What's being done to stop pharmaceutical pirates?

"From 2013 to 2022, about 10% of independent pharmacies in rural America have closed." - Hannah Garden-Monheit

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Welcome to **Code WACK!,** where we shine a light on America's callous healthcare system, how it hurts us and what we can do about it. I'm your host, **Brenda Gazzar.**

(music)

This time on **Code WACK!** How do Pharmacy Benefit Managers, those powerful middlemen between health insurance providers and pharmaceutical companies, have the upper hand with independent pharmacies? What are lawmakers and the Federal Trade Commission doing about their undue influence over inflated drug prices and access? To find out, we interviewed **Hannah Garden-Monheit,** the FTC's director of the Office of Policy Planning. This is the second episode in a two-part series with Hannah.

Welcome back to Code WACK! Hannah.

In the last episode, we talked about the FTC's recent interim report on **Pharmacy Benefit Managers,** those powerful third-parties that deal with negotiations and

payments up and down the drug supply chain. We talked about how they're controlling the industry through vertical consolidation, when a company can control the supply chain from manufacturing to sales, and horizontal consolidation, where a company merges with one or more competitors. So are vertical and horizontal consolidation equally worrisome in this industry?

Garden-Monheit: I think they are both worrisome and the two, you know, sort of interplay with each other. So when we think about the dynamic with independent pharmacies, for example. So when you're talking about PBM services of managing and processing claims, horizontal consolidation means that there are, you know, those three companies control the overwhelming majority of prescription [claims] processing. So if you're an independent pharmacist, because there are only three players, you don't have a lot of bargaining leverage, right? About how much you're gonna be reimbursed. You don't really have anywhere else to go if you wanna have access to customers who have insurance, right? So that is, that starts from a problem of horizontal consolidation. But then when you add vertical integration, the PBMs are not some neutral middleman that you're dealing with. They are themselves interested parties, like not only [do] you have three of them that you can deal with, they're also your competitor potentially in pharmacy, right? Because they also own the pharmacy. And that combination with that vertical relationship means that you're stuck dealing with entities who themselves have an opportunity and incentive to disadvantage and squeeze you.

Q: Wow. So are you noticing an effect on independent pharmacies? Are they closing down or what's happening to them?

Garden-Monheit: So we hear a lot about this from independent pharmacies – what they have been going through. And the data in our report does show that in recent years, from 2013 to 2022, about 10% of independent pharmacies in rural America have closed. And that is really alarming because in rural communities it can be the case that the local pharmacy is really the [only] healthcare option there for a lot of critical things, [like] getting your flu shot, getting your EpiPen and other life saving medications. And at the time when our study came out, we don't have all of the data yet from the PBMs to do calculations on reimbursement rates and things like that. But we can see, we do have a lot of their internal documents. And

what we can see from those internal documents is a lot of these bargaining dynamics that I've been talking about.

So, for example, we can see that in the contracts between the PBMs and the independent pharmacists, what's happening is not the kind of business to business negotiation that we think about as contract formation in the typical sense of, you know, two business entities negotiating over how much we're gonna get paid. Instead, what we see often in the documents is that the PBMs are unilaterally imposing terms on the independent pharmacies, and in fact, their internal documents themselves refer to these contracts as 'unilateral passive contracts.' Like they themselves say it. And what we see is in these documents is often you get a fax blast where the PBM makes some change to the contract, and it can be a really significant change to the contract. It can be changing how much you're gonna get paid for dispensing a drug.

It can be whether a drug is covered at all. And usually you get it via fax and it's opt out, it takes effect, right? Non-response means that this term change, we also see when we review these contracts that they're incredibly opaque, right? So even if you get the fax blast, you have the time to review all of the terms and you think like, 'oh, I'm gonna respond and somehow opt out even though I have no other option.'

You can't even tell from reading these contracts what you're actually gonna get paid because the reimbursement methodology that's set out in the contract, it's a formula that's based on a set of shifting variables that you don't have access to. It can be based on proprietary list prices that are set by the PBM and in the contract or subject to change at will by the PBM. So that makes it incredibly difficult to operate your business, right? If you have no predictability in what you're going to be compensated for your services. And a lot of challenges understanding it and not a lot of elsewhere to go. It's putting independent pharmacies in this country in a very difficult spot we're hearing. We're hearing about that quite a lot. Hmm.

Q: So what is being done and what can be done about these negative effects?

Garden-Monheit: So at the Federal Trade Commission, we are absolutely committed to using all the tools that we have. This report comes out of our what's

called our 6B study authority, where we can use a compulsory process to get information from companies and then report about what's going on in the industry. And that's, that's the authority that was used for this report. We're continuing to receive and review materials and are committed to continuing to report publicly on a timely basis as soon as we have insights to share.

We're also a law enforcement agency and so, you know, there are lots of concerning practices that are raised in this report, and we're continuing to develop the facts and follow along that. And if things develop to a point where we think there are actionable violations of the antitrust laws. The chair of the commission is very committed to bring our enforcement tools to bear anytime we see law breaking. You know, we're encouraged to see bipartisan interest in Congress in addressing these issues. We're pleased to see that folks are working across the aisle on this. We also work and talk closely with our partners at other agencies like the Department of Health and Human Services about what insights and tools they have for addressing these problems.

Q: Hmm, great. Do you know if there's been any hearings in Congress on this issue?

Garden-Monheit: Yes. there have been quite a few including very recently the [House] Oversight Committee under Chair [James] Comer, held a hearing with the CEOs of the big PBMs. So a great example of how this issue is neither blue nor red. Both parties are really seeing, I think, the urgency of dealing with these problems.

Q: Great. Has there been any legislation introduced that you're aware of?

Garden-Monheit: Yes, there are quite a few bills, a number of them that have gotten out of committees in, in the Senate you know, hope, hope to see additional progress made on those in, in the near future. I'll note, you know, a number of them focus on transparency efforts, which is, you know, that's salutary and an important step. But given some of the practices that we're seeing from the structural dynamics in this industry, I think there's also a reason to think that more regulation beyond just transparency is likely to be needed to resolve these issues.

Q: Wow. So is the legislation that's been introduced so far, was it related to the work that the FTC is doing or separate?

Garden-Monheit: I think, you know, there's been a good positive ongoing dialogue between our colleagues on the Hill and the agency. We always stand ready to provide technical assistance whenever we can to policy makers and so there are good open channels of dialogue there.

Q: So is the FTC doing anything else to help curb drug or other healthcare prices?

Garden-Monheit: Yeah, we absolutely are. So we're an independent agency, but we're very proud to be part of an all of government effort to curb drug prices. I will leave it to my colleagues at the Department of Health and Human Services to talk about things like their efforts under the Inflation Reduction Act to cap insulin costs for seniors, for example, and negotiate with Big Pharma. Here at the FTC one of our flagship initiatives has been working with the FDA to tackle abusive practices by pharmaceutical companies that can raise the cost of medications like inhalers and EpiPens.

There's a wonky thing called the Orange Book where listing a patent in that document that doesn't belong there essentially triggers this ability to block competition from lower cost generics and so we've been doing a lot of work with FDA on that and have had some significant wins in getting some companies to cap inhaler out-of-pocket costs at $35 a month.

We've supported and worked with the patent office on efforts that they have to address patent thickets on prescription drugs that raise prices. We've worked to support the Department of Commerce's efforts to revitalize what are called marching rights, which is the right of the government when it's the taxpayers who fund an invention to make sure that it's available to the public at reasonable prices. There's this whole host of burgeoning, all of government efforts on this front and all of that ramp across government work is on top of what has always been bread-and-butter work for the Federal Trade Commission to lower prescription drugs. And that includes our enforcement work, so things like enforcement action to ban Martin Shkreli from the pharmaceutical industry for

life, for the price gouging he did. And jacking up brace of life saving drug Daraprim from, I believe it was $17 to something like $750 a pill.

We've had enforcement actions in the opioid treatment space where we return tens of millions of dollars to consumers. And then part of our bread and butter work is also reviewing mergers and acquisitions to see if they're anti-competitive transactions that would raise braces or otherwise harm competition in the market. And we've had a number of victories there as well in blocking transactions in the pharmaceutical space that we viewed as very likely to raise prices for consumers. Right. So it's a lot.

Q: ***Yeah, that's great. Thank you so much. So the general inquiry into the PBMs, where is this headed, this general inquiry? And what's the timeline?***

Garden-Monheit: Yeah, so that report was based on a compulsory process that we issued to the companies starting in 2022. The report is pretty transparent in saying that not all of them were very timely and fulsome in their responses. So we did the interim report because we were committed to getting information out as quickly as possible, even in the face of potentially delaying tactics by the companies. We are continuing to press them for materials. We are in the wake of the report seeing more information come in the door, which is great. We are working very swiftly to analyze it and assess next steps. We are a small but mighty agency and so the team is pedal to the metal on obtaining and reviewing additional information and figuring out next steps on what information we have to share with the public. And as I said, also, you know, following the facts in the law to see if law breaking has occurred.

Q: What could enforcement look like, for example?

Garden-Monheit: Yeah, so I don't want to get ahead of where that factual development will lead. It is very much work that is, you know, underway and so it's not for me to say where that will go. You know, as a general matter, we're an antitrust enforcement agency. We enforce the FTC Act, including its prohibition on unfair methods of competition and the antitrust laws.

Okay, great. Hannah, was there anything else you wanted to mention?

Garden-Monheit: Just thank you for your time and your attention to these issues. It's a pleasure to be able to join you today.

Thank you so much for being here. We really appreciate it. And thank you for speaking to this very important issue. It is kind of shocking that we're here at this point, but it's reassuring knowing that something's being done about it now. So thank you for the work that you're doing.

Garden-Monheit: Of course. Thank you. Thank you for saying that.

Thank you, Hannah Garden-Monheit of the Federal Trade Commission.

Do you have a personal story you'd like to share about our wack healthcare system? Contact us through our website at heal-ca.org.

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Code WACK!'s powered by HEAL California, uplifting the voices of those fighting for healthcare reform around the country. I'm Brenda Gazzar.