



# **Principles for Patient-Centered Prescription Drug Coverage**

A conference sponsored by  
Center for Medicine in the Public Interest  
& National Community Pharmacists Association

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## **PROGRAM PARTICIPANTS**

**PETER J. PITTS**, President, Center for Medicine in the Public Interest

**B. DOUGLAS HOEY**, CEO, National Community Pharmacists Association

**NICK FERREYROS**, Communications Director, Community Oncology Alliance

**DEREK DAGGETT**, Senior Business Development Executive, SmithRX

**ROBERT M. GOLDBERG**, Vice President, Center for Medicine in the Public Interest

**SHAWN LOVERING**, CEO, RxTE

**SUSAN PILCH**, Vice President Policy & Regulatory Affairs, National Community Pharmacists Association

**A. MARK FENDRICK**, M.D., Director, Center for Value Based Insurance Design, University of Michigan

**BURT ZWEIGENHAFT**, Managing Partner, Upstream Partners

## INTRODUCTION

“If you think health care is expensive now, wait until you see what it costs when it’s free.”

Writer and commentator P.J. O’Rourke made that quip way back in 1993 while the nation was debating HillaryCare.

The riposte has some connection to the current debate over pharmaceutical drug prices. No one is seriously suggesting that they’ll ever be free. However, there have been no end of promises about how drug prices can and will be reduced, accompanied by a vigorous and longstanding battle over prices with contentious Congressional hearings and scary news headlines.

Efforts to reduce prices include the Medicare prescription drug program and the growth of pharmacy benefit managers (PBMs). In practice, though, PBMs “rarely pass the rebates they wrench away from drug companies along to pharmacies, insurers or patients. PBMs instead hoard the cash,” notes Peter Pitts, President of Center for Medicine in the Public Interest (CMPI).

In the U.S., nearly \$15 of every \$100 spent on brand-name drugs goes to PBMs, which claim they lower drug costs. However, the share of annual drug price increases that PBMs pocket – as opposed to pass on to consumers – has soared from 5 percent in 2011 to 62 percent last year. Three large PBMs control 78 percent of the market and use this market power to control what medicines people can use, what they pay, and where they get their prescriptions filled.

The Center for Medicine in the Public Interest and the National Community Pharmacists Association (NCPA) recently sponsored a conference in Washington, DC, titled, “Principles for Patient-Centered Prescription Drug Coverage” to bring together individuals and organizations that are involved in legislative, regulatory and entrepreneurial efforts to address these problems. The goal of the conference is to identify the principles and opportunities for collaboration in enabling patients to receive the medicines that work best for them without obstacles or high out-of-pocket costs.

One panel discussed how the PBMs use rebates, formulary placement, drug-switching and narrow/restricted pharmacy networks to limit patient choice and access to medication based on questionable claims about savings. Rather, PBMs often use this growing control to steer patients to their own mail order and/or specialty pharmacies or other entities in which they have an ownership stake.

In addition, the panel discussed how PBMs use clawbacks of retail pharmacy revenue, spread pricing on generic medications subject to maximum allowable cost (MAC) pricing and non-medical drug switching to increase revenue. Clawbacks in the form of direct and indirect remuneration (DIR) -- fees PBMs extract from pharmacies that push many Medicare consumers into the program’s catastrophic coverage, driving up total spending.

Some highlights of the conference:

“We believe that PBMs contribute to the higher costs of drugs, which is exactly the opposite of what they have claimed to do for practically all of their existence. Over the last 30 years since PBMs have become publicly traded, we’ve seen a 1,000 percent increase in prescription drug costs. There has got to be a better way,” said B. Douglas Hoey, Chief Executive Officer of National Community Pharmacists Association.

“It’s mind-numbing bureaucracy,” Nick Ferreyros, Communications Director of Community Oncology Alliance, said of dealing with PBMs. “It’s just jumping through hoops, endless prior authorizations, endless phone calls, faxes, information missing, changed dosages, changed physician instructions, delays of six weeks. If you have cancer, you do not want to wait six weeks to start receiving treatment. That could mean the difference between going from Stage 3 to Stage 4 cancers.”

“The PBMs really aren’t set up to help members, and really not to help clients either. One of the fallacies behind prior authorization is that it’s set up to make sure the right drug gets distributed to the right member. The person you have reviewing it might be a registered pharmacy tech, but typically not. They’re charging \$35 to \$40 to have it reviewed by someone who is not a doctor and not a pharmacist,” notes Derek Daggett, Senior Vice President of RxTE.

“The biggest myth in Washington is that people believe that the improvement of high quality healthcare actually will lower healthcare costs. They hardly ever do. Living longer, better lives is something we should invest in. We have to change the healthcare conversation from how much we spend to how well we spend it,” said A. Mark Fendrick, M.D., Director, Center for Value Based Insurance Design, University of Michigan. “My view is that people in Washington care more about money than they do about individual and population health. We have to get this conversation back to the patient.”

“PBMs really are sitting in the cat bird seat in the pharmaceutical supply chain. They take advantage of the fact that they have unparalleled insight into everything that goes on upstream as well as downstream and have managed to build in revenue streams for that,” said Susan Pilch, Vice President of Policy & Regulatory Affairs, National Community Pharmacists Association.

What follows is a lively discussion about this controversial and important topic.

--Edited by Mark Crane

## Session 1: How PBMs affect access and affordability

**PETER PITTS, President, Center for Medicine in the Public Interest:** Up until relatively recently, the 30,000-foot view when it comes to pharmacy benefit managers (PBM) has been absent. To my mind, the industry has done a very good job deflecting the conversation to other people. I hesitate to say blame, but certainly they didn't appear in many stories up until perhaps the last 12 to 18 months.

How do PBMs affect access and affordability? When a patient says, "My drugs are too expensive," what do they mean? They generally mean that my copay is too expensive or my coinsurance is too expensive.

The second issue is how does this impact specific therapeutic categories? This issue becomes important especially as new products come online, as we debate and develop and approve biosimilars. Yet somehow prices aren't going down. What does this all mean? Where is the money going?

As many as 40% of patients who as their primary diagnosis of rheumatoid arthritis or diabetic neuropathy or fibromyalgia get as their first line treatment opioids when there are non-opioid FDA approved label indications, medications on the market. Why aren't they getting prescribed? Why aren't they getting reimbursed? Why aren't they more aggressively tiered?

It isn't about deflecting blame from one group onto PBMs. It's understanding that there are lots of people in the game here and we need to begin to understand how this ecosystem works so we can try to fix it.

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**B. DOUGLAS HOEY, Chief Executive Officer of National Community Pharmacists Association.** Thank you, everyone, for attending this important forum today to discuss prescription drug pricing and why prescription drugs cost what they do and what are some better ways we can figure out how to make prescription drugs more affordable for patients.

Part of the tenet of this forum is that we believe that PBMs contribute to the higher costs of drugs, which is exactly the opposite of what they have claimed to do for practically all of their existence. The model that we have is not working as well as it should. Prescription drugs amount to 10% of the trillions of dollars we spend on healthcare. Part of the solution is discussing how

prescription drugs can be used to affect the 90% of total expenditures on healthcare. I don't know that we're doing a great job with the system that we have on using that 10% of the spending on drugs to affect the 90%.

The model we have right now with PBMs is really judge, jury, and executioner -- certainly when it comes to pharmacies and increasingly so when it comes to consumers as well and increasingly so when it comes to plan sponsors. What we have seen over the last 30 years since the PBMs have become publicly traded is a 1,000 percent increase in prescription drug costs. There has got to be a different and better way.

I think that what we're talking about here today is how do we make that system more efficient and then how do we make that siloed prescription drug benefit really harmonize with that 90% of healthcare spending.

The big drugstore chains are competitors to us and we engage in healthy competition, but it's really the PBMs that by far and away are what our members are waking up thinking about and going to sleep thinking about because of the burden and the excessive influence that they have on these small business owners.

We have looked at the 10Ks for Express Scripts and our estimate is that their EBITDA (earnings before interest, tax, depreciation and amortization), so this is after they have cleared out a lot of expenses, is about \$6.15 per prescription. And I can assure you when I talk to my members that they're not making anything like \$6 in EBITDA per prescription. I don't think the big chains are as well.

To be paid three or four times as much as the provider per prescription, which is \$6, represents three to four times what a pharmacy would be paid in EBITDA. I would contend that seems like a pretty big premium for the administrative part, for the paper-shuffling part of this, but we need to let the marketplace decide that and right now the marketplace, we believe, does not have the information to make an efficient decision.

**"It's mind numbing bureaucracy. It's just jumping through hoops, endless prior authorizations, endless phone calls, faxes, information missing, changed dosages, changed physician instructions, delays of six weeks. If you have cancer, you do not want to wait six weeks to start receiving treatment. That could mean the difference between going from Stage 3 to Stage 4 cancers."**

**NICK FERREYROS, Communications Director, Community Oncology Alliance:** The Community Oncology Alliance, or COA, is the only nonprofit organization dedicated solely to

community oncology, which is the care setting in which the majority of Americans with cancer are treated.

We started COA because a lot of our practices were starting onsite dispensing pharmacies. It's very clear to us that PBMs are a huge problem for our members. With COA we have regular meetings, calls, etc. and I mean we have a listserv, and not a day goes by that I don't get a half dozen to a dozen emails just about PBMs.

It's mind-numbing bureaucracy. It's just jumping through hoops, endless prior authorizations, endless phone calls, faxes, information missing, changed dosages, changed physician instructions, delays of six weeks. If you have cancer, you do not want to wait six weeks to start receiving treatment. That could mean the difference between going from Stage Three to Stage Four cancers. You have a ticking time bomb inside of you and these PBMs, because of all the barriers they put up to patients getting their drugs and forcing them to go through the mail order pharmacies.

We have DIR fees, at a minimum we're seeing 3.5%. It's percentage-based, which is great when you're talking about pricey cancer drugs, minimum 3.5%, on more of an average around 11%. So, you have practices getting trimester reports from their PBMs six to 12 months after the prescription was dispensed that are in the five or six figures easily on a regular basis.

All of that money, No. 1 it's coming out of the system and it's going into the middleman's pockets where they're not even providing any value or beneficial service in my mind. And then No. 2, Medicare patients who then pay the higher price up front before the discounts are applied retroactively are pushed into the donut hole, so then they have much higher burdens for cost sharing. Then it goes out of the donut hole and then we as the taxpayers are paying more for that care.

PBM is forcing this into mail order pharmacy. Right there you're removing them from the point of care. You are relying on often elderly patients to follow very detailed instructions, take once a day with food and before 6:00, little things like that that become very difficult, so adherence and compliance issues are there.

**“The PBMs really aren't set up to help members, and really not to help clients either. One of the fallacies behind prior authorization is that it's set up to make sure the right drug gets distributed to the right member. The person you have reviewing it might be a registered pharmacy tech, but typically not. They're charging \$35 to \$40 to have it reviewed by someone who is not a doctor and not a pharmacist.”**

**DEREK DAGGETT, Senior Business Development Executive, SmithRx:** I have worked for various PBMs for the better part of 15 years. I got my career started with Anthem when they

owned their own PBM and worked on it from an insurer side, worked at Express Scripts very briefly during that whole sale, saw the contract between Express Scripts and Anthem, and I can tell you exactly why Anthem is suing Express Scripts for a very small amount, in my opinion, of \$15 billion -- it actually should be quite more than that -- worked with CVS Caremark as they started acquiring more organizations and bringing specialty in house.

I was at CVS when they introduced the first exclusionary formulary in the marketplace. CVS looked at the landscape and saw that a lot of big brand or blockbuster branded drugs were coming off patent. They decided, “Well let's create this formulary which we call a limited formulary or a narrow formulary to help control costs.” For anybody that has been around long enough, as these drugs start coming off of market and losing their patent they become generics, so the market should correct itself. So, Lipitor, for example, the PBMs had to do absolutely nothing to control the Lipitor cost. Lipitor typically was about No. 2 or No. 3 on the top spend for most clients. Well, once it lost patent and became a generic the usage rate of branded Lipitor went from a No. 2 highly utilized drug, and obviously a high cost drug, to 95% generic utilization, and there is nothing that the PBM did, other than move Lipitor from a preferred brand to a non-preferred brand. The market corrected itself, because a generic was available.

These exclusion formularies were not really set up to benefit members, if you will. That's how they were marketed and that's how we were told in our sales meetings to market these, but it was really to drive rebates. If you'll see probably over the last five or six years the average rebate for most clients went from anywhere from \$15 to \$20 per branded script at retail to now you're seeing upwards of \$80 to \$90 per branded script at retail. Specialty drugs, before they weren't even passing the specialty rebates back to clients, they were included in that retail brand, now you're seeing upwards of \$1,000 per specialty drug as a rebate.

An interesting number that I heard was that a very small PBM received \$10 million in rebates just off this one drug that they do not pass back to clients or members. So, when you think about the utilization of Humira for 1 million total members you're looking at less than 1 percent of the population is on that, so now you're probably looking at about 1,000 people probably in their entire population that is on that drug and the PBM itself is collecting \$10 million annually off that drug. That is one drug.

The PBMs really aren't set up to help members, definitely not to help members and really not to help clients either. One of the fallacies behind prior authorization is that it's set up to make sure the right drug gets distributed to the right member.

The person you have reviewing it might be a registered pharmacy tech, but typically not. They're charging \$35 to \$40 to have it reviewed by someone who is not a doctor and not a pharmacist.

When Express Scripts negotiated the contract for, I believe it was Ribapak for Hepatitis C, they made a big show in the marketplace about two years ago about how they stood toe to toe with the manufacturers and said, “We're going to lower this cost of this drug.” And the Hepatitis C drugs

at the time were for a 12-week course of treatment were about \$100,000. And we looked at a lot of the research on Hepatitis C, talked to a lot of physicians, the drug does have a 95% cure rate. It's an important drug. It needs to be out there. However, not everybody with Hepatitis C needs to take a drug for it. There are instances where the disease can lie dormant, you don't need to be on a \$100,000 course of medication.

Really what Sovaldi was supposed to do and the reason why it came out was for those patients that were facing a liver transplant or facing life-threatening consequences for the disease, this was a chance for it to cure it without having to go through a transplant surgery which costs upwards of \$1 million over the course of a lifetime. Once Express Scripts "played hardball", and I use that with quotation marks, the approval rate for Ribapak went from 30% up to 80% for that drug, so any time the drug was coming back through.

I could go into step therapy and the value of step therapy. CVS has a step therapy program that is preferred, and step therapy should be set up so when you have a high-cost brand drug that has multiple generics within the class drive the people to the generics that are going to make a difference. They include preferred brands as a first line of treatment. So, you can look at when Lipitor came off patent, Crestor was a preferred step. If a member took Crestor that would not run up against step therapy. Well, Crestor at the time was probably anywhere from \$180 to \$200 per script, whereas you had Simvastatin, Atorvastatin on the marketplace, Pravastatin, all somewhere within \$10 to \$4, and if the doctor prescribed Crestor you could take it. It wasn't subject to step, or if it was subject to step the Lipitor, if they prescribed Crestor that went through.

So, again it's all about access and what are we doing to our members at this point? We're putting them through the bureaucracy essentially, because it's driving revenue.

**PETER PITTS:** How has PBM consolidation exacerbated this problem?

**DEREK DAGGETT:** Great question. What it's done is it's essentially created a monopoly between the largest PBMs out there. Express Scripts, Optum, and CVS Caremark control about 80% of the marketplace now. What they have found is that some of these smaller PBMs that have very regional focuses, instead of these large corporations going out and saying, "We have the right tools, the right formularies, the right products for you as a client," what they do is they buy up and they buy market share. What that does is that enables them to go back to pharma, it allows them to go back to the retail pharmacies and create better contracts for themselves. The more volume that they have the more power that they have.

**PETER PITTS:** My question, Derek, is now that biosimilars are coming on the market the amount of money that patients are saving is zero, could you explain that?

**DEREK DAGGETT:** It's all about rebates.

**PETER PITTS:** Is it accurate to say that biologic A goes off patent, biosimilar A comes on the market, and yet prices do not go down? And specifically I mean prices for the patient.

**DEREK DAGGETT:** Correct. The reason for that is when you're looking at the list cost of the medications the biosimilar companies have access to what that list price is. They do not have access to what the rebated prices are.

**PETER PITTS:** That's commercial confidential.

**DEREK DAGGETT:** That's commercial confidentiality. When they are, when the biosimilars are determining their price it's based off of that list price, because they have no other information to go off of at that point. Now, part of it too is that when they try to go to one of the larger PBMs, because the volume is not there in the marketplace for the biosimilar, the PBM is going to limit the access for that drug, because the money coming in from a rebate standpoint, the biosimilar doesn't have the access, so they can't give as much in rebates to get it onto the formulary and therefore it limits the access of the drug.

If you're a patient on Humira, first of all, the rebates aren't even passed back to the client until about 180 days after the script is written. You're a member, you're six months into this drug, if you're paying some kind of coinsurance you're not getting that rebate, those rebates aren't helping you. It would be like going out, buying a TV, and the store says, Target says, "You get a \$200 rebate for buying this TV" and then Target keeps the rebate and you still pay the \$1,000 for your TV, and Target says, "Yay. Thank you for buying this Magnavox. You just made me \$200." I don't think anybody would do that if that were the case, but that is what is happening with drugs. It's the PBM is saying, "I have negotiated this. You as a member will continue to take this and now you have made me \$100."

**PETER PITTS:** Doug, there have been stories, I can think of two, both in *The New York Times* over the course of maybe the last five years that have talked about drug prices, and somewhere in the jump of the story, in like the 18<sup>th</sup> paragraph it says, "Company X, innovator Company X has raised their prices over the course of the life of the patent by X percent and yet they are making less money off of these drugs because of rebates and refunds" and all of the things that we have been talking about.

**DOUG HOEY:** I mean insulin may be the posterchild for what you just said as far as the rapid increase, again this crescendo effect of the cost of the drug. So, I was looking at a drug over the weekend, Humalog, and it's gone up. It was introduced in 1996, I think, so 20 years, and it's gone up from about \$20 to more than \$100. Lantus is another example where it's gone up several



hundred percentage points over a short amount of time, but yet the companies that make it say, “Time-out. I’m not making any additional funds, any additional money.” Some of them say they’re making less money. I mean I think that deserves some pricing transparency as well, just quite candidly, but the fact that the PBMs are extracting more and more rebates -- In the insulin case you have got some similar therapeutic agents and so the PBMs would argue, “This is what a PBM is supposed to do. They play one manufacturer off the other to get the best price.” And if that is how it actually worked I don’t know that we would even be here today, but it doesn’t work that way. What happens is. Yes, they extract rebates from the manufacturers, so the manufacturer has to make their shareholders happy as well, so the PBM gets a bigger and bigger rebate. Some of that rebate is passed on back to the manufacturer, mostly because of the increased scrutiny of PBMs where they are willing to pass on some of the rebate back to the plan sponsor. However, they figured out other ways to pull money from the manufacturer, the pharmacy, and lately the consumer.

I think that is one of the reasons we are here today too is because the consumer all of a sudden has been drawn into this rebate game. Epi-Pen is the classic example. A year ago, you have Congressional hearings, you have the CEO of Mylan saying, “Look, we know our list price is \$608, but we only make \$284. It’s the middlemen who are making the difference.” Okay, well middlemen, that could mean a lot of different things. Someone could call a pharmacy a middleman. We would take some umbrage at that, but they could say, “Well, pharmacy is in the middle.” I asked our members, “Give me a range of what you make on an Epi-Pen.” \$15 to \$25 was typical.

So, that means \$284 plus \$15 to \$25 still leaves about \$300 floating around somewhere that consumers are paying. Maybe some of that is making it back to the plan sponsor, but the consumer is on the hook, the pharmacy is not getting rich, Mylan says it’s not getting rich, at least as rich as media is saying it is getting, so where are the dollars going? And the answer is the PBMs. So, it is a real problem. The rebates are going up, some of it gets passed back, but a lot of it doesn’t.

I wanted to mention one important point that maybe many in the room know, but if you don’t know it can be a real forehead slapper. That is that the PBMs have no fiduciary responsibility for their clients. They are not a fiduciary and they have fought tooth and nail at any hint of becoming a fiduciary.

Fiduciary would mean that they have the obligation to do what is in the financial interest of their client, their plan sponsor. They do not have that obligation. When it’s been suggested that they should have that designation they have gone apoplectic and brought out all of their big K Street lobbyists at any hint of being a fiduciary.

**DEREK DAGGETT:** If you look at a contract, what is defined as a rebate back to a client, it’s typically very specific language that mentions the word manufacturer rebate. So, that is not all

the money that pharma is passing back to the PBM, but that is what under the contract that the PBM contractually has to pass back to the client. There are administrative fees in there, but it’s not called a rebate. Because it’s called an admin fee PBMs don’t have to pass that back. There are disease management fees, again for programs to help with the disease. That doesn’t have to be passed back to the client.

So, I think the admin fees alone are somewhere in the neighborhood of more than 3 percent of the drug cost that is not going back to anybody but the PBM at that point.

When we talk about transparency we have to be a little bit careful, because the PBMs have begun to adopt the word transparent into their lexicon. So they’re saying, “Well, we’re transparent. You can see whatever you want, except for that proprietary stuff would cause markets not to function efficiently.” And we’re saying, “The markets are really not functioning efficiently as it is now, which is why we have so many higher costs.” But transparency can be misused if not used carefully.

**MADELINE FELDMAN:** I’m a rheumatologist in private practice in New Orleans and Vice President of the Coalition of State Rheumatology Organizations. I do not have an in-house pharmacy and most of our American College of Rheumatology members do not. I became interested in PBMs about three or four years ago when I saw step therapy, nonmedical switching, and tried to get to the bottom of it. And basically, what I’ve learned is in the rheumatology specialty medicine sphere we have rheumatoid arthritis, and Humira is obviously probably the most widely used drug, I learned that the total rebate is equal to the list price times the rebate promised times the market share.

If any one of those three things go up whoever has the total rebate largest amount, they get to be first tier. If you are not first tier you do not get used first by the rheumatologist. So, you can see where the incentive is. You raise your list price, and it’s like a bidding process. Every year pharmaceutical manufacturers send in their bid, and unlike if you have a contract where the lowest bid gets it, it’s actually the highest bid that gets to be first tier. So, you’ve got one or two drugs that put in the highest, so if you’re new to market and you have no market share, I mean that is one of the variables. What happens is my patients pay their coinsurance on the list price and so do Medicare Part D beneficiaries, they don’t pay it on the rebated price.

**PETER PITTS:** How much are you as a physician getting paid to do the prior authorization?

**MADELINE FELDMAN:** We get paid nothing. We have hired a person and a half to just handle the prior auths every year.

**PETER PITTS:** What percent of your office’s time is spent on prior auth?

**MADLINE FELDMAN:** I would say again it's a person and a half, so it's a 40-hour work week, so we have 60 hours.

**DOUG HOEY:** If PBMs have a fiduciary responsibility it helps. It doesn't solve everything, but if they have a fiduciary responsibility and are forced to be what we would call, our definition of transparent, which again there is a lot of definitions of transparency, all of a sudden you see their motivation, their conflicts of interest would start to dissipate. I'm not sure how that happens while they're a publicly traded company, because their shareholders would have a massive revolt, but I think as a fiduciary, things begin to look a little bit clearer.

**DEREK DAGGETT:** A couple of great ideas I've heard recently is start carving out some of these pieces from PBMs, carve out the prior authorization process, hire out an independent contractor to do the prior auth.

It's the analogy of the fox guarding the henhouse. You've got the fox is saying, "Oh I'm going to guard the henhouse and take the hens when I want them." So carve that piece out. Carve the specialty piece out of one of the large PBMs, go to independent contracting pharmacies. You can build the rebates back into the drug price and pass that through directly at the point of sale. There are some opportunities to do that.

What PBMs were set up to do originally was to create more access to pharmacies, being able to control drug prices, and working with big pharma to keep those costs down. The problem now is that the PBMs are almost in control of pharma and how those prices are being controlled.

**BENJAMIN BROOKS, of Health HIV.** I'm here primarily because my first interaction with the PBM was when United Healthcare's PBM, Optum Rx, and their specialty pharmacy, Briova Rx, decided to increase the prior auth requirements and the mail order requirement for a HIV prevention drug. We were thankfully able to get that reversed relatively quickly with some advocacy work. My question for the panelists is what can we do sort of when things are on a case by case basis getting worse over, and of course when you look in the long term that there is a progressive trend, if you will, I'm not going to call it intention, but there is a trend of increased barriers to good preventative medicines that can reduce the overall healthcare cost over the course of a generation?

**DEREK DAGGETT:** I firmly believe the best way to do this, and you really have to start going after large plan sponsors and really getting them on board as well.

You've got some great organizations like the HTA that have come together to really try and figure out a way for their member clients to bring these costs down. Caterpillar a number of years ago carved out specialty. They still use Express Scripts for their back-end adjudication, but they completely carved out specialty from Express Scripts and they actually went out and negotiated with specialty pharmacies and created their own specialty network that they use, and

they have actually had negative trend on their specialty for the last four or five years. Where everybody is seeing a trend of 18 to 20% they have actually shown negative trend.

But again, and I think to Doug's point before, you've got a broker community out there as well that have been kind of snowballed, and they have contracts with PBMs to specifically sell these contracts.

**“One thing that PBMs loathe is attention. They do not want to be in the spotlight. Most consumers have no idea what a PBM is. I think the patient groups, the HIV groups in particular, have done an awesome job of saying, ‘We’re not going to take this.’”**

**DOUG HOEY:** I want to applaud the HIV groups that have done an excellent job of saying, "We don't want our HIV meds to be restricted through the mail" or the latest case where there has been potential HIPAA violations and they have really made some enormous noise about that. I think that has been a great example of patient groups coming together.

One thing that PBMs are loathe for is attention. They do not want to be in the spotlight. They want to go under the radar as much as possible. As Derek said, most consumers have no idea what a PBM is, let alone be able to name it. They're Fortune 20 companies. I think the patient groups, the HIV groups in particular have done an awesome job of saying, "We're not going to take this."

**BURT ZWEIGENHAFT, former president of National Association of Specialty Pharmacy.** Would you say that a co-conspirator in this are the health plans?

**DEREK DAGGETT:** You're absolutely right. From a health plan side of it, rebates are shared with your self-insured or what they call ASO, Administrative Only fees clients. The fully insured clients never see a dime of the rebates. The contracts that were negotiated on a health plan side were from 10, 15 years ago if they have been with it, and those discounts have not been improved. You've got some clients on a fully insured side that when they carve out from the health plan and may go with a fully transparent PBM, without changing the formula, without changing anything, I mean the plan stays exactly the same, and they can see 32% savings without making one change and just simply going to a fully transparent model.

I think what we need to do as consumers and as advocacy groups is really talk with our plan sponsors, talk with our members, and really get in and just dive into those contracts and open those contracts up.

I saw a study at a conference about two years ago where 80% of plan sponsors hadn't looked at their PBM contract in almost 10 years.



The contracts were set up deliberately to confuse people and to hide things and to get through these loopholes. I mean you're talking about drugs being dispensed, it shouldn't be a 100-page contract, frankly, it really shouldn't.

And find experts that understand these contracts and really dive into it and set it up so that you as the client and you as the patient benefit from it and not these PBMs.

**DOUG HOEY:** We have been out there screaming at the top of our lungs for a long time. We need more voices, so CMS certainly, Capitol Hill, they're familiar, when we walk into an office they know what we're going to talk about. We need voices from other sources. We need other people to also be concerned about the role that PBMs play. And we say that they are contributing to the higher costs of drugs and if you believe that you need to add your voice to that message.

Disrupting the current prescription drug business model which relies on PBMs is a means to an end. The end is really our healthcare system and making that a better place and taking that 10% to be synergistic with the 90%. Short term tactically fiduciaries, we have DIR legislation that has been introduced that could be helpful in the short term, but crescendo-ing, adding your voice, having the decision makers, the plan sponsors, the media hear it from others in addition to Community Pharmacy but hearing it from your organizations is how we will eventually solve this and have a better pathway forward for consumers and for our healthcare system.

**KEYNOTE ADDRESS: A. MARK FENDRICK, M.D. Director, Center for Value Based Insurance Design, University of Michigan and the "Father" of Value-Based Insurance Design**

**“The biggest myth in Washington is that people believe that the improvement of high quality healthcare actually will lower healthcare costs. They hardly ever do. Living longer, better lives is something we should invest in. We have to change the healthcare conversation from how much we spend to how well we spend it.”**

I still practice general internal medicine at the University of Michigan, where I run the Center for Value-Based Insurance Design. I've worked in a lot of areas, including looking at the cost of the common cold, blockbuster drugs, health IT, health reform. This issue has broad multi-stakeholder and rare bipartisan political support, which is, I think, one of the reasons why value-based insurance was designed

This is an unusual meeting in Washington, where a lot of time is spent talking about the health of our population. Because most of the time, when I run into Washington, nine out of 10 comments

are talking about the cost of care. And my opinion, at least, is all my time I spend on the Hill, and talking to both the past and current administration, is how to lower healthcare costs. I like to people I did not go to medical school to learn how to save people money. I think it's really important to restore health to these healthcare cost discussions.

If I were to ask any of the stakeholders what we should be spending our money on, I think all of you would acknowledge that the most important things that we should be spending our money on are underutilized, and that we actually have to spend more. We have to spend more on healthcare than we're spending now, if we're going to achieve those goals of individual and population health. My career has not been based on cost of care, but it's the underutilization of things that I beg my patients to do, whether it be prevention, diagnostic tests, chronic care of diseases, or end of life care, as we look at the things that we should be doing for which the evidence is strong, whether it come from clinical trials or real-world evidence. There is substantial underutilization of those things.

The biggest myth in Washington is that people believe that the improvement of high quality healthcare actually will lower healthcare costs. They hardly ever do. That has been my holy grail. But it shouldn't lower healthcare costs. Living longer, better lives is something we should invest in. We have to change the healthcare conversation from how much we spend to how well we spend it.

I've been quite outspoken that, if I were designing the American healthcare system from the bottom up, I wouldn't be kind of apologetic for 16 percent of the spend going to pharmaceuticals. I think it would probably be about 25 percent, given the data we have on safety and efficacy.

The rub is, when I think about what's coming down the pike, the innovations that are before me, I like to call them Star Wars science. And the world in which I practice, I like to call Flintstones delivery. And I think that before the ACA, there was quite a gap between what I could do and what I actually was able to do. And I'm sad to say, from my own individual perspective, I think that gap has gotten wider, not closer, even with the expanse of insurance to millions of people. And I'm even more fearful that the gap is going to get wider and wider.

I think every stakeholder sitting around the table should get serious about the identification, the measurement, and removal of care that does not make anyone healthier. You would call it low value care. You'd call it wasteful care. I think it's the only opportunity we have over a couple years to maybe get rid of \$600 billion, or some people think \$900 billion in services that do not make anyone healthier, to allow us the time to figure out how we are going to allocate the remaining money on services that actually work.

Volume to value, I love saying, because it's alliterative. And we were talking about value-based care long before it became popular in this town. We have to focus on providers and value-based payment. Myself and Michael Cherner, ex-Vice-Chair at MedPAC, now at Harvard Medical

School, have been working on patient-facing or consumer-facing initiatives for now getting on two decades, which is now called Value-Based Insurance Design.

But what keeps me up at night are deductibles now, the fact that my patients with commercial insurance, or public insurance outside of Medicare, actually have a donut hole at Day One on January 1<sup>st</sup>. That's sometimes up to \$12,000 dollars where a family has to come out of their pocket before any insurance kicks in.

As I travel around the country, it's about deductibles. It's about copayments and cost sharing and the fact that I find it humiliating that my patients have to have a bake sale to pay for a drug that was designed to treat them. You know, this would be first line or targeted therapy. This is not overuse. These were not drugs that people want to take. These are drugs that are the only option for many of these people.

Our small solution to this problem of cost-related non-adherence is what we call smart cost sharing. We call it clinically nuanced cost sharing. It's the type of cost sharing that, instead of basing my patient's out of pocket spending on what things cost, we base the out of pocket spending on the amount of health that would be produced.

The issue with drugs or any clinical service, this nuance idea, there's no such thing as a high value service or a low value service. It depends on who gets it, and when in the course of their disease, oftentimes by whom, and now with this interest, particularly in Medicare, around sight of care, where it's provided.

We have evolved value-based insurance design into something we call precision benefit design, or dynamic benefit design. And I could give a number of examples of this. But the purchasers, that being the employers and health plans and the PBMs, I get them onboard because I say—and I strongly believe this—that we should support low-cost services first line if they're clinically indicated.

Unfortunately, many of my patients—let's just say diabetes, since this is something that people know well—they take the low cost generic drugs. They take all of them. They take them religiously at the maximal doses that allow, and they still need more. I find those patients who do everything they were supposed to do as advised by their plan in the PBM, why should they be penalized by their biology?

No one wants to pay more than the lowest price. But when your only option, as is a patient who fails generic therapy, or in the world coming into Star Wars patient, the patient who has now received a genetic marker to say, "You should not take the low-cost drug. In fact, it might harm you. You must go for this drug that was designed for you," I strongly believe that those patients should not be penalized; but, in fact, should have a benefit design that makes those drugs affordable for them in that clinical instance. You don't get to have the drug that you saw on TV first line if there is a low-cost alternative. But, if you are unlucky enough to either not do well,

have an allergy, or have some test that tells you should not take it, you should not be penalized. We call this precision benefit design.

We're just starting now to get organizations behind this, because the neat thing about precision benefit design, it is a strong commitment to first line therapy and many of the situations that the plans have in place. But it appreciates what, in my opinion, is not appreciated now, is that the life of people is a dynamic process and not static. And I don't know, outside of two out of about 25,000, and maybe the folks in the PBM world could tell us, that actually have a different copayment, coinsurance, or deductible, for this same medication.

That's what I think we could take advantage of our multi-billion-dollar investment and health information technology, to which, in my opinion, has not at all benefited my patients as much as they benefited other parties.

The idea that the things that are most profitable in healthcare are not the things that produce the most health, is the disconnect. And what I mean by that, I had the great honor to speak with Speaker Newt Gingrich when he was primarily a healthcare guy. And I said, "This is the line I typically use when I talk to the *Wall Street Journal* or other types of places, that if we aligned profits with health, then I wouldn't have problems with profits, because the monies would be going to the right things."

What do I mean by that? If I were to ask many of you, "What are the most valuable things that we do in healthcare?" some of you, if not many of you, would say vaccines. And it turns out that our work in Michigan, now it's probably five or six years old, showed that over half of community-based pediatricians lose money vaccinating kids. And then, when I asked the speaker, "Well, what do you think those pediatric practices have to do to make up for the losses they incurred for doing what many people thought was the most valuable thing they could do?" of course he said, right away, do a bunch of stuff that really doesn't help the kids very much.

People ask me all the time, "Well, low value care is challenging." But the folks who showed up in the large firms that put value-based insurance design (VBID) in place, who saw their visits to see nurse practitioners. And they saw their insulin's cost sharing be cut in half. And they were actually not discouraged, but actually made easy for them to go to see the eye doctor. No one complained about that. I think that if we put in the right balance, which is what I argue for anyone who works with me, while the idea of removing low value care to a payer is so attractive, almost red meat, because the savings are immediate and substantial, I think that what we've shown in the management of certain chronic disease is that we could actually get to cost neutrality by having people be healthier, by having greater amounts of visits, and most importantly, filling their evidence-based indicated drugs.

The worrisome part for me, with the VBID demo in Medicare, is there is this term that I'm just getting used to in this town, called Pay-Go, is that we, to get the VBID demo to expand, we have to show that the programs that we have for the 10 chronic conditions have to be cost-neutral in

year five. And while there are some conditions, like congestive heart failure for the nonclinicians in the room, lots of avoidable hospitalizations, that's why people are jumping in that direction. But having advocated for other conditions, like mental health issues, like depression, we got rheumatoid arthritis added as well as dementia last time around, because I really wanted to see these demonstrations fall into those conditions where hospitalizations were not the cost drivers, but other issues would.

My two words that I tend not to say in Washington are: capitation and rationing. And I was asked about trying to get trapped in a recent hearing around the rationing issue, to which I say, "I ration harmful care." It's really hard to argue against rationing harmful care.

What is challenging is identifying what is harmful. But there are some things where we're starting—like pap smears under the age of 21, and now pap smears every year, now that everyone recommends it, every three, these are easier to identify, Dexa scan. Our list of low value services that we would start with are not the ones that the CBO will want to see. These are not going to be gigantic chunks out of Medicare spending.

What we are hoping to do, like we've done on high value care, is to get people to understand, which we recently had some NPC-funded work to do, that people think it's too hard. And I think to get rid of 30 percent of waste, I think that's hard. To get rid of 3 percent, to get a dialogue going that more is not better in this country, I think that is doable. And that's the way I kind of approach this.

**“My view is that people in Washington care more about money than they do about individual and population health. We have to get this conversation back to the patient.”**

If organizations, particularly those that represent patients, do not get serious about low value care reduction, I'm going to use an academic term here, we're screwed.

When I think about the idea of being able to take cells from one of my patients' bodies and have them put into those bodies, and have that drug only available to them, I'm not sure what the price of that should be. But damn it, I want to be able to use that drug. And if I'm going to be able to use that drug, and I'm not sure how many payers are in the room, they'll say, "That's fine. You want more eye exams? Mark, great, as long as it's not going to cost me any more. Because some consultant came in and told me that, this high-quality care is going to lower my total spend." I think that is the biggest issue that we have to overcome.

Most of you are in health plans, that you pay the same co-insurance for all specialty drugs. You pay the same percentage for a drug that will cure cancer 90 percent of the time as the same for a

drug that will never cure a case. And I ask CFOs of Fortune 50 companies every week, "You went to Wharton. You went to Harvard. You went to Stanford. And this is how you're spending your money on specialty drugs?" To which a typical response is, "Tell me this isn't true. You know, how did it happen? And how do we fix it?"

I said, "I don't know." The point is that the current one-size-fits-all system, even within the tier, makes no sense. Ninety percent of the attention and the urgency in the world of prescription drug is talking about drug classes within the tier, generics first, branded.

We have to fix this idea that cheap drugs are cheap to patients. I think particularly the National Community Pharmacists Association should get behind that and try to help us. My view is that people in this town do care more about money than they do about individual and population health. We have to get this conversation back to the patient.

## **Session 2: Principles for PBM Reform and Patient-Centered Prescription Drug Benefits**

**ROBERT GOLDBERG, Vice President of Center for Medicine in the Public Interest:** This panel is to continue the conversation about plans and PBMs, how the plans affect a lot of this stuff downstream. That also relates to the fact that the value of new medicines or the value that we can benefit from new medicines is not being shared by the patients, either in the form of lower out of pocket cost or in the benefit.

I would just like to mention two studies that I have done. In the first study, I just looked at how much money it cost for people taking specialty drugs, which is about 2 percent of the population, how much are they generating to plans and PBMs in the forms of rebates and copays, which is another rebate back to the plans and the PBMs. And it turns out that 30% of the \$120 billion in rebates and discounts, which doesn't include the cost sharing coupons and stuff, 30% of that \$36 billion comes from 2 percent of the population, 4.4 million people. Then I looked at the copay amount, and again the average copay or coinsurance on specialty drugs in commercial plans and in Medicare plans, ACA plans, Medicaid is an exception, again it's about 27% of coinsurance of the retail price. That revenue is another 30-35% of total cost sharing from prescription drugs in total. So, 2 million patients, 4 million patients are generating about \$50 billion to the PBMs and plans in the forms of rebates and cost sharing.

**SHAWN LOVERING, CEO of RxTE (Prescription Therapeutic Equivalents):** We look at those therapeutic categories. We develop a pricing file. We work with PBMs for our clients,

primarily in the multi-employer, Taft-Hartley industry, and we develop a new copay. To incentivize the member to switch and have that conversation with their doctor, we select a low-cost alternative. There are several different ones in that area, but these are therapeutic equivalents, so this is not a prescription that can be switched at the counter. It requires a new prescription because it's a different chemical in most cases. Instead of looking at direct generics, we start with, "Okay, if the goal is to reduce LDL cholesterol by X percent, what drugs in all of the drugs out there can get there and can achieve that and are therapeutically get to the same outcome?" And by doing that we identify a lower cost drug for the specific target drug, which is like maybe a brand drug or even a generic drug that is high cost.

So, our product actually drives a ton of savings for both the member and the employer or sponsor, around 21%. The study that Bob spoke of that UC Berkeley did looked at one of our clients that has our product in place. They tested it against a like client that the PBM had and they studied what was the outcome of having reference based pricing in place versus not, and they found that there was a 13% reduction in the plan spend, there was a reduction in the member spend, but there was also an increase in adherence. And so that is what other studies that we have done have found as well that when the member has the option to speak with their doctor, switch to a lower cost drug, they actually, adherence goes up.

One of the other outcomes that we found was ... we didn't want the PBM to be driving the decision of what drugs that member takes, so exclusionary formularies, prior authorization, step therapy, those are all things that the PBM puts in place to drive them towards certain drugs. What we wanted to do was have a choice architecture in place that took away those exclusions, because if that drug is excluded the member doesn't have access to it.

**ROBERT GOLDBERG:** Can your architecture be used to eliminate copays for drugs that a physician or the plan thinks is optimal to increase adherence, etc.?

**SHAWN LOVERING:** Absolutely. We have done that for several of our clients. To interface with their disease management programs for a lot of the maintenance drugs, we look at it as a zero-dollar copay for the member. If they are drugs that must be taken, and diabetes is always a good example, because controlling and taking your medication and being adherent really drives your overall health, and so by making that a zero-dollar copay for the member you ensure that adherence is driven, they have the appropriate incentive to go to that drug and take that drug.

**BURT ZWEIGENHAFT, Managing Partner, Upstream Partners:** Today is 9/11, so I can give you kind of a story on 9/11. My brother in law was the Battalion Chief in the city. He survived it, but about six months later he was in the hospital. He had Hep C, which is not unusual for emergency response people. It co-infected. He was in the hospital with a lot of pain. He was on PEGylated interferon, he was taking opioids for the pain from another doctor. They had had one pharmacy with the PEGylated interferon. I think Express Scripts had the Ribavirin, and he was getting the opioid from a CVS drugstore. Well, for about four or five weeks he had the

stabbing pain. He had a burst appendix. By the time they went in and operated, they had nicked the intestines and of course he had staph and he almost died from that, not 9/11.

Everyone is trying to compete on price, so there is no incentive for the insurance providers to continue to support disease management. Aetna makes the investment in me today, but Cigna or someone else might see it differently. Employers probably should hold insurers more accountable to long term, but why can't we monetize performance?

Mark, another thing you brought up is, "Gee, I'm compliant, I take all my meds and I'm still paying copays. I should be the one that pays no copays." It's like I'm a drunk driver and I pay the same insurance as someone who stops at stop signs and calls Uber when they had too many drinks. It doesn't make sense again in the system.

**ROBERT GOLDBERG:** A couple of months ago, I asked a couple of CEOs, "Let me get this straight. You rebate the drug so it gets on formulary, and then your customer pays a percentage of the list price and you pay the copay, the coinsurance for that. Then you're hiring people to do all the prior authorization work and the reimbursement. Why not just take all that money and reduce the price of the plan and make it available to the patient at no cost?" And I got a blank stare, because I think maybe I said, "So the Emperor has no clothes."

**"PBMs really are sitting in the cat bird seat in the pharmaceutical supply chain. They take advantage of the fact that they have unparalleled insight into everything that goes on upstream as well as downstream and have managed to build in revenue streams for that."**

**SUSAN PILCH, Vice President Policy & Regulatory Affairs, National Community Pharmacists Association:** PBMs really are sitting, for lack of a better term, in the cat bird seat in the pharmaceutical supply chain. They take advantage of the fact that they have unparalleled insight into everything that goes on upstream as well as downstream and have managed to build in revenue streams for that.

It's very interesting, because we were talking with someone else here about how a lot of the other segments in the supply chain were somewhat segmented. Manufacturers understand the manufacturing world, pharmacy understands the pharmacy world, but we don't have a really good idea about what the other segments are doing. The PBMs have all of the data because they have contracts with everybody. They contract with manufacturers, wholesalers, pharmacies, everybody, and so they have unparalleled access into that.

The people that contract with the PBM to administer their drug benefit, and these are plan sponsors, employers, unions, government entities, and really a lot of what goes on with them,

and particularly their contractual provisions really set the stage for a lot of things that go on downstream, all the way down to the patient.

Someone mentioned rebates. We all think we understand what rebates are, but think about it. Once the manufacturer negotiates the rebate and the PBM has it, the manufacturer no longer has any incentive to know or really care what the PBM calls anything. So, the PBM, what was a rebate, well that is really a formulary management fee. That goes onto the fact that PBMs claim, “We pass along the majority of our rebates.” What do you call a rebate? What is a rebate?

What is a brand drug, what is a brand, what is a generic, what is a specialty?

Sometimes those definitions are very vague and the PBM is free to interpret them any way they want. Or they’re drafted in such a way that the PBM can pretty much determine, that enable them to classify many drugs as either one or the other. Most contracts allow them to switch that classification throughout the life of the contract. When it becomes more advantageous for them to classify something as a brand they will do that. When the pendulum swings the other way, magically it becomes a generic. You might say, “Well, why would they want to do that?”

They can charge the client more if they classify it as a brand. If it’s a generic, if they need to bump up their generic substitution rate they want to filter that into that. A lot of definitions of generic is any drug with a sufficient number of suppliers. Guess who determines what sufficient means? How pharmacies are going to be reimbursed for those drugs, what tiers those end up on, and those start off at the contractual level where most people really have no insight into that.

**SHAWN LOVERING:** PBMs don’t like us at all, because we directly impact their revenue stream. We move people off highly rebatable drugs to other drugs, we do brand to brand, we do generic to brand, we do a switch that is therapeutically equivalent. PBMs don’t like us, because we have to interface with them and we overlay their current pricing and methodologies and we directly impact their revenue stream. I would say probably the biggest driving reason that we have been successful in getting almost 1 million members on our program is because we have gone to extremely large multi-employer trusts where they have 100,000 members where they have been told by the trustees, “Look, either you do this or we’ll go shopping for one that will.” And that is the only reason we have been successful in getting our product in.

There are some new PBMs coming out or small guys that are trying to get started in the industry that will take fiduciary responsibility, that will give their clients a seat on their board so that they can be guaranteed transparency, real transparency, not fake PBM transparency. Getting a large employer, multi-employer trust to utilize them, it takes a change in thinking at the consultant level as well as the client.

**DOUG HOEY:** We’ve talked about PBMs a lot. But really, that’s a means to an end. The end is a different pricing system, a different model for making prescription drugs even more affordable.

It just so happens that PBMs are in the center of every pricing decision that involves pharmacies, most manufacturers and wholesalers. We start with them.

In community pharmacy, we’re going to continue to be raising our voices on the things that we’re seeing. But hopefully there has been at least one, maybe two, maybe more, several things that is new information to each of you around the table. We really have to have you carry your voice to members of Congress, to other provider groups, to consumer groups. And then also to plan sponsors or employers.

**ROBERT GOLDBERG:** Thank you all for your passion and interest in this. We thank the panelists for your participation and interest.

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The National Community Pharmacists Association, founded in 1898 as the National Association of Retail Druggists (NARD), represents the pharmacist owners, managers, and employees of more than 22,000 independent community pharmacies across the United States. The nation's independent pharmacies, independent pharmacy franchises, and independent chains dispense nearly half of the nation's retail prescription medicines.

The nation's independent pharmacists are small business entrepreneurs and multifaceted health care providers who represent a vital part of the United States' health care delivery system. They have roots in America's communities. They are community leaders actively involved in community-oriented public health, civic, and volunteer projects. Many hold local elected offices; others serve as state legislators.

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- We are dedicated to the continuing growth and prosperity of independent community pharmacy in the United States.
- We are the national pharmacy association representing the professional and proprietary interests of independent community pharmacists and will vigorously promote and defend those interests.
- We are committed to high-quality pharmacist care and to restoring, maintaining, and promoting the health and well-being of the public we serve.
- We believe in the inherent virtues of the American free enterprise system and will do all we can to ensure the ability of independent community pharmacists to compete in a free and fair marketplace.
- We value the right to petition the appropriate legislative and regulatory bodies to serve the needs of those we represent.
- We will utilize our resources to achieve these ends in an ethical and socially responsible manner.



