THE BROOKINGS INSTITUTION

FALK AUDITORIUM

FOSTERING COMPETITION IN THE PHARMACEUTICAL DISTRIBUTION CHAIN

Washington, D.C.

Wednesday, June 14, 2017

PARTICIPANTS:

Introduction:

DANA GOLDMAN
Leonard D. Schaeffer Director's Chair, USC
Schaeffer Center for Health Policy & Economics
Distinguished Professor, USC School of Pharmacy and Price School of Public Policy
Nonresident Senior Fellow, Center on Health Policy, The Brookings Institution

Presentation of Paper: "The Flow of Funds in the Pharmaceutical Supply Chain":

NEERAJ SOOD
Director of Research,
USC Schaeffer Center for Health Policy & Economics
Vice Dean for Research and Professor,
USC Price School of Public Policy

Panel 1: Fostering Competition in the Brand Drug Distribution Chain:

Moderator:

PAUL B. GINSBURG
Senior Fellow and Director, Center for Health Policy
Leonard D. Schaeffer Chair in Health Policy Studies,
The Brookings Institution

Panelists:

ED ADAMCIK
Chief Pharma Trade Relations Office
Express Scripts

MATTHEW EYLES
Executive Vice President, Policy and Regulatory Affairs
AHIP

JENNIFER BRYANT
Senior Vice President, Policy and Research
Pharmaceutical Research and Manufacturers of America (PhRMA)

LYNN QUINCY
Director, HealthCare Value Hub
Consumers Union

Presentation of Paper: "Would Price Transparency for Generic Drugs Lower Costs for Payers and Patients?":

STEVEN M. LIEBERMAN
Nonresident Fellow, Center for Health Policy
The Brookings Institution

Panel 2: Fostering Competition in the Generic Drug Distribution Chain:

Moderator:

DARIUS LAKDAWALLA
Professor and Quintiles Chair in Pharmaceutical Development and Regulatory Innovation
USC Schaeffer Center for Health Policy & Economics

Panelists:

THOMAS MORIARTY
Executive Vice President, Chief Policy & External Affairs Officer, and General Counsel,
CVS Health

B. DOUGLAS HOEY
Chief Executive Officer
National Community Pharmacists Association

CHRISTINE SIMMON
Senior Vice President, Policy & Strategic Alliances,
and Executive Director, Biosimilars Council Association for Accessible Medicines

MATTHEW EYLES
Executive Vice President, Policy and Regulatory Affairs
AHIP

* * * * *

P R O C E E D I N G S

MR. GOLDMAN: I think we are going to get started on time. And I'd like to begin by welcoming you all to today's event, which is Fostering Competition in the Pharmaceutical Distribution Chain. This conference is a joint product of the Schaeffer Initiative for Innovation and Health Policy, which combines the expertise and collaboration between Brookings and the Schaeffer Center at the University of Southern California.

My name is Dana Goldman. I am the director of the Schaeffer Center. I'm also part of the Schaeffer Initiative team. And I'd like to especially thank Leonard Schaeffer, who is not with us today, for making today's event possible. And also extend my thanks to Brookings for hosting this, and providing an opportunity to have this discussion.

I think a lot of you I'm sure were riveted to your television screens yesterday to watch yesterday's Senate HELP Committee hearing, and the expert testimony; maybe you were watching Jeff Sessions, I don't know. But I think if you see that, that was organized around a similar topic, and as a policy wonk like myself, it's a little disappointing, because there seems to be a lot more smoke than light right now, on what we are going to do about drug pricing, and also the flow of funds.

And so I'm really pleased that my colleagues and I are able to host this event, and actually what might be some policy solutions to realize more value from the supply chain. And you know, when we think about the supply chain, we are talking about how money flows from both the patient's pocket all the way up to the manufacturers responsible for producing the drugs.

And just a word about format; we are going to have two panels today, one is on brands and the other is on generics. The issues are quite different in both cases. In the case of brands, we are often talking about higher-priced drugs that have some -- that account for about two-thirds of spending, but only about 10 percent of prescriptions, and there's concern about high prices, but also about the value and how we think about rewarding innovation.

On the generic side, that dominates the prescriptions in the marketplace, probably about 90 percent of them, and that's a market that works surprisingly well, in my view with a few very notable exceptions that have really monopolized the attention. And so figuring out how to get these right, without destroying what works in the market, and I do think some things work, is really quite important.

With that, I want to turn it over to my colleagues. Paul Ginsburg will be moderating the first panel on brands, and I know he's going to be excellent in that role. Paul is a colleague of mine at USC, but he also leads the Brookings Schaeffer Initiative, and he holds the Leonard D. Schaeffer chair here at Brookings.

But before I invite Paul up, we are going to have a presentation on the flow of funds in the pharmaceutical distribution system by Neeraj Sood. Neeraj, is the director of research at the USC Schaeffer Center. He is also my dean, so I have to be nice to him. But I think very importantly, he brings an expert voice. And, again, as I said, there's a lot of smoke and not much light. He really is starting to shine a light into this area. He has also done extensive work with the National Academy of Sciences, thinking about novel strategies to eliminate Hep C, so I can't think of someone better suited to start us off, than Neeraj. Thank you. (Applause)

MR. SOOD: Dana, thank you for the introduction. And welcome everybody, and thank you for being here. So, the goal for my talk today is, let me first start by the disclosure, since the talk is about following the money. So, this research was funded by the Schaeffer Center, and by Amgen. All views expressed here are mine.

So, I'm going to talk about two things. One is just explaining how drugs reach from manufacturers to consumers, and who were the different players involved in the supply chain. And the second is, I'm going to give you a big-picture idea of who is making how much money.

So, kind of the idea is, if you as a consumer are spending $100 on drugs, how is that $100 split across different layers in the supply chain, and how much of that $100 ultimately reaches the manufacturer, who is one who is kind of manufacturing the drug or came up with the drug.

So, if you start with the drugs, they start from the manufacturer, the manufacturer then sells the drugs to a wholesaler, the wholesaler in turn sells the drugs to a pharmacy, and finally you go to the pharmacy, to the CVS, and you get the drugs. So, the parties who were kind of touching the drugs in the supply chain, are the manufacturer to the wholesaler, to the pharmacy, to the beneficiary, and this seems like a pretty straightforward supply chain, but when you start looking at the flow of funds, things get a lot more complicated.

So, you as consumer have insurance and so you are paying, when you go to the

pharmacy, you are paying the copay or a cost-sharing to the pharmacy when you get the drug. At the same time you are paying premiums to your health insurance plan, and your health insurance plan is using some of these premiums to pay for the drugs; your employer, which in this case s USC for me, is also paying premiums to the health insurance plan.

The pharmacy is paying drug acquisition cost to the wholesaler, and the wholesaler is paying wholesale price to the manufacturer, but now, there's another party called the PBM [pharmacy benefit manager], the manufacturer also sometimes directly assists consumers through copay assistance programs, or patient assistance programs.

What PBMs do is they get rebate in terms of the flow of funds from manufacturers, and they also get money from the health plan. They pass on some of these rebates back to health plan, and they take the money from the health plan and also pay the pharmacy for drugs. So, you can kind of see that the flow funds here is fairly complicated with a lot of money changing hands, and a lot of different parties involved.

So, the reason this money is changing hands is because these different parties are providing different services, and it's an important context to think about when we show you the numbers in the end, about who is making how much money, you should be thinking about who is doing what in the supply chain, and you should be juxtaposing the two things.

So what the health plans do, is they provide you prescription drug coverage, so they are taking on some of the medical risk. If you have high prescription drug costs, it's the health plan who is responsible for them.

Similarly the pharmacy is responsible for retail distribution, so they are the ones who have the brick and mortar stores. They are the ones who take on some of the inventory risk in terms of keeping the drugs, and if the drugs aren’t sold then, you know, that's their loss. Wholesalers also take on some inventory risks, but typically they take the drugs from the manufacturer and quickly kind of supply them to the pharmacy.

PBMs are in some sense pure middlemen that they don't take on any inventory risk or medical expenditure risk, what they do is to negotiate prices. They negotiate prices with the manufacturer, and also they negotiate prices with pharmacies, so in that sense they negotiate prices, they

keep some of those price savings and then pass some of them back to the health plan.

And finally the manufacturer is the one who first came up with the drug through R&D, and then is responsible for selling the drug through marketing, and actually producing the drug. So, they take on huge risks in terms of, you know, if the clinical trial is not successful they bear the cost of that, or even once a drug is successful, if health plans don't cover the drug, then they are -- you know, they are taking a loss on the drug.

So, what we are going to do is, we are going to use this conceptual framework that we had before, and then first we are going to identify who are the players in each market segment, so who are the top PBMs, who are the top retailers, who are the top manufacturers, health plans, and so on.

And fortunately for us, a lot of these top players are publicly traded, and publicly traded firms routinely disclose financial statements to the Securities and Exchange Commission. So we are going to use those financial statements which are publicly reported to look at two things. One is gross profits, so here, what gross profits capture is basically the revenue that comes in less your cost of goods sold.

So, let's look at, say, gross profits for wholesalers, the revenue they get is from pharmacies, or from the retail segment, because the retail segment is buying the drugs from the wholesalers, so their revenue is whatever money they got from the retail pharmacy, and their cost of goods sold is whatever money they gave to purchase the drugs through the manufacturer.

So, you can see that by looking at the gross margin, you are basically looking at the total markup of the wholesaler, which is: how much money did they keep in the middle between the pharmacy and the manufacturer, so between the player up the supply chain, and below the supply chain.

And now what do you do with this money? Some of this money you spend on operating costs that, you know, you need to have your warehouses and so on, and the other part of the money you keep as profits. So, that money that you keep as profit is what we call net profits. So, financial statements report both things, they report gross profits and net profits. So once we have this information and you combine that with the conceptual framework we had before, we can kind of paint a picture at a big-picture level, who is making how much money, and who is keeping money along the way in the supply chain.

So if you look at the profit margins, not surprisingly manufacturers have the highest profit margin, because they are the ones who are doing the R&D and making the drug. The other two players who have high profit margins are health plans and pharmacies at about 20 percent each because, again, they are taking on risks. Health plans take on medical risks, pharmacies take on inventory risk, PBMs who are pure middlemen make about 6 percent, and wholesalers have a gross profit margin of about 4 percent.

So if you take these gross profit margin numbers and combine them with the conceptual framework, what you get is, if a consumer who is insured goes to, say, CVS, a retail pharmacy and guys a prescription drug, so out of the $100 in spending by this insured consumer on part of the consumer as well as on part of the health plan: about $19 are going to be kept by the insurer. About $5 are going to be kept by the PBM, about $15 are going to be kept by the pharmacy, and $2 are going to be kept by wholesaler, and what remains is the $58 that goes to the manufacturer, and what the manufacturer does with this is about $17 goes towards cost of goods sold or production cost, and about $41 goes into marketing, R&D, profits, and other operating costs.

Now, if we can kind of paint the same picture for brands versus generics, we are going to have a generic panel after this, and these numbers are not directly from SEC statements because the SEC statements don't break out revenues by brand versus generics, so these are based on industry reports.

So, I think the key point here is that generic manufacturers, even though they have, and it makes sense that they should have lower profit margins than branded manufacturers, they still have pretty high gross profit margins, so they are still at 50 percent despite not having any expenses for R&D, and so on.

The other kind of important thing is that the middlemen, which are the PBMs, pharmacies and wholesalers, they make much more money on generics compared to brands, and maybe this is the reason why 90 percent of the prescriptions in the U.S. are generics, because there is a clear incentive for the middlemen to push generics compared to brands.

So, basically if you now take these gross profit margins and then do the same calculation what would happen to $100 spent on a branded drug, versus what would happen to $100 spent on a

generic drug, what you get is that PBMs will make, say, roughly $7 on a generic, compared to $2 on a branded drug. So again much higher incentives for PBMs to have generic volumes, similarly pharmacies have a lot more market power here, they make about $32 on every $100 spent on generics, compared to only $3 on brands.

And wholesalers also capture about $8 on every $100 spent on generics, compared to $3 on brands. So you can see that all the middlemen have stronger financial incentives to push generic sales.

Now you can kind of look what do net profit margins look like. So these are not the total operating costs for the middlemen, this is the actual money they give back to their shareholders, so this is the actual returns to shareholders of these publicly-traded firms.

So manufacturers have a net profit margin of about 26 percent, wholesalers have a very small net profit margin of 0.5 percent, pharmacies have net profit margin of 4 percent, PBMs have a net profit margin of 2.3 percent, and health plans have a net profit margin of 3 percent.

So, if you take these numbers from the SEC filings, and then again do this thought experiment, that if a consumer spends $100 on prescription drugs, how much of this is in some sense pure profit for people in the supply chain? And the answer to that is: for every $100 in spending, you get $23 in net profits for different players in the industry.

And how is $23 split across various players? Insurers make about $3, PBMs make about $2, pharmacies make about $3, wholesalers make $0.30, and manufacturers make, or the people who do manufacturing and R&D make about $15.

So, in some sense this is where kind of the easy part of my talk stops, that this is kind of the descriptive part of the talk, that who is making how much money, how does the market work? The more difficult question is, is any player making more money than they ought to be? Is any player making excessive returns, and what should we do about it?

And that is where I think, you know, the panel and the moderator come, that they are going to answer that question, or they are going to debate that question. But to just kind of start the discussion going, or the debate going, I have a few thoughts on that.

So, if you are thinking about, is any player making excessive profits, maybe there are like

three things you could do: you could compare the profit each player is making to actually what each player does and the risk they take, so players who take on more risks should be making more profits.

You can compare profits to other "similar" industries, and here I have similar within quotes because it's very difficult to come up with what industries are similar. You know, that depends upon their business model, it depends upon the risk they are taking and so on, but I still wanted to give you some numbers on what this looks like.

And finally, you can evaluate, as economists we say, you make a lot of profits, if there are monopolies, if you have market power, so you can look at kind of degree of competition in the market or the degree of concentration in the market. So, if you look at the risk that different players take, manufacturers probably take on the highest risk, so they take on the R&D risk of all the clinical trial activity in coming up with the drug, and then take on the sales risk of actually selling the drug once they've produced it.

Wholesalers and pharmacies take on some inventory risks, so that is basically, they purchase the drugs, and then if the drugs are not sold, that inventory is their risk. And insurers take on medical risk, so if they have a consumer who purchases a lot of drugs, the insurer is just getting a fixed premium from this consumer, and they are responsible for the excessive medical costs.

PBMs here are pure middlemen, as I said, they are basically negotiating prices, so they are not actually taking on any risk. They don't touch the drugs, they basically negotiate who is going to get how much, and they take a cut in the middle.

If you look profits of what we've done is kind of compared branded and generic manufacturers to others in the manufacturing industry, and you can see that these are fairly disparate industries, so I don't know if this is a valid comparison. For example, we are comparing manufacturers to manufacturers of auto parts, semiconductor, software, and so on, but at least among manufacturers it seems that the net profit margins or pharmaceutical firms are higher than those of others in the manufacturing sector.

We see that drug wholesalers make, you know, a little less than food wholesalers, and we see health insurers have net profit margins lower than other insurers. And we see, PBMs was a tough thing; that you were like: who do we compare PBMs to? And so the best example we could come up with

was realtors. That, you know, it's like a realtor who matches a buyer to a seller, so PBM is matching the health plan to a manufacturer, the only thing is that, you know, with the realtor I know what my seller is selling at, and what my buyer is buying at, with PMBs it's more complicated because they negotiate rebates, but I don't kind of see the rebates, or either parties might not see the full rebates.

But it seems PBMs are making lower net margins than real estate. And similarly pharmacies are kind of making more margins or higher margins than several other retailers, other than, you know, building supplies. So it seems Home Depot makes more money than CVS.

So when you look at the markets, the last question was, you know: are these markets highly concentrated? And the answer is, yes. So, the top three PBMs control about two-thirds of the market, so that by, you know, traditional, antitrust standards would be, FTC standards would be highly concentrated markets.

The top three wholesalers control 80 percent of the market share, and the top three pharmacies control 50 percent of the market share. Manufacturing is less concentrated, but in some sense concentration is less important here, because manufacturers have patents on the drug and market exclusivity granted by the FTA, so by design, or the government is in some sense granting them some market power.

Most players also have some questionable practices, I'm not going to go into details of these because I have 30 seconds left but, you know, manufacturers use -- sometimes are accused of using aggressive promotion practices, health plans, sometimes charge consumers more than the actual cost of acquiring the drug, so you are paying the health plan a premium and the copay on your drug could be higher than the actual cost of the drug, so that doesn’t seem fair.

Pharmacies seem to -- there seems to be, you know, some market power there, that different consumers pay different prices to pharmacies, and PBMs, I think the biggest thing is, they seem to hide their rebates. Like when I look at the SEC statements there isn't a separate line for saying revenues from rebates. So that's hidden from me, so I don't know how much of these rebates are passed on to the health plan.

So, in some sense things brings to the panel discussion that, what are the policy solutions for making the drug distribution system more efficient. So, maybe Amazon will be the answer

here, because they said they are going to get into this business, but I think we really need to think hard about what the policy interventions here are. And we have an esteemed panel to help us with that. Thank you. (Applause)

MR. GINSBURG: Well, thank you, Neeraj for the presentation. There will be an opportunity for the audience to ask questions of Neeraj, as well as the panel, toward the end of this panel discussion.

I want to introduce our panelists. We have Ed Adamcik who is the chief pharma trade relations officer at Express Scripts, and he is responsible for all rebate contracting with pharmaceutical manufacturers.

We have Jennifer Bryant who is the senior vice president of policy and research at the Pharmaceutical Research and Manufacturers of America, known as PhRMA.

We have Matt Eyles, who is the executive vice president of policy regulatory affairs, and America's Health Insurance Plans or AHIP.

We have Lynn Quincy who is the director of the HealthCare Value Hub at Consumers Union, and her group at Consumers Union monitors and synthesizes evidence to help consumer advocates work on health care costs, quality and value.

And I want to start off the panel inviting the panelists with any reactions they have to the Neeraj Sood paper and presentation.

MS. QUINCY: Can I go --

MR. GINSBURG: Any order, yes.

MS. QUINCY: Since I'm sitting next to him, I'll go first. One clarification in my bio, you may not know this, but Consumers Union is part of Consumer Reports. And I know you've all heard of Consumer Reports.

Well, I thought this was a great paper. We have a similar, I think, understanding that flow is extremely difficult for all of us, it's very difficult for policymakers who really need to make this work better. We have our own little chart that was somewhat similar.

And I think this framing is important. It's really important to understand what's going on at every step in the distribution chain in order to get to better solutions. A few things that I hope, perhaps,

we could inject as part of -- as you promote this research effort, would be to maybe provide additional context.

So, for example, you anchor it to the IMS number of it's like 325 billion in spending, and IMS actually has a higher number which is the invoice number, and some people are familiar with that number, so can we help get your readers from this invoice number, which is an even drug-spending number, down to where to you started.

We talked a lot about how generic drugs are the majority of prescriptions, but of course the majority of spending is on brand drugs, and a small percentage of a very expensive brand drug, may actually provide a bigger incentive to your middle suppliers than a large percentage on a very, very cheap generic. And I think we need to get that in.

Also we are leaving out drugs that are not flowing through the retail setting, but instead flowing through hospitals, where markups are absolutely enormous, and as we'll be talking about that, I know what Paul's next question is, we are going to be talking about the kind of consumer harm. And so those are some things, I'd love -- some contextual things that I'd love to see in there.

MR. EYLES: Great. Good morning, everyone. Thanks for having me here. So, just a couple of thoughts. I also thought it was an interesting piece of work, and I would echo Lynn's comments that there's a large percentage of spending on drugs that is outside the retail chain. And we need to recognize that. Whether you look at the data that Medicare puts out that shows Part B spending versus Part D spending, and we are not seeing a lot of flow through or rebates on that side of the equation.

Really also, I think the bigger issue is around, you know, pricing competition, what do we see within the marketplace for prescription drugs, prices are, you know, higher and higher. Launch prices continue to rise relative to older therapies. To Lynn's point that provides additional incentives when you are looking at a percentage of an ever increasing price. You know, we use the hundred dollar examples of up to, you know, because it's simple to illustrate, you should probably add a zero though, to that, when you are -- no, just to be realistic when you are looking at like the monthly cost of branded prescription drugs, there aren't that many left that would cost $100 per month, if you are going to be honest. So, you really need to look at what the real prices are.

You know, of course, and when you think about the distribution system and potential

rebates and, you know, this whole issue about where are rebates occurring, and where are they being passed through, I think it's important to recognize that rebates, at least from the health plan perspective, are being used really to reduce premiums for every consumer.

So, we are talking about where rebates might go to particular individual, and if we are going to channel them there, then we have to expect higher premiums for everyone else. I've touched just a couple of points.

And then the final point is, you know, what we really need to look at is, how many products are out there on the market that have not had any true competition for, you know, a decade plus. You think about some of the largest products on the planet, HUMIRA, Enbrel, you know, tens of billions of dollars per year in sales, and we don't have any meaningful competition out there, and if we are able to get some meaningful biostimulus competition, we might actually be able to talk about things that are more affordable.

MS. BRYANT: I'm tempted to start with some of the things that Matt said. But look, I think it's a healthy conversation for us to have to start looking at a more -- in a more sophisticated way at some of the payment issues in the prescription drug space. So, I think it's terrific that we are having a conversation, and that we are -- Brookings, in a typically thoughtful way, is breaking it up into one conversation about brands, and one about generics because they are so different, and like that's a mark of getting more serious about trying to solve real problems, and not just throw around rhetoric.

I would say that I'm not convinced that the treatment of profitability is the right way to think about what we are talking about here. For a number of reasons, I think you know, Neeraj did highlight the very huge dissimilarities between industries, but the reality is that the business model of a pharmaceutical industry which is investing billions of dollars in long-shot development of new medicines. You would expect to have much higher profits than an industry which is about moving palettes of medicines, you know, from warehouse to a pharmacy.

So, that's not a surprise, and I think that any -- really when people have looked at questions of profitability in the pharmaceutical industry over a long period of time, economists have all suggested that the ways that we account for profitability, tend to overstate returns in the pharmaceutical industry.

You don't have to take my word for it, you can CBO's word, Joe Newhouse's word, like, this is a sort of standard accounting problem for high R&D and tech-intensive industries. But I think the bigger point is to not be thinking about just profits, but think about what are we getting from the system, how is it working for patients, how is it working for employers? That's what we actually want to achieve, right?

And I would argue that the reality is the drug costs are not swirling out of control, so the system is largely working, but there are clearly high frictional costs that are being pointed to here.

And the Sood paper, like, you know, you are finding results similar in some ways to other studies that are already out there, that show that brand manufacturers and generic manufacturers, do not represent as much of the spending as most people think.

So, if you look at the policy debate we are having about prescription drugs, all of the policies are aimed at addressing brand manufacturer spending. But in work that we recently did, which is very comparable here, we found that brands are about 47 percent. So, I think it's a healthy thing to begin to broaden the focus, but I have a number of questions about the ways, the particular technical results in this paper.

MR. ADAMCIK: Good morning. Thank you for having me. I thought It was an interesting way of breaking things out, and looking at the market, and I think you did a good job at picking it, and actually digging through, and how you broke out some of the profits, because it was, you know, kind of tough to figure out some of the piece. I thought it was interesting.

The one piece I found interesting, you talked about the net price increase, and you talked about earlier in the discussion how prices increased, but overall the net was down around, I think it as 2.8 in the summary, and which goes along with what a lot of the PBMs had stated in our trend reports recently, where trends overall, are decreasing.

So, I think ESI report 3 and 3.5 percent, CVS was in the same range, Optum was in the same range. So, I think while the last slide depicts, or the big schematic depicts lots of moving pieces, it actually drives a lot of competition in the market place, which ultimately, you know, with trend or net prices being where they are at, you know, it helps to keep premiums to a certain point, and if they weren't, I think premiums may be higher and, you know, we don't know what the market would look like if some of the

pieces of that puzzle that you show there, aren't there. So that's one of my take away from it.

MR. GINSBURG: Thanks. Anything you want to respond to, Neeraj?

MR. SOOD: Sure. So thank you all for your comments. I just think Jennifer should have been in the end, and Ed would have been in the middle, then the supply chain would be in order; (laughter) from the consumer, to the health plan, to the PBM.

Thank you for your comments. I agree that in the presentation I didn't talk about invoice prices, and invoice prices are the things that you see in the news. So, when you read a newspaper and you say, you know, Hep C drug costs $1,000 a pill, that's the invoice price, and then PBMs come into the picture, and other parties come into the picture, and what the manufacturer is actually getting is much lower than that $1,000 a pill.

But how much lower that is, we don't know because these contracts are confidential. So, yes, I think the picture could be more complicated with the invoice prices and that's in sense an important part of the picture. And I think I'll stop there.

MR. EYLES: And that's, I think, an important point, but you need to have competition within the therapeutic area, right, so the example of Sovaldi, right, when it's out there on the market as the lone therapy, the list price probably is the price. It's only when we have competition within therapeutic areas do we actually see prices decline. And that's, I think, an important point to note.

MS. BRYANT: Right. But I would note that net prices for Hepatitis C medicines have declined really rapidly, and we do see prices decline, and one of the challenges for patients is that if net prices decline, cost sharing doesn't necessarily follow.

MR. GINSBURG: Okay. We are going to have more time to get into this. My second question, and I'll give you the third also, the second question is, I want each panelist, and we'll go in the reverse order this time: what are the most significant issues that we need to address in the distribution chain for brand name drugs? And the final question that we'll get to later, is going to be: what are your policy ideas to deal with this? So, Ed, if you could begin?

MR. ADAMCIK: Sure. I'm kind of echoing a little bit on Matt's comments. I think one of the biggest challenges, is how do we continue to drive competition, because with that creates -- makes people think in different ways to handle products, maybe more value-based contracting which comes out

of that in showing the value of the products.

So, ultimately I think it's some launch prices which are challenging sometimes for payers, and ultimately consumers, because every -- you know, I've been doing this for a quite a while, and I'm a pharmacist by training, so you see that prices change over time. And, you know, a lot of these drugs come out, and they are pretty high-priced, and some of the specialty drugs, and I know this isn't on specialty it's mostly retail.

So to me that's one of the challenges that we face, and how do we create that competition, and to me, in the PBM space, it's about driving competition, and the more competition we can create, the better it is for ultimately, the payer, the consumer, and I think the market overall. And it drives trends down, and it drives waste out of the system.

And today, you know, we squeeze the balloon as much as we can to try and drive cost out of the system that are excessive and, you know, what's left is we try and put the right drug in the right patient's hand, for the right price, and make sure they stay on that. So some of the challenges are: how do we keep people, like with that supply chain that you showed, how do we help people stay on the product once they get it.

Everybody has access to the products, some may pay more than others, but how do we make sure that patients stay on those products, and that become the bigger challenge, I think.

MR. GINSBURG: Thoughts on the supply chain?

MS. BRYANT: I think the main problem we need to be talking about is to make patients -- make medicines affordable for patients, right? That's why we are all in business to begin with. And so I think there are a couple of key ways in which the supply chain system that we have affects patients, one is that patients are increasingly now faced with the list price, which is a fictional price, and not the price that the end payer is paying.

So that happens when they have a deductible, that happens when they have co-insurance, so I think that's the problem. It's made, of course, much worse when patients -- because of the way we buy drugs, right, so patients buy it at the pharmacy and can't spread that payment out over time, and that's very unlike other kinds of health care services. So we are increasingly seeing all of the cost-sharing for the year being squeezed into January, February, so that's another problem I think we need to

address.

And it's a benefit problem, but I think that we don't need to be splicing this into supply chain and benefits, like, you know, the question is: what works for patients? And clearly the situation we have now of, you know, very high cost sharing in January, February, and then having that happen year after year for patients who have chronic conditions is not a workable system, and the reason is that we have benefit systems that were designed in the 1990s for a really different marketplace.

And so I think it's sort of a bigger question than just the supply chain. I would argue that there are some -- beginning to be signs that there are some misaligned incentives in supply chain broadly. I'll take one example, they are not here on the panel, but you mentioned non-retail, there are clearly, there are some examples where hospitals are abusing market power, and saying essentially: if you want our beds, take our inflated prices for cancer medicines. That's an example of a problem we ought to be able to focus on.

And with regard to PBMs, I would argue, it's not so much the rebates, but all the fees that are imposed on pharmacies, specialty pharmacies, and manufacturers which are sometimes also contributing to higher costs for employers, and for patients. So I think there are challenges in the distribution chain, but we need to keep our eye on the ball, which is, what's happening for patients.

MR. GINSBURG: Matt?

MR. EYLES: I agree with Jenny on that, I think, but it comes back to a much more fundamental problem of broader affordability within the health care system, and you know, drugs are certainly an important part of that, and a growing part. And it's wonderful that we have these life-saving and life-changing therapies, but at the same time, you know, when you look at the overall affordability, especially of newer drugs that are coming out to the marketplace.

I mean, it's really eye-popping when you see some of the prices for new drugs coming out, and you go, well, you know, that's a great therapy, but do you know what, that's like the cost of a family premium, you could cover four families for one drug, and that's only like the cost of one drug, not the entire health care costs that these individuals face.

And we really need to look at this balance, overall. And I don't want to, like, lose sight of that picture to start with because it's not improving in that area, and I think we are all working to look at

novel arrangements, value-based payments, et cetera, and a lot of the system has evolved. The drug world is still, I would say, catching up significantly to the type of value-based arrangements that you see.

And I know there are barriers, and there are reasons why, and it's hard, but I also don't want people to believe that moving towards value-based payments for drugs is really going to solve our fundamental affordability problem, it's not -- we are just not going to be able to do it across the entire spectrum of medicines.

And then finally, if you think about this issue of rebates and high deductibles, and I experience this with my own son the other day, we got a prescription, a topical dermatological agent, and the cost of the drug was $600 for one tube. And you go like, okay, well let's say there was a pass through rebate, let's say it was 20 percent, and the list price was, say, 550 so you are taking $110 off, would it have been that much more affordable, if through a pass-through of the rebate going from $600 to, you know, ballpark $500? I don't think that that's really the issue here. We want to figure out ways to make the overall system much more affordable.

MR. GINSBURG: Lynn?

MS. QUINCY: Well, carefully sticking to the question about what's most important, because I know we are coming back to, what are our proposed solutions? I'm delighted to know about the concerns with respect to patient affordability; that is the overriding concern here. Patients consume -- about 8 percent of consumers go to the hospital in any given year, and maybe 12 or 13 percent have an outpatient surgery, but 50 percent or more go and get prescription drugs, and they pay a high -- on a percentage basis there's more out-of-pocket costs for prescription drugs than there are for other medical services, if you are insured.

And so this is very, very top of mind for consumers, and it feels like prices are spiraling out of control for them. Regardless of what some views of the aggregate data say. And I also want everyone in this audience to remember, we have a lot of uninsured consumers, and they may be paying those invoice prices, and those invoice prices matter. And they are out of control.

So, I think that the most important thing is to look at every step of the supply chain, and figure out, where can we deliver better value to consumers? Where can we make it more affordable, and I think we have to reduce the opaque nature of these transactions. I think, maybe particularly with

respect to PBMs, we've testified both in front of the Department of Labor and in front of Congress, in terms of, it's hard to know whether or not consumers are getting a good deal from PBMs; and not putting aside those list prices for drugs.

But most PBMs don't, in fact, have a fiduciary responsibility to payers, and then you have this opaque set of transactions where you don't really know what the rebates are, or the pricing spreads, and I don't think that's serving us well. So I guess, to wrap up, I think the overriding problems in the supply chain are looking every step of the way to see where we can get to greater affordability and greater transparency.

MR. GINSBURG: Thank you. Okay. As you know the next question is about policy proposals. And Lynn, you can continue?

MS. QUINCY: Oh, I was hoping. I was hoping. And I have to play off of what Neeraj said. In addition to being in the right order, we should have had an oversized pill bottle and an oversized dollar, we pass up and down. So Brookings and Schaeffer Center can keep that in mind for next time.

So, I think that there are a number of policy solutions we need to look at, and unfortunately I don't really think competition is one of them. I think there may be areas of the pharmaceutical sector where that's going to help, but we have lots of evidence -- there are a lot of natural monopolies in this sector.

We have patient populations that are very small, and really can't support more one developer or manufacturer, we have government-granted monopolies as have already been described, and we have oligopolies. Look at the price of Gleevec and what happened to that when competitors were introduced into the market, the price of everything went up, because they were higher-priced than Gleevec.

So, you know, there may be areas where competition is going to help us, but we had better not rely on competition to solve all our problems. I think the problem of having cost sharing front-loaded is easily solved and we should not spend any time on that, it can be distributed across the year quite easily with little effect on actuarial value.

I think other solutions that we need to look at are, we need to get specific, like these aggregate analyses again are really useful from a framing device, but when it comes to how consumers

experienced this sector, it is very specific to the type of drug they are trying to take. Is it Duraprene? Is it an EpiPen? Is it some drug where they are actually are benefiting from competition and they are good value? Are they getting it from Costco? Or are they getting it from CVS?

It's extremely different depending on what the drug is, whether they are insured, and what type of retailer they are getting their drug from. We need to even out that experience so it's uniformly high value for everybody. And this is actually, I think, one of the toughest policy problems, because of the elements of natural monopoly that are there, so we can look at things like re-importation, which we support to a limited -- you know, to a certain degree.

We can look at things like negotiating -- Medicare negotiations, but I think we are going to have to even look further at when those approaches don't drive drugs down to their proper value, and look at price regulation where needed. So, I'll stop there, having stirred the pot.

MR. GINSBURG: Thanks, Lynn. Before I go on to Matt, I just want to -- a follow-up question for you, Lynn. You were mentioning about, that maybe competition doesn't have much potential, and I was thinking that, you know, to the degree that you are going to engage consumers in competition, you know, if it's a $50-drug, a lot of potential, but if it's $100,000 drug, probably very, very little potential. And I wonder if this trend towards the new extremely expensive drugs, is just actually making it a problem to use competitive tools?

MS. QUINCY: I think that is a great question, but I mean, I think, like, as with all these programs to fill in the copay, we are just trying to leverage the insurer payment at the end of the day. You know, we are not going after a consumer's house, and things like that in order to pay for these drugs. We are trying to leverage an insurer's payment and get that into the hands of the supply chain, and all the way down the line.

And consumers, this is very well established. When it comes to their health care, when they are in pain, when their quality of life is awful, they don't treat these things like a commodity, and if their doctor says, you need this one, and not this one, and there's any way they can get to the one their doctor recommends, they are going to try to do it. I don't think there's a lot of potential to leverage consumer shopping in this space, and I actually think that's actually fairly common throughout the health care space.

MR. GINSBURG: Matt?

MR. EYLES: I would agree with Lynn on some points. I would disagree a bit on the competition piece. When you are talking about orphans and ultra-orphans, I think that you are right, that competition is probably not going to solve the problem, especially when you look at how, with orphans that are being used for, you know, much broader populations.

But I would say that competition really does help, and to the extent that we can encourage competition and make sure that, whether its patents states aren't being built up around products to protect them, essentially, indefinitely from competition, or other sort of ways that manufacturers are essential trying to extend the market exclusivity period, competition can help in making sure that we get additional therapies on the market, you know, more quickly, can be really, really helpful.

We are also very focused, like Lynn is, on transparency, and we think that there are appropriate ways that we can protect the competitive marketplace, but have greater disclosure around, you know, what to expect with respect to launch prices, price increases, what's going around with inputs. With pharmaceutical manufacturing we know that there's a huge -- manufacturers, we know there's a huge disconnect between actual R&D expenses, and pricing. If anything, it would be helpful to illuminate some of those.

We don't want to get in the middle of proprietary, contractual negotiations, because there's pretty good evidence out there that if you have that kind of price disclosure it actually leads to higher prices down the line. So, we are focused on competition, on transparency and also towards -- a greater move towards value, and if we can incorporate more value-based concepts, both within benefit design in terms of the economic relationships between manufacturers' plans and other payers it can be helpful.

Again, I don't want to mislead anyone and say, "you know what, that's the silver bullet," because there's so much talk about this move towards value, and yes it's helpful, but it's not going to, I think, fundamentally change the affordability discussion we are having.

MR. GINSBURG: Let me interject something about transparency, because I've been focused a lot on that, usually outside of the pharmaceutical world, but there are two audiences to think about for transparency. There is, the consumer is making decisions, or physicians, there are also

policymakers, and outside of prescription drugs, I've seen the real successes in transparency have not been giving consumers better information, it's been informing policymakers, large employers to make decisions. And we probably ought to make that distinction as we discuss transparency. And a lot of what Matt was suggesting, really is to inform policymakers which could be very useful.

MS. BRYANT: So, I think, again, if I was going to focus on what needs to be done, especially with regard to the kind of conversation we are having here today, I think we need to work on making sure that patients are benefiting from the negotiated discounts that are already in the system. I'll just say, I think it's a little crazy that when you go to see a physician, or you have a hospitalization, that you get the benefit of your insurers-negotiated discount. And when you buy the medicine, you don't necessarily get that benefit.

And so I don't think this is rocket science, and I think there are ways to do this, that are not going to be disruptive as a market, it can be phased in gradually, it can be done thoughtfully, it doesn't have to be done in a one-size-fits-all way, but there are lots of -- you know, I just think it's common sense that patients ought to benefit from those discounts.

And it might not reduce every single patient's prescription, Matt, but it would reduce some of them quite substantially, and it's a violation, I think, of common fairness for patients to more than their insurer pays for the medicine. So, I'd start there. And I do think that just stepping back it's worth it to think about how to reduce frictional administrative costs in the system. AHAP's own data shows that we spend 1 out of $5 on the cost of insurance. That's more than we spend on prescription drugs.

So I'd say, if we want to think about how to reduce health care costs in this country we could decide to cut into the, you know, new cancer treatments that are going to change the standard of care for patients who desperately need new hope, and we could do that even though the net spending on medicines is supposed to grow at 2 to 5 percent over the next five years. Or we could work on reducing the administrative costs, maybe standardizing preauthorization forms, you know, looking at ways to bring IT to revolutionize health care. That, if you ask me, will be a more productive place to go.

So, this discussion on the supply chain is a piece of that. How do we make the competition work in the way we distribute medicines, and can we focus on that, because that doesn't have the same kind of risks to innovation that some of the other more draconian policies we've talked

about do.

MR. GINSBURG: Jenny, following up on having consumers pay cost-sharing based on real prices, is there a proposal that you and your colleagues think is workable?

MS. BRYANT: I think, as I tried to suggest, there is not one proposal, but many ways that this could happen. I mean, we think that every insurance commissioner in the country could be thinking about what are the ways to make this work. Health plans could pass on average discounts, they could pass on across the whole plan, they could pass on discounts that are an average by the tier, they could work to -- the simplest thing is to move more toward copays which show that patients are more likely to stay on their medicines in any case, because there's a lack of transparency when you have co-insurance.

They are afraid about what they are going to face at the pharmacy in terms of the cost. They don't have that information, that's transparency we think that -- not the silver bullet but useful for patients, they ought to know that. So, shifting the copays, there are lots of ways that health plans can do this on their own, or that regulators could encourage them to.

MR. ADAMCIK: A couple of angles here. One, I think in a way to bring about more competition but also help the manufacturers, I think the length of time that Pharma has to put in to create some of these new breakthrough drugs is remarkable, and the amount of effort that they spend recruiting patients, and doing studies, and then however long it takes to get something through, and get approved is a challenge which, you know, drives up their cost and the cost to bring a drug to market now is like a billion or something quite large.

And so that leads, you know, how big is the big market size, and what are their prices? So, I think if things got through quicker, and got approved faster, would help the system, I think, and potentially drive more competition which I think is healthy. Also biosimilars and getting generics approved, you know, in a more timely fashion.

It helps the market, brings lower-cost products to the marketplace, ultimately, again, I'll get back to competition but all those dollars when we either come out with lower-cost products because the system is acting more efficient, will lead to, I think, hopefully lower cost for consumers. It should bring down cost for payers, which hopefully won't change benefits in a dramatic fashion, which is, I think,

somewhat playing in the space of how much skin in the game does a patient have, versus how much skin a payer has. Because prior to a couple years ago, most patients had -- or most benefits were a flat copay, and they've kind of evolved over time, and the pharmacy benefit was extremely rich.

When most people are paying 25, 30, $100 for a prescription when the cost might have been for $500, it's pretty rich benefit that you were getting, and the supply chain was working to make sure that those benefits didn't, you know, change much. But, you know, for whatever reason benefits have changed over time, and so that becomes -- now we are in this kind of challenge where we are worrying about how much the patient is paying for a product which is, you know, a concern.

With that, and I don't know what could be done about it, but there are preventative drug lists also, so for maintenance drugs, and things that are important, diabetes, insulin, things like that, if we could expand the preventative drug lists, that allows, I think, plans to -- and I'm not an expert in the space, but I think it allows plans to cover certain medications at -- like what a patient would pay after their copay is through -- or after they are through with the deducible -- I'm sorry.

So, that's something, you know, maybe that could be done as well. And then lastly, just, I know there are a lot of -- pharma does provide a lot of copay [assistance], good or bad, you know, some people say copay cards are bad, but they do help consumers in a large fashion try to get through that. Now whether coupons and copays are always as easy to get to, you know, that's another topic. But anyway, I'll stop there I think.

MS. BRYANT: Can I just --

MR. GINSBURG: Sure.

MS. BRYANT: I was just going to go back to the question about value-based contracting. Because I think that a lot of the conversation about that has been kind of narrow, and the way I would think about it, is that we have a system right now, which is all about chasing rebates, and chasing discounts and we want to get to is a system in which payers are truly -- the whole system is geared toward getting lower net costs, and getting better value. And the shift to new forms of contracting I do believe is part of the answer.

So I do believe there's a lot of regulatory gridlock at the moment, and barriers to the kind of flexibility that would allow manufacturers to work with PBMs, to work with insurers to get to new types

of contracts. And I believe that that would actually change the terms of competition in ways that would lead to not just changing of the form of the price from, it was the same discount, but now it's tied to a clinical value, but it's actually the level of the price would come down, because you would find that there will be much more aggressive competition, especially in areas like oncology, where there are a lot of challenges with offering treatments as part of a combination, and you want to be able to reduce the price for the third and fourth drug in that combination.

So I think that there is actually quite a lot here and that he would, despite the fact that there's also this tension on the panel at times, like you would find that there's a lot of agreement that the market and competition can actually improve things quite a bit, if we can get some regulatory change to make it possible to contract in different ways than we have before.

MR. GINSBURG: You know, actually --

MS. QUINCY: Can I make on quick point?

MR. GINSBURG: Oh, sure.

MS. QUINCY: I just want to mention one thing, connected with what Jen was saying about making sure consumers don't, like, pay more than the acquisition cost of the drug, which is that we can ungag pharmacies. And pharmacies are often under contractual arrangements where they cannot volunteer to a patient that's in front of them: that they could get this other drug, or they could, you know, not use their insurance and pay less for a given drug. They are not allowed to volunteer that information, so that's an easy -- a low-hanging fruit thing that we could do.

MR. GINSBURG: That's right. I want to put in a clarification as the moderator, I think as a moderator, on value-based payments. I think there are many attractions that go in that direction if we can, but when we talk about it, we shouldn't only talk about price decreases, because if there's a drug that works in 20 percent of the patients, yes, it will be great to have a price decrease for the 80 percent that doesn't work. But what about the 20 percent that does, can't there be a price increase there? And isn't that what we would expect?

MS. BRYANT: Well, I guess in theory, but I think all of us would expect that the market is getting more and more competitive and with the advent of biosimilars, I don't think that we are looking forward expecting that there are going to be large opportunities for price increases. The market actually

works very, very well.

MR. GINSBURG: Any other comments?

MR. ADAMCIK: I'll just close with two points. One, if we had lower prices -- lower net prices for branded drugs to start with, we wouldn't be having all this value conversation, because we wouldn't need to be having it. The second point is around transparency, it's a little ironic that Jenny talks about, you know, greater transparency and the administrative cost from health plans, when we are in fact one of the few entities within the health care system that actually had regulatory oversight for the rates that you charge, and there's absolutely zero oversight for the prices charges by pharmaceutical companies. So, I'll just close with that.

MR. GINSBURG: I'm going to let this session a little later, because I would like to get some questions from the audience. Yes. And the woman in the red jacket. So could you wait for a microphone, please? And say your affiliation, and which panelist it's directed to.

MS. BOURBON: Hi. Thank you for this important panel. My name is Contessa Bourbon from The New York Times and London Times, and any of the panelists can answer this question. Is there legislation in Congress that can increase competition or can lead to price control? Who is the author, and what is your view on this legislation?

MR. GINSBURG: And I want to this -- I'm sorry, but I want to keep this conference on distribution and competition. The next question? Yes, the gentleman in the short-sleeved shirt back there?

SPEAKER: Tom Timber; drug consultant. This is really for Professor Sood. Is there a source you can give us for how you pulled out the non-American factors in the SEC Filings, because particularly the manufacturers, a lot of their accounts are dominated by that, and of course there may be reversed problems of non-American manufacturers who don't have SEC Filings. And it's connected with a -- as usual the American supply chain is idiosyncratic, and the one thing you didn't mention is the role of the wholesalers proprietary softwares in reducing the inventory risk, both for them, and especially for the retailers -- and I shouldn't retailers, hospitals all, if you will, intermediate-level consumers. So, I wonder (a) how you did that, and (b) if you could address this role?

MR. SOOD: Sure. So, you are right that a lot of the SEC statements, so for some forms

they split out U.S. sales and global sales, and report margins separately, for others they don't. So, this is a big-picture view of what's going on. We did look at how gross margins are a function of the fraction of sales that are U.S., and they are an increasing function, but it wasn't a very strong, positive correlation.

So, you know, like right now we report gross margins of 71 percent for all manufacturers, if you look at manufacturers which had very high U.S. share, they'll probably go to 75 percent. So they are kind of in the same ballpark. So, I think the bottom line is: you should view my numbers, you know, they are not accurate to the exact dollars or cents, you know, they give a big-picture overview of what's going in these markets, and in some sense the reason, like ideally I'd like to do what Lynn was suggesting, which is follow a consumer who is actually buying a drug, then follow the pharmacy, the wholesaler, you know, follow all the people for that one particular transaction.

But we don't have that data. You know, that data is confidential, and in some sense, having the data, greater transparency would help policymakers kind of see who is taking exactly how much, per what type of drugs, and then devise policy solutions. And I think at the same time, like as consumers, what Lynn said, is that, you know, we are not engaged in drug purchases, or in health care purchases, and maybe that's the reason why there isn't price competition here, or the extent of price competition there should be.

That if I as a consumer said, oh, there's a cheaper drug and I want to be on that, because it will save me on my co-insurance, then that would lead to changes in the pricing dynamics. So, I think some of the blame also goes to us as consumers, not just to people in the supply chain.

MS. QUINCY: Well, I just want to remind everyone that, you know, consumers have an incentive, if they feel that they are going to be equally well off between two drugs, they'll go for the cheaper one. The problem is it's very difficult weigh, an expensive drug with an uncertain outcome for that consumer, and a less expensive drug with an uncertain outcome for that consumer, it's really impossible, and that's why we really have to look at the entire care team, and there is not a solution that puts that entire burden on the consumer.

MR. MYERS: This is a question for Dr. Sood, and for the panelists. My name is Jeff Myers, I work for the Medicaid Health Plans of America. As you know, as you know 22 percent of Americans don't have any copay at all because they are in the Medicaid system, and that has a

significant impact on the distribution of the way the rebates work through the system, because of the Medicaid Drug Rebate Program.

I want to know, first, had you thought as you looked through putting your data together, breaking out the way the Medicaid system works, and the fact that three-quarters of Medicaid enrollees are in managed care, where states are either setting the formula or giving it to the plans, and would that have affected your design?

And then secondly, for the panelists, as you think about Medicaid now insuring 1 in 5 Americans, practically 1 in 4, and those Americans face no copay, or a dollar, because it's a nominal amount, except for Indiana. What does that mean for possible changes in terms of value-based purchasing arrangements, or other ways to make the economics of the distribution system work a little bit better?

MR. SOOD: I'll answer your first question. That we didn't look at Medicaid separately, and I think the picture would be very different for Medicaid. So, I know like manufacturers would have lower margins on Medicaid because of Medicaid Best Pricing rules, administrative costs of Medicaid might be different than private health insurance plans, and so on. So we didn't look at that separately, and that's a valid point.

MR. GINSBURG: The panelists really had a lot to say. We've exceeded our time. I want to thank them. (Applause)

We'll take a break until 10:20.

(Recess)

MR. GINSBURG: I'd like to introduce my colleague Steven Liberman who is president of Liberman consulting and he is also a non-resident fellow at the Center for Health Policy at the Brookings Institution. Steve discloses that he is a consultant of Pharma of issues that are not related to the paper he's going to be presenting on generic drugs.

MR. LIBERMAN: Thank you, Paul. It is a pleasure to be here and I want to acknowledge that this project, while it was more involved than I originally thought, it was a terrific partnership working with Paul. This morning I'm going to go over nine slides and those slides present the work that we have done in more detail in the paper that is available. I will try not to repeat what was said at this morning's

excellent session.

But to underscore a couple of points to help frame the discussion, there are annually 4 billion generic prescriptions dispensed at retail at a cost of slightly over $100 billion. That's 27 percent of overall retail spending on prescription drugs. And as was noted in this morning's discussion, rebates play an extremely important role but an extremely dissimilar role between generic and brand drugs. With respect to brand drugs, rebates flow from brand manufacturers, through PBMs to plans and they lower plan costs. In contrast, generic manufacturers send their rebate typically through wholesalers now, to pharmacies. As a result, the pharmacy cost of acquiring drugs, are dramatically different than the listed or the published price.

The PBMs as we heard this morning play a central role in the drug distribution system and just to highlight two of their roles. One is, as we heard this morning, they negotiate on behalf of plans, the terms that plans pay to pharmacies when they dispense drugs. In their other roles, PBMs run very large mail order pharmacy operations. What we're proposing is to address the fact that different parties have very different information about the actual cost of generic drugs when pharmacies buy them. And we believe that selectively disclosing those prices to plans would have the effect of empowering plans to negotiate lower rates. To the extent that that is true, that could produce significant savings. Just as a sizing exercise, if the average prescription generic drug, which costs $26, had its price reduced by a dollar, which is less than 4 percent, that would result in $4 billion in lower spending by the health system.

We've already heard that generic drugs now dominate the market. They are 89 percent of the scripts. The pharmacy market has changed very significantly in a number of ways. More recently, driven by a trend in Medicare part D prescription drug plans, narrow networks of preferred pharmacies have become common. About a decade ago, there was a disruptive innovation when Wal-Mart pioneered the notion of what are now called $4 generics, a program that has become widely adoptive by many mass retailers such as pharmacy chains and big box stores. Part of the reason that that was so disruptive is that 10 years ago, the estimated cost of dispensing a drug which has remained pretty much the same today, is estimated at $11 without regard for having to pay for the ingredients.

Another change that has occurred quite dramatically over the last 10 to 20 years is that 20 years ago, most pharmacies contracted directly with generic manufacturers, now most of them

contract with wholesalers or similar organizations. Those organizations don't only distribute the drugs but also arrange the rebates.

As we've heard, the business to business relationships in the drug distribution chain are extremely complicated and they involve manufacturers, wholesalers, plans, PBMs and pharmacies. Again, just to underscore and important point, the actual net price that a pharmacy pays for acquiring generic drugs and the actual price that a health plan pays for brand drugs are not at all public nor do they approximate the published prices.

There is a slide that I've attached which I'm not going to spend any time on but if you look at the paper on page 12, it has similar information that summarizes the five major price indices that are currently in wide use although AMP is an important measure but it is not at all public. The most common prices that are available are so called AWP and WAC and those are list prices because they exclude discounts and rebates, they markedly overstate actual prices paid by users.

I want to quickly highlight two others. NADAC, which was created in 2013, is a new measure. It purports to represent the national average drug acquisition cost, and it unfortunately has serious if not fatal flaws. Just to highlight one of the serious deficiencies, and there are others: NADAC only includes on-invoice discounts and it ignores off-invoice rebates. Just a quick work about Medicare's ASP, or average sales price, which was created in 2003: that is a list price but it's reported at a very aggregated level for a very limited number of drugs, those that are covered under Part B of Medicare.

To put the drug distribution system in context, it is very important to identify how this market for consumers differs from more to conventional consumer purchases. The first and perhaps most obvious thing is before a consumer, otherwise known as a patient, can acquire a prescription drug, they need to have a physician or other licensed clinician write that prescription. Second, health plans have become extremely sophisticated in using formularies and cost sharing to steer or influence consumer choice. Third and perhaps most importantly, the actual cost of a drug as we heard this morning is masked from a consumer in large part because third party payors are paying the bulk of the cost.

Again, I don't want to repeat what we've already heard this morning but precisely because the manufacturer rebate bypassed pharmacies for brand drugs, pharmacies typically acquire brand ingredients very close to the published price, what is called wholesale acquisition cost or WAC. In

fact, the best estimate we've seen, on average it's 96 percent of WAC. However, because generic rebates flow directly to or indirectly to pharmacies, that lowers their net price well below the published price. In fact, our estimate is that on average and there is obviously there is a wide distribution of cost depending upon the individual drug, the time period, the characteristics of the purchaser. On average, pharmacies pay WAC minus 70 percent.

Now, let me state that slightly differently. On average, when a pharmacy acquires a generic drug, it pays 30 percent of the published list price. The interesting point, if you look at the top of this slide, the average brand drug costs $308 and the average generic script was approximately 1/12 of that. In spite of that, a 2016 report by the Department of Insurance in the State of Washington confirmed what CBO had previously reported, which is that pharmacy profits are greater on generic drugs that on brand drugs which is consistent with what Neeraj reported this morning.

Our proposal is to make information about average generic drug acquisition costs available to health plans in a restricted selected way. The way we propose to do this is if require all wholesalers to report what their actual net prices when they sell drugs to retail pharmacies. We would make this condition of licensure and all wholesalers in 2013 have been required to be licensed. We would take advantage of the fact that the wholesalers have extremely sophisticated highly capable information systems. Would have CMS collect aggregate and deidentify the information, would have the averages reported and there would be exceptions to this but our accepted starting position would be to have the averages reported at the ingredient, dosage, strength and route of administration level. The HHS secretary would issue regulations much as he's done with Medicare's ASP and Medicaid's AMP program and would have plans pay for this through user fees. Importantly, the information that would be reported would be both confidential and treated as a trade secret and it would not be capable of being reverse engineered to identify the prices that either individual manufactures or individual customers were incurring.

As I'll describe in a couple of minutes, we also think there are significant ways to either increase or decrease the level of granularity in the degree of price transparency that could be reported. We are sensitive to this because the anti-trust experts in the Federal Trade Commission, in particular, has long standing concerns that increasing price transparencies we heard briefly in the previous panel can

have the effect of undermining competition and leading to price collusion.

Before getting to an analysis of what we think the plans, our proposal, will actually do, I just want to underscore that, and maybe the simplest way to say this is to update Polonius's advice to his son which: was neither a lender nor a borrower be. For PBM it might be, don't be both a price setter and a price taker. The question is, to the extent that PBMs have very detailed information about what actual ingredient costs are because they run mail order pharmacies and health plans typically do not have comparable access, would that redress the current level of reimbursement that plans are incurring. Clearly to the extent that the prices that PBMs negotiate as reimbursement at the retail level, are linked to reimbursement at the mail order level, they directly benefit from keeping prices high.

Unfortunately, the economics literature has relatively little research to inform the question of whether, in a concentrated market or consolidated market, whether knowing the sellers' cost structure would assist the buyer. In our paper, we site three examples. The most relevant one to healthcare is a relatively recent study which suggests when hospitals share information about the costs of purchasing stents, they've been able to have their prices go down without it having adverse effects. Again, we're proposing to have our price information report information to plans that would be kept confidential and we believe there are ways to reduce the risks of having that pricing information being disclosed and as a result, allowing manufacturers to engage inclusive pricing because the increased transparency which is the traditional FTC concern.

First, we would suggest disclosure only of national averages and as I mentioned before, only on a deidentified basis that could not be reidentified. Second, given the very sophisticated IT systems and capability, it is quite possible to avoid a one size fits all approach and to tailor the level of disclosure to the characteristics of individual products. So, consider two examples. If we have something like Amoxicillin and let's say there are ten or more manufacturers and no signal dominant customer, then one could have potentially much more granular disclosure of information. In contrast, if you have a product where there are only two manufacturers or there is a dominant customer, one would report information in a much more aggregated way. In our paper, we identify a whole series of dimensions which essentially are policy levers that could be adjusted to change the level of granularity of reporting. We also suggest that it would be prudent to start at the level of relatively aggregated reporting with limited

disclosure only to plans but that on a selective basis, one could use demonstration authority to experiment and to try in the appropriate setting to increase levels of granularity.

So, let me conclude, and I look forward to our discussion, by reemphasizing four points. The retail market for generic prescription drugs is enormous. It's extraordinarily complicated, and there is significant information asymmetry among key players. Given the role of PBMs, the question becomes would providing health plans with more information enable those health plans to negotiate lower rates. And just to reemphasize the sizing exercise. A less than four percent reduction, one dollar, in the cost of a generic script would lower costs or spending by $4 billion.

We believe that reporting actual average prices to plans would have the beneficial effect of putting them in a more informed place. The question is, if the plans have the information, does that enable them to get lower prices to be sure to the extent that lower prices are achieved which means that payors and consumers, patients, are paying less, that money would directly come out of the profits and retention of pharmacies and PBMs.

In the paper, we outline a very specific proposal about how to do this and our analysis suggests that selectively reporting averages to plans would not impair manufacturer competition, nor would it facilitate price collusion on the part of manufacturers. With that, thank you and I look forward to our discussion.

MR. LAKDAWALLA: Good morning everyone and welcome to our second panel on the generic drug distribution system. My name is Darius Lakdawalla. I'm a professor and health economist at USC Schaffer Center. I'll be moderating and it is my pleasure to welcome a distinguished group of panelists to the discussion. First is Christine Simmon who is the senior vice president of Policy & Strategic Alliances at the Association for Accessible Medicines, previously known as the Generic Pharmaceutical Association, welcome Christine. Next is Tom Moriarty who is the executive vice president, chief policy & external affairs officer and general counsel at CVS Health, welcome Tom. Dough Hoey is the CEO of the National Community Pharmacists Association. NCPA represents 23,000 community pharmacies and their pharmacists. And to reintroduce Matt Eyles who is doing double duty today. You'll recall Matt is the executive vice president of Policy and Regulatory Affairs at AHIP and we're also joined by Steve Liberman and Paul Ginsburg, the co-authors of the paper we just saw. Welcome

everybody and we're looking forward to a great discussion.

There is a lot to talk about here. Before we get to the policy question, I'd like to begin by getting everyone to weigh in on what they think is the size and scope of the policy problem to be solved in the generics drug distribution system. The policy barometer here is what are the prices that end users are paying for generic drugs so end users being consumers and other third party payors like employers. Are these prices close to being competitively determined in the sense that they can't be driven any lower without making people go bankrupt or is there a lot of room for them to fall. So, Steve and Paul's study suggested that ingredient cost is a relatively small fraction of the price that end users pay. Does that mean we have room to squeeze these down or is that the real cost of delivering drugs. So, let's go around the panel and get people's thoughts on the scope of the problem. Christine, what do you think?

MS. SIMMON: Thank you, Darius, and thank you, Steve, for the paper. A lot of good work being done on these topics and no shortage of panels, presentations, papers, policies so obviously a great deal of concern out there. We, in the generics industry, are really happy to be a key part of the solution around drug pricing. You've seen some numbers up there, we just released our access and savings report yesterday updating the number. So, right now we are 89 percent of the scripts and we're only 26 percent of the costs. When you look at a variety of policy solutions and I must say this one at least doesn't impose any burdens directly on the generic manufacturers, so thanks for that.

The one we're discussing today really deals with a lot around MAC pricing and sort of the relationships between PBMs and plans and pharmacies. We're a little bit on the sidelines. I would say when you look at the idea of less than a dollar reduction and having a $4 billion savings, that's good. But we just did a paper last week, released a paper on how the abuse of restricted distribution systems or REM's, patient safety programs by some brand consumers is protecting over $22 billion in profits. We feel that there are potential for additional competition in the marketplace. There is a little discussion of that in the previous panel and it's not the silver bullet but the more generics we get on the market, the more competitors you have in a therapeutic class, the more patients and the entire system saves a tremendous amount of money. I think this is one area of focus but perhaps a better area of focus or a more impactful area of focus is if we're 89 percent and 26 percent of the costs, then others are 74 percent of the cost with only 11 percent of the scripts. So, we need to be focused on specialty medicines and

higher cost medicines. We need to be focused on increasing opportunities for biosimilars competition and some of the other, I think, ways to really drive down costs. This is nibbling at the margins, it's not without value but at the end of the day, I think there are bigger fish to fry.

MR. MORIARTY: I would say the market really does function very efficiently here. I think there are a number of public data points to show this and the various drug reports that have been put out there will reference this. You'll see within those, the impact that generic discounting drives in reducing overall drug spend in this country. It's dramatic in terms of that impact and that's because deeper and deeper discounts are being driven around generics and it is the lion's share of dispensing. While it is not the lion's share of spend, it has a disproportionate impact on the ability to reduce that spend.

The other aspect to this is while there is reference to rebates on generics, I do think the lion's share of generics being purchased do not involve rebates. In fact, they're direct purchasers and straight discounts and those straight discounts do get included in the publically available databases. So, put the potential flaws from that aside. There are other state Medicaid's that require direct acquisition costs to be reported. We report that so that clearly influences what happens and that information then is used to determine the MAC which is essentially the generic reimbursement for retail pharmacies.

The other element of this is the reference to a potential conflict at the PBM level. That issue has been investigated three separate times by the Federal Trade Commission. In 2003 under the MMA there was an investigation done on that, whether mail order pharmacies being owned by PBMs and having them within the same house, clearly found by the FTC that is not a problem. In fact, it leads ultimately to lower prices. It was looked again in 2007 and again in 2011 with the same result. We'll get into this later but I think there are elements in the marketplace that actually are addressing this and that is the availability of 90 day prescriptions at retail and that 90 day prescriptions are actually at the mail order discount, not at the retail discount. That discount is substantially deeper than straight live retail. So, there is a lot happening in the marketplace that has addressed this issue already and I know Doug will have some insights as to whether or not the reimbursement for generics at retail is appropriate or not.

MR. HOEY: Thank you, Tom. Thanks for that set up. We agree that this is an important issue. However, as far as the magnitude, as Christine said, yesterday there was hearing in the Senate on prescription drug pricing and it was stated there that 10 percent of healthcare costs come from

prescriptions, that's brand and generic. If you look at the 27 percent of overall healthcare costs, you're talking about 2. 7 percent of overall healthcare costs come from the generic side which is a very small amount. And even 10 percent if you look at overall prescription drug costs, 10 percent out of all we spend on healthcare is a very small amount for arguably the best investment that we have in healthcare. While this is very important, when you look at whether it is the 2.7 percent of generic or the 10 percent overall on the retail side, there are other ways to get greater value from the healthcare side.

It has been mentioned a couple of times, the dollar reduction resulting in a $4 billion savings. The market does operate very efficiently and our member standpoint, perhaps, over efficiently at times. So, the reimbursement for us, our net is around 200 basis points. The average prescription drug costs in independent and I think this is true for chains as well is about $55 to 60. Based on that, that's about $1.20 that at least the average small business owner pharmacy is clearing. So, you take a dollar and you're putting 20,000 pharmacies potentially out of business. So, that dollar, the margins are so small that even though it sounds like it is just a dollar, it is very important.

Also, again on the efficiency side, because of the MAC pricing, MAC pricing really dominates the way generics are configured. AWP as Steven said, is not really that relevant although it is increasingly becoming relevant. But MAC prices are often used and those MAC prices, some payors are paying pharmacies below their acquisition cost. There is one of the large PBMs pay the pharmacy below their acquisition cost 15 percent or more of the time. That's atypical, it is typically 5 to 10 percent of all generic prescriptions are paid below cost. That's an important factor so we're seeing some of that market efficiencies already.

One other thing I'll mention before passing it down to Matt is the conventional wisdom that pharmacies make more on generics than on brands has really been stood on its head in the last two to three years. That was true for many, many years. There was an incentive, it was a win, win, win for the plans, for the patient and for the pharmacy when a generic product was dispensed. That is no longer always true, in fact, it is often not the case. There are many situations in which there is higher dollar reimbursement for dispensing the brand. Some of that is due to the generic deflation that has taken place, especially in the last couple of years. The advent of generic deflation has really drastically changed the marketplace and made the pricing even more aggressive on the retail side. Thank you for

the invitation to be here.

MR. EYLES: Thanks for not kicking me out after the first panel and having me back. So, with respect to the paper and it is a lot of interesting concepts in it, I'd say from the health plan perspective, in general, we'd like more information to be able to understand pricing situations. That said, I'd say our biggest concern really is around sole source generics and what is happening in the market. I'd have to think through all the implications throughout the distribution system but anything that potentially could have additional downward pressure that would lead to longer term having more sole source generics and I don't know that that would actually be an outcome. I'd have to think through if that would happen but that would be a negative thing for the healthcare system. To bring it home to a patient level, I mentioned my son earlier. One of the other prescriptions he got yesterday was for a generic, minocycline, now a sole source, $200 and it's an old, old drug because there is not a lot of competition when you only have one there. What I hear consistently again from the health plan side is how do we ensure FDA gets generics without a lot of competition or any competition out there, how do we get them approved more quickly so that we can see the dynamics that we see with multisource generics which the savings are enormous when you get down to commodity price levels that are much, much lower.

MR. LAKDAWALLA: Steve, what are your thoughts?

MR. LIBERMAN: Thank you. Let me try to run through a couple of things. In some ways, Paul and I took the opposite approach of Neeraj. We started at a very global level with very aggregated data. We tried, and there are clear data limitations, but we tried to look in a very detailed way at a very specific problem. So, no we're not trying to deal with the fact that there are very high cost specialty meds that are consuming a large portion of that 74 percent of health spending. No, we're not trying to deal with the fact that there are things that are delaying generic introduction or generic competition. No, we're not dealing with the fact that there are supply chain disruptions on the manufacturer side where you have single source generics or an adequate supply of generics. What we are focused on is looking at the distribution of generic drugs which are a high volume commodity. In answer to your question, I think I would say that with the exception of the oddball circumstances where you don't have effective competition, this is a very effective market. In the slides and I didn't say this, our estimates are well under a third of what pharmacies get reimbursed, goes to pay the generic

manufacturer. The lion's share of that is retained by the pharmacy.

In our paper, we are pretty careful to footnote our sources. We would love to have more data and transparency in this area. But just to quickly respond, there is an excellent study that the Department of Insurance in the State of Washington published in late 2016. They looked and had a fair amount of transparency into these issues including things like the level of appeals of where MAC pricing was below acquisition cost. That 2016 study explicitly stated that pharmacies make more money on generics than brands. The MAC pricing, which I didn't discuss and would be happy to, we discussed it briefly in the paper. MAC pricing, according to that study, on average was significantly above NADAC which is significantly above dead net prices. That is what net ingredient costs are.

The last thing I would say is I think from Paul and my perspective, given that we believe that it is a very competitive market currently in place for multisource generics and they are essentially commodities, we don't think our proposal will change the price in those competitive settings that manufacturers receive. We believe that we're squeezing margin out of the distribution system. Thank you.

MR. LAKDAWALLA: Thanks Steve. Paul, do you have anything?

MR. GINSBURG: No, Steve covered it well.

MR. LAKDAWALL: Great. This has been an interesting discussion so far and many people have been pointing out that the generic drug distribution system in a reasonably efficient system. In fact, some people have said it is a highly efficient system. Yet if one reads the news and not just the news but pronouncements of policy makers, for instance, there has been a lot of focus on these single source generics as a location of rapid price increase. Scott Gotlieb has made increasing generic competition one of the pillars of his approach for cost containment at the FDA. So, what are we to make of these apparently disparate facts. On the one hand, is it the case that we have a really well functioning market or could it be that we have historically had such a well-functioning market but there are threats looming on the horizon or are these threats over stated. What do people think about that? Christine, what are your thoughts on the debate around the generic drug industry.

MS. SIMMON: Well I think we're talking about several different components here. The distribution system versus the market overall versus sole source generics. So, talking about the last one

first, first of all let's not be confused about what's a sole source generic and what's not a generic at all. I'll just say it again because I say it all the time. Daraprim is not a generic, Daraprim has never been a generic, it is a drug that was approved under a new drug application, that makes it a brand, and it never had any competition. Its patent expired and no one else came into the marketplace so it jacked up its prices as a brand. There are sole source generics that have no competition and simple econ 101 will tell you that that usually results in higher prices. There are potential policy solutions for that. We're very excited to have Dr. Gotlieb at the FDA. He has a very substantive understanding of the generic drug landscape and the marketplace and clearly is interested in many of the different ways to increase competition in the market. Some of which I touched on, for example, the abuse of restricted distribution systems so that manufacturers can't get access to samples and make the drugs in the first place.

There is a lot of potential there. The distribution system, again most of what we're talking about and what Steve touched on in his paper occurs after the drug has left he manufacturer and is making its way through the supply chains so I'm not really going to speak to that. I will say that Doug was right in pointing out the deflation. Generics have actually been in a deflationary trend with about 8 percent deflation over the past several years. There has been consolidation at all levels of the pharmaceutical supply chain and there are impacts from that consolidation. We do have to be careful that we don't try to drive down some of the incentives in such a way that generic manufacturers end up exiting markets because they simply can't afford to stay in them. That is something we want to have sustainable competition, sustainable reimbursement so that we can keep a balance in the marketplace and ensure that patients can have access to affordable medicines.

MR. MORIARTY: I would build on Christine's points. I think if you look at what is happening at the FDA and what Dr. Gotlieb has talked about is really a two-fold approach. One is clearing out the backlog of existing generic applications but also creating a more efficient pathway for newly filed applications. That element is very, very important and Christine will know this better than me. I think last year, you saw a decline in the number of newly filed applications which should be concerning to all of us from a market access and pricing perspective as well. It is both ends of the equation that need to be focused there.

The other element I'll bring up which is a little outside this panel but I think is very

important as well is the role of the biosimilars, which are essentially for the lay person, generic biotechnology products, and the role that they play. We really should look at what has happened in Europe and Japan with the creation of a pathway for the introduction of those products and how far behind we are here. Because when we look over the next several years with the lion's share of drug spend and medical spend will be going, it is going to be on specialty drugs and those biotech drugs. If we don't introduce competition into those spaces, what we're talking about here will pale in comparison.

MR. HOEY: I want to comment on one of the things in the paper that I think was really spot on was the imperfect information, the asymmetrical information that we think is very true. Because this marketplace is moving so fast that the information, not only is there imperfect information but the information gets dated very quickly. So, if you know what happened in 2014, you actually know what happened in 2014. It may have less to do with what's happening in 2017 and what will be happening in 2018. So, for example, the MAC pricing above NADAC, MAC prices are invisible to retail pharmacies. They change from hour to hour, pharmacy to pharmacy, minute to minute. So, there is really no way we can know how MAC's compare to the NADAC's. The information does become very dated. On MAC appeals, we're not really able to do MAC appeals very often because we actually get threats from PBMs if we give too many MAC appeals. So, there is that challenge as well.

With the generics, again there has been a major shift. Generic inflation on certain NDCs was occurring rapidly throughout the marketplace. Some of our numbers show using NADAC data so that 400 NDCs went up over 200 percent in 2014. That has been going down. There have been market corrections and it seems like in looking at that same list today, the number of NDCs that are going up over 100 percent, it is still a lot. I think 60 is the number that we calculated but it is a fraction of what it was a few years ago. So, while whether it is the Digoxin or the Doxycycline example, there are lots of examples. We are seeing fewer and fewer of those. Not to say the problem has been completely corrected, but the marketplace has adjusted. For whatever reasons, those prices were going up 500 percent overnight or whatever the percentage was. That seems to have abated. Again, very different than it was two or three years ago. So, the market is constantly adjusted.

MR. EYLES: I think Doug is right. I still hear it from our members on occasion. I think they would say the market, overall, functions very efficiently. To Doug's point I'd say 18 months to 2

years ago I was hearing a lot more complaints about generic drug price inflation and generic drug cost increasing rapidly, even to double digit levels but again on a relatively low base. I think Tom made the good point that it's important to focus and find efficiencies wherever we can but to the extent we can find the really big savings, I think that's where either through getting additional generics approved to improve competition in those areas where there are back logs or to the bigger area of biosimilars and thinking about that. Certainly, that would be our priority but again, we're all for efficiencies and anything that would improve affordability overall.

MR. GINSBURG: Let me say something about efficiency. When I think of distribution, one aspect of efficiency is for drugs where there are no shortages at the manufacturer level, are they getting out to the consumers that need them and it seems that yes, they are. The other aspect of efficiency is are the prices too high. I think there is real evidence that Steve presented that in a sense, the pharmacy level, the prices are not too high and that there really are opportunities. I think above competitive returns are being earned and that we got some of the tools to try to foster some greater efficiencies. There are others, health plans can pursue narrower networks of preferred pharmacy. This would foster compensation at the pharmacy level. I think there is a lot to be done here.

MR. LIEBERMAN: I want to add one quick point which is interestingly an outgrowth of our proposal which is essentially to get real time weekly or biweekly updates on pricing if there are, in fact, price spikes from generic that reporting which actually make that known. So, it is a way to actually deal with the rapid cycle of pricing changes.

MR. LAKDAWALLA: So, I want to pick up on two points that Paul raised and get people's thoughts on them. The issue of pricing at the pharmacy and also shortages. There has been a lot of attention paid to these two issues in different contexts. Doug, what are your thoughts on Paul's comment regarding the pricing at pharmacies? How would you respond to that comment?

MR. HOEY: You know I'm going to disagree with that.

MR. LAKDAWALLA: I'm trying to stir up some disagreement here.

MR. HOEY: Yes. No, we obviously disagree with that. The example I gave where the average net profitability for prescriptions is about $1.20 I think speaks volumes. We would also disagree very strongly with the WAC minus 70 assertion that was made in the paper. That would say that a rebate

of 70 percent, I may be doing the math wrong but I think it says a rebate is 70 percent. The rebates do vary from product to product which is very true. At least from the reports that we get and we don't get reports because we're a non-profit trade association. But just anecdotally what we hear in the marketplace, the rebates are nothing like that. So, I think the one-third is the cost of the drug and two-thirds the pharmacy makes on it, we would strongly disagree with that.

Another important thing to mention though is sometimes when generic profitability is talked about, it's talked about in percentage terms. So, for example, I'll use an inexpensive drug like hydrochlorothiazide which is a diuretic for blood pressure. That's a very inexpensive medication. So, one could say the pharmacy is making 100 percent margin on this drug. Well yes, but the product costs $.45. In fact, because generics in some cases are so inexpensive, a cost plus mechanism actually is more attractive and makes more sense to pharmacies. That changes a lot when you start talking about biosimilars and specialty because then you're talking about 5, 10, 15, 25 thousand or more dollar drugs but a cost-plus methodology, which is essentially what many of the state Medicaid programs have done, actually, makes a lot of sense in many ways.

MR. LAKDAWALLA: Matt, what are your thoughts on this? Do you think pharmacy prices are about where they should be for generics?

MR. EYLES: I'd say overall that's not our members' big concern. I'd almost pose a question back to Steve which is let's say under the price reporting system we do get a sharp spike in generic drug price. What can really be done about that? You learn there is a sharp spike increase and with a generic there probably isn't an alternative out there. We're probably seeing a spike for a reason. A health plan probably can't change their formulary or wouldn't change their formulary to exclude coverage. It would be important information to know but I'm not quite sure what we could actually do with it.

MR. LIEBERMAN: I think there are two implications of the scenario you posed. One is you don't want pharmacies to be upside down when they're acquiring the drug. So, one would adjust whether it's a MAC price or whatever the other reimbursement is. The other is it would be an early signal, for example, in the FDA of some kind of disruption in the supply chain. Either an ingredient shortage, a manufacturing problem. So it becomes an early warning system. It is not a panacea but it starts to address specific issues.

I entirely agree with Doug's point about it is much more useful, I believe, to look at dollar markups rather than percent margins, particularly when you're comparing vastly different products or you're talking about a shortfall on a $3 ingredient to make up a $1 shortfall requires a huge percentage increase. I would recommend to everybody, a 2004 report that CBO did and CBO has a unique advantage. Outside of the OIG and the people in CMS who actually administer the Medicaid drug rebate program, they're really the only people who have access to AMPs, to dead net prices. I hope they have the 2007 report that somewhat updates that. But the 2004 report makes the point about markups versus percent margins. My hope is that my former colleagues will update those reports because it is very difficult to get good information to inform policy makers in this area.

MR. MORIARTY: I would just add, since this is a broader policy discussion, two policy implications of further reductions and reimbursement. One would be the formation of networks and the availability of retail pharmacies to dispense. I think Doug will weigh on this as well. You're reaching points now where your reimbursement is below your ability to cover your costs so you see pharmacies make the decision that they won't participate in certain networks because the reimbursement just isn't enough.

The second is as we engage in this value-based reimbursement discussion, we really need to focus on and highlight the role of the pharmacist. The reimbursement here is all about the dispensing reimbursement. It's not at all about the cognitive skill sets that pharmacists bring to bear in the healthcare system. What is the reimbursement appropriate for that. All studies show that pharmacist engagement with patients increase adherence to medications by three to four times any other engagements. We should be looking at a system that actually compensates for that type of engagement in a way that truly compensates for the value being driven as well. So, just two broader policy points that we should keep in mind as we go down this discussion.

MR. LAKDAWALLA: Thanks, Tom. I do want to get us to the other point that Paul raised because we haven't talked about it so far and it is not strictly a question of distribution but there has been a lot of attention paid to what appear to be growing shortages in generic drug manufacturing and distribution. Whether that is real or perceived I guess is the question that I'd like to pose to the panelists. Are we seeing more shortages for essential generic medicines today than we did 15 years ago or not and

what do you think of the implications? Why do we have a lot of attention paid to this issue, what are your thoughts on that, Christine?

MS. SIMMON: Drug shortages can be a problem for sure. There are different factors that create shortages. Sometimes it's a ingredient sourcing issue, getting the API and getting it to the facility. Sometimes it's a result of FDA inspections, shutting down facilities, that's something that when we negotiated the first user fee act for generics and now are, of course, hopefully wrapping up the second round for generics this fall. We wanted more and we paid for more for an inspection of facilities because that is critically important and patient safety is paramount. So, that can be a reason for shortages.

I don't know that they're on the increase as much as we're keenly attuned to them maybe now more than we had been in the past and they are more easily reported and the implications are perhaps more widely localized. That's not a bad thing. In terms of focusing, there are many things in place to address drug shortage issues and it's just an ongoing challenge that I think the whole supply chain has to deal with. I can't speak to specific products or manufacturers but I know that our manufacturers work very hard to avoid shortages.

MR. LIEBERMAN: I'd just point out that unfortunately, I think your question has much more to do with the, what I would consider, the manufacturing supply chain, than the distribution chain. Our paper was focused on the distribution chain.

MR. LAKDAWALLA: Okay. Let's talk about the price transparency proposal in the study that Steve presented and that he and Paul prepared. Let me open that box up for everybody to talk about. I want to consider a couple of angles on this question. First of all, to what extent do you think greater price transparency of the form indicated, to what extent would it reduce the prices that end users face for generic drugs? Is it, in your view, the first order policy reform that's needed in the distribution system and if not, what other reforms would you consider. Let's begin with Matt.

MR. EYLES: We are definitely supportive of more price transparency to help inform decisions at the plan level. The question is, what does it get us at the end of the day. Again, anything that can improve affordability that flows down to consumers and premiums and copayments, I think, is potentially a positive. Still, I was trying to digest how far the proposal would go to actually accomplish that. Again, anything that the margins would be helpful but what would it actually mean in terms of what

the end user pays at the pharmacy, the consumer or what would the impact be on premiums and overall affordability is still a little questionable, I think.

MR. LAKDAWALLA: Well, Matt, what do you think would be an alternative? If you could snap your fingers and change one thing in the drug distribution chain, what would it be? I'll let you think about it and we'll go down the rest of the table on this question regarding price transparency. Doug.

MR. HOEY: I think the proposed solution is transparency overall is important. That's almost a silly thing to say. Of course, transparency is important which we don't have the imperfect information that we have now. I think, the paper as I understand it, really is very tactical versus strategic and that sounds critical but I don't mean that as quite as harsh as it sounds especially with the two authors right here. It would only look at one part of a much broader problem of a lack of transparency that we have in our healthcare system. Again, it is 2.7 percent of the overall healthcare costs. Trying to get pure transparency there first doesn't really make a lot of sense to us. If we're going to look at that 10 percent part of the overall health care spend which goes to retail prescription drugs, we would suggest looking more on the PBM space. There is a lot of opaqueness in that area rather than in the prescription drug pricing.

MR. LAKDAWALLA: Let me just quickly follow up on that point, Doug. We haven't talked about that and that's the issue of PBMs in the distribution system. Tom is going to get a chance to weigh in on this as well. There has certainly been a lot of criticism that the incentives for PBMs encourage higher list prices because they get rewarded on the spread. Just confining your attention to generic drugs given that that's our remit here, do you think that's an issue here that we should be particularly concerned about in the generic drug space and what would you view as a potential solution to it if you do think it's an issue.

MR. HOEY: Yes, it's definitely something that needs to be looked at as well. It is a different mechanism so the pricing for in a PBM contract for generic drugs is different than on brand so it may not be as rebate driven as it might be on administrative cost or on an AWP minus or different MAC schedule. There is no transparency into any of that. But because the AWP spread is so wide on generics, any manipulation of the second part of that AWP minus can lead to some pretty lucrative profitability on the PBM side especially the pharmacy, the price setting and the price taker. I definitely

think that's an area that needs more insight, more focus, it's just tough to get data, very tough to get data from that side of the house.

MR. LAKDAWALLA: Tom.

MR. MORIARTY: I'll follow up on that. As I indicted in my opening remarks, the issue of the conflict has been looked at three separate times by the FTC and the issues haven't changed. Since 2011, 2012, you've had some highly deflationary marks in generics as Christine can confirm. You have, perhaps even high competition in the PBM space where you have very sophisticated purchasers like Matt's members who are very, very smart people doing that negotiation. They also leverage highly informed consultant community. As a result, what you see is the net effective pricing has, in fact, compressed and decreased. I think that is demonstrated not only by the trend reports but also by the fact that you have mail order basically flat to declining now from a client perspective. That's because and you actually now have more increased discounting at mail order to try and maintain that share and that is driven by a number of different issues. Obviously, the event of 90 day prescription availability, retail and other things. So, this issue has been looked at any number of ways both at the federal and state level and I think the data bears out how competitive the marketplace is and the value that ultimately is delivered to Matt's members, employers, state and federal governments, labor unions, et cetera.

MS. SIMMON: I don't have too much more to add to that. We do think that it's a very efficient marketplace and sometimes from our perspective, a little too efficient. There are other ways to try to reduce costs and increase competition in the marketplace. You can't get blood from a turnip so you do need to sort of pick where you really want to focus policy makers and policy solutions. This has been an interesting exercise and I think the paper did a great job of elucidating the market and really looking at different factors. I think you have to come up a few hundred thousand feet to the bigger picture and focus on things that will really drive savings.

MR. LAKDAWALLA: So, let's open up for a few audience questions and then we'll wrap up.

MS. LUPKIN: Hi, I'm Sydney Lupkin from *Kaiser Health News*. I have a question about generic competition actually related to a different middle man that we haven't really discussed here which is GPO's. If I am a generic manufacturer and I want to sell a product to hospitals through a GPO but the

fee to be part of that GPO is something that I can't afford and there aren't that many GPO's, could that force me out of business and if so, how widespread of a problem is that as it relates to competition with generics.

MR. HOEY: So, on the hospital GPO side, I'm going to have less insight into that. I can share with you on the retail pharmacy GPO side but it's a different model than on the hospital side. I don't know that my answer on the retail side would really answer your question.

QUESTIONER: Yes, thank you very much. I have a question that relates to the end user distribution and technology software and apps. It is my impression that for the gentleman who got the $600 ointment, that there is not software or an app that you could use that plugged in the name of that prescription and found out the range of prices in a certain geographic area. The same there wouldn't be an app. So, my question is, if at the end user consumer level, there was something that said, if you want this prescription in this geographic area, these are the eight different prices that you would pay. Sort of like you can do with an appliance. Would that help in a trickle down backwards.

MR. LIEBERMAN: So, two comments. One, Medicare for part D has plan finder which essentially does that. Second point, what you get out of that app, I assume, is what the plan would charge the beneficiary, not what the true cost of the good is. So again, the question of and we have a glossary in our paper that sort of unfortunately tediously goes through the different price perspectives. And so, the question is are you trying to get transparency about the cost to society or the cost to the consumer and those are different measures. I assume that one could take plan finder and make that mobile. Again, the question is whether or not people use it.

MR. GINSBURG: If I could add something, I think when you mention that the plan finder, not too many people use it, this unfortunately is the story throughout healthcare. There are some very sophisticated tools that have been placed in front of consumers, often by insurers, to get negotiated prices. They don't use them. The upside of it is there needs to be other ways to foster competition in the market. Often network strategies, reference pricing, far more effective than just provided a lot of information to consumers.

MR. HOEY: It's not an app but as far as cost savings, it is your local pharmacist. I know that sounds like something I would say but in the example of the Minocycline without divulging too much

HIPAA guarded PHI, my son also takes Minocycline. I am a pharmacist so when the prescription was written, the prescriber whatever came up on their handheld, and they wrote it for the tablet. I know there is a tablet and a capsule because I'm a pharmacist but most consumers aren't going to know that. So, when I took it in I said hey, I know the tablets are sometimes more expensive, would you check out the capsule. Saved more than half the cost on the drug because I got the capsule instead of the tablet. That's knowledge that I have because I'm trained. There are 300,000 retail pharmacists in the country who have knowledge like that and who can help like in a steroid cream, there is quite a range of different steroid creams, ointments, lotions and so the pharmacist can provide an alternative. Especially in those cases which are becoming rarer where the product has gone up 500 percent overnight. That's actually what happened during the time when it did.

MR. LAKDAWALLA: Thank you very much everybody and I'll turn it over now to Paul for closing remarks.

MR. GINSBURG: I want to thank first the paper presenters for the great job they've done. All the panelists who really provide a great deal of insight. To you the staff who made this run smoothly and also the gift from Leonard Schaffer to USC and Brookings that supports the Schaffer Initiative for Innovation and Health Policy. Thank you very much.

* * * * *

CERTIFICATE OF NOTARY PUBLIC

I, Carleton J. Anderson, III do hereby certify that the forgoing electronic file when originally transmitted was reduced to text at my direction; that said transcript is a true record of the proceedings therein referenced; that I am neither counsel for, related to, nor employed by any of the parties to the action in which these proceedings were taken; and, furthermore, that I am neither a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

Carleton J. Anderson, III

(Signature and Seal on File)

Notary Public in and for the Commonwealth of Virginia

Commission No. 351998

Expires: November 30, 2020