FTC Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics Workshop
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Segment 3: Panel 2
Transcript

DAVID SCHMIDT: Good morning. I'm Dave Schmidt. I'm an assistant director in the Bureau of Economics, here at the FTC. I'd like to welcome everybody here to this panel, those here in person plus the people watching on the internet. I'd especially like to acknowledge Congressman Buddy Carter of Georgia. Welcome, Congressman Carter. Just a little time bookkeeping here. We started a little late because of a fire alarm in the building or a security thing. We're going to try to get back on time. We're going to end this panel at 1 o'clock, at which point we'll break for an hour for lunch, and would like to get back on schedule, then, following lunch. So we'll start the third panel at 2:00 p.m.

So as we heard in the previous session, there are many entities that get involved in pharmaceutical markets between the manufacturer who makes the drug and the patients who take the drugs. These next two sessions are going to focus on the roles of two types of intermediaries in the pharmaceutical supply chain, pharmacy benefit managers, which will be this panel, and then group purchasing organizations. Just to give you a little background on pharmacy benefit managers, or PBMs, as is usually the case in the healthcare sector, the terms of trade for most prescription drug purchases are heavily influenced by insurance coverage. For instance, IMS Health estimates that a little more than half of all prescriptions filled at retail pharmacies are filled under a pharmacy benefit plan managed by a commercial third-party payer, for instance, the health insurance that someone might receive from their employer or from their union. And another quarter of all prescriptions are filled under Medicare Part D plans, which operate very similarly in many important respects. The companies who manage or administer these pharmacy benefit plans are naturally pharmacy benefit managers.

From the perspective of those of us who get our prescriptions filled, the main role that the PBM plays is to help us find a place to get the prescription filled, and to work out all the payments to the pharmacy and from our employer, and work out all the payment schemes. However, the primary client of the PBM is not actually us, the end-consumer. It's the plan sponsor, our employer, or union, or whoever is providing the benefit. In conjunction with that plan sponsor, the PBM works out to design the specifics of the plan, decide which drugs will be covered. They might negotiate rebates or discounts with drug manufacturers. They sign contracts with pharmacies to have the prescriptions filled when we walk in with our prescription. PBMs also, as we heard in the first session, typically own their own mail order pharmacy. And that was the subject of a 2005 FTC study. Additionally PBMs, many of them, own their own specialty pharmacies that dispense difficult to handle or very expensive drugs.

In order to provide all these different services, PBMs have to engage many of the other participants in the drug supply chain. This panel will explore the relationships the PBMs have with those other entities in order to understand what effect they have on drug prices, quality of coverage, and consumer access. Given the complexity of this topic, I'm very happy to have a very esteemed panel here to help us sort through these issues. In the interest of saving scarce

time, I'll just briefly introduce each of the panelists and refer you to the printed biographies that are also posted on the workshop website. In the agenda, the panelists are listed in alphabetical order, but we've previously arranged a slightly different order in which they're currently seated to my left.

To start, Neeraj Sood is a professor and Vice Dean for Research at the USC Sol Price School of Public Policy at the University of Southern California, where I understand it's 70 and in the mid 70s today, so smart move coming here. Second is Mark Merritt, who's the president and CEO of the Pharmaceutical Care Management Association, the national association representing America's PBMs. Next to him is Jennifer Bryant. She's the Senior Vice President for Policy and Research at the Pharmaceutical Research and Manufacturers of America, the national association representing the country's leading biopharmaceutical research companies. Then next, Susan Pilch is the Vice President of Policy and Regulatory Affairs in the National Community Pharmacists Association, which is an organization that represents America's community pharmacists. Then, Rob Andrews is the CEO of the Health Transformation Alliance, which is a collection of over 40 major employers reevaluating how they provide health care coverage to their employees. And then finally is Adam Fein, who's the president of Pembroke Consulting and author of a popular blog on pharmaceutical markets and drug distribution called Drug Channels. So I'd like to invite Neeraj up for his first presentation. And again, in the interest of time, I'd like to ask the panelists to try to keep their talks to around 10 minutes, but certainly no more than 15. Thanks.

NEERAJ SOOD: Thank Thank you, David, and thank you for inviting me here. So I'm going to be covering-- The title of my talk is "The flow of funds in the pharmaceutical forum." So I thought before I talk about the flow of funds in the pharmaceutical forum, I should talk about where I got my funds from. So that's my disclosure. OK, so I'm going to be talking about three things. First, is just kind of a primer on how drugs reach from manufacturers to consumers, and who are the middlemen in the supply chain, and what role do they play. Then, I'm going to use some publicly available data to, kind of, give you a 30,000 feet view of how much money is being made in the supply chain. How Much money our pharmaceutical manufacturers are making, and so on. And the last part, I'm going to give my opinion on, based on this data and based on some economics, on whether I think PBMs are making too much money or not.

So if you look at the supply chain, the drugs start at the manufacturer. Then, the manufacturer sells the drugs to a wholesaler. The wholesaler, in turn, sells the drug to a pharmacy. And the pharmacy-- You, as a beneficiary or a consumer, go to the pharmacy and get the drug. So this seems like a very simple, straightforward market. But when you start talking about how money changes hands, it becomes more complicated. So now there are two more entities involved, which is your health plan that provides you health insurance coverage and the PBM that helps the health plan manage their drug benefit.

So you, as a consumer, pay a co-pay to a pharmacy. You also pay a premium to your health plan. And your employer also pays a premium on your behalf to your health plan. So that's the flow of money for consumers. The retail pharmacy, in turn, buys the drug from the wholesale pharmacy. So they pay money to the wholesaler. The wholesaler, in turn, buys the drug from the manufacturer. So they pay money to the manufacturer. The manufacturer sometimes, you saw in the previous session, assists consumers by giving them a co-pay coupon, sometimes to promote

their drugs. And the manufacturer also gives rebates to the PBM. And the PBM, in turn, in response to these rebates, places the drug on a preferred formulary tier within the health plan. The health plan pays money to the PBM, which in turn, reimburses the pharmacy. And the PBM also passes on some of the rebates it got from the manufacturer to the health plan.

So I think the bottom line here is, when we say pharmaceutical prices, we should be careful about what-- What do we mean by a price here? Is this the price the manufacturer sells to the wholesaler? Is this the price the wholesaler sells to-- There are so many different prices. And, as Steve said, this is a 30,000 feet view. When you start looking at the individual person, for the same drug, a person can get many different prices. But this just shows the complexity of the market.

So I've covered the roles the different parties play. So what we did is, we went-- First, we identified the top publicly traded forums in each one of these market segments. So the top manufacturers, wholesalers, retailers, and so on. And then we went to their SEC filings, which are public. And we estimated two things, their gross profit margin. The gross profit margin is basically the revenue they get in less the cost of goods sold. So if you're a wholesaler, the revenues you get in is the sales to the retailer. So whatever the retail pharmacy gives you, that's the money you get in. And less cost of goods sold is the money you give to the manufacturer for buying your product. So the difference between those two tells you what you're keeping in the supply chain for providing the services you are providing. So basically, the gross revenue for the wholesaler is the money they keep as profit, the money for operating their warehouses, and so on. And the net profit is basically what we normally think of as profit, which is basically pure economic profits.

So when you use this conceptual framework, you see that manufacturers make about 70% profit. Health plans make about 20% gross profit margins. And if you apply these margins, basically what you get is that for every $100 a consumer spends, about $19 goes to the insurer, about $5 goes to the PBM, about $15 is going to the pharmacy. And so what's left for the manufacturer is about $58. So $40 is basically going to middlemen in these markets. And when you look at this for brands versus generics, the big story is that middlemen make much more money for generics compared to brands. So PBMs, pharmacies, and wholesalers make about $8 for every $100 of brand spending, but they make about $47 for every $100 of generics spending. And when you look at the net profit margins, basically what you get is for every $100 I spend as a consumer, someone in the supply chain and the manufacturer is keeping $23, with the majority of the profits going to the manufacturer. But the supply chain is keeping about $8 in profits. So this is, in some sense, the opportunity that if you improve the supply chain, this is the opportunity for squeezing out some of the profits from the supply chain.

So are PBMs making too much money? I'm going to do four different analyses. First, I'm going to be an FTC economist and say, you know, they're making too much money if the markets are highly concentrated, which is the case here. Three PBMs control the majority of the market. And pure market concentration has two sides of the story. One is it helps them negotiate lower prices, which might be good for consumers, but they might not pass on these lower prices to health plans, because they have the market power. And if they don't pass on the prices to health plans,

consumers might not eventually benefit from these lower prices. So the link from market power for PBMs to consumers getting lower prices is very tenuous.

The second thing we did is we, again, looked at financial returns of PBMs, of manufacturers, and of all forms in the S&P 500. So these returns are, basically, the rate of return on investment less the cost of capital for each player. And what we see here is that the three forums that own the PBMs, their excess returns are about 42%, which is much higher than what manufacturers make as excess returns and what S&P 500 benchmark makes it, as excess returns. So again, this is very preliminary, but this suggests there might be some opportunity for savings here.

The other way to think about this is, fine they are making money, but if they're providing the value, then that's fine. So for example, we know PBMs keep about $5 out of every $100 in spending. So if they are helping us get a $10 rebate, then it's a net good for us because we've saved $5, right? That the health plan or the consumer has saved $5, because we gave the PBM $5 and in turn they got us a $10 rebate.

But the other question to ask is maybe there are some other players. Like maybe Rob can do the same job or a better job at less than $5. So there might be new business models. Or Amazon might come in, and they might provide us the same value for a smaller amount of money, or maybe a greater value for the smaller amount of money. And it's still an open question. But there are a lot of new things happening here.

Then there's also some evidence, just based on economic theory, that the incentives for PBMs might not be aligned. So we've heard about drug prices going up. These are basically the list prices of drugs that go up. So here's an example of a drug having a list price of $200. The list price goes up to $250. One story, anecdotally, we hear why this happens is because now the rebates are bigger. So with a $200 drug, the rebate was $50. With a $250 drug, the rebate is $60. And what happens as a result of this is that the PBM makes more money because their revenue source is the rebate. But the cost of the health plan might not actually-- The health plan might actually prefer the lower list price, even though some of the rebates are being passed on to the health plan, because the retail price of a drug might have increased. Similarly, the manufacturer might prefer the lower list price because they're paying more in rebates. And consumers, which is what the FTC should care about, would also prefer lower list prices because uninsured consumers might pay list price or if you're below the deductible, you might be paying list price. So this is an example of prices going up. PBMs might be potentially benefiting from it, but health plans, consumers, and manufacturers might not be.

Another anecdotal example we've seen is where there are two drugs. One actually has a lower retail price, but the PBM prefers a drug with a higher retail price, because again the PBM keeps a larger fraction, gets the rebate while, from a health plan's perspective, the drug with a lower retail price would have been a better bargain. So I have two seconds left. I'm going to stop by just highlighting that a lot of these issues are underexplored. These are, right now, coming from economic theory, so there is a big research agenda for the FTC to actually empirically look at these issues. Thank you

[APPLAUSE]

MARK MERRITT: David started by reminding everybody of the fire drill and giving me a quick little lecture before I got started about-- There is a clock there. It says 15 minutes. Try to stay under it. I said, "Or in my case, I could just kind of keep rolling." But I think I will be relatively brief. And what I want to do is kind of go to a top line. There's a lot of interesting data. A lot of interesting input information on how things work. But there are also a lot of basics to how the marketplace works and who the clients are that we serve, who are the most sophisticated, largest health purchasers, really, in the world. From Fortune 500 companies, to Medicare Part D, to a host of other large insurers, its a very, very complicated marketplace.

And so the question is none of these smart, big, powerful organizations has to hire a PBM. But they all do. Why? Well, there must be reasons. And so I want to talk about that and how we add value. But I also want to give a quick overview, first. A top line on this. My pet peeve on health care is I think a lot of people try to make health care more complicated than it is. And sometimes, it's important just to kind of look at the basics of what's driving this economy, the drive in marketplace, driving what we do, drive what our clients do.

So first question I want to look at and answer is why is there so much concern today over drug prices? I want to touch on the role of the supply chain and getting drugs to market, but also explain why that issue shouldn't be conflated with drug pricing, which is something dictated solely by drug companies and has nothing to do with other people in the supply chain. I'd like to describe the intense level of competition in the PBM industry. It's a very, very competitive and ever-changing space, and also talk about how PBMs reduce costs and improve access for payers and consumers.

First, is price inflation of brand drugs. That's kind of the key issue. When we look at why people are concerned about this, what is driving all the aggravation on drugs, the first reason is the price inflation of brands. That's the most important cost driver. And it's often due to the lack of competition, which Dr. Gottlieb and the FDA are looking at, and we support those efforts. The second issue is drugmakers recent shift from producing blockbuster drugs like Lipitor, which may have cost $3 a day, to drugs like Sovaldi, which costs $1,000 a day. This came on the heels of a decade that actually saw very little brand inflation, thanks to the generic wave that kept prices down.

The third thing that is raising so much concern on drug pricing are the high profile scandals involving three drug makers. Mylan's 400% EpiPen increase, which was all over the news and all over congressional hearings, and the discovery of two companies-- the business practices-- Turing and Valium, who had an explicit business model of buying drugs that were low-cost for the reason of reselling them at higher costs, and then subsequent congressional hearings. I'm familiar with these hearings because I testified at a number of them too. And that, kind of, happened at a time-- kind of a perfect storm-- where everybody was wondering why prices were going up. And even though these business practices aren't typical of manufacturers, in general, it just raised overall doubts of this.

And then finally, the issue we see is with health plans. Health plans are in a response position where they have got to deal with a higher price of drugs and the higher prices and costs of health care, generally. So there is a move towards high deductible plans. Some of that has to do with

drugs. Some of it doesn't. But higher deductibles mean that some patients who've grown accustomed to paying $25 for a co-pay now come face to face with the real price of the drug, which can be hundreds or even thousands of dollars. And, I think, one of the ironies of bringing costs down for patients through a co-pay system is that a lot of people did begin to kind of think that the co-pay was at or near the actual price of the drug, when in fact it had little to do with the price and everything to do with trying to help consumers, but also encourage them to use lower cost drugs whenever appropriate alternatives were available.

Now, a couple of quick thoughts on the supply chain. Supply chains are normal. They're not exotic. They are not unique to this industry. Every product in America, every industry in America uses supply chain. It doesn't have anything to do with prices. It's a normal part of American business. Mylan didn't raise EpiPen prices 400% because of supply chain costs. The laws of supply and demand, not supply chains, determine how drug makers and other manufacturers set prices.

In its simplest terms, the prescription drug market is like any other. It's a market of sellers and buyers. Drug makers are the sellers, and like all sellers, they want to set prices according to whatever they think the market will bear, just as when somebody is selling a house, or a car, or anything else. They want to see what the other options are, how much they can charge, and that's why they surprised at certain levels. Likewise, buyers, who we represent, want to pay as little as possible. And these are the unions, the employers, the government programs, Medicare Part D, and so forth that we represent. And so there's a competitive marketplace, not just among PBMs, but, of course, between PBMs, manufacturers, and drugstores.

Now, let me turn to competition and how PBMs improve access, choice, and affordability for both payers and consumers. To begin, I think it's safe to say that, over the past 25 years, the PBMs essentially created a competitive marketplace that hadn't existed beforehand. It wasn't that long ago that the prescription drug marketplace was essentially a fee for service marketplace where people paid cash for drugs. And the only recourse that they really had to find a better deal was to drive around to different drug stores and, hopefully, find one that had better prices than another. There were few pharmacy networks or formularies pointing to the best values available in the marketplace, and so forth.

Things have changed dramatically. That was a very uncomplicated system, by the way. People talk about how it's so complicated. Always middle men in the middle. There's a reason we're in the middle. It's because payers want us in the middle. They want us to negotiate with drug companies. They want us to negotiate with drugstores. They want to use their buying power more efficiently. They don't want individual people having to duke it out with a drugstore or a drug company for the price of drugs. They want people in the middle. Even though it's more complicated, the savings are significant.

Of course, since then, PBMs and the role of PBMs have been in high demand, and things have changed in the marketplace. We see this all over the place. Of course, Medicare Part D is a shining example of how we do what we do. Now, seniors can choose among numerous competing plans to find one that works best for them. Again, they were the largest segment of cash paying customers in the country, and they are also the highest utilizers. And so, really,

people forget. Now Medicare Part D is such a fait accompli, you forget it was even around 11 or 12 years ago.

Over the past 15 years, the FTC has looked at this extensively, looked at our industry extensively, and found that it is one with a lot of competition. It's highly competitive and provides savings for consumers and the payers that we serve. Competition, including competing business models, innovation, change, and disruption have all been hallmarks of this industry. Currently, there are dozens of competing PBMs. There are all kinds of different PBMs. Just a few weeks ago, we had one large insurer say they're going to create another PBM.

And we have groups like Amazon.com entering the space. And so I think what you have here is payers are driving and calling the shots. It is a very, very disruptive marketplace. If payers don't like what they're getting from one PBM, in terms of prices, transparency, benefit design, pharmacy networks, or whatever, they'll certainly find another PBM who will give them what they want. And they're going to learn that from one of those competing PBMs that wants to steal the business from the incumbent. That's good. That's the way the market should work. There is rapid change, constant change, and that is a good thing in this industry.

Finally, in terms of the role of PBMs and how we help our clients, including employers, unions, and health insurers who provide benefits, it's really a pretty simple process. It's very complicated how it happens, but it's actually pretty simple. We have a proven record of delivering savings, typically saving about 30% for our clients. We administer benefits for 266 million people. And remember it wasn't that long ago where very few people had significant pharmacy benefit insurance. Medicare Part D is probably the shining example, in terms of this town, what people understand in terms of our value. But our savings are significant. And by cutting underlying costs, PBMs can find recommended benefit designs that save money and can work with payers to help them stretch their finite dollars.

Payers don't have unlimited dollars to spend on drugs. Just because a wonderful new $100,000 drug hits the market doesn't mean payers have $100,000 sitting around to pay for it, at least not right now. They may need time to figure out how to finance that. They may need time to look at the clinical data, but we are a very fast moving marketplace in terms of innovation, and payers are working hard to keep up. They want to make sure that people can get access to the drugs they need, even expensive drugs like Sovaldi, but it is a challenge for everybody. But these designs of course include cost sharing incentives and a host of other incentives that PBMs develop and work through.

Finally, a little point about rebates. Rebates, there's a lot of noise about them. But long before PBMs became a force in the marketplace, rebates and the rebate system were created by manufacturers. In the case of programs like Medicaid and 340B, by public policy makers. It was used before PBMs started getting involved in outpatient drugs. And they do reduce the net costs of brand drugs. In fact, about half of the rebates and price concessions reported by manufacturers don't involve PBMs at all and are paid to government programs, or through coupons, or co-pay assistance programs administered by drugmakers. PBMs use rebates to reduce premiums and out-of-pocket costs for patients. Each payer determines what percentage of rebates are passed through and how much, if any, they want the PBMs to keep. 90% of rebates are passed through

to plan sponsors, but about half of our large clients, large employers are increasingly having 100% of rebates pass through, which is fine with us. The marketplace is changing, and we will change with it.

DAVID SCHMIDT: I noticed the clock started at 10 minutes for you. I apologize. I'm wanted it to be at 15. So if you have a couple more minutes, that's fine, even though the light is red.

MARK MERRITT: OK, thanks I was wondering about that. I think we may have shut the doctor off a little bit early too. One other thing about rebates, apart from the fact that they do save money, apart from the fact that our industry has said we would welcome other solutions to rebates if manufacturers could offer them, including just lowering the list price of drugs, should be noted that there's really no connection between the prices drugmakers set and the rebates negotiated with PBMs.

A recent study of the top 200 self-administered patent protected brand name drugs shows no correlation between the price the manufacturers set and the rebates that they pay. There are many cases of high priced drugs that carry low rebates, low price drugs that carry high rebates. Some high priced drugs have no rebate at all. Sovaldi hit the marketplace at $84,000. Was that because of rebates? No, they didn't offer a penny worth of rebates. Rebates came later as competitors came to market. But I think Sovaldi offers a good way to show that drug makers will charge, like any other business-- I'm not saying this is good or bad. Anybody selling anything will charge whatever they think the market will bear. It's pretty simple. That was the case with Sovaldi. That was what they thought it was worth. That's what they charged. But it had nothing to do with rebates because there were no rebates offered.

PBMs have stated publicly, again, that we'd welcome drug companies to offer alternatives to rebates, including simply lowering the list price of drugs. But rebates do remain a key way, in the meantime, to deliver value to our clients. And our clients want us to get that savings. If prices go up, we want to get bigger rebates and pass them on to our clients. That's just the way it is. It'd be better for us, in terms of just getting lower net costs, if the prices stay down. But if they do go up, we will ask for, and demand, larger rebates so we can pass them along.

I would say, also, on one other issue of that, it is the payers who decide where the rebates go. When the rebates are passed through, the payers can use them to reduce point of sale costs. They can use them to reduce premiums, deductibles, whatever they want. Probably typically they use them to reduce premiums, but that really is their call, not our call. That is a plan issue and it is a very competitive marketplace, and plans understand it very well.

We are already working with plans to implement point of service or point of sale rebates in the commercial marketplace, although there is not high demand yet. It is tougher to do it, may be difficult, if not really, really hard or impossible, to do in Medicare Part D for a lot of different reasons. It would increase cost of the program significantly. It would increase premiums significantly. Medicare Part D operates differently than the commercial marketplace. But the point is we get the rebates. We pass them through. If the clients want us to keep any as part of the payment for the services, we do. Increasingly, we're seeing a lot of large clients say they don't want that. They want 100% pass through, which is fine.

So in closing the PBM marketplace is highly competitive. It's driven by the various and ever-evolving demands of the marketplace. It's a disruptive marketplace. When I first got here at PCMA, I'm not sure that even two or three of the companies that were in the industry then, 15 years ago, are even there now. It is constantly changing, and that's a good thing. Marketplace competition gives payers a wide variety of PBM choices, so that each payer can offer the kind of prescription drug coverage that is best for them, that is most cost effective for them, and best for their enrollees. And that is the bottom line. If the marketplace, if big payers find value with PBMs, great. They know what they're doing. They should get it. If they don't, they can go another way. But the reality is, regardless of all the input costs or all the discussions of middlemen, supply chain, and so forth, the reality is PBMs offer tremendous value, or else the smartest, largest, best purchasers in America wouldn't use us as they do today. So thank you very much. [APPLAUSE]

JENNIFER BRYANT: Hello, I'm Jenny Bryant from the Pharmaceutical Manufacturers. I want to just, maybe, jump straight to the bottom line because I think there are some things that, maybe, we all agree on. And that is that this is really all about competition, and that the key here, when we're talking about rebates, which I think we're going to be doing most of the day today, is to make sure that those rebates and negotiated savings are benefiting patients. And the health care system, more broadly, that they're working in the service of getting us better outcomes at lower prices. And I would argue that the degree to which the market has been working is, in part, the result of the success of intermediaries. So it's not about whether we need intermediaries. It's about the terms of competition and making sure that the market is working well for everyone. And I would argue that the market can, in fact, work better than it is today, and that we can bring negotiated savings to patients better than we're doing today.

Since we've talked about drug costs several times already, I won't dwell on this. But I would argue that, in fact, the trends in drug costs growth, despite what you read in the paper, are much more modest than are frequently claimed. I'm showing you here the year over year trend for the largest pharmacy benefit managers, which as you've now heard, control a large share of the market. We're showing for 2016 low digit growth in 2016, right? Much lower than in 2015. And one of the largest PBMs, Prime Therapeutics, has just released data for the first half of 2017 showing growth under 1%. These are not the numbers you, generally, are hearing when you, generally, are reading about drug costs and drug prices you're reading about, list price growth, which we can talk about. But these numbers, I would argue, do not represent an unsustainable path, in terms of drug costs growth. And in fact, these numbers take into account the fact that we've been bringing dozens of new medicines to the market every year, fundamentally transforming the way that care is delivered.

When you hear about drug costs, most of the concern has been about what we would call list price growth. And here I'm showing you data from IMS Institute. The top line shows the list price growth and the bottom line shows the actual final price to payers after rebates and discounts are removed. So here we're showing price growth in 2016 of 3.5%, which is obviously very different from the top line growth. So why does this matter? It matters in many, many markets because the fact is that patients are now exposed, increasingly, to those undiscounted top line prices. And they're not small differences. If you take the example of the insulin market, for example, which is frequently the target of criticism for list price growth, the publicly reported

average rebates in that market now are approaching 70%. And so, for patients, that could make a very large difference

I'd also say that as we just looked at this for a moment, people are asking why do we see this big gap between the gross price and the net price. What caused that? I'm sure people will have answers for that today as we talk more. And what are the consequences, besides the consequences for patients in terms of their cost sharing, is also potentially leading to changes in the way that formularies are created and changing the incentives because so much more of the money now is tied up in these rebates and discounts. Of course, as I think Dr. Sood just alluded to, many of the fees and the revenue streams for the pharmacy benefit managers are tied to those list prices. That's largely passed through to employers, but we'll come to that in a moment.

Again, I just want to make clear that the patients are the reasons that we should be concerned about the system here. And if it's working for patients, then it will work for all of us. So we did some work recently to understand what share of patient cost sharing is tied to the list price. And that showed that more than half of the spending, or about half of the spending, that patients pay out of pocket is in fact tied to this list price. That's because patients have deductibles, and patients pay co-insurance which is a percentage of that undiscounted price. That's one in five brand prescriptions. So, of course, the majority of prescriptions are still paid with co-pays. We're not talking about those prescriptions, but for patients who are sick and who are taking medicines, and particularly medicines that carry large rebates, they are not getting the benefit of these discounts which, as I said, can be substantial and can run into the hundreds , potentially even the thousands of dollars for some patients.

I think earlier Dr. Schondelmeyer made the case that it's the premium that matters, not the cost sharing. Well, of course premium matters for everyone. It matters, especially for healthy patients. But if you're a sick patient, the cost sharing really does matter. And there are very few options, once a drug has been on the market, for a manufacturer to address challenges of access for patients, other than to offer a cost sharing coupon or co-pay assistance. If you were to lower the price to the health plan through a rebate, as we've just now see, though that net price isn't what determines the patient's cost. So we have a situation in which patients are increasingly, because of high deductibles, which are much, much more common, being exposed to this list price. And there aren't too many ways to get those savings to them, other than changing this construct or offering cost sharing assistance.

So as you've heard, the pharmacy benefit manager market is very concentrated. We've talked less about the tools that insurers and PBMs have to control access. I would argue that, in fact, PBMs and insurers can pretty much determine if, when, and how a medicine is used. And they do that very effectively. And that has been the engine for why costs have been kept in check over a long period of time. So I'm not arguing that rebates are something that needs to go. They've been used effectively and they do allow for varying levels of discounts, which can be helpful in keeping the average level of price down, but I do think it's important to recognize that there is quite a lot of concentrated power here and you have three, essentially, large PBMs controlling almost 70% of the market. This is up from the top three controlling less than half of the market back in 2011, and that's a very substantial change.

I think it would be just-- I'm stepping back for a second to say, you know, there's lots of talk about competition, and you would recognize that there are many names in the pharmaceutical industry that are recognized in your households. Large companies, very large companies, but none of the pharmaceutical companies come close to the scale of the largest the largest intermediaries in the supply chain. The largest pharmaceutical companies control 6% of pharmaceutical sales. And there are hundreds of companies that are selling products on the market and thousands more companies that are vying to bring products forward. So when you think about concentration and you think about competition in this market, it's important to recognize scale.

We've been talking a lot about rebates, and I think one reason we've been talking about that is that we definitely see more signs. There's concern that in addition to patients not necessarily benefiting from those rebates or them influencing the choice of products that PBMs might choose to put on formularies, that potentially the rebates are not flowing through to the same degree to employers. And clearly, employers do benefit from rebates and they are used to lower premiums. And it is true that the very most sophisticated employers are in a position to argue for 100% transparency in their contracts and 100% pass through of rebates. I think what's also clear is that you see, among mid-size and smaller employers, a concern that there's just a very large imbalance in the amount of information and expertise between their PBM and their own ability to understand how to make really crystal clear determinations as they procure a PBM service.

So I think there are legitimate questions that are beginning to come up about whether employers have the expertise and the information to make really good procurement decisions, whether they have enough information, whether they can understand whether PPM is operating within the bounds of their contractual arrangements, and whether they're easy to audit. And just going back for a moment to the issues about consolidation, I think it's very clear that the complicated ownership structures that we are now seeing in the supply chain make that project even more difficult for employers. Now most of the PBMs not only own mail orders specialties and they may own specialty pharmacies-- Most people understand that CVS is a large pharmacy, but they don't necessarily recognize that Express Scripts is the third largest pharmacy in the country as well.

So just one tiny example of the ways in which employers can find it difficult to navigate the contractual process and to understand all of the technical issues here. A very standard feature of PBM contracts is price protection, so PBMs will routinely negotiate with manufacturers to be held harmless from any increase in the list price. Now, unfortunately, patients are not held harmless, as we just talked about, because patients are subject to the full price. That's an undiscounted price when they're in the deductible. They're not held harmless, and insurers generally don't pass through all of those discounts to protect their enrollees.

But PBMs do negotiate for that, and that's a standard feature on many, many products in the marketplace now. But if you ask employers-- And this is a recent survey that PBMI put out. They asked employers, "Are you getting the benefit of this type of price protection?" And only 23% of employers said that they are, even though it's a much more common practice than that. So they may not know that they're getting that protection. And even of those who are getting it,

they're not sure if those rebates are actually being passed through. And given the way the market has been moving in the last several years, these aren't trivial amounts of money.

So, I think, this is just one example of why it's important to make sure that we have the best practices in the marketplace and the most visibility into the way things are working now. I would say the market is actually already moving in many directions to remake the system that we are under today. There's been lots of talk about moving toward more outcomes based arrangements, more value based contracting, a whole range of new approaches to paying for medicines that I think PBMs are anxious to pursue, and I know manufacturers are anxious to pursue, as well. That is clearly part of the solution and will help us move toward a system in which we are rewarding value more closely.

But we need to do that at the same time that we're also making sure that patients are benefiting from those discounts. And I would argue that's something that is not unmanageable in terms of the impact on premium. It's absolutely doable. There was a recent study that showed that it would have a negligible impact on premiums to ensure that contracts do allow for patients to see lower prices at the point of sale when they go into the pharmacy. Because there's really not any excuse for patients to be paying a higher price than the price that their insurer is paying for medicine. We don't tolerate that for other forms of health care. We generally extend negotiated rates for hospital and physician care to the patient. That's really the purpose of insurance. We should be doing the same in pharmaceutical care. So maybe I'll stop there.

[APPLAUSE]

SUSAN PILCH: So good afternoon. I'm Susan Pilch. I'm the Vice President of Policy and Regulatory Affairs for the National Community Pharmacists Association. I appreciate the opportunity to participate in this session. A thank you to the FTC for holding this workshop and, specifically, for including this panel and the next on the role of the intermediaries. I think this is a role that has largely been not examined. And this panel focused on supply chain dynamics and the role of the PBM. I know that we're tight on time today and, unfortunately, I'm going to try to speed talk or go my way through my slides because I have a little too much information, perhaps.

So right now we're in an environment where we have legislators, policymakers, employers, and consumers who are all looking for answers. The clarity on drug pricing, prescription drug benefits, and their access to medications. And some of the things that are leading to that are, as other people have mentioned, we have co-insurance now, where the patients are picking up a percentage of the cost of the drug, and we have all these high priced medications now on the market, and consumers have a lot of sticker shock. There's a very poorly understood drug supply chain and drug pricing systems. And that's really across the board. It's not just consumers.

Most employers, most people that you ask aren't really even aware of the intermediaries. There's a real lack of awareness of some of the other hidden PBM revenue streams, so not just rebates. And these are things I'll get into later that talk about a lot of the conflicts of interest. There's plan sponsored dependence on PBMs to navigate drug pricing in the supply chain. It's true employers could do this on their own, but they don't have the resources to do so. They're hiring a PBM specifically for that purpose. Also, this is without a corresponding fiduciary duty on the part of

the PBMs. So translation is the PBM has no obligation to put the client's financial interests above that of its own. And so that enters into some of their other revenue streams. And finally, the PBM influence on formulary and plan benefit design. These have real tangible consequences for patient access to care, as well as what the patients are paying in terms of tiering.

So I'm here on behalf of the independent pharmacy. This is just a quick slide to give you a sort of a snapshot. We're typically in rural, underserved, either rural or urban areas. We serve a very significant number of Medicaid beneficiaries. We represent about 52% of all rural pharmacies and in about 1,800 communities, we are the only retail pharmacy. So independent pharmacy marketplace realities-- As I said, we are independent small businesses. And so, therefore, many times we are represented by what are called PSAOs for us to try to gain some negotiating power. In a nutshell, the PSAOs are no match for the big three PBMs.

In 2013, the GAO did a study, and there's really two phrases in this following blurb that stand out. Little success in modifying certain contract terms as a result of negotiations and many PBM contracts contain terms and conditions that are largely non-negotiable. And I will say that this study was in 2013, and since that time the big three have only gotten bigger. The PBM marketplace-- This has already been covered by a lot of my other panelists. One thing I do want to point out here, there has been significant market consolidation. There was a CVS Caremark merger in 2007, Express Scripts Medco in 2012, and well as Optum Catamaran in 2015.

And we have the big three. And yet, are there other PBMs? Yes, there are. However, for the very large employers and very large other health plans, the big three are realistically the only choice that they have. They are the only ones that have the bandwidth to cover that number of beneficiaries. So when you look at it that way, their options dwindle.

So the PBM influence on the supply chain, and we've heard a little bit about this, so obviously they negotiate the rebates. Rebate negotiations are really what drive formulary placement. This is ultimately what determines what medications patients have access to and at what cost they are at. I mentioned this a little bit earlier. The contract with employers and health plans to administer the benefit with no fiduciary obligation. And then finally, that PBMs own their own mail order and specialty pharmacies that directly compete with retail pharmacies. At same time, PBMs also dictate what these retail pharmacies are reimbursed and, also, what they may charge beneficiaries.

And so this is one thing that I mentioned a little bit earlier that I do also want to highlight. PBMs all will say that employers are sophisticated purchasers and, at the same time, they have no fiduciary responsibility. PBMs consistently say that they are not ERISA fiduciaries, or they specifically contract away any fiduciary responsibility. And keep in mind, again, this means a PBM does not have to put the interest of the client above that of its own. And so as a result, and this is a very key point, they have no obligation to disclose any or all of their revenue streams or that certain plan benefit designs may increase PBM profits, perhaps at the expense of the plan sponsor. So the key take away I want from this slide is that if PBMs were required to disclose some of these conflicts of interests, plans sponsors may make different economic decisions or be better equipped to drive a harder bargain. For example, if the plan sponsor knows that the PBM is going to be selling their beneficiary data, they might have the wherewithal to say, "Well, in

that case, you're going to be making x amount of dollars. I want to drive a harder bargain in my contract with you." But right now, they have are completely in the dark about that.

So some of the different revenue streams, other than rebates, that I want to cover a little bit. Obviously, we have rebate agreements, and PBMs claim they passed along about 90% of the rebates. However, there are some caveats with that. Many PBM contracts allow PBMs to essentially relabel rebates. So these rebate amounts are reclassified as formulary management or data management fees. So even if they have a contract in which the PBM has to return all of the rebates, these amounts would not be covered under that Spread profits. This is specifically at the pharmacy level. So the amount paid to the pharmacy is lower than the amount charged to the plan or the employer on every single drug. And this is not necessarily disclosed to the plan. And keep in mind that's every single prescription that's run through. They make a profit on that. PBM-owned mail order, and specialty pharmacies, and then, also, data. They sell the data of all of all the beneficiary data, which can be significant.

So PBM influence in retail pharmacy-- So as I mentioned, they contract with retail pharmacies to form these pharmacy networks. At the same time, these network pharmacies compete with the PBM's pharmacies. Another example of how this is also convoluted. With the CVS Caremark, you have a combination of one of the largest PBMs with one of the largest retail pharmacy chains. PBM side of that business has direct access to the sensitive records of pharmacies that are in direct competition with the retail chain. And then also, PBMs determine pharmacy reimbursement amounts for virtually all prescription drugs that go through insurance.

PBMs also audit retail pharmacies. They have access to very detailed financial information and drug purchasing records. They can access all the invoices. PBMs also wields absolute control over pharmacy reimbursement for all the generics. PBMs have what are known as proprietary MAC lists. This is key. Brand name drugs have public benchmarks. Anyone can access what those are. MAC lists, these do not exist. That's totally considered proprietary on the part of the PBM.

I do want to touch a little bit on MAC pricing. So maximum allowable costs. These were created by PBMs to determine the maximum amount that they're going to reimburse the pharmacy for a generic product. And the reasoning behind this, originally, was to make sure that pharmacies were purchasing at the lowest prices, which is a valid goal. However, I would say in practice this really does not work because there is absolutely no transparency. Pharmacies have no idea where to obtain some of these prices and the PBM's claim that the methodology as to where they got these from are completely proprietary. This results in a lot of pharmacies being underwater on claims. They're losing money by filling prescriptions. Again, MAC lists. They use one MAC list to reimburse the pharmacy, which is aggressively low, and one to charge the plan sponsor, which is high. Again, that's the spread pricing. Again, pharmacies sign these contracts with PBMs having absolutely no insight into what the MAC list looks like. When a pharmacy gets a contract, it says you'll be reimbursed for all generics based on MAC. That's it.

I would be remiss if I did not cover the next topic, as this is the number one topic for my members right now. Pharmacy DIR fees. DIR was really a Medicare Part D concept. It's stands for direct and indirect remuneration. It was really designed to account for manufacture rebates

that could not be determined at the point of sale. But over the past few years, we've really seen an explosion on the pharmacy side of pharmacy DIR fees. What happens is we are told when we run the claim that we will be reimbursed one amount. Sometimes months later, significant amounts of money are taken back. And just from an operational standpoint, this is extremely difficult for small businesses to run their businesses based on this.

And one reason why we think this has really exploded has to do with the mechanics of the Part D system. It's very financially advantageous for the PBMs and plan sponsors to shift as much as they can past the point of sale. And keep in mind, this also has a very detrimental effect on the federal government and patients. Cost sharing obligations in the Medicare Part D space are based on what is known as negotiated price, and that is a term of art in the part D program that refers to the amount paid by the PBM to the pharmacy at the point of sale. So keep in mind, after the point of sale if they take money back from the pharmacy in the term of a DIR fee or a price concession that ultimately lowers the price, the patient has already paid their cost sharing based on that higher price at the point of sale, and so does the federal government. The federal government picks up the cost sharing for a lot of low income subsidy patients. So the federal government and the ultimate patient, Medicare Part D beneficiaries, are having higher cost sharing because of this very construct.

Finally, specialty pharmacy. This is really sort of a flash point right now in the marketplace. It's very high dollar medications and, as I said, PBMs own their own specialty pharmacies. And so they have a very significant incentive to capture these prescriptions. What we're seeing in the marketplace is an increasing incidence of PBMs terminating or declining network applications of independent specialty pharmacies or trying to impose excessive accreditation requirements or excessive audits. For example, we had a pharmacy that had two national accreditations of specialty pharmacies. The PBM told them they needed to have their own, specific PBM accreditation, that the national accreditation was not sufficient, in spite of the fact that this is a very time intensive and cost the pharmacy about $25,000 to be accredited by the national organization. And I do want to say that a federal judge in the Express Scripts-Medco merger specifically raised the issue about some of these specialty conflicts of interest. And I think that that's certainly being borne out today.

And so moving forward, this is just a last slide about some of the different approaches that are being looked at in the marketplace. I think there's a lot of chatter now, perhaps in a positive way. A lot of recognition of the fact that the current model we have is somewhat dysfunctional. We have a lot of misaligned incentives. We have employers and payers that are looking for new models. We have large employers that are now trying direct contracting with pharmacies, trying to set up pharmacy networks on their own, going around the PBM. We're looking at outcomes based reimbursement. We need a greater connectivity between the drug spend and the medical spend. We need to make smarter choices about using prescription drugs to stave off more costly downstream interventions, and also a renewed interest on trying to capitalize on the expertise of pharmacists. Too often in the past, pharmacy has been viewed as a commodity, putting pills in bottles. We need to allow pharmacists to practice to the top of their license and provide patient care in order to stretch-- What we have are very limited resources right now in the marketplace. So with that, I feel like I've been talking extremely fast. Thank you so much for your time.

[APPLAUSE]

ROBERT ANDREWS: Well, thank you. Good afternoon, everyone. My name is Robert Andrews. I'm the Chief Executive Officer of the Health Transformation Alliance. I want to thank the men and women of the FTC for their typical dedication and due diligence they've done in putting together this afternoon's program.

I want to speak about who we are at the HTA. The question we are asking about the prescription drug supply chain, the drug supply chain. And then the answer we are seeking. And how that all fits together. The HTA is a cooperative. We're a cooperative of, at this point, 43 of the countries of some of the most well-known and iconic self-insured health plans. Chances are that you bought a phone from one of our covered life members, or that you stayed in a hotel where one of our covered life members facilitated a great stay for you. Or that perhaps you drove a tractor, or front-end loader at some point today for one of our members named after an insect. We are $27 billion a year of annual spend in health care. We are 7 million lives, under the umbrella of the HTA. We've come together because we believe that as a country, and as employers and employees, we can do better. We can do better.

So what question are we asking about what doing better means? We are not asking the question of how can we get a better price on a prescription drug. We are interested very much in that question, but it's not the fundamental question we are asking. We are asking the question how can we make the patient healthier. What decision in this crucial interaction between the patient and her physician, or prescription writer, is the right decision, driven by the evidence, driven by the data, driven by the personal circumstances of that patient. We are an odd mix in the sense that we are evangelical about that purpose, but agnostic as to who we will work with to achieve that purpose. The evangelism part comes from the notion that if you ask Americans about the quality of our healthcare, they have an odd answer that they used to give Robert Pear about their members of Congress, which is that they hated Congress but love their congressmen. We've made great progress on this issue now. Now, they hate both Congress and their congressmen, so there has been real progress in this area. People used to say that they didn't like the US healthcare system much at all, but they love their own healthcare. Interesting juxtaposition.

What we've seen, both in data and in our daily practice, is that there are more and more Americans now fitting into the box, unfortunately, of having a negative attitude about the system, but also about how that system directly affects them and their families, their health outcomes, and their pocketbooks. So we're evangelical about the fact that that needs to change. That needs to change. It's essential for the health of our country. It's essential for the health of American business. Auto manufacturers are having a very difficult time competing with their foreign competitors because of the cost of healthcare. This is something that is rife throughout the retail system, throughout a lot of other employers. So we're focused, to a great extent, upon fixing that problem. When I say we're agnostic-- and I mean no disrespect to the very important debate that goes on about the pros and cons of people in the supply chain, companies in the supply chain. I think, as this morning's speakers have shown, it's a very important, very dynamic debate that we listen to, we learn from, and we support and applaud. But we're not going to make our decisions about with whom we work based upon any supposition going into this discussion.

If someone is willing to embrace the objectives that we have set forth, then we're willing to work with that someone.

So at present, in the earliest iterations of the HTA-- we're about two years old. We in fact have strong and positive partnerships with two pharmacy benefit manager companies. We found these to be important for our growth. We found them to be positive for our growth, and we intend to try to make them work better for our members in the future. So when we ask the question what's the right decision at that point of engagement between the scriptwriter, the supply, the physician, remember the scriptwriter isn't that patient. Think about what goes on right now in that moment. The physician very often makes the right decision. He or she puts a lot of time, a lot of effort into learning about her patient, learning the data about what the efficacy levels of different drugs are, maybe learning something about the economic impact on the patient. But that all kind of happens by accident. The incentive system does not really support the physician or the patient engaging in a disciplined and focused way in that decision. That's what we want to change.

So to us success looks like four things. One, it looks like something that might even be called a personalized formulary for each patient at some point in time. What does that mean? It means that as the science of pharmacogenetic testing develops, and as it becomes more accessible to people, we look forward to the day where men and women and their children, on a voluntary basis, on a voluntary basis, who wish to have a genetic test that would indicate the efficacy of various drugs for them. That's something we want to encourage. We certainly want to encourage population health analyses. What tends to be efficacious or less efficacious for people who sit and defer certain categories. We want to be sure that the decision about formulary is more based upon the health status of the patient sitting in front of the physician and not some other competing values or interests.

Second, we want to incent both the physician and the patient to learn about and use that formulary in the most efficacious way. We emphatically are not interested in practicing medicine. We are not interested in dictating the terms of practice to any physician, anywhere in the country, or certainly any patient. But we do want people to know more, learn more, and be incented to use that information in a way that's going to give them the best result. What am I talking about here? And I'm not criticizing any particular company or person. But I'm talking about the person who has psoriasis-- which everyone apparently now does if you look at the advertising-- that the person who has psoriasis gets phototherapy instead of a very expensive biologic because that is indicated as a better care platform for them or care pathway for that them. Or it's a person who is a type-2 diabetic, where there's evidence that shows that a certain blood sugar control drug is going to work better for them, specifically them, at some point than another one would. The goal of the HTA is not to get a discount on a drug that never should be prescribed in the first place. The goal of the HTA is to empower and educate the prescriber and the patient to work together to find what the definition of right drug is for that patient and her care pathway at that point.

The third thing that we want is a dazzling consumer engagement experience. I grew up in the 1960s, and I still make the mistake-- My family and I love to watch Modern Family. Love that show. And I relate to Phil, in many ways, for you who watch the show. The sort of befuddled dad character. And I will come home and literally say this on a Friday night. I wish I had been

home-- I guess it's Wednesday-- because we missed this week's episode of Modern Family. My daughters, who are 25 and 23, look at me as if I'm from the planet Neptune because there's this thing called on-demand.

This is still very dazzling to me, that this is something where you can watch the show whenever you want to. Think about what happens for most Americans when they have to, and I will use this phrase, pick up a prescription drug. What's that experience like? This is meant to be in no way critical of any one but, my goodness, it's organized in the least convenient way for the patient, not the most convenient way for the patient. It's more than just convenience. I don't know if there is data to support this but my years of life support this. I think adherence levels will rise when convenience rises. I think there's a direct connection between how difficult it is to get access to a prescription you need and how often you take it. So we want that.

And finally, we are working for a day when on a fair, equitable data driven basis, the price of the drug from the manufacturer is tied, in large part, to the effect of that drug on the health outcome for the patient, what some of our friends in the industry called indication based pricing, value based pricing. We think that should become the rule and not the exception.

So I'll close with this thought. The popular media are filled with people with provocative opinions on the question of "is drug X too expensive?" And on Capitol Hill, you can make a lot of headlines by having a hearing about the rising cost of drug X and what an outrage it is. Seems to me that there is some context missing in order to answer that question intelligently. If drug X is effective in taking an infant who was born at 1 pounds 6 ounces and helping her live and survive as a fully functioning person, I don't think it's too expensive at all. I really don't. If a certain chemotherapy drug has a huge success rate in full remission or the prolongation of quality of life for a person, I don't think that's too expensive at all. If a type-2 diabetes drug has demonstrated compelling efficacy in reducing strokes, and heart attacks, and blindness, and amputations, what's that worth? Both in terms of the moral achievement of better life for that person and the economic achievement in the reduction of outlays for the person's health claim. The answer you get depends upon the question that you ask.

We are asking in the HTA the question, "What is the right choice to promote and foster the best health result for the patient." Our doors is open, and our minds are open to all those willing to work with us toward that end. Thank you for your time this afternoon.

[APPLAUSE]

ADAM FEIN: You know, I always knew I'd get my 15 minutes of fame. I just never knew it would be during lunch. So thanks for hanging in there. Adam Fein with Pembroke Consulting. I write the Drug Channel's blog, which many people may read. I want to take the opportunity to just think about how this system works a little bit, and I want to bring out two issues which I think are particularly relevant for the FTC, the incentives of everyone in our Drug Channel, and the nature of the relationships. And at the risk of being a little redundant, repetitive, and redundant, I'm just going to briefly-- my way of thinking about it-- just briefly kind of review something Dr. Sood introduced, but I want to just put a little different spin on it. And these are functions shown that are in the supply chain, not entities. Because the functions can be moved

around. The manufacturer can do distribution. The PBM can do pharmacy. The health plan can be a PBM.

So it's not really relevant to think about that but, as Mark mentioned, the distribution system for drugs looks like a lot of other distribution systems. You have a manufacturer, you have a pharmacy, and you have a patient. You have a product moving through a system with money attached to it. It looks just like groceries, or electronics, or shoes. Anything. The difference, of course, is number one, you have no idea what you're buying. Number two, you need permission to buy it. And number three, you're never really paying the full cost of it. Somebody else is paying. And that's where we have this whole third third-party payer system. So you have this set of relationships here, between manufacturers, wholesalers, and pharmacies and what looks like a retail transaction, but of course really isn't a retail transaction.

And the thing that people don't understand-- and I'm going to just jump to the story here-- there's lots of intermediaries in this space. But ultimately, the payer, which is generally your employer, the government, Medicare, Medicaid, a union, somebody else, is sort of funding this drug. They're hiring the PBM to do this. The PBM is the one who's handling the money. I'm going to just put this all up here so we can all see what's happening.

This is like the simple version of what is actually going on. And I want to just draw out one quick thing, without using the fancy build. So you have to use your imagination for one moment. The money flow is going from you and me, in the form of taxes or premiums or something, to the payer. The payer is then giving that money, in some sense to the PBM, who's giving it to the pharmacy, who's giving it to the wholesaler, who's giving it back to the manufacturer, who then takes a piece of everything they collect, give it back to the PBM, and gives a piece of that back to the payer. It's really pretty simple.

So a couple of things I want to draw out of this. Number one, the revenues for a single prescription count in multiple ways for at least four different entities in the system. The manufacturer accounts the revenue when they ship it to a wholesaler. The wholesaler accounts the revenue when they ship it to a pharmacy. The pharmacy counts the revenue when they dispense the product to the patient. And the PBM counts the revenue when they adjudicate that claim. Which is why, by revenues, the Drug Channel companies, the wholesalers, the pharmacies, and the PBMs are among the top 25 in the Fortune 500 list, which is ranked by revenues.

The second thing, which I think we maybe haven't clarified, is that as these entities are earning margins or spreads to cover the costs of providing their services in the channel, those margins are linked, almost exclusively, to the list price, the wholesale acquisition cost, the WAC. So the transactions that are occurring here are based on list price. Particularly for brand name drugs. Generics are a little bit of a different story, as we heard this morning. I'm going to focus on brand name drugs.

They're all linked to that list price, which means that as the list price rises, everyone in the system's dollar value of that margin percent their earning goes up, even the wholesalers in some cases. The CEO of one of the wholesalers got on an earnings conference call and said, "Oh, we're

really unhappy drug prices are not going up fast enough." That's an amazing statement of truth. But everyone in this system, the PBMs, the pharmacies, everyone else-- revenue, profits are tied to that list price.

The ultimate net price, which is that price, after all those rebates and discounts, is not known by most of the entities in this system. It's sometimes not even known by that plan sponsor or payer. It's certainly not known by you or me, the patient. And so when you start to think about how the system is working, in some ways these can drive sensible behavior, but having everyone tied to this list price gives everyone in the system an incentive for those list prices to go up. Now, I know not everyone is going to agree with that statement, but I think it is something that's happening.

Now, I want to pick up on one point that Jenny made, which I think is very relevant. The value of these rebate dollars that are flowing from the manufacturer to the PBM are growing dramatically. How dramatically, Adam? Very dramatically. This is my last slide, by the way. See, we're good. This is the difference between the list price and the net price that the manufacturer is getting. So this isn't channel margin. This is total value of all these rebates and discounts going back. And you can see, if you pay close attention, there might be a slight little trend going on there.

Now, why is it relevant that we have well over $100 billion flowing back in the system. Well number one, this is happening during a period when generic drugs are growing. 2016, you heard this morning from Chip Davis, roughly 9 out of 10 prescriptions are generic, which means the $120 billion being balanced on an ever smaller number of prescriptions-- most of which are for chronic care, many of which are for specialty drugs, many of them are traditional drugs. The availability of generic therapies, the competition in pharmaceutical markets, the size of the PBMs allows these PBMs to negotiate more and more discounts. So you have a lot of money flowing in there. What does that mean? The plan sponsors can negotiate with the PBMs to get whatever deal they want. They, maybe, want 100% of the rebates. They want 90. Whatever they want they get, for the most part. And what do they do with that money? It may or may not be flowing back to the beneficiaries.

I interviewed someone who is human resources benefit manager at a large insurance company, and they said, "Money doesn't know where it comes from." There's a large value of a rebate check they're getting back worth $100 billion. It's thrown into the pot. Is it offsetting that specific prescription for a particular patient? Not really. It's sort of an amount of money. And the plan sponsors can do whatever they want with it. So when you think about some of the incentives here-- what is the incentive of your employer to share that with you in the form of a lower premium? Or to share that with you in the form of a lower co-pay? Or even giving you part of that rebate? They may have none.

So one of the complexities of the system is that everyone is, kind of, working off these list prices and the plans sponsors, themselves, see these bigger and bigger rebate checks as these list prices are going up. So it creates a lot of, I believe, competitive problems and potentially misaligned incentives. And I think from my perspective-- You know, now, I was trained as an economist which, of course, I think everything boils down to incentives And trade-offs, right? That's all you

really learn in economics. Plan sponsors can fix some of these incentives by writing better contracts with their PBMs. Manufacturers can write different contracts. Everyone can write contracts, but one of the things we sometimes lose focus on is that we the patient are not really engaged in a true retail transaction. Somebody else is doing this for us, our employer, our health plan. Someone else is doing it whose incentives and interests may or may not be aligned with our incentives and interests.

So one of the things that, I think, if we think about the FTC and its mandate for consumer welfare is how is this complex system which, I'll be honest, very few people understand, including our elected officials, understand what's really going on in this system. Is it really behaving in the way that we want to deliver the right kind of benefits for patients, especially that increasingly small number of patients taking brand name drugs or even specialty drugs which are 1% to 2% of the prescriptions?

So I think there's a lot of issues to talk about. I'm really thankful to the FTC for inviting me, and I look forward to a great discussion with the esteemed panel that I'm joining. Thank you.

[APPLAUSE]

DAVID SCHMIDT: Well, thank you all. I'd actually like to start out with a question that came to me as I was listening to the first panel and the second panel which was Dr. Schondelmeyer in the first panel had mentioned the notion of co-payment coupons and cited an example where someone comes in, and gets a prescription filled for a very expensive branded drug, and turns out the reason they were able to make that affordable for themselves was they had a coupon from the manufacturer that made their out-of-pocket costs relatively low. And that generated a high cost for the plan sponsor, the payer. And he said, and I think it's probably mostly correct, that of course, what's going to end up happening is the cost is going to get passed along, in terms of higher premiums, to the patients in the future. I want to know why rebates are different. So it's just a different pile of money that's coming to the plan sponsor. With rebates, it's money that the plan sponsor is getting. And for some reason we have this disconnect, that we find it hard to believe that the money that the plan sponsor is receiving in terms of higher rebates will affect their premia, but we don't have a problem believing that the higher cost that they might face on particular drugs will get passed along to us. Is there reason to be skeptical about a differential pass through there, or are we just conditioned to think that way?

MARK MERRITT: I'll just start it off. I mean, I think one thing people don't realize-- and I think Adam touched on this, probably all the panelists did-- is how much the payer pays for drugs. I think people are assuming that patients pay most of the price of drugs or most of the cost of drugs. The reality is 2/3 of the costs of drugs or more are paid by the payers, by the insurer's plans, unions, and so forth. So when they get a rebate from the manufacturer, they decide how to apply that best to reduce overall costs, to reduce patient costs, or whatever. And it really depends on each plan and what they want to do and what their retention goals are, what their goals are, healthwise and for the patients, and so forth.

Coupons are different because all they do is touch the co-payment, which is a very, very small part of an overall drug. You may have a $50 co-payment on a $700 drug. So by the

manufacturing offering a $50 coupon, they're getting the payer to pay 2/3 of $700 back to the drug company. That's a huge net win for the drug company. Now, not all coupons are "bad," I don't mean to say that. Because when they're done in conjunction with the payers, the payers can use it to help people who need help and, of course, manufacturers have patient assistance programs for that same purpose and so forth.

But in terms of coupons, which were, I think, just banned in California just a couple of weeks ago because they do increase costs, the way that we view it is that they are designed to increase expensive brand utilization when there are cheaper alternatives. And then, worse for us, they're processed through a shadow claims system through the wholesalers that we can't see. And so we never know when a coupon was used or not for a drug. So it's very tough to keep a hold on and to restrain those from being abused.

ADAM FEIN: You know I think I think it's important to distinguish between two different kinds of scenarios. One is this scenario I think you referring to, Mark, which is there is a generic alternative and the coupon incentivizes using the brand, which is more expensive for the plan. The other scenario, though, is where you have co-insurance which, again, is tied to the list price, which is going up. And roughly half of all employees have co-insurance for specialty drugs, which are $3,000 to $5,000 per month. If you happen to be unfortunate enough to get one of these horrible conditions, like cancer, you might need this kind of therapy. And you have a 20% co-insurance, which might be $1,000 or $2,000 out of your pocket until you hit a deductible. In some cases, people don't even have a limit on what that out-of-pocket cost is.

So I think you have a challenge there and, in some cases, the manufacturers will step in and will pay that difference. So it becomes another form of a rebate. And I think that's not well understood, but not all patients can get access to those funds, and so this kind of cost shifting of very expensive drugs to the patient driven by the list price is sort of a breakdown in this model. Versus that first model which, I think, a lot of people would say, "OK, I don't like that." But if you've got one of these terrible chronic conditions and you need the latest most innovative therapy, that becomes very problematic.

JENNIFER BRYANT: I would just chime in and say I think we need to have a real discussion about cost sharing, which is not necessarily an FTC issue, but a real discussion about how it's being used. There was an implicit consensus back in the early 2000s that we would have tiered formularies. We would provide better choice, and we'd use those formularies to drive cost to the lowest cost appropriate treatment for patients. And then people would pay more for more expensive medicines. But that consensus, I think, has really essentially collapsed. And now what we have is just a huge pylon of cost sharing to the newest medicines. And as Adam said, it's really unclear to me. What is the purpose of attaching $1,000 co-pays to cancer medicines? Are we hoping people won't take the medicines? I mean we know that Americans don't have thousands of dollars in their savings accounts ready to pay for medicines or anything else. Americans don't have high savings, right?

So now that we have high deductible plans, it's routine to have a $3,000 deductible, and you are taking a cancer medicine. Is the expectation that cost sharing is actually driving them to do research just to challenge their doctor that they should use a lower cost oncology medicine? I

don't think so. I don't think that's what's going on. So we have a challenge with cost sharing more generally. And you have to put the context around this discussion around co-pay coupons. And I think rebates are a part of it. The reality is you say, "Why don't you lower your prices?" But a manufacturer, if they do lower their price by offering a bigger rebate, it doesn't change the cost sharing. So that's one reason that you have co-pay coupons out there.

NEERAJ SOOD: I think we should look at market power for health plans also because, in some sense-- Imagine a health plan that's a monopoly. And now it gets a discount or a rebate from a manufacturer or the PBM passes the rebate to the health plan. The health plan has no incentive to pass that rebate back to consumers in the form of lower premiums. But if this monopolist experiences an increase in costs, say, because of co-pay coupons, they're going to pass on the increase in cost to the consumer. But if the market is competitive and the health plan doesn't have market power, then they're going to pass on the rebates to the consumer as well as the higher costs in the form of co-pay coupons or other things to the consumer. So I think a lot depends on the contract the employer or the individual has with the health plan and how competitive that market is.

DAVID SCHMIDT: So this is a point that I hear brought up often, and it's something I'd like to clarify. It is not the case that a monopolist has no incentive to pass along cost savings. Monopolists do have an incentive to pass along cost savings. It depends on the elasticity of demand. Certainly, in more competitive markets we tend to see higher pass through rates. It doesn't need to be that way necessarily, but we do. But this notion that in a concentrated market you're not going to get pass through of cost savings is just not fundamentally supported by economic theory. It might well be that you get less pass through in a less competitive market than you would in a more competitive market. And I think that is something that we're, at the FTC, constantly aware of when looking at competition in a marketplace. But I've heard that a number of times in these discussions. So I just wanted to clarify that point.

I'd like to move on to a discussion that follows up on a graph that Jenny had and, also, Adam's last graph showing the growth of the gap between gross and net prices, and a number of you have mentioned that. It's something that's been startling to me, as far as a market dynamic, that it isn't exactly clear to me what's going on. And I think it might relate. Some of the theories I've heard talked about, like these discussions, as firms have explored different cost sharing structures in their plans, like tiered formularies. Is that increasing their negotiating power with respect to pharmaceutical companies? And is that driving a larger gap between the gross price and the net price? Are they able to get more rebates by threatening lower placement on the formulary? And does that create some odd incentives to inflate list prices and grant larger discounts off of that?

I guess my question is does anybody have a good explanation for what has changed in the marketplace that has caused this growing gap between gross prices and list prices? Because, of course, as Jenny's graph showed, gross prices were growing at like 12% and net prices were growing at about 4% over the last several years. That difference compounds. And so it can really-- absolute values of the gross and net prices can be quite far apart now. I've heard theories that part of the problem is that PBMs keep some of that money, and so they have an incentive to see that grow, but I've been involved in analyzing these markets for a long time. And, as far as I know, in recent history, PBMs have always, under the terms of their contracts, they have always

kept some share of the rebates on certain contracts. So I don't know that that can be what's changed. I thought that had always been in place. So I'd like to know if anybody knows what has changed to cause that.

MARK MERRITT: I would just say, first of all, I mean the solution is just don't raise the prices. And if prices go up, rebates are going to follow because payers demand that. Remember PBMs aren't on an island. We work for payers, and payers will gladly switch one PBM for another. There's a whole disruptive industry that we're involved in, and that's just the way it is. So as prices go up, the payers understand that they want more of that rebate, and they're going to get that rebate passed through to them.

The prices are something that pharma does because they can. Pricing power for drug companies is no different than pricing power for anybody else. If you're selling a house, you don't say, "Well, gosh I bought the house for $300,000 and put $20,000 in improvements, so I have to sell it for $320,000." No, you look at the house next to you and you hope it sold for a $1 million so you can charge that much. It's basic stuff of why people price products. And manufacturers, I think there's been a big effort to over-complicate that, but they will price it more if for whatever reason they think they can get a higher price. But rebates are a function of that. If the price goes up, our clients are going to demand that we get higher rebates and pass those through.

SUSAN PILCH: I think, if I could maybe say something, and obviously I'm not a manufacturer or a PBM, but I think rebate structure is really tied into formulary placement. Manufacturers have to offer more and more rebates in order to get on certain formularies. In order to do that, they have to raise list price. I think it's created a system where it's kind of out of control. I mean, in my opinion, that's kind of what's going on.

ADAM FEIN: I'll take it back to incentives. You have a number of categories that are incredibly competitive. The products are near substitutes, but technically brands. There may be generic alternatives. And so the products, essentially, have to give up any increase they get, and the net price stays flat. I think Mark is correct. If the manufacturer takes a list price increase, they have to rebate back a bigger number of dollars to get back to that net price. The challenge is that if you have two products that are head to head competitors and one takes a 10% price increase and one takes a 5% price increase, well the one that has a 10% price increase generates more rebate dollars. And whether the plan likes those because they're spending it, whether the PBM is keeping 10% of that and wants 10% of that increase-- I mean, that's part of the incentives here. So the net price can be the same.

One of the executives, the CEO, of the top PBMs put up a chart to investors and said, "Here's the list price of this popular product." And it's a 45 degree line. "And here's the net price," which is a horizontal line, right? He's like, "We did a great job." But the question is where did all those dollars go? And that's the question about are the incentives aligned to get us to a true net pricing kind of model for patients.

MARK MERRITT: And I should add just one thing. I forgot to mention-- I'm sorry Jenny-- also the Medicaid expansion. Medicaid is where a lot of these price controls are. And, of course, there's a big rebate program. That's where half the rebates goes, is Medicaid. And there's price

concessions, Medicaid 340b, coupons, and so forth like that. So one factor might be is Medicaid expansion grows. There's some incentive for manufacturers to raise prices to not get caught up in Medicaid best price situations.

JENNIFER BRYANT: I want to go back to what Adam was suggesting. And I think the reality is if you have the list price growing much, much faster than the net price, and that process is essentially flat, you have to assume that that means the growth in revenue for the intermediaries is also going to grow more rapidly, unless there's a 100% pass through. And I think Mark has made the case that the largest customers do demand 100% pass through but that's just the largest customers. And clearly there are incentives for intermediaries to continue to prefer drugs that carry high rebates because not all customers are in a position to demand that. And I would argue that if you look at the divergence in the curves-- the other relevant thing that happened was, in 2012, you had the very large ESI-Medco merger-- and as the change gets more complicated and as money can move between different parts of corporations, whether it moves between the pharmacy and the PBM, or now we have like PBMs and health plans that are in ownership relationships. I think it's really challenging to audit those contracts for an employer and to know where the money went.

NEERAJ SOOD: So I agree with Jenny, in the sense, from a manufacturer's perspective, the net prices have remained flat. So in some sense that's what they care about, what net price they are getting. So rebate dollars are going up, but net prices are flat. It's not really benefiting the manufacturers. It's benefiting the people who get the rebate dollars which could either be a PBMs or health plans, depending on the arrangement of sharing rebates. So if you want to look for an answer for why rebates are going up, you have to look for-- Is there more market power and PBMs? Is there more market power in health plans? Has that changed over time? Because, in some sense, that's where the incentives are for higher rebates.

ADAM FEIN: And I'll just make one more quick point. The manufacturer pays fees to wholesalers. That's a percent of list price. They pay fees to the PBMs. That's a percent of list price. In some cases, there's products where the nets are $0.20 on the dollar, but the percent they pay to the distributor might be 5%. So it's 5 out of 20 not $0.05 out of 100. So that's where some of these weird distortions come. And since we're basing it on this fanciful list price, which no one pays, it creates a lot of warped strange incentives that I don't think people fully understand.

JENNIFER BRYANT: Well, unfortunately, sometimes patients do pay.

ADAM FEIN: Well, the patient angle, yes.

JENNIFER BRYANT: It is a benefit design decision. I mean, I hear Mark say, "It's not us, it's the health plans." I got that. But I think as a system we need to work on ways to protect the patients. I would say it makes no sense to ask a patient to buy a product that is carrying a 70% discount and ask them to pay that on undiscounted amount. And, what's worse, with the high deductible plan, which many of us will have going forward, all of your annual cost sharing is compressed into the first several months of the year. So if we want patients not to take their medicines, this is a good approach.

DAVID SCHMIDT: OK, well, I see that the red light is on now, and I will try to abide by it. So I'd like to thank all of our panelists for your presentations and the great discussion.

[Applause]

I'd also like to remind people that we would like to restart at 2 o'clock and that the cafeteria is essentially on the other side of the building, so just follow the hallway around, and you'll find it.