out this lump sum. Is that possible? I mean we think of what, you may not be old enough to remember, of Buck Rodgers solutions. Buck Rodgers was a space ranger with power raised and the like and we like to think of those things. Australia actually has a scheme that's like this. Australia says, come to Australia, you can sell your drug for any price that you want to sell it or we will give you \$5 million and you'll sell it at marginal costs and it will be part of our drug scheme and it seems to work pretty well. But Australia is on the other side of the world and it doesn't produce many drugs itself.

MR. ZECKHAUSER: There is also a budget problem because you'd have to put very large schemes up front onto the federal budget and that the very least is politically fraught.

MR. PEARSON: I'm Steve Pearson. First of all, I love the way that you've help suggest that we focus attempts to think about pricing, that's a very important perspective and I know in some ways it goes all the way back to your paper, Richard, with Joe Newhouse about unique drugs back when Part D

was created. I also understand this idea of a default price that would cover somehow the cost of development with some kind of reasonable profit. I do worry a little bit that since risk is the one thing that corporations like the least that they would go after the 19<sup>th</sup> drug in a category knowing that they are guaranteed a default price, they don't have to worry about market competition a little bit.

But I want to focus on the second piece. You've decided to suggest a floor, if you will, and then a buildup which would be negotiated. Other people have obviously thought of a ceiling price that would reflect the marginal, basically the high end of what society would consider as reasonable value and let the companies price lower if they wish for market reasons. I'm just a little bit worried about what the "negotiation" looks like with the floor price going up. Unless the government is going to use some very explicit metric for, we'll give you this much more for so many queleas or other measures of health gain, what does it really look like. A drug company says I want \$200. How does the government say that that is right or wrong. How does that really work unless the government decides that it has a fair transparent approach to deciding that build up?

MR. FRANK: Yes, I think the idea is exactly what you said which is that the bonus payment is a schedule that would be negotiated so it would be set out clearly. But the question is in a sense, because there is a lot of private information through the testing and things about how something works as it starts, you'd want to have a negotiator schedule because you've used more of the information and then as the drug comes out you would revisit it as you saw the actual performance on the ground. But it would be very much, as you say, going up.

What we're concerned about in the top down approach is that as Louise mentioned at the beginning, most of the surplus in these markets is going to the companies. So, if you start up there, you're more likely to wind up with a large portion of the surplus going back to the companies which, in a sense, I think, at least our analysis suggests there is too much of that going on right now.

MR. ZECKHAUSER: First, the default price would not be such that you would be making a significant profit. The full price would be, actually we talked about having the full price so if you aren't making a profit, you have to participate in our scheme to do okay. The difference between the ceiling and negotiating down on the floor and negotiating up, if they reach agreement, economic theory would suggest that they would be the same. The benefits, I believe, of having a floor price in going up is that if

you won't agree then you get the floor price. That's okay with us. There is also, I mean, if you worry about first economy sorts of types of things, people like getting more, they hate taking less. Every year my Dean writes me a letter and he says, oh you did a great job last year. By the way, everybody else in my school gets roughly the same letter. You did a great job last year Richard, we're so happy that you did A and B and C. By the way, we're going to raise your salary by this amount. You can imagine how you would feel if he said, well this is the standard for full professors but you weren't as good as Richard Frank, so we're taking \$9000 dollars away from you. Well, not bad. I mean we took \$11,000 away from Harry but Richard Frank was the only one that got the top. I would hate that. I wouldn't even teach my class the next year.

MR. GINSBURG: All right, well we're out of time for this session so thank you. Let me introduce Thomas Bollyky, senior fellow for global health, economics and development of the Council on Foreign Relations and co-author, Aaron Kesselheim, associate professor of medicine, Brigham and Women's Hospital and Harvard Medical School. I understand you're going to be sharing the presentation.

DR. KESSELHEIM: Thanks everybody for coming out. It is a pleasure to be here and I want to thank Brookings for hosting this even. Tom and I are going to talk about high generic drug prices and these are some pictures from recent news stories including, that is Martin Shkreli there in the middle. That's now twice that we've said his name and I think if you say it a third time, he appears on stage. So, our goal today is to talk about the role of generic drugs in the U.S. market. Some of the market failures that have occurred leading to high generic drug prices, available strategies to address these issues in our proposal as well as an impericle analysis applying our proposal to the current market to see how it would work.

So, first to set the stage a little bit about talking about the role of generic drugs, generic drugs make up about 89 percent of dispensed medication in the United States but only 27 percent of overall drug spending. It is very important to recognize that high drug prices in the United States mostly relate to high brand name drug prices. We are going to be talking about the corners of the market relating to high generic drug prices. But in general, generic drugs are the best value that the U.S. healthcare system has and by one estimate, has saved over a trillion dollars over the past decade. Since the Waxman-Hatch Act of 1984, for which Congressman Waxman is here and will address later. We have seen the percentage of overall generics making up a percentage of the amount of prescriptions in the

U.S. raised to about 90 percent today.

There are some important unique aspects of the generic drug markets. Generic drugs are small molecule drugs, are very inexpensive to manufacture and can be sold close to the cost of development. They are interchangeable at the pharmacy level meaning that is a physician writes a prescription for a brand name drug, that in all 50 states, pharmacists have the power to automatically substitute that product. So, there is no marketing for generic drugs. Generic drugs compete on price and this price competition is the only kind of competition in the U.S. drug market that consistently and substantially leads to reduced prices. Competition between different branded products does not lead to reduced prices as substantially. But just because something is generic doesn't mean that it is cheap. Generics are cheap because of competition and, in fact, when you only have one generic drug for a brand name drug, prices only decline to about 55 percent of the brand name price. It is not until we get more like four or five or six drugs on the market or even more that you see prices as low as what we might expect.

Another is that the supply and demand here is pretty inelastic. It is more difficult to enter the generic drug market because you have to do some tests to show that your drug is bioequivalent to the brand name product and you have to go through the FDA approval process, which until recently, which somewhat lengthy because of the lack of resources that had been dedicated to the review and staffing in the generic drug office. Most resources at the FDA being focused on the single minded need to get new drugs on the market. So, what we've seen is that makes the supply elastic and the demand can be inelastic too, particularly if there are certain patients who have to take a certain generic drug and don't have the ability to take other versions that might be available as well.

So, what we've seen in the last few years is some price hikes on generic drugs. One review of over 20,000 products, showed that 2 percent of them increased over 1,000 percent. The really good news is that most generic drugs in most circumstances are still very inexpensive but there are these corners of the market where generic drugs have become quite expensive. Here on the screen you can see a few examples of some older generic products where you've seen massive increases of prices over the last few years. There are many reasons why this occurs and I just want to focus on two of them to set the stage for Tom's discussion of our proposal.

So, first is that we see examples of companies exploiting natural monopolies in niche



markets. So, in some cases, generic drugs, older products are used by so few people, that there aren't enough manufacturers drawn to manufacture the product. This is an example that we published in The New England Journal a few years ago, looking at the prices of Albendazole, an antiparasitic agent used mostly in immigrants and refugees. Not a very common product, was sold at a very low cost by Glasgow Smith Kline until a pharmaceutical entrepreneurial outfit bought it and raised the price because it had never attracted other generic competitors even though it had lost its patent. After that, even though it was being sold for a very small amount, after the purchase, the price went sky high. It went even higher after the only other competitor in the market, Albendazole was withdrawn by its manufacturer for economic business related reasons. And then there were truly no other potential alternatives and the price jumped even higher. So, this kind of market activity is the kind that we're seeking to address with our proposal.

Another reason why generic drugs might increase in price is because of consolidations and mergers. So, in one case, the drug Digoxin, there used to be eight manufacturers and due to various consolidations, mergers, exits from the market, it reduced to two or three and the price went up. One of the major drivers of these kinds of exits from the market are shortages of some of the products that went into the manufacturer of the generic drugs. Shortages of the products lead manufacturers to exit the market and then again, it is a little bit harder to get back into the market after the shortages resolved. This is a graph again showing that shortages of older generic drugs is a really important issue and where I work at Brigham Women's hospital, we get reports all the time from our pharmacy about older products that all of the sudden aren't available any further even products as silly as salt water, which you would think that a country as powerful as ours should be able to maintain a supply of.

This was a study that we did that is going to be coming out in Annals of Internal Medicine that shows the association between consolidation within a generic drug market and the increases in prices. You can see that based on the amount of consolidation in the market as measured by the HHI Hirschman Herfindahl Index that the manufacturers that are remaining are able to increase their prices in a direct way based on the amount of market power they have. If you look at price changes for these generic drugs over the last five years, stratified based on the amount of consolidation within the marketplace itself.

So, there have been a number of strategies that have been attempted to try to solve this

issue. The first was the Generic Drug User Fee Act in 2012 which increased the amount of funding for the FDA and currently the delays at the FDA for getting new generic drugs on the market is much, much improved over what it was a few years ago. Other people have suggested waiving the user fees for priority generic drugs that the Generic Drug User Fee Act implies. Another proposal that the FDA has enacted is they have decided to start accelerating the review of generic drugs for sole source products so, for products that have no generics on the market. There have been other alternatives suggested including accelerating the review further for maybe up to generic drugs that don't have more than two or three other manufacturers on the market. Other suggestions include the government getting in as a purchaser and offering long term contracts for niche products to try to stabilize the market. The creation of non-profit generic drug manufacturers to try to address this issue, waiving the Medicare non-interference provision that doesn't allow Medicare to negotiate the price of drugs for multisource products and the suggestion that we temporarily import products from overseas. The FDA actually already does this. In the case of shortages, it allows drugs to be imported from overseas and that is the idea that we are basing our idea on.

MR. BOLLYKY: We're just switching slides. You may think of this as a relay race where Aaron has handed me the baton. I like to think of it more as the Pony Express where the presentation really gallops forward and delivers the information that you need.

So, let me tell you about what we intend with this proposal. The first is that, of course, we want to propose something that sustainably addresses U.S. generic drug costs and improves patients access to safe and effective medicines. We'd like it to be a proposal that is able to attract bipartisan support. There is not very much these days that can do that but we'd like to think the idea that we put forward here might. The third is, I don't know if our proposal is a Buck Rodgers solution but we've looked for something that is feasible and that doesn't require significant new legislative mandate to achieve or new institutions to run. The last is, we don't want to propose something around importation that undercuts the essential role of the FDA in assuring quality, safety and efficacy of medicines used in the United States. This is what we came up with.

The first is, and I don't have to spend a lot of time on this, is that it's very important that we pass the Generic Drug User Fee Act reauthorization. There is no version of insuring adequate

competition and supply on the market without a strong office of generic drugs at the FDA. So, that's important. The parts I'm going to spend my time on in this talk are the single window. We propose a single window where you'd have a common application for seeking abbreviated new drug approvals in multiple countries. The second is the possibility of creating a reciprocal drug approval pathway. The single window would be a common electronic application to apply simultaneously to the U.S. and other designated stringent national regulatory authorities. We would propose initially limiting that to Canada and European Union but expanding it over time to other short lists of stringent national regulatory authorities. The good news is that this would be voluntary and it wouldn't remove FDA from the process, it is still approving and still has the decision to approve the application or not and it builds on existing precedence and infrastructure.

The U.S. and Canada have recently concluded an agreement to have a common electronic submission gateway project in which you can have submissions go to both agencies. Canada is already receiving 86 percent of its applications this way and this has happened in just under a year. The U.S. will implement this soon. There is also, in the European Union, there is the centralized procedure that creates a single pathway. It still has national regulatory authorities underneath that. It didn't result in harmonization or the elimination of those agencies but has been seen as quite successful.

Our third proposal is reciprocal drug approval. So, this is approval base of generic versions of drugs already on the U.S. market that have been approved in other stringent national regulatory authorities. Again, here in this system, we propose that the FDA would still have the ultimate decision and you may even be able to carve out pieces of it where the discretion would remain with the FDA to address local factors like labeling. Again, we would limit this to drugs with inadequate generic competition which we define as fewer than four generic competitors on the market. We would initially exclude complex generics from this pathway. Again, hereto, you can limit it to a set of countries like the European Union and Canada. We lay out in our paper, a procedure of how these types of arrangements have been negotiated and the types of executive agreements that underlie them using the international civil aviation organization model. Again hereto, existing precedent and infrastructure, there is currently in the international generic drug regulators pilot that is being run by the world health organization but the U.S. participates in that pushing for convergence of these standards.

Again, there are multiple precedents. European Union has a decentralized procedure where one national regulatory authority can grant approval and other national regulatory authorities have a procedure. Again, it rests ultimately with those other national regulatory authorities to grant reciprocal approval. Mexico has a similar system.

Could this make a difference? So, we did an analysis to assess whether or not it might. I'm going to draw, this is a complicated table, I'm just going to draw two conclusions from it. What it is, is we looked at the novel therapeutics that have been approved since the Waxman-Hatch Act October 1984 to January 2016. We looked at only tablets and capsules and which of these drugs are eligible for generic competition but have insufficient generic competition. You find 60 of them. Of those, we then assessed looking at other stringent national regulatory authorities, first EU and Canada but then looking at other ones that made the proposal and the results act as stringent national regulatory authorities. Which ones of these drugs are being approved by a different manufacturer as the sponsor in other stringent national regulatory authority.

So, you might be able to introduce international competition. You find 44 of them, so two-thirds, have been approved by other stringent national regulatory authorities. 23 of these, one-third of them, there is enough other different manufactures that make it in that stringent national regulatory authority that you could reach what we set as the standard of adequate competition, so for generic versions. So, that's a number in terms of two-thirds we have 44 drugs that might be able to benefit from this proposal. Is that significant. That is not a lot of drugs. How many patients does that represent, how large are the markets.

So, we just looked at 2015 Medicare Part D spending for these drugs and saw how much was being spent on drugs with insufficient U.S. competition. What you find, and again, I'm just going to draw three points out of this. The medium for U.S. generic drugs with insufficient competition, so these 69, is that it's \$8.6 million spent medium just by Medicare Part D in 2015. A total of 2.4 billion. If you look at the drugs that would benefit or are available from different manufacturers that goes to 1.9 billion. So, 1.9 billion of that 2.4 billion could be potentially reduced by introducing international competition and again, this just looks at Medicare Part D.

So, we draw from this that there is the possibility of sustainable price competition that

might be spurred by our proposal. This is particularly true for drugs. You see the benefit really for drugs with no generic version currently or only one generic version. If you just limited it to the EU and Canada, still useful. If you expand it to the other stringent regulatory agencies, obviously you get more benefit but still useful for there. This strategy again, just addresses a subset of the generic market. So, it is by no means the only solution out there for U.S. generic drug prices.

Just to quickly point out here, did we meet our standard of those four goals that we're going at. We think so in that this is by limiting it just to already approved generics, it doesn't have the same safety risks. It keeps the FDA in the process. It shouldn't require legislative changes to implement. The FDA, you may even get benefit for the FDA from complying with the recent executive order, the two for one on reducing regulatory costs and it is competition based. So, it is something that might be able to attract support from all sides of the aisle.

The risk, just to briefly mention, is that, of course, New York drug prices tend to be higher than other markets so they would have to price them competitively to compete in our market. Long term consequences of doing this are hard to predict in terms of the way you see more consolidation in the generic drug industry. And this places demands on FDA's international resources to negotiate these arrangements and it would need to be properly funded to do it. Thank you.

MR. GINSBURG: Thank you both. Are there questions? Someone is standing in the back.

MR. HERSHEY: Lorne Hershey. I was a guest scholar here in 1986-1987 on telecommunications policy, restricting AT&T. I really enjoyed hearing Hirschman Herfindahl Index mentioned, thank you very much. Kind of a process question but a point of fact question also. What percentage of American adults and what actual number would you know off hand, let's say over the age of 30, are using a prescription medication just to sort of check out the constituency that's out there on these complex questions. Point number two, and I want to thank Brookings very much for taking the lead on this. Do you predict sometime in the next year or two with all the political brew ha-ha, the pharmaceutical companies for there to be oversight hearings and proposed new legislation and if so, what might that be. And I know it is going to be addressed later in the day but I'd like to hear your remarks.

MR. GINSBURG: Yes, I think that is beyond this paper. Why don't you answer the first one.

DR. KESSELHEIM: Okay, I can look that up. I think that is an easily noble number that I don't happen to have off the top of my head about what the number of the percentage of U.S. people over age 30 who get at least one prescription in the last year. I don't know if I can throw that off the top of my head. Maybe someone in the audience does. Let's crowd source this.

MR. GINSBURG: Let's go to this lady here.

QUESTIONER: A couple of things that perhaps are basic. First of all, you and the predecessor's kind of have an East Coast presence. So, I'm wondering if you purchase something from a CVS or a Wal Mart in South Dakota, is the price of that generic the same in South Dakota and Arkansas. And second of all, sometimes people say that even if it's a generic, you should shop between two providers. So, go to Giant and go to Wal Mart or whatever. So, in terms of generic, I'm thinking about the horizontal and vertical comparisons is that's within the scope. Thank you.

MR. BOLLYKY: Sure. So, I guess the two issues so, the price of a generic drug, there are some variations and there have been some studies that have shown that there may be some slight variations between different chain pharmacies versus individual pharmacies et cetera. But in general, the prices are generally pretty consistent across the country and actually we're doing additional work to kind of look at this question more recently because I think a lot of those studies are a little bit older. There is a really good website called goodrx that you can go on and you can plug in your generic drug and you can look for all the pharmacies in your area and to see where the different cash prices are at the different pharmacies. So, there are efforts being made to try to address those kinds of issues.

In terms of shopping for generic drugs, in general, most patients don't know which manufacturer is making their generic drug. The great thing about the system that we have in place that was created by the Waxman-Hatch act was that you don't have to know because you can assert that all the drugs are going to work exactly the same and we've done a lot of research showing that generic drugs work exactly the same as each other and work exactly the same as the brand name drug that they're interchanged with. So, that kind of shopping process shouldn't need to be done.

MR. GINSBURG: Let me just mention that this paper is about the price that goes to the

manufacturers. There are issues in what happens to the distribution afterwards which is going to be the subject of a conference here on June 14<sup>th</sup>. Next question.

QUESTIONER: I was always told by my doctor that you do diagnosis before therapy. You said two things that were quite interesting at the beginning which is, you talked about the importance of shortages as leading to price increases and you talked about dramatic price increases quite unlike anything we see in ordinary areas to the economy. Could you say a little bit more about the reason that we get these shortages? We don't get shortages of Drano, we don't get shortages of almost any of these other things that are made with chemicals, so on and so forth. I presume that most of your shortages come when there are zero competitors or one competitor. It is kind of hard to orchestrate a shortage if there are a lot of people providing. Once you do that diagnosis, do you think of anything other than, well let's import from overseas or let's import from North of the border?

DR. KESSELHEIM: Sure, I'm happy to start answering that question and then I'll let Tom take over as well. I mean I think that there are a number of reasons why shortages occur and they may occur because of a disruption in the origins of the chemicals that go into making the product. It may be that there is an enforcement action that the FDA brings against a substandard manufacturer, closes the manufacturer. Shortages can occur because when a company decides that they don't want to produce the drug anymore there are other more profitable ways that they can use their pill press machine and so, they leave the market. They are one of the only two or the only one manufacturer making it. So, there are a number of different reasons why shortages occur. I think in the normal course of the market, the prices will go up based on the remaining competitors if there are any left and other manufacturers then should be brought in but I think that the problem is, is that can be challenged by the need to engage in the new testing that is needed to occur. Again, if mergers and consolidations are such that there aren't any manufacturers that want to enter in. So, we envision this as a potential solution to that issue. Particularly, if there are manufacturers that have gone through the approval process in other similarly strong countries, similarly strong regulatory system countries that this would be a short efficient fix to that issue while the market rights itself.

MR. BOLLYKY: Yes, so I'll just add a couple of things. The first thing, Aaron quite rightly laid out the reasons for shortage but probably the deeper question is why do you have so few

manufacturers making older generics, which is really the precursor to getting shortages. You only have one or two suppliers on the market and that is because, by enlarge, the great profits are to be made early in the generic cycle and for smaller sized markets, older generic drugs tend to have fewer competitors. If you have a disruption in your pharmaceutical ingredients or a uptick in FDA inspections, this happened with sterile injectables in 2010, you can see shortages happen because there aren't many suppliers. As Aaron quite rightly mentioned, the supply tends to be inelastic. Not only do you have to get your drug approved, you also have to build the manufacturing capacity for that.

This is why importation is useful because these entities have already built the manufacturing capacity for it. They may need to build additional to supply the U.S. market but at least they're on that road and it is more of a question of expanding something that exists or maybe they can even do it with their current capacity. That's the big benefit.

The other thing to understand about importation, we import now. The U.S. is the largest importer of finished pharmaceuticals in the world. 80 percent of our active pharmaceutical ingredient is imported. This is not a new idea. What really is the new idea here is leveraging the assessment of another regulatory agency as a way of speeding up the approval process.

MR. GINSBURG: Last question, Louise.

MS. SHEINER: So, I wonder if you've thought about what the implications might be if we had this system in place in terms of how many manufacturers might there then be. So, you're talking about there is not many incentives, a lot of competition. Would we think that maybe we would lose the benefits of competition if they would merge across countries or some countries would just bow out and leave that one manufacturer in the U.S. or in Canada and then have the same problem.

DR. KESSELHEIM: Yes, so this is something we've debated a lot and looked at. I mean, I think probably the right analogy to think about although it is something we're still sorting through is the trade context where you have trade barriers decline and suddenly you have new entrance being able to access a market. What happens there, normally what you happen to see, and this is a regulated market so you would still have to meet standards, but it would go to lower cost production centers over time. Then the question is, are there any political economy reasons why they would still be in multiple places. You can imagine, it gets complicated to predict which is why we put it as a risk. I think in terms of getting,



particularly for the single window, getting applications sooner, this is a cost free exercise. This is the way the world is, for a lot of other entities, moving already and it is a question of getting the U.S. on board with that.

MR. GINSBURG: Thank you very much. Next we'll be hearing from Fiona Scott Morton who is the Theodore Nierenberg professor of economics at the Yale School of Management.

MS. SCOTT MORTON: Hello everybody and thank you very much to Brookings for the invitation to be here. Lysle Boller and I have a paper that is looking at barriers to competition in the pharmaceutical industry and this really builds off of what you've heard already but goes into some detail on three broad topics.

First, let me give you the motivation and the positioning of this paper. I think it's well acknowledged that we have a bit of a problem in the United States with the spending we have on pharmaceuticals. Louise did a beautiful job explaining that already. Competition can bring down prices and also generate the kind of innovation that people value. So, it's a really good solution to a lot of these problems. However, because it is so very effective, manufacturers attempt to avoid it. How do manufacturers avoid competitive forces, they use influence with regulators to get regulations that dampen competition. They use influence with legislators to prevent procompetitive legislation and they utilize creativity and complex markets to reduce rivalry. What this paper does is it goes through a number of examples of all three of those things happening in the U.S. I think they've built up over a number of decades and now we really have a lot of niches where we have a market system creating prices and really when you look at it, it's not very market oriented.

So, the motivation here is that we should remove some barriers to competition, some created by manufacturers, some created by science, some created by regulators. And then maybe we could get low prices without needed to regulate. If we really had competitive markets in most places, the caveat here is that really the case that Richard discussed in the first paper is one that we don't address in our project because that's a case where there is a unique drug that is not facing therapeutic competition.

Okay so, you've seen versions of this graph already. The top set of bars is the growth rate for what we call specialty and biologic products. So, these are biologic entities and then also the stuff that is really, really, expensive but a small molecule drug. Down below, is everything else and you can

see that the problem in terms of price increases is largely located on the top part of that graph. Why is that, this is the stylized picture. A small molecule drug hums along raising price by 3 percent a year or something like that until it gets to the end of its patent. There is six months of single generic and then lots of generics enter and we see price declines down to the let's say 25 percent of the original branded price.

What happens to a biologic, it keeps merrily ongoing. It has a higher rate of price increase to begin with and that doesn't stop. Why doesn't it stop, we don't have a generic biologic. There is no such thing in the United States at the present time. Why is that, because we have lagged behind Europe in proving pathway for interchangeable biologics. We have one for biosimilars. Biosimilars are almost identical to -- these are enormous proteins that you stew in a vat and it is hard to get them to be identical to each other. A biosimilar is very similar. Europe has had biosimilar since 2006. They have more than 20 on the market. These generate significantly lower prices. In the United States, we have two. We have approved a grand total of five, three are not for sale. So, most biologic drugs have an infinite patent. So, when you think about the good that the Hatch-Waxman Act did, we're just missing that whole force in this sector.

Now Lysle and I put together some data looking at the example of the first biosimilar released in the United States. You can see that the price of the brand goes up over time. The first dotted line is the arrival of a second brand. So, this is the same molecule but entering as a second brand in the expensive normal pathway that is a BLA that's hard to do. The arrival of the second brand, stabilizes prices. They've stopped going up. The arrival of the first biosimilar in the first six months, we see a 12 percent decline in price, and that's just the first six months without a lot of infrastructure to help that along. So, I think that's just a taste of what we could be getting if we had vigorous biosimilar competition in the United States.

So biologics, we think, are a big area where we're lacking competition. We need biosimilar entry. The FDA needs to approve these quickly and make an interchangeable pathway. We also need to name them all the same thing. Right now, we have a system where biosimilars have a nonsense suffix so, they are filgrastim-abcd. A nonsense suffix is obviously not helping anybody learn anything about the drug. But what it does is it means when you put these drug names into a database, you can't sort them in a way that shows what is the substitute for what. J codes in Medicare Part B, do not incentivize the use of biosimilars and that is a problem. There are some issues in the orphan drug law

which I invite you to read the paper to hear about.

Generics is a second big area. So, I told you there is three big areas and I want to save time for the third one because it is the hardest. The second big area is generics. We've heard about importation. There are big problems with brands not wanting to face generic competition because it is so dyer as you saw from that previous slide in terms of the amount of competition it generates. So, we have well-known tactics like pay for delay, withholding samples from the generic so the generic can't backward engineer the product. The argument is that the product is dangerous and therefore only sick patients can have prescription and not a generic for trying to enter the market.

Product hopping is I'm going to move from a capsule to a tablet to a scored tablet back to an extended release capsule and do that in a way that makes it difficult for generics to enter. These three can be addressed with anti-trust enforcement, we think. Small market monopoly, you've heard about that already. Approval delays, that's just an ongoing issue. I think the FDA is doing a pretty good job with approvals now but you need to keep an eye on that because the longer the approval lags, the less competition there is for the consumer.

And then there is some generic complex products like the EpiPen. So, what's going on there is epinephrine is an old generic, that's not the problem, the problem is the pen in which it is injected into the person which is a patented device. And other entrants have not been able to replicate the pen or produce a pen that was sufficiently reliable. So, these complex products, the guidelines from the FDA are not firm and it takes longer to get in to those combined markets then it might if guidelines were a little clearer. And then shortages, we just had a productive discussion about that so, I will skip that.

Okay so, I want to spend my remaining time on our third big bucket which is demand side. What do I mean by demand side. The patient has to care about saving money. If the patient doesn't care, then you prescribe her a \$10,000 product or a \$1000 product and if she's paying zero either way, she's susceptible to marketing to buying the \$10,000 product. When you fully insure people, that's what is going to tend to happen. So, you need to not fully insure them, you need to make it worth \$100 of their while to buy the product that is more cost effective. So, my out of pocket price is \$50 for the \$1000 pill and \$250 for the \$10,000 pill and then I buy the cheaper one. So, that's the demand side.

What happens here is we are dampening the demand side with our regulations with some actions by

manufacturers. So, Part D has protected classes where the government says you must buy to the insurer, you must buy all of these products. Well, if the insurer has to buy all the products and can't steer people around, it's very difficult to get a price reduction. Those protected classes could be relaxed, I think, in a productive way. There's also a Part B problem here. We don't essentially create a flexible enough formulary in Part B. We could do reference pricing, least allowable cost. But the same issue arises in Part B where we need to have the government reimbursement process incentivize the physician to purchase the lowest cost drug that is suitable for the patient.

Now, PBMs. I think there's an issue here with PBM's that is a little bit subtle. First of all, it's not clear to us that there is enough competition in the PBM market and we would recommend that the FTC undertake their 6B authority to study the PBM industry and report back on that. But there is also an issue with PBM incentives. The way rebates work, because they are confidential and that stimulates price competition which I think is good, but the confidential rebate means that the end payor doesn't see the total magnitude of those rebates. And therefore, has a hard time contracting with the PBM because they're trying to contract on a net number, total cost minus rebate, and they can't see how big the rebate is. So, this is not an argument for making rebates public because then, I think, it is very difficult to stimulate price competition between manufacturers. But it is an argument for making the total flow of those rebates go back to the final consumer, who can then negotiate with the PBM about taking a fraction of those rebates as an incentive payment or having some other incentive that depends on the net price, the list price minus the rebates which is actually borne by the consumer. So, we're concerned about the PBM and we think the FTC could study that issue and perhaps come up with a solution.

The final thing I want to talk about is kickbacks to patients. The problem with kickbacks to patients is, again, they make these price incentives go to zero. Suppose that I really did have a \$250 co-pay for the expensive medicine and a \$50 co-pay for the inexpensive medicine. Then suppose the maker of the \$10,000 product offered to pay my \$250 co-pay. Now, I pay zero and \$50 for the other one. I'm going to buy the \$10,000 medication. Now, that manufacturer did have to pay me \$250, on the other hand, they're getting \$9000 in revenue that they weren't getting before, assuming that \$1000 was the competitive price. So, by returning money to the patient in the form of a kickback, the manufacturer can charge a high price and stimulate sales at the same time. How does this work, it works through coupons.

Many of you may have seen a coupon card that you can use at the pharmacy to swipe instead of your Visa card and it pays exactly the difference between the \$50 co-pay and the \$250 co-pay, it pays \$200. So, the patient is indifferent between the two medications and this is a way to incentivize, for example, sales of the brand over the generic. The consumer now gets to consume the brand and doesn't have any additional out of pocket expense.

This has been addressed by OIG. You're not allowed to do this in Medicare and Medicaid because it is a kickback that raises costs to the federal government. States like Massachusetts have actually banned these coupon cards because they raise expenditures. People are consuming the brand instead of the generic.

Another big issue is patient assistance programs. Let me show you two visuals on those. Look at the largest foundations in the United States. Some of them look familiar, the Bill and Melinda Gates foundation but most of them are drug companies. Most of them are drug company's foundations. These are foundations that the firms give tax free medication and then they give away that medication as free samples which then generates revenue. So, the tax payer is funding the marketing efforts of these drug companies and it is a very large marketing effort, as you can see by the magnitudes here. So, that is one kind of patient assistance program.

A second kind is an actual foundation that gives away money. This is something we found in a trade publication describing the benefits of giving a tax deductible contribution of \$10 million to a charitable foundation. The charity takes 20 percent to run itself. You're left with \$8 million. This particular manufacturer has a 25 percent market share so, of the \$8 million, it assumes that \$2 million is spent on co-pays for its medicine. Because the insurer cost share is almost 90 percent, spending \$2 million on co-pays generates \$16 million in revenue. So, the firm has given away \$10 million in a tax deductible way and receives \$16 million back in incremental revenue. So, that's the tax payer subsidizing the firms marketing efforts to get incremental revenue by absorbing the cost to the consumer.

So, we feel that these patient benefits are really a big problem, they're driving up prices. If you've got a \$100,000 medication and a 30 percent co-pay, that's a \$30,000 co-pay. Most American's can't pay that if they don't have a second source of insurance, they're not going to pay it. So, it is really a notional payment. What will happen is the manufacturer will give financial aid, absorb that \$30,000 and

take what it was really expecting to get to begin with which is the \$70,000 payment from the insurer.

So, this is something we might want to think about restricting at the state level. For example, a state could say, a person's total out of pocket exposure in the state of Massachusetts is \$3000 a year. That's the most they can pay for everything put together and in exchange, we ban this kind of activity. That way the insurer returns to having a role in bargaining over prices and setting some incentives for the patient that causes the patient to be prudent in her choices of drugs.

So, those are our three big areas to focus on. Demand side, generics and biologics and we think that returning competition in those areas would be very helpful. Thank you.

MR. GINSBURG: Let me start off with a question for Fiona. Because you have a great variety of ideas, many of them very compelling, and presumably different policy makers might pick up on different ones. What would be the one or two that you think has the greatest potential to make a difference in paying less for drugs?

MS. SCOTT MORTON: Biologics. Biologics. We really need biosimilars. We need a lot of them quickly. Interchangeable biosimilars that the pharmacist can substitute so that we can just ride on the Hatch-Waxman kind of train. I think that would be incredibly useful. These drugs are growing very fast. More and more of us are taking them and they are generally expensive. So, I think, an argument against worrying about biosimilars was that, oh they'll only reduce prices by 30 percent instead of the 90 percent we see with small molecule drugs. Well, 30 percent, there's a lot of dollars there.

MR. GINSBURG: And to pick up on something you said later in your talk about the Part B issues, the fact that many of these biosimilars, biologics, are physician administered and we just don't have the whole infrastructure formularies incentives that we do so, that probably has to be fixed too.

MS. SCOTT MORTON: Yes, that probably has to be fixed because, of course, many older people are taking these drugs and they are in Medicare. So, Medicare really has to find a way to create an incentive for the physician to administer the lowest cost option.

MR. GINSBURG: Questions. Yes sir, the gentleman there.

MR. CLARK: Hi there. My name is Bobby Clark and I have two questions.

MR. GINSBURG: Just one please.

MR. CLARK: All right one question. You mentioned EpiPen as a complex generic. You

mentioned that FDA guidance was, in part, could be useful in this area. My understanding is there is actually guidance about these types of products out there and there were other manufacturers in the marketplace. Some had to go on and come off so, is it really a question about more guidance from the FDA or are there quality issues there and how do you get around those issues or how do you work with manufacturers around those quality issues.

MS. SCOTT MORTON: I think you just have to understand that there is an incentive to get it right if you want to sell your product. The quality issues, I think, we don't have anything to say about. Guidance you want as explicit, I mean, these complex products are harder than regular generics to evaluate and the FDA, to my understanding is, could do better in making that a smoother and swifter process.

MR. GINSBURG: Yes, the gentleman in the middle.

MR. RATNER: Bob Ratner from Georgetown. I'm curious about your wording on that demand side slide. The PBMs were incentives and rebates and the patients were kickbacks. Can you differentiate kickback from a rebate for me?

MS. SCOTT MORTON: Yes. A rebate comes because I have elastic demand. I, the insurer, I have a million people and they can consume drug A or they can consume drug B. And I can create a tiering structure on my formulary to shift them around and I can say to drug A and drug B, whichever of you offers me the best terms, I going to send my guys to that drug. And then I reduce the price that way, I create price competition that way.

The kickback is not creating price competition, it is eliminating price competition. The patient is facing \$250 to buy this and \$250 to buy that and the kickback is eliminating the price competition that was created by the PBM. So, that's the difference between them.

MR. RATNER: If physicians sends a patient to a laboratory or a radiology practice, because there's a negotiated price, that's called a kickback.

MS. SCOTT MORTON: I think we're going to stick to drugs here but there is guidance about how financially integrated those entities are as to how you evaluate that.

MR. GINSBURG: The woman there and then we're going to go to the person standing near the door.

DR. POMPLIN: I'm Dr. Caroline Pomplin. What do you do about drugs like insulin? We now have where a drug company instead of making biosimilar, makes a different insulin and it gets the top price. So, there is tremendous competition it is just it's not price competition it's "quality" competition. So far, there hasn't been a biosimilar for insulin and insulin is something that people can't live without.

MS. SCOTT MORTON: Right. So, Lysle knows a lot about insulin but he wants me to answer anyway. I think the issue with insulin is that you have an agency problem between the doctor and the patients. So, what happens is every year we have new nifty gizmos to inject insulin to a patient. If those are very expensive and the patient has high co-pays, the patient is arguably not going to be as healthy because they're not filling their prescription compared to if you gave them last year's fancy gizmo that really has a lot of competition and is much less expensive. So, we have an issue but with insured patients and physicians who don't know what the price of anything is nor do they know the co-pay, being unable to choose well for the patient in a way that satisfies the patients price quality tradeoff. There are many old insulins that are inexpensive so, you can get the lifesaving medicine. But if you want yesterday's injectable thing, that's going to be expensive. So, the question is, is that really worth it for any individual patient.

MS. SIMMON: Hi, I'm Christine Simmon. I'm with the Association for Accessible Medicines. We used to be known as the Generic Pharmaceutical Association but we have our new name. Obviously this paper and the ones that proceeded it, but particularly this panel, very interesting to us. We're absolutely proponents of additional competition for generic medicines and improving patient access. I did want to thank you for your paper but I did want to point out a couple of items.

At one point in your paper, you do make the common mistake of calling Daraprim a generic. Daraprim is many, many things but it was not, is not and never has been a generic drug. A drug being older and off patent without competition doesn't make it a generic. A generic drug has to be approved through by the FDA through an abbreviated new drug application process in order to be a generic. So, I just think that Daraprim, also EpiPen not a generic. The epinephrine is a generic medicine but the product itself if a patented medicine. So, the reason I raise these because I so enjoy talking about Daraprim not being a generic over the last 18 months, is to note that these are certainly problem products and outliers and they do make good poster children for the lack of competition and the consequences



thereof.

I would also make sure that folks realize that generics are delivering 90 percent of prescription medicines at only 27 percent of the cost. Brand drugs are delivering the inverse of that, the 11 percent at over 70 percent of the cost. I think that you've seen recent, hopefully, papers by AARP as well as the campaign for Sustainable Drug Pricing that point out, while we're focused on the shiny squirrels of Daraprim, which truly do deserve our focus, but there are other routine daily high cost brand medicines on the market. Some of the competition's solutions for this, are not getting the full cooperation of the entire pharmaceutical sector. Some of these were mentioned in the paper such as improving access to biosimilars and not building patent fortresses that keep patent protected biologics on the market virtually indefinitely.

Also, the Creates Act was introduced. This is a bill that has bipartisan, bicameral support to stop the abuse of restricted distribution systems.

MR. GINSBURG: You want to wrap it up.

MS. SIMMON: Yes and REM to block the access to samples that was mentioned. So, I just wanted to point out a couple of things. We appreciate this forum and thank you for your paper.

MR. GINSBURG: Do you have any response, Fiona?

MS. SCOTT MORTON: No.

MR. GINSBURG: The gentleman in the back.

MR. SALS: Thank you, I'm Jordan Sals, I'm a student at Howard University. My question was about, I heard your speak out and I'm with you, but I wanted to know, how do you solve the out of pocket cost for the consumer?

MS. SCOTT MORTON: This is the fundamental problem with insurance in healthcare. So, the reason people buy insurance is to smooth their financial expenditure over time so that they're not exposed to a big shock at the moment they get sick. If you don't give people any price exposure, then they don't care how much something costs. And those two forces are, we want them both. We want price exposure so that we get price competition and we want insurance so that we don't expose people to risk. It is very difficult to get that balanced. One of the things you can do is give the insurer lots of tools to create price competition and then the insurer insures the patient. But the insurer is elastic across drugs

and tries to create price competition. But, I think, consumers are quite responsive to small amounts. If you make an out of pocket payment \$100 more for one thing than another, you will get people to shift. What doesn't work is the 30 percent co-pay for a drug that's \$100,000, that's a \$30,000 co-pay. That is out of reach for most people and so, I think, they want insurance for that and very reasonably so.

MR. GINSBURG: Thank you very much. We're going to take a 10 minute break and then we'll be back for the rest of the conference.

(Recess)

MR. WESSEL: If we can reassemble, we'd like to continue the program. We appreciate the lively conversation and we hope it will continue.

So, Louise, do you want to bring up your panel? So the people who are on the panel with Louise, if you want to come up and the technicians will make your mics perfect.

MS. SHEINER: Okay, terrific. I really want to thank my panelists for being here. I'm going to introduce you all very briefly. I'm not going to read your bios because we only have half an hour. And if I went through all the degrees and the tremendous expertise here and all experiences, we would be here forever. But really, look on the website. This is a really impressive panel. We're just really lucky to have them.

So this is Troy Brennan. He's executive vice president and chief medical officer for CVS Health, and formerly from Aetna. Is that correct?

MR. BRENNAN: That's right.

MS. SHEINER: Yes. So that means you that really understand this issue from multiple perspectives: as a physician, as an insurer, and as somebody from the PBM, or from the pharmacy benefits perspective. Right. So that's great.

And then we have Jennifer Bryant. She's the senior vice president from the Pharmaceutical Research and Manufacturers of America, so she is going to represent the brand name perspective.

We have Steve Pearson, who is president of the Institute for Clinical and Economic Review, or ICER, which is a really interesting organization that does, I think, the kind of thing that Richard

would suggest the government should do in its negotiation, which is to look at drugs and decide what their value is and how that value relates to costs.

And then finally, I have Rachel Sachs, associate professor of law, Washington University School of Law, who is an expert on all things FDA, at least, on top of other expertise, as well. So she can at least speak to the FDA issues.

Okay, great. Let me start with sort of big picture in terms of the scope of the problem. Richard Frank said that he thinks that the markets in Part D work pretty well except for a small number of cases where insurers and consumers have little incentive to care about prices. I think other people might say that the scope of the problem is much bigger, that prices are just way too high throughout the system and that we need a larger approach to -- larger than a sort of surgical approach to dealing with the problem of high prices.

I'm going to go down the row and see what is your perspective on sort of how big is this problem and where does it really lie?

MR. BRENNAN: Bigger than the 10 or 12 drugs that were on their table, I guess, yeah. It wasn't my major contention with the paper, but I think you make a good point that it's broadly seen as a much wider thing that we have to address.

MS. SHEINER: How about you, Jen?

MS. BRYANT: I think the challenge with going after a small handful of drugs, the 10 or 12 drugs that he characterized, is that it kind of misses the point that the entire R&D enterprise rests on the very small number of successful medicines. So if you do that, it sends a signal to the entire industry and sends a chill into investment incentives.

That said, I also think that there's a misunderstanding about the size and scale of the problem related to drug costs and spending. Healthcare costs are a problem. Drug costs are a piece of that. There's a lot that can be done to reduce prescription drug costs. But if you open the newspaper you would think that prescription drug costs are exploding, literally, and they're going to eat the whole healthcare budget.

But all the best estimates show that spending is going to grow about 4 to 7 percent per year, healthcare costs are growing about 6 percent per year. That's not acceptable, we need to reduce it,

there are lots of things we can do, but it's not an exploding unsustainable crisis. And so we need to make sure we don't have rash solutions, but that we go after the niches that Fiona was talking about.

MS. SHEINER: Steve?

MR. PEARSON: So I guess when I talk with states and private purchasers and employers, I mean, they do have an experience of having to kind of look at the big picture and the pie. And to them, over the past several years, it has been drug costs, especially specialty drugs that seem to be the component that they feel like is both growing faster, but also that they just don't have the levers that they thought they might have to control it. So there's the spending that kind of makes people pivot and look at the issue.

And then what they find is a lot of what was discussed earlier, which is it's really hard to figure out when we're getting a good value for a drug and when we're getting ripped off, when the value just doesn't seem to align with it. We know that it seems to be really random and all over the map. Our reports themselves have found some areas where we find virtually every drug in that area relatively well-aligned with the added benefit to patients, which is the way that we talk about value; and others where literally every drug is somehow out of whack and much usually higher priced than you would assume if you were going to give it kind of a fair margin for that value.

So even though I'm very attracted with the idea, as I mentioned, of figuring out a way to target and to focus on where the market seems to be working less well, I think it is a broader issue that a lot of patients are grappling with in a variety of different disease areas, but especially where there are those usually self-injectable drugs where sometimes the market incentives, again, as Richard I think pointed out quite well, there are areas where it seems to be just structurally, systematically difficult to get a fair deal for patients. And even the drug companies at our public meetings have complained. They say we want to come to market with a lower-priced drug. There are structural reasons that we have a hard time doing that as part of a competitive landscape. So there are some important problems.

MS. SHEINER: How about you?

MS. SACHS: And one thing that I think is so wonderful about this conference is how complementary all of the papers are, right. So you've got the Richard Frank paper saying here is this particular set of high-cost branded drugs which are of concern. You've got Aaron and Tom saying and this is

also a particular problem for a set of generics. And then you've got Fiona's paper saying actually all across the industry there are these particular ways in which competition isn't working to the degree that we're encouraging it. And so I don't know which of those is the biggest in terms of being a driver, but I do think they're all really important to the puzzle.

MS. SHEINER: So I'm going to start with you again on this next set of questions. I'll come back, you don't all have to answer every question. But I want to ask some questions about the FDA.

So we heard a lot of proposals for the FDA to do things differently this morning. And one question I have is, does the FDA have the right balance between worrying about safety and worrying about competition? And what is their mandate, actually, and does the mandate fit what they should be doing?

MS. SACHS: I mean, if you ask 10 different academics, you'll get 20 different answers to this question because we all -- you know, it depends what I had for breakfast, how I'm feeling that day, who's the commissioner, things like that. And so I think the FDA has done an enormous amount over the last decade or two to really change the ways in which it reviews drugs. It's done an enormous amount to speed up the process for innovative new drugs or particular classes of drugs. And I think a lot of the rhetoric we hear today is really stuck in an older sense of the FDA that's very tied to a more rigid drug approval system than we actually have.

So I think there's some value in allowing the systems we've just created as recently as a couple of years ago to really come to fruition and see how those actually work. But I think it's tough to say that we've created the platonic ideal of a drug approval system. Right? It's tough to say what that would even be.

MS. SHEINER: Does anybody else want to chime in on that?

MR. BRENNAN: I mean, generally speaking, the dynamic has been, you know, sort of are we getting the drugs out fast enough? Is the FDA holding things up? And with the whole (inaudible) and things like, I think I would personally be kind of where the (inaudible) Kesselheim papers have been, which is that, you know, you don't -- we want to make sure that we can get all the drugs that we need, but these protections are very important. And we should be willing to sort of put up with some delays in order to make sure that patients aren't going to get injured.

It goes back a little bit, to Aaron's paper, though, on sort of importation. I think it's a good idea, you know, from a PBM point of view. That's where you make your money, in PBM and retail pharmacies, on generic medications, so the importation would be a good thing. But, you know, what you're really worried about is touching the third rail of getting very bad products coming in through a process like that.

So I think, you know, those gentlemen have to be very confident, we'd have to all be very confident that we weren't missing the protections that the FDA brings to bear. Because at least from the point of view of sort of like you go into your CVS store, we're utterly dependent on the FDA to certify that these medications are exactly what they're supposed to be. We don't do any of that work ourselves. And if there starts to be importation, I think we're going to get drawn into that.

MS. SHEINER: And is the worry that -- so they had a very specific set where you said there's probably not a problem. But I guess the worry might be that once you went that route, then it's kind of a slippery slope and perhaps then the demand for, you know, well, why that country and not this country or this drug and not that drug, is that kind of what is the biggest impediment to that?

MR. BRENNAN: Yeah, I think that crooked people making bad drugs are amazingly innovative in terms of the ways they import those drugs. And the FDA's own presentations on this would suggest that things that look like they should be benign aren't, so I just think you have to be very careful. And I appreciate the fact that in both the first two papers, you know, there was a relatively sort of narrow focus that was well-supported academically.

MS. SHEINER: Great.

MR. PEARSON: The one thing I wanted to add -- I'm sorry, go ahead.

MS. SACHS: I was going to say, I think the FDA already has a really big job in assessing the safety and efficacy, so I don't know that it's about adding to their mandate, but I do think that it's become clear that there are some places in the marketplace for older, off-patent medicines and for generic medicines where there needs to be more competition and that there are a combination of things that could be done through the FDA to either get first generic approvals through sooner or to make it more attractive for generics to enter.

And so I think that ranges from things like technical assistance to make sure that there is

adequate understanding of the manufacturing standards to making sure that there are other incentives. I think the range of them, some of the things that I think Aaron and Tom this just might be worth actually looking at, but I think we're on the right track in sort of figuring out how to make it attractive to enter essentially a commodity market where if things go well, the prices should approach marginal costs. That's a very different kind of problem than the problem -- the kinds of things people talked about in the brand market and there needs to be more policy attention community. I'd say it's the mandate of the policy community and the health plan strike competition there, not the FDA.

MS. SHEINER: You wanted to --

MR. PEARSON: I was just going to add, I mean, the FDA has an incredibly difficult job. There are a couple things, though.

Insofar as they have created new accelerated pathways through a variety of different ways to try to speed up and to foster innovation, if you will, and that's the good. The challenge is that now when drugs are approved, we really do know less and less about their clinical effectiveness, much less their comparative clinical effectiveness. And there are some things that the FDA I think could pay a little bit more attention to in terms of making sure that the way that outcomes are measured in the development trials are similar or exactly the same across different drugs. Because that way patients and clinicians who are really going to be making decisions, as well as payers, can do a better job of trying to do indirect comparisons at the time of launch.

And as far as the FDA has been evolving, we've done nothing to kind of create a tag-on or a bolt-on process for the first two or three years after approval. PCORI was often thought as a potential kind of actor that would help us gain that kind of information. It really hasn't served that role. And so we are --

MS. SHEINER: Tell people what that is.

MR. PEARSON: Oh, sorry, PCORI is the Patient-Centered Outcomes Research Institute that was founded as part of the ACA. But for a variety of reasons, it hasn't done that kind of research, certainly much of it. So we're still left with drugs coming through around which we know less and less, and the pricing structure is still, at launch, a company announces a price and the market kind of reacts. So that part is starting to feel even more dysfunctional, I think, than it did a few years ago.

MS. SHEINER: So let me ask you a question about FDA budgets. So we now use user fees to help sort of supplement any kind of budget that the FDA gets from the government. Is that a smart thing to do? Would the government actually end up saving money if FDA budgets were larger and the cost of entering were lower for generics and things could get approved quicker? Does this kind of make sense to starve the FDA? Is the FDA being starved? Rachel?

MS. SACHS: I'll ask the easier version of what you just asked because I think it's a genuinely tough question of how much do we want industry to be sharing in the cost? And I also study intellectual property law where the PTO is almost entirely funded by applicants for patents. So I think there are arguments for and against it.

I think the user fee act process itself leaves a lot to be desired. Right? The fact that you have must-pass legislation every five years across all of these different topics really provides an opportunity for it to become a Christmas tree of different provisions, of different kinds being added that really don't relate to the setting of the user fees themselves, but are gifts to particular constituents of various kinds. And so I think that process itself is not the ideal way to be doing this.

MS. BRYANT: I mean, I would argue that the PDUFA process has actually worked incredibly well and that it's led to shorter approval times, really quite dramatically; that it's improved consistency and predictability. And no process is perfect, but I think in the difficult fiscal environment we're in right now, the last thing we want to be doing is sort of completely blowing up the structure for funding the FDA, which still is the world gold standard in terms of drug approval. And I think we want to keep it that way.

MS. SHEINER: Okay, let me move on. Let me talk a little bit about what opened the panel with this morning, which is this trade-off between the incentives for innovation and the desire to have lower prices. And let me just go back to, again, the Hatch-Waxman Act and ask about when that introduced and when -- you know, if you make it easier for generics to enter, that effectively lowers the return on innovation. Right? If you thought that it was very hard for generics to enter, then your patent sort of doesn't expire the way Fiona said, with biosimilars.

So I don't know what happened then, but was there the argument when this passed that this was a terrible idea because we were not going to get innovation that now has just been accepted as



a reasonable thing? I mean, one of the interesting things in this area is I don't think there's a consensus on what the optimal length of time is, right, in terms of are the returns too small or are they too big for innovation? I don't think there is a consensus.

And so I'm just wonder whether or not there was sort of a view that allowing generics in was going to reduce innovation and was, you know, not a good thing. Anybody know or remember?

MS. BRYANT: I mean, of course I would defer to the author on this, but from -- and if you want to answer, you can -- but from my understanding it was really a compromise. Right? There were efforts to pass -- well, so Hatch-Waxman did two things, right? It created a generic pathway, but it also provided for patent term restoration for a lot of these branded companies who lose time during the FDA approval process. And so it's really bringing together those two interest groups and saying we're going to give one thing to each party. And if I recall, there were efforts to pass either bill alone and those had failed, but I'm not sure exactly why that is, if that was for procedural reasons. But it really was conceived as a compromise and I think that's all to the good.

MS. SACHS: Yes, I mean, I can't speak to the history and way back when, but I think it's indisputable that the presence of this kind of system in which a patented drug goes off patent and the price falls, I think actually often to 10 percent of the what the branded cost is, is a huge force for savings. And one of the misconceptions, I would say, is that we've exhausted all of the savings from that system. Because you'll hear a lot of people say, well, the patent cliff is over and how we have a lot of medicines that are biologics and we don't have biosimilars yet, so we don't have those savings. But actually, if you look at the projections of the number of drugs that are coming off patent in the next five years, the dollar value is more than over the last five years.

So a lot of people are referring to the, you know, mini patent cliff or the patent cliff 2.0 is happening now. And actually it's just a cycle and there are huge ongoing savings. And biosimilars were just at the very beginning.

The one thing I know for sure about the history is that no one in 1984 thought that we would get to a point where 00 percent of the prescriptions would be generic. That was actually not the expectation, I'm fairly confident, or maybe you would have seen more objections to the time. But we're the early days for biosimilars. And I would argue that biosimilars are going to be a huge force for savings

going forward and we're just beginning to get the first inklings of that, you know, and the parts of the market where insurers are making use of the first biosimilar for diabetes. We are seeing in cases where it's been preferred, it has 50 percent market share.

So don't count the payers out would be sort of my advice. Don't assume that biosimilars will just be small discounts and that there will be slow take-up because we have a very creative payer sector that is anxious for savings.

MR. BRENNAN: Yeah, well, I agree with that because I feel like rarely do we payers get called creative. (Laughter) And I thought, you know, Fiona was firing in a lot of directions, more at Pharma than at the PBM, so I was happy about that. (Laughter)

But with regard to this, when you ask what's the major issue, the major issue is getting the biosimilars out because, clearly, the pipeline for Pharma is in the biologics. The exciting things that you see are almost -- even when they have relatively sort of small molecules and they're going to be taken orally, they're still going to be coming under biologics. And so we need to get more biosimilars out there. and once the biosimilars are out there, you know, we will do a good job of it.

We just took Lantis off of our major commercial formulary and replaced it with Basaglar. Basaglar didn't come through the biosimilar pathway, but it's essentially a biosimilar. And, you know, we ended up replacing about 99 percent of the utilization of Lantis. And it's a much less expensive medication because we were able to get discounts in the form of rebates to reduce the cost associated with those.

So I'm a strong believer and I think that everyone in the industry can agree that the more biosimilars that we have available is going to be a very strong thing in terms of sort of reducing costs.

To go to Steve's point, those biosimilars come out, we're basically reducing the cost per quality adjusted discharge by simply decreasing the price that we have to pay for them.

MS. BRYANT: Just one other point about this because that life cycle is so different from what you see in other parts of the healthcare market. I mean, you think everybody has acknowledge that there are savings, but what tends to be sort of taken for granted and not fully appreciated is that those savings sort of are cumulative and explode over multiple decades.

So if you look back at like what happened with the development of statins for high

cholesterol, at the time that they were new medicines there was a lot of complaining about the cost in the sense that they were expensive. There's been academic work looking back at those molecules. I think there's Hasskamp, Chernu, I'm forgetting somebody, McKellar maybe is the other author, looked at like 19 molecules and said that just those 19 molecules, if you looked at, you know, the 20 years post the patent expiry, it produced like \$400 billion in savings or consumers. So there's a huge consumer welfare surplus that happens at the end of that patent expiry, and you don't have that for hospitals. You don't have that for surgeries. You don't have it for physicians.

So that's one reason that the pricing is so very different for prescription drugs.

MR. PEARSON: One of the things I wonder that I haven't heard people talk, I mean, some of literally the smartest people I know work for pharmaceutical companies. They're smart scientists, they're smart business people. So they see biosimilars coming and they're not dummies. So their corporate structure is based on a certain return on investment and revenue and profit margin, and it's very hard to leave that.

So with biosimilars coming, if I were in their shoes I would say I'd better bring my prices up as quickly as possible so that 30 percent off looks like what I was hoping to get otherwise, or I'd better do something else. But the business strategy doesn't go away, the search to use the existing legislative and regulatory framework to maximize the return.

So even though I also think that competition is always better than no competition, I'm a little bit less sanguine that -- again, that's probably because I've already experienced it. If we just go back four or five years, in the drugs for multiple sclerosis, their prices align well according to our metric with the added benefit to patients. Everything since then has been price increase on a year-on-year basis for the same drugs, so that now they're way out of that alignment.

So I'm curious whether we think -- because I'm asking you and maybe Troy, too, but do you not anticipate some reaction from the innovation community to try to continue to make those profits one way or the other, despite biosimilars?

MR. BRENNAN: Well, monopolies are monopolies and patents are monopolies and so, you know, they have a lot of discretion over the pricing associated with the branded medications and with new launches. I think if you look at it a little bit sort of historically what you had, if you go back to sort of 10

years ago, you had a lot of drugs that had come out through the physiological revolution that we had, including statins, in the '80s and '90s, and those all were going off patent. And there was an expectation of a very reasonable profit margin at the pharmaceutical manufacturers.

And so the only way you can really address that is either by increasing the prices on existing branded drugs or increasing the launch price. And that basically sort of got set in place sort in the '10-'11 period of time. Even in '12, though, overall as a country we had deflation in terms of the costs of medications because we had a lot of big drugs go off patent thanks to Hatch-Waxman and save the country a lot of money.

But you really caught up with the increasing price in '14 and '15. And as a result, the PBMs have had to sort of up the game in order to try to reduce the costs overall for our clients and be a lot more stringent with regard to the use of formulary and things like that. But at least us and everybody else reported that our clients saw about a 12 to 15 percent increase as recently as '14 and '15. Now in '16 and '17, that's down in the sort of 2 to 3 percent range.

So, you know, be that as it may, the pricing and the fact that people face a lot of this pricing when they're in a deductible phase is just making for a system that doesn't seem to me like it can persist exactly the way it's persisting right now.

MS. SHEINER: That's interesting. I'm just going to ask a question. So if you know you're going to hit your deductible anyhow, in some sense you shouldn't care, but maybe people think they do. Like they still see this big number and it feels expensive even if, you know, it's February, you're going to hit your deductible and basically it costs you nothing at the margin. But is it --

MR. PEARSON: Or our own data and data the IMS publishes, we've published several papers on this, shows both that the walk-away rate from an initial prescription increases about 20 percent when the medication's going to have a cost of over \$90 and that people go off -- stop taking their drug at a much higher rate when they face that kind of thing. And the sort of elasticity curve there seems to be somewhere between 90 and \$120, and then after that. And look, a lot of these people are paying 3- or 4,000 bucks for medications when they're in the deductible phase.

MS. BRYANT: Yeah, I mean, I would love to pick up on that because one of the themes I think you heard earlier was that, well, people are -- because of insurance or because of co-pay cards,

people's cost-sharing is reduced so far that they're insensitive to the cost. And I think actually that masks a lot of the real dynamics in the pharmaceutical market.

So we've had a couple things happening simultaneously. There's been a growth in the rate of generic use and generic cost-sharing is very low. Payers are really skilled at driving cost -- driving use to the lowest cost therapies. Right? So about a third of prescriptions, a quarter to a third, are free, co-pay zero for generics. So that's coming down, but the cost-sharing for brands has been rising really rapidly at the same time that you're seeing very large growth in high-deductible health plans.

And the way the cost-sharing works for patients who are taking a brand in the deductible is their cost-sharing is tagged to the list price, which is not actually the price that the insurer is paying. And in the case of insulin, for example, that list price might be twice the price that the insurer is paying. So you're charging patients an artificially inflated price in the deductible and you're taking a year's worth of cost-sharing and cramming it all into January.

So what does that mean? It means that for the small number of patients who are taking really expensive medicines, their cost-sharing is going through the roof. So it's very bimodal. You have like lots of people who don't have any problems because they're taking generics, it's going down, and then you have the small group of the sickest patients who are facing rapidly rising cost-sharing. And so that averages to it's been about flat, but that's sort of the old joke about averages, right?

MR. BRENNAN: I just have one point. In the murky world of sort of rebates, you know, we offered clients they were called point-of-service rebates, point-of-sale rebates. So basically, like for our 250,000 people at CVS, you get the rebate deducted at the time that you pay your -- at the pharmacy itself. And I think we're going to see more people interested in that because, you know, traditionally the rebates travel right back to the employer and then the employer decides what to do with the rebates. But as the deductible increases, more people are beginning to sort of see that it's important to have the rebate deducted at the time of sale.

MS. BRYANT: I mean, just kind of one more point here about why drugs are different from hospitals that I think is just worth keeping in mind. If you have a hospitalization, you need to get hospital care and you show up in January, and the cost of that care is going to exceed your deductible or maybe you're out-of-pocket for the year. You work out a deal with the hospital, you get your care, and you

pay it out over 12 months. No problem, right? If you can't pay it, the hospital wipes it off, it's bad debt, they're a hero, and they get a tax credit.

If you have a drug that you need that's going to put you over your out-of-pocket, you show up at the pharmacy in January, what do you do? How many families have \$5,000 in a savings account ready to pay for a drug in January? They don't have it. So we've taken all of that cost-sharing and put it into January. And if the pharmaceutical company offers you a cost-sharing assistance, a co-pay card, we're going to consider them a villain for having done it and run around the benefit design or else the patient doesn't get their care.

So I think we need to rethink how we're like characterizing this and what's -- you know, I understand that there are a lot of nuances here, but essentially we have to make it possible for people to survive in high-deductible plans and to get through the first few months of the year. And I think we're past the point at which we can say all cost-sharing coupons are just kickbacks. I think we have real problems in affordability and patients are needing help and manufacturers are trying to respond.

MS. SHEINER: That's really interesting. I never really thought about this idea of, you know, this smoothing through the year, but that makes a lot of sense. That'd be very difficult for a patient.

Let me talk about rebates again because the role of rebates is just confusing to me, frankly, and there's different rebates going to the consumer, not going to the consumer. And why are rebates such a big part of this industry? And Fiona was talking about the benefits of hidden rebates and I don't quite understand that that well and I was wondering if you could explain.

MR. BRENNAN: Well, I thought that that was a mistake on Fiona's part, but she might disagree with me on that. (Laughter) But, you know, rebates are very transparent to the people who are actually paying for the pharmaceutical benefit, that is the insurers or the employers that we have as our major clients. And they can do it several different ways. You know, they can go through a completely transparent approach and have the rebates go directly to them and then we're just paid fees and never touch the rebate.

We can do situations in which we say we'll guarantee this amount of rebate and then if we get more rebates than that, then we both share in the amount. And that's how there are some retained rebates.

But if we look overall at sort of the ways in which reduce costs, sort of what we do as a PBM, and we have all this on our website, you know, rebates are actually a relatively small portion of the overall decrease, but they make good sense.

You know, when Sovaldi's out there and it's the only hepatitis C drug, it's a situation where it's a single source brand, and that's a pure patent monopoly, there's nothing we're going to do about that. When Harvoni comes out and Viekira comes out, AbbVie and Gilead, it gives us a great sort of bargaining situation. And so we're able to sort of halve the cost. Now, I'm not revealing what our rebates were, but anybody can go onto the Medicaid website and find out what Medicaid best price is and it reflects the best rebating that's available.

So the reason why we don't talk about them sort of publicly is exactly why Fiona said, because we feel like that there may be sort of competitive loss as a result of doing that. But you know that when we basically did a deal with the manufacturers of Basaglar and moved patients off of Lantis onto Basaglar, the manufacturers of Lantis immediately going off for a much steeper rebate to ESI. ESI, us, Optum, we're in sort of cut-throat competition that's based completely, almost completely, on price, with employers and insurers who are backed up by very sophisticated consultants. So they all know exactly sort of what's going on in the rebating situation.

So the fact that rebates are murky, they're murky to people who are sort of outside the industry, but most people in the industry understand them pretty well.

MS. BRYANT: Well, can I just -- I think that there's a huge amount of negotiation that's going on and I think we would agree that the PBMs are really fierce negotiators and do a good job. The result of that, though, is that net prices after accounting for rebates for prescription drugs, net prices went up last year about 2.8 percent.

The problem with rebates is largely that the entire public debate is about the list price, which is not the price that anyone actually pays. Right? That's the problem, I think, is that we're having a public discussion that's not -- you know, we talk about reining in prices, all of the things you read are essentially about the list price, not about the net price. Because if you look at Troy's earnings calls, you know, they're suggesting that a third of their customers had decreases in spending last year. And their net spending is about like 2 to 3 percent. Right? And if that was clear to most people, we wouldn't be having

the huge amount of furor about prescription drug prices, I think, because that 2 or 3 percent includes all of the new orphan drugs, all of the fancy cancer medicines, all of the generics, all of the biologics without yet having biosimilar competition.

So I think that's essentially the problem. And it's not that we should make it public either because we would also agree that, I think it was said earlier, full disclosure of prices would actually lead to compression of rebates and higher costs. So we have to as a system work toward a more sensible discussion about what's really happening on net trends.

MS. SHEINER: I could ask you a million questions and keep this going forward, but I'm going to open it up to audience questions. We have mics coming around. If you have a question, raise your hand, stand up and tell us where you're from, please. Let's see, right here. Raise your hand.

MR. POSER: Yeah, I'm Carl Poser and I started a project that's trying to promote greater economic inclusion and equity. And my question is for nursing homes and hospitals we tried productivity adjustments through administrative pricing. And none of the talk here is about administrative pricings and I guess that's off limits. But could you do something that would encourage a little more productivity, like have a shorter patent for Medicaid?

So, in other words, subtract a year or two from the patent time if you sell to low-income populations so there would be more competition. Or is there something we can do with the patent system to calibrate it?

MS. SHEINER: I mean, I think one way of asking that question differently is, are the patents too long? Right? Does anybody think that the patents are too long?

MS. SACHS: I mean, even if the answer is yes, the response is sort of too bad, there's not a lot we can do about that under international law. So there are certainly steps we can step to reduce things like secondary patents and the grants of secondary patents for some of these products, but it is really, really tough to use patents as a lever for improving access. We can use other tools, many, many other tools, but patents I think have, for most academics, not really been on the list.

MR. BRENNAN: I would just say it's a creature of our law and in some ways patent law, and there are articles. Aaron's been writing about this. My daughter's been writing about this when she was at Yale Law School, about the fact that there are situations where the government basically sort of



walks in and invalidates the patent. And there's been proposals that have been raised about that.

For instance, hepatitis C in prisons, do we have to have sort of absolute respect for the patent law sort of throughout or should we be treating all these people at low cost in prison? From a public health point of view and from an equity point of view that would be an excellent thing to do because it's such a huge reservoir of hepatitis C infections.

But I think for now those views are seen as relatively sort of radical, but it just reminds us that sort of in this particular area, if people can't afford their medication, all bets are off in terms of where the government might go.

MS. SHEINER: Anybody else?

MR. SELLERS: Again, I'm Jordan Sellers. I'm a student at Howard University. I'm curious to know really in what we were just talking about, is there a way to explain healthcare from the perspective of saying why people are not getting their industry needs met? And they'll shop for a private healthcare plan as opposed to something that they can go and compete for this market that really says why people aren't going to benefit from that. And I don't know if anyone can answer that question, but I'm just curious that why people are going to start looking at the industry and how healthcare is being taught and maybe take their healthcare and privatize it.

MS. BRYANT: So I guess I'm a little confused. So you're talking about -- so most people do have private health insurance, so.

MR. SELLERS: So the idea is that there's always government intervention in terms of public policy and like where we're going to go with this whole debate recently about healthcare. But we're starting to see social scientists report that why people are basically saying there is no government public policy that's going to solve healthcare for those people and why people are saying that, you know, the trend is now showing in social science that they're going to privatize their own healthcare and say you know what, look at what we just did currently. And they keep bringing up healthcare again. So maybe it is a public policy question. I'm just curious and maybe why people are sitting there saying the government's not going to really regulate healthcare.

MR. BRENNAN: Well, I think, you know, Part D's a good example of sort of what you're talking about where it's basically sort of a government program, but it's administered largely by private

firms. And, you know, certainly it's solved a real problem in terms of making medications available for the elderly under the Medicare benefit.

I would go back to the paper that Richard and Richard presented since it was fascinating, and just note that there's a major assumption there that when there's a lot of reinsurance available, 85 percent reinsurance or 80 percent reinsurance, there's only 15 percent of private firms. So the private firms are just basically going to sort of back off and accept higher cost medications.

But I think that's a good view from an academic point of view and I was an academic for 20 years. But actually, every little bit of profit makes a difference to a for-profit firm, and so you're not going to give up on that 15 percent you've got there. And, in fact, the drugs that are listed in their table, the loss ratios associated with those are all over 200 percent, which means that basically almost anybody who's using those medications is costing the overall plan money.

So it's actually just the opposite of what they would infer, which is that often I'm the one as the doctor sort of recommending what is a high-priced drug because I say this is a matter, the sort of standard of care, it has to be on the formulary. And the people who are running the program saying do we really need to have this drug on? You know, Optum doesn't have this drug on. ESI doesn't have this drug on. So Acthar is a great example. No need for that medication really to be on, from my point of view, to be on a Part D therapy. But it's a protected class for MS and there's nothing you can do about it. If you don't put it on your formulary, the government's going to force it on the formulary.

So I think that, you know, if you take that assumption out, I think a little bit of it starts to sort of fall apart in terms of the overall MSIC analysis. I'm lucky that they're not on the panel up here to debate that. (Laughter)

MS. SACHS: And just to add really quickly to that, I mean, there are enormous equity questions here about access to care, access to insurance. So I think we would all have to say that if there were particular conditions which were more prevalent among the uninsured population than among other populations, it would be tough to justify investing in new drugs for those disease as a business proposition if the patients can't afford them.

And so I -- my background is in access to medicines and global health. I take that really seriously and I think it's one concern many of us have about the way the system leaves out groups of

people on race, gender, class lines.

MS. BRYANT: And just to build on that, I think one thing that's just worth noting, again about how prescription drugs are different is that prescription drug spending is really persistent year over year. Right? So if you have high drug spending this year, you're likely to have high drug spending next year. That's actually not so much true with hospitalization. If you get hospitalized this year, you might not next year.

And that's another thing to keep in mind when we think about the sensitivity of patients to cost for prescription drugs. If you take the case of someone who's got a chronic illness, like diabetes, they could be spending quite a lot on medicines this year and next year and every year without ever actually meeting their full deductible or their out-of-pocket costs. And so one of the problems for patients is that their sort of lifetime costs are so much higher with chronic disease because they're taking medicines year after year. And that does contribute to disparities in health outcomes and you see that underuse of treatment, you know, among vulnerable populations is much more severe.

And that's another indication, I think, that cost-sharing is a real problem and that we do need to worry about patient affordability. But, again, we have to think about it not just sort of in a blunt average, but think about it for the patients who are really suffering year after year and also for patients that are taking specialty medicines where we're asking to pay too much at one point in time when we really need to be able to spread it out.

MS. SHEINER: In the back let's take the last question that we have time for.

MR. HERSHEY: Thank you very much for giving me the last question. I'm Loren Hershey. I was a guest scholar here 30 years ago, but the subject was telecommunications. I said that earlier. I want to thank Brookings very much for what you're doing.

I'd like to take you up on the last point that you mentioned about diabetes and being on the medication protocol, if you will. I understand that there are some people who are able to find a way to leave that protocol, so my question is for the industry and for the scholars and for the academics. Is anybody looking at the incentives that are created for individuals to cease taking medications and finding whatever alternative pathway there is? I'm not advocating anything. I'm just very curious about the point. I know several people who have faced that dilemma.

MR. BRENNAN: Well, with Type 2 diabetes the critical thing is to lose weight. And if you lose weight you can go off the medications.

MS. SHEINER: So do high co-payments --

MR. HERSHEY: Are there any studies done on that?

MS. SHEINER: -- for diabetes medication leads to weight loss?

MR. BRENNAN: No. (Laughter) No, I think you had the causal (inaudible) in the wrong direction there. But, you know, to be serious, I think that most people -- I mean, I'm an internist and most of my patients who have chronic disease are going to stay on their medications. Pharma's come out with some great drugs recently. Hepatitis C is a great example, perhaps never a more successful drug in terms of reduction of morbidity and mortality, actual cures. But most people are going to be on their medications. And I think that those of us who are involved in this industry have got to figure out how we're going to make those affordable to people who have these chronic diseases.

MS. SHEINER: Great. Well, that's a great place to end. I want to thank the panel so much for being here. It was great. (Applause)

MR. WESSEL: Thank you very much for that last panel. It was fascinating. And for people who have stuck around with us all day, it's a real honor to be here with Senator Hatch. (Laughter)

Henry Waxman, of course, was a Democratic congressman from Los Angeles for 40 years. That is the presidencies of Ford, Carter, Reagan, H.W. Bush, Clinton, G.W. Bush, and Obama -- so many I had to write them down. He was responsible for a number major pieces of legislation, but the most relevant today, of course, is the Hatch-Waxman Act of 1984, which really led to the expansion of the generic drug industry.

There was a chart earlier, in 1984, 20 percent of the prescriptions were for generics. Today it's close to 90 percent. And I really do think that there's a consensus that the law which set up the current regime for managing and regulating generic drugs is largely responsible.

I do want to mention that since Henry has left Congress, he's a lobbyist for a bunch of interests, including the 340B Coalition, which is seeking to preserve a program that provides discounts for certain drugs for hospitals and clinics, and also has been a lobbyist for a number of hospitals in California, just so this is on the table.

Now, I'm tempted to say, Congressman, that if Andrew Jackson had had more foresight, Hatch-Waxman would have passed in 1884. (Laughter) But since very few of us were involved in this industry at the time that Hatch-Waxman passed, I wonder if we could start with just explaining a little bit the question that came up in the early one. What were the political conditions that led to this piece of legislation, and the coalition that led to the final product?

MR. WAXMAN: Thank you very much and I want to congratulate the scholars who made excellent presentations, and for Brookings to hold this forum. I feel like Marshall McLuhan in that Woody Allen movie. No, this isn't what I said. (Laughter)

Just a little clarification on what I'm doing now. I left Congress and I joined a firm called Waxman Strategies. I didn't establish it, it was already in place. My son had been working in the public relations area and he said to me, I will make you chairman of Waxman Strategies. And I said, well, that's pretty good, people could still call me Mr. Chairman, and I could get that deal if I stayed on the Hill.

And I said, I will work with you in a public affairs group, but I want complete say over who I represent. So, we don't just represent just a bunch of hospitals, we represent the public hospitals in California. We also represent Planned Parenthood. We represent a group that's been trying to establish a diabetes program, a 24-hour, 7-days-a-week diabetes program. So we do have a lot of clients.

We do have the 340B Hospital Association and the National Community Health Centers, so we represent a lot of the groups that I fought for when I was in Congress. I was one of the authors of the 340B program and so now I'm enjoying the fact that I can now continue my work in a different way. But in the 1980s, I was the author of a couple of bills that were pertinent to high drug prices and the situation we have today, but we didn't think about in that context.

In the 1980s, the Pharmaceutical Manufacturers Association, PMA -- it wasn't called Pharma then -- were concerned about the fact that a few years earlier, FDA had to not only establish the safety of a drug, but its efficacy, which meant more time was being spent for FDA approval. And they felt that they were being denied the full exploitation, the full reward for their patent because so much of the time was being spent at FDA. And they tried to get a restoration of the time lost at FDA for approval. There was a bill that they pursued solely for that purpose, and it got very far. It passed the Senate overwhelmingly, it passed the Judiciary Committee in the House, and they were so confident that it would

pass the House that it went on what's called the Suspension Calendar, which required a two-thirds vote, but no amendments were allowed.

Well, at that point, I teamed up with a young Congressman that was on my committee named Al Gore and we said, you know, that really is going to dramatically increase the price of drugs, and we didn't think that was fair to do that just to increase the price of drugs. So we went to work to keep that bill from getting the two-thirds majority -- it certainly had a majority.

After it lost on the Suspension Calendar, the sponsors of the bill wanted to get a rule, and a rule would allow it to be brought up and passed by a majority vote. All these intricacies of the legislative process are well known now that we see the reconciliation process being used by the Republicans to repeal and replace Obamacare, as best they can, using the reconciliation process.

They're using it because they can't get a bill through the Senate which would require 60 votes to stop the debate, even if they have the majority.

MR. WESSEL: Which is, as I recall, the way we got the ACA in first place.

MR. WAXMAN: No, we didn't.

MR. WESSEL: Yes, in the Senate.

MR. WAXMAN: No, that's not accurate. The ACA was passed by the Senate.

MR. WESSEL: Right, and it came back.

MR. WAXMAN: It didn't come back.

MR. WESSEL: After Scott Brown.

MR. WAXMAN: It didn't come back. It passed the Senate and the House passed an ACA version and we would ordinarily have gone to conference and brought one version. And we sat in the Oval Office with the President and we were quibbling, and we were only Democrats because Republicans weren't working with us. Well, it's just not surprising, we even see Republicans disagreeing on their replacement. But we were trying to figure out how to reconcile the differences between the House version and the Senate version.

At one point the president said, you have to stop fighting among yourselves because I might lose the 60th vote in the Senate, in the special election that was going to be held the next week. And that's exactly what happened. So the only way we could pass the ACA at that point was for the

House to take the Senate passed bill and pass that bill. And then we tried to correct it as best we could, some of the problems in the Senate bill, by using reconciliation.

MR. WESSEL: Fair enough. I didn't mean to -- let me get back to Hatch-Waxman. We're there.

MR. WAXMAN: Hey, Hatch-Waxman.

MR. WESSEL: You and Al Gore have won this big victory.

MR. WAXMAN: We won this victory and the bill was defeated. And the next Congress we said, let's look at the two issues: restoring the patent period, but also providing a pathway for generic competition. Now, the generic drugs had to go to FDA and go through the whole process of showing not that it's the same drug that's been on the market, but establishing the safety and efficacy of the generic, which may even raise -- well, I think it raised ethical questions, to have to go through that whole process again, and it was redundant and unnecessary. So we said, let's provide an abbreviated new drug application process for generics. And that was the basic framework of the Hatch-Waxman Act.

I appreciate those who wanted to call it the Waxman-Hatch Act. (Laughter) My mother called it -- may she rest in peace -- the Waxman-Hatch Act. But she also called the bills I authored with Senator Kennedy the Waxman-Kennedy bills. (Laughter) Just don't call it Haxman-Watch or one of those other combinations. (Laughter)

Senator Hatch was the chairman of what is now the Health Committee in the Senate and I was chairman of the Subcommittee on Health in the Energy and Commerce Committee and we worked out this framework. So we passed the legislation with the expectation we would have a balance. We would be able to have competition to lower prices and a greater incentive to develop new drugs.

Also in the '80s, we adopted another bill to provide incentives for development of drugs for rare diseases, the Orphaned Drug Act. And we looked at the problem as one where there were not sufficient incentives for the pharmaceutical companies to produce these Orphaned Drug Acts because the number of patients was so small that they didn't offer a big enough profit potential. So we worked on giving them the incentives to get as much profit as they could being approved as an orphaned drug. And those incentives were some tax breaks, but the big incentive was the seven years exclusivity.

We never envisioned that the Orphaned Drug Act would provide a process for the

manufacturers of these drugs to constantly evergreen their products, charge exorbitant prices when insurance companies in particular were willing to pay for the cost of the drug. And there has been a real problem in the Orphaned Drug Act of very high prices for drugs that we thought were not going to be profitable and were, in fact, extremely profitable.

MR. WESSEL: What about if I had asked you in 1984 if by 2017, do you think we'll have 90 percent of the prescriptions generics, would you have said, yeah, that's my plan? Or never happen? Or who the hell knows?

MR. WAXMAN: I would have said that I wouldn't know. I don't know what's going to happen within the next couple of years, let alone so many years down the road. The brand name companies and the generics were very separate organizations. And the brand name companies looked down their nose at the generics, even though the generic manufacturers produced a lot of the drugs that were being sold as brand name drugs. And today, if you would have asked me then would I have envisioned the brand companies and generics would all be intertwined, where some of the same companies are producing both brand and generic, I would have doubted that because of the hostility between the two manufacturers.

MR. WESSEL: What about the political climate on the Hill? Do you think that it's just over and the idea that there could be a Democrat in the House and a Republican in the Senate doing a bill on some aspect of prescription drug prices, one of these proposals or one of the others that are out there? Is that just impossible in the current climate?

MR. WAXMAN: Well, I've never operated on the basis that something's impossible. You just keep pushing the issues forward, and sometimes it takes time. And a lot of the legislation that I authored, that became law, took an enormous amount of time. The Ryan White Act was an issue that when we first discovered AIDS without even knowing the word AIDS in 1981, and then we finally passed a bill, I think it was by 1990. Or the regulation of tobacco where, in 1994, we had the tobacco executives tell us things that they knew weren't true, but it took us until 2009 to pass the legislation to regulate tobacco. So, nothing to me is impossible.

Nor do I think it's impossible in this year because there's a public clamor about the high price of drugs. So my team, some of whom are here with me today -- Bill Corr and Sophia Duong, Kristi



Martin's not here, and others that are working for Waxman Strategies are working on a proposal funded by some foundations to try to present to the Congress a way to frame the issue that could lend it to bipartisan support for -- not a magic bullet, because there is no magic bullet, but to look at the issue. What is driving the costs? And how we might directly and indirectly impact the driving of those costs.

And they're very different than the discussion you read about. There are many members who are very attracted to the idea of saying, let's import all these drugs because it's cheaper elsewhere. Well, that sounds good. It sounds easy and people understand that if they go to Canada, they pay less for the drug. If they could import the drug from Canada at the price they would pay in Canada, and then pay the same price here, that solves our problem. What they miss, however, is that the drug manufacturers are not going to produce the amount of drugs for Canada that's going to also supply the market in the United States.

And then, of course, it could look like it's coming from Canada, but it could have been made somewhere else. It could be a counterfeit drug and it's going to be an enormous burden on the FDA to decide whether it is a drug that we're going to allow to be sold in the United States, particularly on the safety side of it.

So that's a magic bullet that everybody liked, but people forget that we already adopted it. We already adopted a change in the law to allow importation of drugs, with the qualification the FDA has to approve the safety and efficacy of these drugs that are being brought here. So, people forget that and then they say, what we need to solve the problem is importation.

Now, importation could solve some problems and we heard about that earlier. If there's a shortage, if there's a lack of competition, but can be established as a generic drug, both here in the United States, but Europe and other places. But it's not the answer. A lot of people say, what we need is the negotiation for Part D. Well, I think that's right, but it's hard to negotiate with somebody who has a monopoly. And it's also hard to negotiate when you can't base a formulary on what is the better drug. We don't have some of the work that Steve Pearson's doing on ICER.

We thought PCORI might do that when we were adopting the ACA, but that got weakened very, very fast. So we need to find out the relative value of a new drug, and that could be the basis for formularies that could be based on a rational calculation. There are a lot of issues, we need to

break them down. We're coming up with a report, probably in a matter of weeks, we hope, that the Commonwealth Foundation and the Arnold Foundation and all of us at Waxman Strategies are going to put out that will look at some of these issues.

When I look at the Congress, not all of the issues are in the same committee. The patent issues are the judiciary, a lot of the issues are in the health committees. So there are different committees that have different aspects of this, but if we can break it down and have Democrats and Republicans sit down, we're not going to give solutions, but we're going to say, these are the drivers. What are some of the ways we can deal with it? What do you want to work on? What can you pass for the near term? What can you pass for the longer period in the future to bring back the balance we thought we achieved in the 1980s, to give the incentives? Because we do need incentives for the investment on developing drugs, but also we need the competition.

MR. WESSEL: Well, it's refreshing to have a former member of Congress answer a question that we might actually be able to get something done which, frankly, my recent experience is that most former members of Congress throw up their hands and say, it's not like it used to be. So I appreciate the spirit in which you answered that question.

But I want to go to the last part, so do you think basically, as Louise and others have pointed out, there is a trade off here. You want to give Pharma an incentive to develop new and wonderful drugs. They're curing diseases that our grandparents died from, but we don't want them to have too much more than necessary monopoly profits, and we don't want people to be unable to afford these meds. So are you suggesting that we have the balance wrong? That, over time, we've gotten too much on the incentives and not enough on the other side?

MR. WAXMAN: Well, I think we've got the balance out of whack for a number of different reasons. We don't just have problems with the rollout of a new brand name drug, we have high-priced generic drugs. If they're the sole source drug, what can we do to reinvigorate the generic side of things?

We have anti-competitive behavior with the Pay for Play, where the brand company will say, we don't want a generic.

MR. WESSEL: Pay for Delay.

MR. WAXMAN: Pay for Delay, right. Pay for Play is the way Congress works. (Laughter) I

take that back if you want that camera working.

MR. WESSEL: I'm relieved that you have a little bit of cynicism left. (Laughter)

MR. WAXMAN: So there are issues that we need to approach to what is the balance we want? What is the problem that's driving up the price? What can we deal with on a bipartisan basis? What can we get done? And I think it has to be bipartisan. It was bipartisan in the '80s, it was bipartisan when we added the Medicaid coverage of drugs. It wasn't bipartisan on Medicare Part D, but it -- well, I guess it was. It just wasn't that many Democrats.

MR. WESSEL: Right. (Laughter)

MR. WAXMAN: But we need to get some more rationality in the system.

MR. WESSEL: And how would you evaluate the current state of the FDA? Are they doing a good job? A bad job? Could do better if they had more money? Not aggressive enough?

MR. WAXMAN: Well, I think they could do more if they had more money and I think they've been underfunded. I don't like the idea of the user fees, even though I authored the original user fee, because I think it's a public function to approve drugs and for the FDA to decide safety and efficacy. And when you have the brand name companies, which was the original user fee, paying a fee for having their drugs evaluated, it doesn't sound great. But I think the FDA has handled it well.

One thing I don't want to see, and I don't think we will see, is that FDA should only go back and approve the safety and not the efficacy. And we have people expressing that point of view. I think President Trump expressed that point of view, but that's going to take a bill that's going to have to have 60 votes in the Senate, and I don't think a lot of people in the Trump administration would want to have the FDA do that job.

But the FDA -- and this is one of the concerns that I had in the 21st Century Cures bill -- must have the ability to follow the science. FDA decisions have to be based on science, not on politics. And I took issue when the FDA had the science to approve the day-after drug for reproduction, but didn't because even though they had the science, they didn't want to go forward with it because of the politics of it. FDA needs to be science-based and science-oriented in their decisions.

MR. WESSEL: And what about the antitrust authorities? I mean, Fiona suggested basically that they're not doing their job adequately. Do you agree with that?

MR. WAXMAN: I think there's a lot of anti-competitive behaviors, whether it's antitrust that could solve the problem or not remains to be seen. We had the Federal Trade Commission look at the Pay for Delay and they made a very strong recommendation not to allow it. It went all the way to the Supreme Court, and so now we have to look askance when you have a Pay for Delay, but why should we have a Pay for Delay? Who benefits?

I know that the argument, both from the generic side and the brand name side, is you're avoiding litigation and it makes things easier, dah, dah, dah. But it is clearly anti-competitive and we need to eliminate some of the anti-competitive aspects in the law.

MR. WESSEL: Richard -- or I'll keep going.

MR. WAXMAN: Or I'll go home. (Laughter)

MR. WESSEL: No, no, we don't want to do that. We don't want to do that.

MR. WAXMAN: Really?

MR. WESSEL: Thank you, the mic is coming. Richard Frank?

MR. FRANK: Richard Frank. I'm going up to your last point on the antitrust, which is -- and I think I agree that more could be done -- antitrust is really cumbersome, right? It's rule of reason, it's very costly, it's very long. Aren't there legislative things or regulatory actions that we could take that would at least take some of the burden off the antitrust authorities?

MR. WAXMAN: Well, I think that's a good question and I want Democrat and Republican members of the Congress to look at that issue and come up with some ideas that they feel comfortable supporting on a bipartisan basis.

MR. WESSEL: Fiona made a really good point that, on one hand, we want patients to have some skin in the game so they make good choices, but, on the other hand, we don't want to discourage them from taking medication. So do you think we've gone too far or not far enough in giving patients some share of the costs of prescription drugs?

MR. WAXMAN: Well, I don't know that it can be answered in a general statement because you have different situations with different drugs. But I think when we are trying to restore a balance, I think we have to keep in mind what is going to enable the patients to get the drugs they need? And the coupons are a pretty clever way of keeping us paying for higher priced drugs than we need to,

though I would like to have that sorted through. I don't think we have a lot of transparency in the way PBMs operate. I'd like to see more there. Those are my views, but we have to have sitting members think these issues through.

MR. WESSEL: And how is this going to work? Do you think that if you go to Congress and say, okay, I've got money from these foundations, I've come up with a diagnosis of the problem, and suggest that the shortcomings of Congress are they don't understand the problems, so if you present them with --

MR. WAXMAN: That's a good starter. (Laughter)

MR. WESSEL: The diagnosis that the spirit of bipartisanship will be rekindled on the Hill and your heirs in Congress will realize that the voters are so angry about prescription drugs and this might be one thing that they could agree on, that they will bury the -- take the knives out of each other's backs and we'll actually get some legislation? Is that kind of the game plan?

MR. WAXMAN: Well, I don't think it's that. I think you sit down and say, what's driving up the price of drugs? Well, anti-competitive behavior is one of the drivers of cost. Orphaned Drug Act is a driver of cost. Sole source drugs is a driver of cost. We have high launch prices, but then annual increases. Those are problems. What can we do about it?

The biosimilars is a very big issue that breaks my heart because we had worked for a pathway for biosimilars and the whole issue got hijacked with the ability to have an inordinate amount of time for protection against competition, and the evergreening problem that goes along with it. Well, is Congress happy with that? Is that a good way to have settled the issue? It isn't what President Obama had said he wanted. That's what the bio companies wanted, but then what could we do? Because that's driving up the cost and the public does want incentives. But the benefit of competition, we're not getting the benefit of competition.

MR. WESSEL: Fiona?

MS. MORTON: I just wanted to correct the impression that you might have given everyone by saying that I said the antitrust authorities were not doing their job.

MR. WESSEL: Oh, sorry.

MS. MORTON: Okay. So I think they are doing their job, but I do think they could do

more. And it is certainly a problem when we have legislation that everybody's trying hard to make right, but then, after the fact, firms figure out what little loopholes are in it that they can exploit. And that's, I think, when you can have a complementary effort of legislation and antitrust enforcement. It's very clear the legislative history of Hatch-Waxman was not to allow Pay for Delay. And so then you can go in and that's part of the anti-competitive case.

But Richard's right, it's slow. It's slow. And it would be nice to fix some of these problems quicker.

MR. WESSEL: Peter? Fiona, could you just bring the mic over here, and there's a gentleman kind of right behind you.

SPEAKER: I'm curious, of the proposals that you heard today, what do you think are the least politically sellable and the most politically sellable?

MR. WAXMAN: Well, I'm not going to guess. I'm not going to guess. They're all very well thought-out proposals. They're excellent recommendations and they ought to be considered. And I think that the authors of the papers thought through what might be practical under the circumstances, so let's let the policymakers think it through. But we're trying to frame the issues in this report to help members of Congress in the House and Senate to look at these issues anew.

Like price information would be very helpful. What are you getting for paying more for the drug? What is it that would make this drug more valuable when it comes on the market than a drug that's already on the market? What added value? And even some of the pharmaceutical companies say this would help. It would help because we think that we get priced out by a drug that doesn't do as much as the drug we already have on the market. Somebody talked about insulin as maybe an example of that.

MR. WESSEL: Steve?

MR. PEARSON: Thank you for your comments. I had a question about the politics, also, of actually what I thought was emerging before the presidential election. As people talked about drug pricing, there was the concern about the prices and the effect, the cost on the health system, and then there was the part about out-of-pocket costs. And as I'm sure you remember, Secretary Clinton's campaign suggested that there would be caps on out-of-pocket costs and approaches to making sure that prices and costs for the whole health system were brought into a reasonable range.

Going forward politically, do you see that kind of linkage of a law that would address out-of-pocket costs as well as the structural issues around pricing coming together? Or would those be completely separate issues?

MR. WAXMAN: I think a cap on out-of-pocket costs would probably drive up insurance costs, so that everybody would be sharing in those cost increases. But that doesn't necessarily produce a reduction in the prices for the drugs, but it's one way of handling it.

Look at what we've done under Medicare Part D. We pushed people through the doughnut hole fast, so that the government pays mostly for the reinsurance of the cost of the drug that people had to pay for, more out-of-pocket, in order to get through the doughnut hole. So that was not an ideal solution. We've got to figure out not just to protect the person who's paying for the drug, but the system is paying for the drug, as well.

MR. WESSEL: But he was asking, basically, do you see some political appeal to the out-of-pocket cap as a way to get legislation through, even if you don't think it's a great idea?

MR. WAXMAN: Well, I think it certainly has its arguments and a lot of people will find it very attractive to do that.

MR. WESSEL: Rachel?

MS. SACHS: So I'm curious about something you mentioned --

MR. WAXMAN: Yes?

MS. SACHS: -- about the changing nature of the industry structure. So, at the time of Hatch-Waxman you said this is a compromise between two separate parts of the industry, the branded and the generic firms. But we've seen a lot of intermingling and these days the biologics and the biosimilars are the same companies oftentimes. How do you see that affecting, if at all, prospects for other compromises going forward from the political economy perspective?

MR. WAXMAN: Well, I think we have to now ask why aren't the generic companies producing more generics? And what would reinvigorate the competition from the generic companies? And I think that's a good question to ask and to try and figure out some answers to.

I think that it's not just the brand companies. We think of the brand companies, they develop the new products, they have the patent, they have the monopoly. By the way, in the 1980s, we

didn't have companies that had the monopoly because of a patent, charge whatever the market would bear. In fact, many of those pharmaceutical company executives thought that would be unseemly. Something has changed. It's not the law, but there's something changed in our culture that says you've got the power to get every last cent out of this, just go for it. I don't know if that's a Wall Street issue, but it's nevertheless, I think, a factor in the high price of drugs.

MR. WESSEL: Gentlemen -- Anna can you give the mic here? This guy. Stand up so -- no, no, right here. No, we'll go to you next. Tell us who you are?

SPEAKER: Hi, I'm Jonathan, again. I was wondering if you view the BPCIA as a successful successor to the Hatch-Waxman Act in terms of an act that was developed in the spirit? And if not, how can a more efficacious biologic/biosimilar pathway be developed? Is the burden on Congress or is it on the FDA?

MR. WESSEL: All right, no acronyms here. So what the hell is BPCIA?

SPEAKER: The Biologic Pricing and Innovation Act.

MR. WAXMAN: Oh, well, I think we needed to figure out a pathway. It's a little different for the bio products than it is for the small molecule products. They don't have to just show they're the same drug and then go right on the market through an abbreviated process. That's more complicated and all of us wanted FDA to figure this out, and there's still more for FDA to do to get these drugs through. And the key will be the interchangeability of a new drug so that the price will actually come down.

But even if you get another bio-drug competing with an existing bio-drug that helps, but it's not the same as the interchangeable and that's part of the pathway issue. But in that legislation, the Hatch-Waxman had 5 years of exclusivity, this law provided 12 years of exclusivity. Exclusivity is better than a patent because you can break a patent, but exclusivity means they cannot even consider another drug to compete. So that's just something to keep in mind and it's one of the troubling aspects of it.

MR. WESSEL: The patient gentleman here?

MR. WILKERSON: John Wilkerson. I'm a reporter at Inside Health Policy. I have a question about the Independent Payment Advisory Board. I won't get into the intricacies of how that works, but suffice it to say that the power of IPAB is expected to land in the lap of the Trump administration this year. If that happens, do you see this as spurring action on drug prices either in



Congress or within the administration? Is this a good opportunity to do something?

MR. WAXMAN: Well, IPAB was one of the ways to hold down costs of healthcare and President Obama wanted every possible way to hold down healthcare costs because he said we're going to expand healthcare for those who didn't have the ability to buy insurance in the individual market. We wanted to make changes in the overall system that would hold down costs and when Medicare asked to hold down cost it becomes very effective in the private insurance market, as well.

But it's controversial and I know that it's going to be a point of contention. It provides the ability to come in with a proposal of how to hold down some costs in Medicare that could be picked up elsewhere. But the most controversial part of it is that Congress can be read out of it if they can't come up with an alternative to the proposal from IPAB and, more importantly, the proposal from the administration because you don't even have to have IPAB. It's never probably going to be established, the way it looks now. But the Secretary could come in and say, this is what I think could hold down costs and let's go after pharmaceutical prices.

Well, that's pretty bold. And then to have it go into effect without Congress approving it ruffles the feathers of a lot of congressmen.

MR. WESSEL: Wouldn't they have to appoint people to IPAB before it can actually --

MR. WAXMAN: No.

MR. WESSEL: They don't?

MR. WAXMAN: No. IPAB was to recommend to the Secretary some ideas --

MR. WESSEL: Oh.

MR. WAXMAN: -- that the Secretary could propose that would go into effect unless Congress came up with something that achieved the equivalent reductions.

MR. WESSEL: Hmm, interesting. That's a lot of power to Tom Price. I want to thank everybody for coming today and particularly to our panelists. (Applause) To our colleagues Kerry Grannis and Peter Olson and others who helped us, and Lilia Cherchari.

One favor, as you leave, if you'd take the papers and coffee cups that are at your feet and put them in the trash barrel on the end, our staff would appreciate it. Again, thanks to everybody for coming. (Applause)

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