U.S. SENATE COMMITTEE ON
COMMERCE, SCIENCE, & TRANSPORTATION

U.S. Senator Maria Cantwell

Senate Committee Subcommittee on Consumer Protection, Product Safety, and Data Security
Hearing: Ensuring Fairness and Transparency in the Market for Prescription Drugs

Witnesses:
David Balto, Antitrust Attorney (David A. Balto Law Offices);
Robin Feldman, Professor & Researcher (UC Hastings College of Law);
Craig Garthwaite, Professor and Director of the Program on Healthcare (Kellogg School of Management, Northwestern University);
JC Scott, President and CEO (Pharmaceutical Care Management Association)

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Opening and Q&A Part 1
[VIDEO]

CANTWELL: Thank you, Chair Blumenthal and Ranking Member Blackburn for holding this important hearing.

We know that the lack of transparency in the marketplace is a concern to all of us. And let's understand where we are today. Since 2014, prescription drug prices have increased much faster than the rate of inflation -- drug prices have gone up 35% while the cost of all goods and services have jumped just 19%. So price increases for prescription drugs have outpaced wages, gas, telephone, internet services, food, tuition, transportation and personal care.

So there is a consistent issue here. We've found that prescription drug prices have increased for 30% of Americans who take prescription drugs medications, many of whom have experienced increased annual cost of more than $100.

The worst news, however, is that many who saw such spikes in their out of pocket costs were almost twice as likely not to fill a prescription or skip their medication. So this is of concern.

We know that the average list price for insulin has doubled over the past 10 years, even though insulin has been available for patients for over 100 years. And significant hike prices have become a matter of life or death for many Americans with diabetes.

In my state, Molly Stenson, a Washington resident used to travel from Mason County to Canada just to purchase insulin. That's because at the time, the average price of insulin was $450 a month. It wasn't until Washington state passed a law to put a cap on insulin at $100 a month that she was able to finally stop making these trips.

Unfortunately, only 18 states have this cap on insulin copayments. So there are drug insulin prices increasing faster than most goods and services.

According to Senate Finance Committee staff report released by Senators Grassley and Wyden, the price increases are due in part to the business practices of pharmacy benefit managers. So that's the subject of today's hearing.

PBMs are contracted by government programs, insurance companies, self-insured employers to negotiate on behalf of the pharmaceutical firms. And the way the system works, they also make a lot of money driving up the price on consumers.

Today, fewer than five PBMs control more than 80% of the drug benefit for over 260 million Americans. These companies -- who most Americans know nothing about -- set drug costs, decide what drugs will be included in your plan, and determine how drugs are dispensed. And these companies have abused their responsibility to protect Americans from this drug pricing crisis, continued an opacity on the drug supply chain.

So we want to shine a bright light here. We want to understand how PBMs affect drug prices for consumers.

First, PBMs develop what is known as formularies, which are list of covered drugs on behalf insurers or payers to get their drugs placed on the formulary manufacturers provide rebates to PBM, some of which are passed on to consumers.

But they keep some for themselves. And because PBMs retain a share of that rebate, they have an incentive to keep those list price high. And who bears the brunt of that? Consumers. Particularly if their cost sharing is based on a percentage of the list price or if they're among the 25% of Americans who have a high deductible health plan.

The second way PBMs are affecting drug prices is something called spread pricing. Spread pricing occurs when a PBM charges an insurer a higher price for the drug than the amount it is reimbursed by the pharmacy, with the PBMs keeping the difference.

According to an investigative report, PBM skimmed off $1.3 billion of the $4.25 billion that Medicaid insurers spent on drugs and 2017.

There are examples of that. In 2015, PBMs charged Indiana's Medicaid program $204 for a drug and reimburse the pharmacies only $197, with the PBMs pocketing the $7.

Three years later in 2017, PBMs charged the Medicaid program $147 but reimburse the pharmacy $17 with PBMs, pocketing $130. That's right. PBMs profit increased by $123 for a single 30-day supply of a heartburn medication all at the expense of the American consumer.

And what makes spread pricing possible? The lack of transparency in the PBM market. PBMs affect drug pricing for consumers by enforcing a number of post-sale fees on pharmacies, effectively limiting the pharmacies profits.

Let me be clear. I'm a big fan of the pharmacies. There's a guy across, or a woman across, the counter when you go in to get your prescription who tells you some things about that medication. Oh, be careful of this. What about this? Are you taking this? So they are part of our healthcare delivery system.

So, the notion that some people want to have mega-conglomerates control pharmacy drugs by mail and control the market and have a continued concentration -- mark me down as not a fan.

PBMs keep these fees and rarely pass them on to consumers, thereby raising the costs for pharmacy, pharmaceutical markets as a whole.

Now, believe me, I'm from an innovation state and I also worked in software for five years, it's easy to raise capital if you're going to produce a product in six months and ship it. It's a lot harder to raise money for a product you have to have for 18 years. So no one is saying that it isn't hard to get capital to invest in new groundbreaking drugs. But the issue is do we have enough transparency in this market.

In 2019, the Washington legislature passed a law prohibiting PBMs from charging phantom fees that raise the cost of dispensing medication. Several states have enacted laws requiring PBMs to obtain a license to operate in their state, and some have gone further prohibiting or regulating spread pricing and requiring PBMs to report pricing and rebate information to promote transparency. And they have brought enforcement actions.

For example, April 13 2022, the Louisiana Attorney General sued Optim RX for inflating the price of prescription drug charges and their state's Medicaid program, included by spread pricing and claw back money from pharmacies without passing it back to the state.

But we in Congress must do more to ensure that all Americans and all American consumers are protected. That's why I'm so appreciative of Chairman Blumenthal holding this hearing this morning. And using your experience as a former AG to help us work through these issues at today's hearing.

If our system is where patients get inferior treatment and still pay more, this is setting us back. So it is time for us to take action on this.

Mr. Chairman, I will put the rest of my statement in the record. But I'd like to turn to our witness.

Start of Questioning Part 1

CANTWELL: Mr. Balto, I understand that you were an attorney at the FTC for several years and were involved in many FTC earliest enforcement actions involving pharmaceutical and healthcare companies.

Could you explain why the FTC action against PBMs under a current authority of unfair and deceptive practices, and what more authority could help us in moving the market to a more transparent market?

BALTO: Thank you, Senator. I think the FTC has made some major errors in terms of enforcement in this area.

And part of it is relying a lot on economic theory and not looking at the reality of what's going on and also not properly defining who the consumer is. You and I and everybody else in the room know that the ultimate consumers, you know, real people. The FTC focuses almost exclusively on the question of the first buyer, the plan sponsor, and whether the plan sponsor is harmed. And in that way, misses a lot of the anti-competitive effects.

Just to give you one example, that sort of hits with the point you're making about the service of the community pharmacists. Assume that you're a person who needs a complex specialty drug, in which you really need the services of your community pharmacist. The PBM engages in various tactics to drive that community specialty pharmacist out of business or make it very hard for them to compete. You're forced perhaps into an exclusive PBM owned specialty pharmacy. And by the way, the FTC has permitted the PBM is to acquire all these specialty pharmacies. You move then from having being able to see your community pharmacist having the monitor your health care, having them give you advice, to all of a sudden having a pharmacist at a 1-800 number.

And there's terrific testimony that about HIV patients, that I cite in my testimony, that it suggests how this is a problem.

The FTC act is broad. And one thing that could be very helpful, besides the efforts by Senator Blackburn and other members, to compel the FTC to do, well to have the GAO do a comprehensive study of this mark, and I know Senator Grassley and others have suggested the FTC to do a study, would be for Congress to specify what are unfair methods of competition. That the FTC should scrutinize. And this FTC act is broad, it prohibits unfair methods of competition and unfair trade practices. And Congress can specify what some of those practices are.

And when you look at things like the gag clauses, you know, preventing pharmacists from telling consumers where the lowest price drug is, I mean, that’s blatantly an unfair method of competition. It blatantly is something that harms consumers. Consumers are in no fashion better off when a pharmacist can't tell them what’s the lowest price, the means of getting the drug at the lowest price. And there's no reason for that other than for PBMs to protect their PBM rebates. So, you know, that's the kind of practice that could be specified.

Also some of the practices that prevent generics or biosimilars from getting on the formularies because, again, PBMs are preferring drugs with a high rebate to these lower costs biosimilars or generics, which offer a lot of promise for ultimately lowering drug costs.

In my testimony, I specify about five or six practices that could be outlined in legislation to attack these unfair methods of competition that ultimately harm consumers.

CANTWELL: Could you remind me, Mr. Balto, because I feel like we had this hearing a decade ago or maybe longer and I thought we took action as a Congress to outlaw PBMs being owned by drug companies. So that some of these same practices wouldn't be continued. What did we do before and why are we here again?

BALTO: In the Clinton administration, we recognize that pharmaceutical manufacturer owning PBMs was like the fox guarding the henhouse. Unfortunately, in the past several administrations, we forgot that basic principle of economic policy, you don't want foxes looking after chickens.

And so they've permitted the PBMs to acquire all these major pharmacies. They all have their own mail order pharmacies, which they prefer. They go in aggressively audit independent pharmacies. They reduce their reimbursement to ultimately force them to dispense below cost. They capture these retroactive DIR fees. Do you think they do those things with their own

pharmacies? I don't think so. And so that kind of fox owning the henhouse operation is just a poor recipe for competition.

And by the way, senators, you know, there's a lot of legislation going on right now to address this problem in high-tech industries, where we're very concerned about the major tech firms preferring their own businesses. I don't know why we should let this happen with PBMs.

As important PBMs being able to secure part of the rebates, it distorts their incentives and turns competition on its head so that PBMs prefer higher not lower drug prices. And by the way, many of you have identified the key issue here, which is ultimately noninsured consumers lose. And that's even Professor Garthwaite’s way to identify that problem. And that's why consumer groups, if you'll note in footnote five of my testimony, consumer groups supported the past administration's proposal to eliminate the anti-kickback safe harbor for PBM rebates. Aggressive. And PBM rebates are just screwing up health care decisions right now, and leading to a rapid escalation in drug prices, as demonstrated by the Grassley-Wyden report.

CANTWELL: Thank you. I wanted to ask you about the FTC brought a case against AbbVie. If you recall, the court awarded the FTC $448 million in consumer redress which had to be invalidated as a result of the AMG decision. So how does the absence of 13(b) redress affect the FTC’s ability in this space?

BALTO: It should be a significant priority of everybody in Congress to pass legislation to return the FTC its power to secure financial redress. I know as being the former Policy Director, how crucial that is to being able to effectively enforce the antitrust laws. If bad actors including major corporations, know that they can engage in conduct and basically get a slap of the hand, just stop now, that's not going to deter them much from engaging in bad conduct. It's only when you can stick a significant monetary penalty on them that they know that they're going to have to pay the piper.

So I think that you absolutely have to, that this is a major priority to strengthen the FTC enforcement powers here. And certainly, if the FTC had that restored, it could look at these egregious practices that PBMs engage in and possibly bring actions under the Section 13(b) to provide redress to payers and consumers for these egregious actions.

CANTWELL: So what exactly does the Committee need to do to give the FTC the authority to properly police this market?

BALTO: I think the Committee needs to strengthen the FTC’s powers. Let me start off first, I think the importance of a study is crucial. Again, I agree with the professor, that study and more information is really vital.

However, the Committee needs to instruct the FTC. It needs to identify the right consumer. The FTC’s past studies, like their mail order study, two decades ago, just looked at the impact of the plan sponsor, you know, in a plan sponsor may or may not care. You know, if the consumers are harmed in the fashion that Senator Blumenthal and Ranking Member Blackburn described. They're not necessarily going to care.

They need to do a study and actually focus on the real consumer. Then I think it's vital for the Committee to consider identifying specific practices by PBMs that are unfair methods of competition that aren't consumers. For example, the DIR, and to me, the gag clause is a very straightforward example. But also the DIR fees, especially DIR fees imposed by a rival. It seems

relatively, it seemed like the kinds of things that you put considered to be an unfair method of competition and that the Commission needs its powers strengthened by identifying some of those practices that they should look at as unfair methods of competition or unfair trade practices.

CANTWELL: But you think that those, in your testimony you outline, I think it's on page 13 here, legislative action to prevent PBM abuses. So you think there are known practices now? Is that correct?

BALTO: Absolutely. Absolutely, and the fact I mean, the FTC has brought no actions. I mean, they've received hundreds upon hundreds of complaints by pharmacies, about some of these actions about PBMs going and taking information from its PBM affiliate, and sending it to its pharmacy affiliate, so that the pharmacy could target and try to steal those customers or PBMs imposing, you know, egregious audit practices to try to drive those independent pharmacies out of market.

Again, in other industries, when you see those kinds of practices occur, fire alarms go off, and they should certainly go out in these industries because consumers really care tremendously about their ability to access community pharmacies.

CANTWELL: Thank you. Thank you, Mr. Chairman.

Question and Answer Part 2

[VIDEO]

CANTWELL: Well, thank you, Mr. Chairman. I think I just wanted to drill down on this a little bit more given some of your questions and the response and certainly, our witnesses, which who we appreciate them being here.

But Ms. Feldman, I saw on her testimony where she said, trying to get to the bottom of this is like shadowboxing and that's the point. The point is PBMs negotiate on behalf of some consumers, but they pocket a lot of the discount and that's what we're trying to get at. What is we believe in buying in bulk? That yet, you get a discount, but who's getting the discount? And the question is, they're pocketing that and when we want to understand what this is about this issue of spread pricing, there's no transparency.

So the consumer doesn't have the information to make the choice, or the plan that someone's representing. Who wants to say, why should I let somebody go to negotiate a deal for me and say that they're going to give me a 30% discount. And then basically, only give me a third of that discount and then pocket the rest. And then when I go to the pharmacy, I end up having to pay more because the out of pocket expense is different. So this lack of transparency is not giving us choice.

So do I have that right, Mr. Balto or Ms. Feldman on the spread pricing, do I have this correct?

FELDMAN: The spread pricing and all the price and the price terms are held as deep secrets, both the pharmaceutical companies and the PBMs assert that they are trade secrets, and they're deeply hidden. Even from the plans themselves. Auditors aren't given full access to the terms, regulators aren't given full access to the terms. Certainly, consumers in those who might

disrupt the industry don't have access at all to any of these things. Markets, in general, thrive on information and you've got to throttle on information here.

BALTO: I totally agree. Information is essential for consumer sovereignty. And look at the PBMs won't even allow your pharmacist to tell you, don't use that card, just pay cash, you'll pay less. Obviously, they're doing a lot to throttle information so that they can protect their stream of rebates.

CANTWELL: I think we had a similar situation with, was it Ticketmaster? Where people were going and buying all these tickets up in bulk and then charging extra pricing and then saying to people, I'm doing you a favor because I got these tickets. But in reality, they were just had supply and gamed the market and then charged up at increasing pricing.

And so I think the issue here is where is the transparency so that consumers can understand or a plan, who's making a purchase can understand, because there may be other avenues. Not saying that every PBM isn't doing something but at what cost at what, what price should PBMs just because they got to go to negotiate a deal, how much should they be pocketing instead of passing that on to the consumer? So Mr. Chairman, I think that's my question and it's always been my concern, because I do think buying in bulk should get you a discount. I just believe that most of the money should go to the consumer and the fact that we can't get answers or the consumer can't get an answer about this is very frustrating, because then they can't make decisions about these plans, or they certainly can't make judgments as it relates to what kind of savings that their plan is entitled to.

I do really, though, have a concern about this, where this keeps going. And not surprising that more people want to jump in. Well, why not? If you can make this much money in a dark transparent situation, why not jump in? So that doesn't that doesn't mean anything. And the key thing though, is by undermining the system and undermining that line of delivery that I think pharmacists represent as part of our healthcare delivery system, then I think you really do take away the part of the system. And there are people who are definitely would love nothing other than to just have major control over a mail-in pharmacy market and thereby have less even less kind of delivery system for us.

So, Mr. Balto, your time at the FTC, did they deal with spread pricing and other areas?

BALTO: No, these problems have become phenomenally worse and again, because you create an environment that's sort of a petri dish for all of this anti-competitive conduct, lack of competition, lack of transparency and conflicts of interests. They've just gotten phenomenally worse because and then you don't regulate. And it's, you know, this is just it's a real fertile environment for this kind of anti-competitive conduct.

CANTWELL: And what's the conflict of interest?

BALTO: The conflict of interest is that they make more money by securing higher rebates when they're really supposed to, which would result in higher list prices, when they're supposed to be seeking lower list prices. And that's the conflict of interest.

And if you're a payer and again, I do represent some payers, if you're a payer and you want that rebate information, no way, absolutely not. You want to bring your auditor in, have your auditor check. They limit who can audit, they limit the kind of information you audit. This isn't like other

markets, you know, I mean, they just come up with new and novel ways of preventing the market from working effectively.

By the way, when you think about state regulation, and PBM is trying to require state regulation, akin to the transparency provisions that you included in the Medicare Modernization Act, the PBMs fight those tooth and nail, they know darkness is the best environment for them to engage in anti-competitive conduct.

CANTWELL: Well, why can't we do something right now about that, about making sure that there's a transparent market as relates to these rebates?

BALTO: We can, you know, there are transparency provisions that, you know, that Congress can consider enacting so that at the very least the plan sponsors have the information so they can properly audit and make sure that they're getting the benefit of the rebates that are being secured.