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FTC Sues Pharmacy Benefit Managers over "Artificially Inflated" Insulin Prices

- On September 20, 2024, the Federal Trade Commission (FTC) announced it had filed an administrative complaint against three pharmacy benefit managers (PBMs)—Caremark, Express Scripts and OptumRx—alleging that they artificially inflated the price of insulin drugs through "anticompetitive and unfair" rebate practices in violation of Section 5 of the FTC Act.

- According to a July 9 interim staff report chronicling the FTC's two-year investigation into the industry, the three PBMs named in the complaint handle nearly 80% of prescription drug claims in the United States, covering over 270 million people. Express Scripts sued the FTC in Missouri federal court last week to compel the agency to withdraw the report, which it claims is "false and defamatory."

- The FTC's complaint comes amidst greater legislative and regulatory interest in lowering the cost of prescription drugs—also a central goal of the Biden administration. The suit also reflects the agency's expansive interpretation of its authority under Section 5 of the FTC Act.

Background

PBMs manage prescription drug insurance benefit plans on behalf of health insurers, employers, and other healthcare payers. PBMs negotiate with manufacturers on key terms and conditions of prescription drug access—including which drugs are available under a person's insurance plan and how much pharmacies must pay to acquire drugs.

PBMs maintain that they are reducing—not inflating—prescription drug costs for consumers. But in recent years, several PBMs have vertically integrated with major health plans—Caremark with Aetna, OptumRx with UnitedHealth Group, and Express Scripts with Cigna—leading to increased interest among policymakers in regulating the industry.

The FTC's Study and Interim Staff Report

On June 7, 2022, the FTC unanimously voted to authorize a study into PBMs and their practices pursuant to Section 6(b) of the FTC Act. The agency ordered six PBMs (Caremark, Express Scripts, OptumRx, Humana Pharmacy Solutions, Prime Therapeutics and MedImpact Healthcare Systems) and their group purchasing organizations (GPOs) to hand over business records in an effort to determine whether their conduct negatively impacts affordability and access to prescription drugs.

While the Section 6(b) study remains ongoing, in July 2024 the FTC voted 4-1 to publish an interim staff report summarizing its findings to date. The report reaches three main conclusions: (1) that increased concentration and vertical integration have led to PBMs gaining significant power over prescription drug access and prices; (2) that increased concentration and vertical integration may have enabled PBMs to lessen competition, disadvantage rivals and inflate drug costs; and (3) that rebate contracts between PBMs and brand drug manufacturers may impair or block less expensive competing products. The report noted that some PBM business practices "warrant further scrutiny and potential regulation."

Interim reports are rare; most Section 6(b) studies culminate in a single final report once the FTC has received all the requested information. The PBM report was particularly unusual in that it relied, in large part, on public information that was not collected

from the PBMs or their affiliates during the 6(b) process. But the three Democratic commissioners in the majority reasoned that issuing the report at that time would "inform the constellation of state and federal policymakers who are also scrutinizing the PBMs." Dissenting from the report's release, Commissioner Melissa Holyoak opined that it failed to meet the FTC's historically "rigorous standard" for 6(b) reports due to, among other things, "process irregularities and concerns over the substance—or lack thereof—of the original order."

The subject PBMs also criticized the staff report, stating that increased regulation of PBMs would reward drugmakers and hurt consumers. On September 17, 2024, Express Scripts took further action, filing a lawsuit against the FTC and its Chair, Lina Khan, for common-law defamation, violation of the Administrative Procedure Act, and related constitutional violations in the U.S. District Court for the Eastern District of Missouri. The complaint—which does not include Caremark or OptumRx—alleges that the FTC defamed Express Scripts and violated its due process rights. It asks the court to order the report retracted and require that Khan be recused from any administrative proceedings involving the company. The FTC has not yet filed a response, and it is unclear how this case will proceed alongside the agency's action against Express Scripts. The suit represents a significant effort to counterbalance the narrative from regulators.

The FTC's Recent Enforcement Action Against PBMs

On September 20, the FTC announced that, by a 3-0-2 vote (with Commissioners Holyoak and Andrew Ferguson recused), it had filed an administrative complaint against Caremark, Express Scripts, OptumRx and their affiliated GPOs, claiming they engaged in "anticompetitive and unfair" rebate practices that artificially inflated the price of insulin drugs. Specifically, the complaint alleges that the three PBMs threatened to exclude certain drugs from their formularies to extract higher rebates from drug manufacturers in exchange for favorable formulary placement. In bringing this case, the FTC joins the states of Arizona, California, Hawaii, Indiana, Kentucky, Mississippi, Ohio, Utah and Vermont, along with a group of municipalities that have challenged the practices of the PBM industry through litigation. This represents a sea change in the outlook of the FTC, which years ago had opposed state efforts to regulate PBMs.

At least three aspects of the FTC's enforcement action are particularly significant:

- **"Standalone" Section 5 Returns**: This may be the first case under Chair Khan in which the FTC will fully litigate a "standalone" claim under Section 5 of the FTC Act. In a November 2022 Policy Statement, the FTC took the position that Section 5 reaches beyond the Sherman and Clayton Acts "to encompass various types of unfair conduct that tend to negatively affect competitive conditions." The Policy Statement offered minimal practical guidance on how the agency would approach enforcement of Section 5 under this theory, creating uncertainty and potential compliance challenges for businesses. In early 2023, the FTC brought a series of Section 5 claims under this theory to challenge the use of noncompete agreements, but those cases were ultimately resolved by consent degree. This case, if argued on the merits, will likely test the bounds of the FTC's "standalone Section 5" authority and could foreshadow expansive theories of harm that the agency may pursue in other future cases.

- **Emphasis on Insulin**: The complaint focuses specifically on the cost of insulin, which the FTC asserts has increased 1,200% between 1999 and 2017 as a result of the PBMs' "chase-the-rebate" strategy. However, nothing in the interim staff report limited its findings to the insulin market, and early reporting suggests that agency officials hope this lawsuit will eventually lead to changes in drug pricing practices across the pharmaceutical market. The FTC may have strategic reasons for framing its first enforcement action against PBMs around insulin—a drug whose high prices are well known to many Americans and are a key policy target of the Biden administration. If a court eventually finds that the practices alleged here are anticompetitive as to insulin, that could materially impact the PBM business model as to other drugs as well.

- **Drug Manufacturers Spared—for Now**: Although the 6(b) study also criticized the role that drug manufacturers allegedly play in negotiating prescription rebates, the FTC ultimately elected to name only the PBMs and GPOs as defendants in this action. However, all signs indicate that the agency is still weighing its enforcement options as to other entities in the pharmaceutical supply chain. In a separate statement about the lawsuit, Rahul Rao, deputy director of the FTC's Bureau of

Competition, warned that "all drug manufacturers should be on notice that," although not targeted in this case, their alleged participation in the conduct challenged here "can raise serious concerns, with a potential for significant consumer harm," and that the agency "reserves the right to recommend naming drug manufacturers as defendants in any future enforcement actions over similar conduct."

The case will now proceed before an administrative law judge. We continue to monitor developments in this and related areas.

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This memorandum is not intended to provide legal advice, and no legal or business decision should be based on its content. Questions concerning issues addressed in this memorandum should be directed to:

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