## **PBMs and the FTC: A Timeline**

For almost two decades, and across presidential administrations, the Federal Trade Commission (FTC) studied pharmacy benefit managers (PBMs), and the health care industry writ large, in an objective manner. In numerous studies and comment letters, the FTC and its staff, along with other officials, found that PBMs could promote competition and reduce costs for consumers:

- 2004: After 27 days of hearings, the FTC and Department of Justice's Antitrust Division (DOJ) issue a Joint Report on Competition and Health Care, which concluded that PBMs operate in a competitive marketplace ("States should consider the potential costs and benefits of regulating pharmacy benefit manager transparency. In general, vigorous competition, rather than regulation, in the marketplace for PBMs is more likely to arrive at an optimal level of transparency. Just as competitive forces encourage PBMs to offer their best price and service combinations to health-plan sponsors to gain access to subscribers, competition should also encourage disclosure of the information that health-plan sponsors require to decide which PBM to contract").
- <u>2005</u>: An FTC Study "Shows PBM Ownership Does Not Result in Higher Costs for Consumers" ("The report concludes that . . . sponsors generally paid lower prices for drugs purchased through PBM-owned mail-order pharmacies than for drugs purchased through mail-order or retail pharmacies not owned by PBMs").
- <u>2012</u>: FTC Closes Post-Closing Investigation of CVS/Caremark Merger ("After a thorough and comprehensive review of the other consumer protection and competition issues in this matter, the Commission has determined not to take any additional action at this time").
- <u>2012</u>: FTC Closes Eight-Month Investigation of Express Scripts/Medco PBM Merger ("Our staff's investigation revealed that [PBM] competition for accounts is intense, has driven down prices, and has resulted in declining PBM profit margins").
- <u>2014</u>: FTC Staff Letter Opposes Proposed Rule Preventing PBMs from Building Preferred Pharmacy Networks for Medicare Part D Plans ("Prescription drug prices are likely to rise if Prescription Drug Plans are less able to assemble selective pharmacy networks" and would result in "fewer choices" for Medicare beneficiaries).
- <u>2018</u>: DOJ Clears CVS/Aetna Merger After Investigating Vertical Concerns ("After a careful analysis, the Division determined that the merger is unlikely to cause CVS to [harm its] rivals due to competition from other PBMs and retail pharmacies . . . Some commenters raised concerns about the effectiveness of firewalls at Caremark, despite CVS's commercial incentive to maintain those firewalls . . . The United States investigated this possibility and determined that CVS is commercially incentivized to maintain firewalls because that customers could switch to an alternative PBM if their information were not kept confidential").

- <u>2019</u>: A Federal Court Approves CVS/Aetna Consent, Observing Vigorous PBM Competition ("[T]he evidence showed that CVS must compete vigorously to retain its PBM customers . . . CVS' s and the Government's witnesses, when combined with the existing record, persuasively support why the markets at issue are not only very competitive today, but are likely to remain so post-merger").
- <u>2019</u>: A Government Accountability Office report found that "PBMs passed nearly all rebates received from manufacturers through to Part D plan sponsors," about 99.6% of rebates.

The FTC's current leadership initiated an abrupt change in the agency's approach to PBMs, and health care markets generally – one that reflects deep hostility to PBMs as a business model, without the benefit of an updated study and prejudicing any investigations underway inside the agency.

- February 10, 2022: Chair Khan announces that the Commission would vote on a proposed study into PBMs.
- <u>February 16, 2022</u>: The FTC's Bureau of Economics director abruptly quits, a day before the FTC was set to vote on a study into PBMs, apparently out of concern over the biased nature of the proposed study.
- February 17, 2022: FTC tries and fails to vote in favor of 6(b) Orders to "Study Pharmacy Benefit Managers' (PBMs) Relationship with Affiliated and Independent Pharmacies." The vote was 2-2 with Khan and Slaughter voting yes and Phillips and Wilson voting no.
- February 18, 2022: FTC's Chair <u>tweeted that she was "greatly disappointed"</u> by the FTC's failure to authorize the study, saying "an inquiry into PBMs is urgent and overdue."
- <u>February 24, 2022</u>: Via a Request for Information, the FTC Requests Public Comments on the Impact of PBMs. In subsequent <u>comments</u>, the Chamber points out that "[a]lmost every single question appears to presuppose negative intent and actions."
- May 5, 2022: Chair Khan sends letter to Senator Maria Cantwell:
  - "I believe that PBMs play a critical and under-examined role in determining the price and availability of prescription drugs to patients at the pharmacy counter and clinic, and I am concerned that certain incentives and the surrounding lack of transparency means that PBMs' interests may not always align with patients and others who pay for prescription drugs."

- "I am also concerned that PBMs' vertical integration and dominant market position may allow them to under-reimburse independent pharmacies and steer business to PBM-owned mail-order and specialty pharmacies, which may threaten the long-term viability of independent pharmacies in both urban and rural communities."
- June 7, 2022: In a unanimous vote, the FTC's commissioners vote to approve a revised study into PBMs (deemed a "6(b) study" based on the agency's statutory authority to investigate markets).
  - Chair Khan described PBMs as "powerful intermediaries at the center of the U.S. prescription drug system [that can] practically determine which medicines are prescribed, which pharmacies patients can use, and the amount patients will pay at the pharmacy counter."
  - Commissioner Bedoya's statement included: "For most Americans, pharmacy middlemen control what medicine you get, how you get it, when you get it, and how much you pay for it. Yet PBM practices are cloaked in secrecy, opacity, and almost impenetrable complexity."
  - Commissioner Slaughter statement stated: "Something is rotten in the state of the U.S. pharmaceutical market, and it warrants serious investigation."
  - In their concurring statement, Phillips and Wilson stated their support for the new version of the study but said: "In February, the Chair moved a vote on a 6(b) study that was neither comprehensive nor rigorous, and that failed even to examine the topic the agency announced on its website at that time the competitive impact of PBM contracting practices. It omitted a number of matters raised by proponents of issuing the study, including the impact upon consumers. The study was hastily prepared. Unbeknownst to us at the time, it was modified minutes before it was circulated for a vote."
- June 14, 2022: Commissioner Slaughter as the joint FTC/DOJ Pharmaceutical Task Force Workshop stated, "anticompetitive conduct in the pharmaceutical industry is so widespread that we have an entire division of our agency, Health Care, dedicated to investigating and halting it."
- June 16, 2022: The FTC issues a policy statement committing to ramp up enforcement "Against Any Illegal Rebate Schemes, Bribes to Prescription Drug Middleman That Block Cheaper Drugs."
  - Chair Khan's <u>statement</u> said that "[s]ome have suggested that these rebates and fees, in turn, encourage drug manufacturers to further increase their pre-rebate list

prices in a cycle of ever-increasing list prices and ever increasing middlemen rebates. Others have noted that PBMs and other middlemen may exclude the lowest-cost generic and biosimilar drugs from patients' formularies entirely to maximize rebates and fees. Such practices violate the fundamental bargain at the center of the American prescription drug system, which is that brand drugs are given a period of patent exclusivity that is then followed by free and fair competition from generic or biosimilar alternatives at dramatically lower prices."

- Commissioner Bedoya's <u>statement</u> noted: "For those of you who are not lawyers, what the Commission is saying today boils down to this: We will use every tool we have to investigate what's going on with drug manufacturers, pharmacy middlemen, and insulin prices. I want to highlight one of those legal tools the commercial bribery provisions of the Robinson-Patman Act. . . . If buyers (say, an insurer and their insured customers) use an agent (say, a PBM) to negotiate on their behalf, and that agent takes payment from the seller (say, a drug manufacturer), this may create a conflict of interest. It may also be commercial bribery violating Robinson-Patman."
- Commissioner Rebecca Slaughter noted: "This Statement affirms the Commission's commitment to use its full authority under the FTC Act to help tackle the illegal practices that result in high drug prices or reduced innovation."
- June 22, 2022: In a sharply critical speech, Chair Khan suggests that the FTC and other policymakers should consider restructuring PBMs, "There is nothing inevitable about the current structure of the market or the current business practices that occur and are permitted—these are all the result of policy and legal choices, that were made by public officials, and that can also be remade by public officials through the democratic process."
- <u>September 22, 2022</u>: Commissioner Alvaro Bedoya remarks on "Returning to Fairness" to the Midwest Forum on Fair Market, "And so today, when most people fill a prescription, just one of three entities mediates what medicine they get, what they pay for it, and how they will get it and that corporate entity makes money by making sure that prescription is filled by its own pharmacy.
- <u>October 3, 2022</u>: Chair Khan headlines NCPA convention where she acknowledges NCPA for its "help" to shape the FTC's PBM work.
- <u>April 27, 2023</u>: Bedoya speaking at NCPA Event (Cap Forum)
- <u>May 4, 2023</u>: Lina Khan Interview, 2023 American Economic Liberties Project Anti-Monopoly Summit, "In healthcare we see these Pharmacy Benefit Managers that are sitting right in the middle and controlling the types of practices that independent pharmacies are facing, and the medicines consumers are or have not been able to access."

- May 17, 2023: On a 3-0 vote, the FTC expands its 6(b) study to include other market participants.
- June 7, 2023: In a Capitol Forum interview, Commissioner Bedoya gave remarks suggesting that he opposes vertical and horizontal integration in healthcare. He indicated he is focused on reexamining "rebate walls" and "spread pricing, DIR fees, clawbacks, et cetera," especially where they lead to the closure of PBMs' denial of insulin coverage at independent pharmacies because the "PBM wanted to ensure that was filled by a pharmacy that they owned and that the vertically integrated entity that they were a part of would profit.."
- June 8, 2023: On a 3-0 vote, the FTC expands its 6(b) study to include other market participants.
- June 29, 2023: Bedoya attends event at Eric's Rx Shoppe in Horsham, PA
- July 13, 2023: Chair Lina Khan's opening Statement before the United States House of Representatives Committee on the Judiciary, Hearing on Oversight of the Federal Trade Commission: "Last June, the Commission launched an inquiry into the practices of pharmacy benefits managers to shed light on the opaque operations of these large middlemen who can dictate pricing and access to life-saving drugs for millions of Americans."
- July 20, 2023: FTC votes 3-0 to issue a <u>statement</u> withdrawing its prior PBM advocacy
  - Chair Khan issued a <u>statement</u> saying: "In the past, the FTC was concerned that mandated disclosure requirements between PBMs and payors (such as larger employers) and healthcare plans—as proposed in state legislative initiatives—could encourage price coordination and collusion. However, given the trends toward extensive consolidation by PBMs and extensive vertical integration by these PBMs into the entire drug supply and payment chain, employers and other payers in this marketplace appear to have been placed at a severe information disadvantage. In such a situation, it may be appropriate for policymakers to require that PBMs provide accurate and timely information for buyers."
  - Commissioner Slaughter issued a <u>statement</u> saying: "[T]he competitively troubling changes in the PBM market have increased significantly. To name a few, vertical integration and horizontal concentration among payers, PBMs, pharmacies and providers have accelerated while the number of independent pharmacies and visibility into PBM contracting practices have decreased; and list prices and patients' out-of-pocket costs for prescription drugs have increased as PBM rebates and fees have mushroomed. In light of these troubling market developments, the Commission authorized in June 2022, a study under Section 6(b) of the FTC Act of certain PBM market structures and practices. This ongoing

study is an important step towards helping the Commission identify and understand what roles PBMs play in contributing to the opaque and complex web of challenges that adversely affect price, quality, consumer choice, and competition in the U.S. pharmaceutical market."

- October 26, 2023: Bedoya featured at NCPA event on vertical integration
- October 26, 2023: Commissioner Bedoya interview with the Capitol Forum
  - "there's nothing wrong with verticality per se," it is problematic in the healthcare market because "three vertically integrated entities [including Optum] handle 70 to 80 percent of the scripts," with greater concentration in specific markets. The healthcare sector is not "marked by relentless competition on price," so consumers are harmed.
  - Verticality also features the "aggressive use of rebates." PBMs are a "gatekeeper to [the] insured" and "use that to get more rebates for the insurers." This "seem[s] to drive up the list price" and undermine access.
  - Commissioner Bedoya accused "vertically integrated entities [of] systematically steering business to prescriptions to their pharmacies rather than [to] independent pharmacies," which is especially harmful in rural America.
- <u>February 13, 2024</u>: In a letter to Senator Grassley, Chair Khan described the Commission's investigation of PBMs. She accused PBMs of "having substantial influence over independent pharmacies."
- February 14, 2024: Chair Khan addressed the American Medical Association
  - "Healthcare markets are a key site of this work, and the FTC is squarely focused on tackling illegal business practices that deprive Americans of access to affordable and innovative healthcare. First, we are scrutinizing opaque middlemen across the healthcare supply chain . . . We've heard concerns from patients and medical professionals that the rebates that PBMs demand may function as kickbacks that raise costs and limit access to affordable medicines. We've also heard concerns about how PBMs may unfairly discriminate against independent pharmacies, making it difficult for these pharmacies to stay afloat and depriving communities of access to the high-quality local service they provide."
- <u>March 4, 2024</u>: At the White House, Chair Khan again sharply criticizes PBMs, albeit without the benefit of a complete 6(b) study: "PBMs say that they help bring down drug costs. But the stories we hear from patients and healthcare workers instead describe PBMs as dominant gatekeepers who have outsized power to decide how people do or

don't receive the life-saving prescription drugs they depend on. Too often, Americans are price gouged for these medications."

- March 4, 2024: Chair Khan interview with Institute for Local Self-Reliance
  - "And so connecting the dots between problems in the world and our policy choices, be it high grocery store prices or independent pharmacies being run out of the market, and the policy questions and decisions that underlay those outcomes I think has been key. At the FTC we've really been focused on: what are the biggest pain points for the public? And so we have been focused on, for example, dominant middlemen that may be distorting the market.
  - "We're looking at, you know, the plight of independent pharmacies and how PBMs might be affecting them. So we have an enormously busy portfolio under way and a key through line is making sure that our economy and our markets are serving everybody, that means consumers but it also means independent business."

In response to a question from NCPA President about PBMs and merger policy, Chair Khan says,

- "I actually just came from an event at the White House about corporate middlemen in the healthcare system—particularly PBMs—so there is currently a whole of government effort here to make sure that our healthcare markets are really served by the public. Thinking about the PBMs and potentially addressing their practices is going to be a key part of that."
- <u>April 15, 2024</u>: Chair Khan Interview with Senator Bernie Sanders she states: "Pharmacy benefit managers are again these obscure players, but basically they're these middlemen so they determine who gets access to what medicines and at what price.....In the coming weeks and months we'll be able to share what we've been doing on that."
- <u>April 3, 2024</u>: Chair Khan visits with a roundtable of independent pharmacists.
- <u>May 14, 2024</u>: Rahul Rao, deputy director of the Bureau of Competition, said in an interview that "there clearly is something that is not working in our pharmaceutical marketplace."
- <u>May 15, 2024</u>: Chair Khan's testifies before House Appropriations Committee hearing that she hears from pharmacies and independent pharmacists about how it is difficult for them to stay afloat "squeezed by practices of PBMs."
- <u>May 21, 2024</u>: Chair Khan statement at the American Economic Liberties Project's Anti-Monopoly Summit, Chair Khan said: "I went to Philadelphia and heard from community

pharmacists about how prescription drug middlemen use coercive contracts and punishing fees to hurt their businesses and their patients."

• July 9, 2024: The FTC issues an interim staff report, a highly unusual maneuver, as the agency normally completes deep dive studies before launching investigations that result in complaints. At this stage, the report is woefully short of expert analysis guided by rigorous economic analysis.