What's being done to stop pharmaceutical pirates?

featuring Hannah Garden-Monheit
Director, Office of Policy Planning
Federal Trade Commission



This time on Code WACK!

What are lawmakers and the Federal Trade Commission doing about Pharmacy Benefit Managers and their undue influence over drug prices and access? Who is watching out for consumers when the pharmaceutical industry pursues self-serving arrangements? And what's the impact on independent pharmacies and their patients?

To find out, we recently interviewed <u>Hannah Garden-Monheit</u>, the FTC's director of the Office of Policy Planning. Prior to joining the FTC, Garden-Monheit worked at the National Economic Council (NEC), where she served as Special Assistant to the President for Economic Policy and Director for Competition Council Policy. At the NEC, she was extensively involved in shaping the President's Executive Order on Promoting Competition in the American Economy, and much more. This is the second episode in a two part series.

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WE DISCUSS

Last time we talked about how pharmacy benefit managers exert control through consolidation. Horizontal consolidation involves the supply chain and vertical consolidation reduces competition. Which would you say is more worrisome?

"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.

"...horizontal consolidation means that there are, you know, those three companies [that] control the overwhelming majority of prescription claims processing. So ... you don't have a lot of bargaining leverage, right? About how much you're going to be reimbursed. You don't really have anywhere else to go if you want to 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...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." – *Hannah Garden-Monheit*

What is being done - and what can be done - about these negative effects?

"So at the Federal Trade Commission, we are absolutely committed to using all the tools that we have [such as using] compulsory processes to get information from companies and then report[ing] about what's going on in the industry. And 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.

"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. And 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." – *Hannah Garden-Monheit*

Talk to us about what the FTC is doing to help curb drug and other healthcare prices -

"... we're very proud to be part of an all-government effort to curb drug prices. 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 ... 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 [made] to address <u>patent thickets</u> on prescription drugs that raise prices. We've worked to support the Department of Commerce's efforts to revitalize what are called <u>march-in rights</u>, 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.

"[And] things like enforcement actions to ban Martin Shkreli from the pharmaceutical industry for life, for the price gouging he did. And for jacking up the price of the 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 prices 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." - Hannah Garden-Monheit

Helpful Links

<u>Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug</u>

<u>Costs and Squeezing Main Street Pharmacies</u>, Federal Trade Commission,

Office of Policy Planning

<u>Private Equity's Healthcare Problem: The Coming Investigations into Vertical and Horizontal Integration</u>, *Capstone*, *DC*

Patent Listing in FDA's Orange Book, Congressional Research Service

The FTC Is Attacking Drugmakers' 'Patent Thickets', KFF Health News

FTC Submits Comment on March-In Rights to Promote Efforts to Lower Drug Prices, Federal Trade Commission press release Pharma vs. the FTC, Politico

Martin Shkreli ban from pharmaceutical industry upheld by US court,
The Guardian

<u>Statement on Second Circuit Order Upholding "Pharma Bro" Martin</u> <u>Shkreli's Lifetime Ban</u>, Federal Trade Commission press release

Episode Transcript

Read the <u>episode transcript</u>.

Guest Biography -Hannah Gardner-Monheit

Hannah Garden-Monheit is the Director of the Office of Policy Planning at the Federal Trade Commission. Prior to joining the FTC, Garden-Monheit worked at the National Economic Council (NEC), where she served as Special Assistant to the President for Economic Policy and Director for Competition Council Policy. At the NEC, she was extensively involved in shaping the President's Executive Order on Promoting Competition in the American Economy and its implementation, as well as the bipartisan Ocean Shipping Reform Act, the high-speed internet title of the Bipartisan Infrastructure Law, the nursing home reform agenda, and other matters.

Prior to joining the Administration, Garden-Monheit served as a Senior Advisor to the **CARES Act Congressional Oversight Commission**. She previously worked as a Supreme Court and appellate attorney in private practice, as a trial attorney at the Department of Justice Civil Rights Division, and as an analyst for the Iowa State Senate. She has served as a law clerk to the Honorable Judge Stephen Reinhardt, Ninth Circuit Court of Appeals, and the Honorable Judge Randolph Moss, District Court for the District of Columbia.

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