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## FTC to Increase Enforcement Efforts Against Drug Industry Rebates and Fees

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The Federal Trade Commission is escalating its enforcement efforts on the drug industry's rebate and fee arrangements, focusing on practices that block payees' and patients' access to lower-cost competing drugs.<sup>1</sup> The Commission has also launched an extensive study on drug pricing practices. On June 6, 2022, the Commission voted 5-0 to investigate the impact of business practices of the six largest pharmacy benefit managers (PBMs) on the access and affordability of prescription drugs.<sup>2</sup>

In February, the FTC failed to obtain enough votes to conduct a study on the impact of PBMs on drug prices and pharmacies.<sup>3</sup> The Commission asked the public for comments on drug pricing practices, however, and has received more than 24,000 comments, prompting it to revisit the matter. The newly authorized investigation will focus on:<sup>4</sup>

- fees and clawbacks charged to unaffiliated pharmacies;
- methods to steer patients towards pharmacy benefit manager-owned pharmacies;
- potentially unfair audits of independent pharmacies;
- complicated and opaque methods to determine pharmacy reimbursement;
- the prevalence of prior authorizations and other administrative restrictions;
- the use of specialty drug lists and surrounding specialty drug policies;
- the impact of rebates and fees from drug manufacturers on formulary design and the costs of prescription drugs to payers and patients.

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<sup>1</sup>"Federal Trade Commission." June 16, 2022. *FTC to Ramp Up Enforcement Against Any Illegal Rebate Schemes, Bribes to Prescription Drug Middleman That Block Cheaper Drugs*. <<https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-ramp-up-enforcement-against-illegal-rebate-schemes>> (accessed June 22, 2022).

<sup>2</sup>"Federal Trade Commission." June 7, 2022. *FTC Launches Inquiry Into Prescription Drug Middlemen Industry*. <<https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry>> (accessed June 23, 2022).

<sup>3</sup> See "Federal Trade Commission." February 17, 2022. *Remarks of Chair Lina M. Khan Regarding the 6(b) Study on Pharmacy Benefit Managers Commission File No. P221200*. <[https://www.ftc.gov/system/files/documents/public\\_statements/1601071/p221200khanstatementrpbms.pdf](https://www.ftc.gov/system/files/documents/public_statements/1601071/p221200khanstatementrpbms.pdf)> (accessed June 22, 2022).

<sup>4</sup>"Federal Trade Commission." June 7, 2022. *FTC Launches Inquiry Into Prescription Drug Middlemen Industry*. <<https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry>> (accessed June 23, 2022).

PBMs manage prescription drug benefits on behalf of private health care providers, Medicare Part D plans, employers who provide health care plans for their employees, and others. They negotiate with pharmaceutical companies to secure substantial drug price discounts for those they represent. They also negotiate which drugs the plans will cover and facilitate reimbursement to pharmacies for the prescription drugs they dispense.

Antitrust experts have expressed concern over the recent consolidation in the industry. The FTC says the largest PBMs are vertically integrated with the largest health insurance companies as well as wholly owned mail order and specialty pharmacies.<sup>5</sup>

Independent and small community pharmacies say PBM-owned or affiliated pharmacies pull patients to their own pharmacies, making it harder for small and independent pharmacies to survive. Smaller pharmacies also claim that they lose money on certain drug sales because of the reimbursement practices of PBMs. Others say PBMs conduct their business in secret and opaque ways so as to prevent information comparisons. Many claim PBMs actually contribute to higher drug pricing, overall.

PBMs, however, say they have secured significant drug price reductions for large groups of patients. They say they are ensuring the local competition that patients want, which keeps drug costs down. They point to the large groups they represent as a base of negotiating power that allows them to go head-to-head with the drug manufacturers.

PBMs have published statistics showing that most employers find that PBMs have reduced drug costs for their organizations. PBMs also argue that their services help extend and improve patients' quality of life and prevent medical errors.

### **Focusing on Rebates and Fees**

Health insurance often covers some or all of a patient's prescription medicine costs. Health plans use formularies to indicate which medications are covered. Citing a Senate report, the FTC has expressed concern that drug manufacturers are paying fees and rebates to PBMs and other intermediaries in exchange for getting their higher-cost drugs on the formularies and for getting their drugs placed on a preferred formulary tier.<sup>6</sup>

The drug companies' rebates may require a certain volume of sales for particular prescription drugs—often those with higher prices—or may require that their medications remain in a higher,

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<sup>5</sup> *Id.*

<sup>6</sup> "Federal Trade Commission Press Release." June 16, 2022. *FTC to Ramp Up Enforcement Against Any Illegal Rebate Schemes, Bribes to Prescription Drug Middlemen That Block Cheaper Drugs.*

<<https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-ramp-up-enforcement-against-illegal-rebate-schemes>> (accessed June 22, 2022). See also, "Federal Trade Commission." June 16, 2022.

*Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower-Cost Drug Products* at 4.

<[https://www.ftc.gov/system/files/ftc\\_gov/pdf/Policy%20Statement%20of%20the%20Federal%20Trade%20Commission%20on%20Rebates%20and%20Fees%20in%20Exchange%20for%20Excluding%20Lower-Cost%20Drug%20Products.near%20final.pdf](https://www.ftc.gov/system/files/ftc_gov/pdf/Policy%20Statement%20of%20the%20Federal%20Trade%20Commission%20on%20Rebates%20and%20Fees%20in%20Exchange%20for%20Excluding%20Lower-Cost%20Drug%20Products.near%20final.pdf)> (accessed June 24, 2022)(citations omitted).

preferred, position on the formulary or the rebates can be withdrawn.<sup>7</sup> The FTC expressed particular concern that these rebate practices have led to higher insulin pricing, which has increased dramatically over the past two decades, leading to patient rationing, suffering, illness, and death.<sup>8</sup>

The payments are not always passed on to the consumer and the FTC believes they result in cost-shifting and incentives that crowd out competition from lower-cost drugs. The risk, they say, is particularly high where generics and biosimilars are excluded from—or placed in lower priority—on formularies.<sup>9</sup>

The FTC's enforcement policy will focus on rebates and fees paid to middlemen that lead to the exclusion of competition from generics and biosimilar alternatives.<sup>10</sup> The agency will focus on three specific legal violations in its enforcement efforts:<sup>11</sup>

- Exclusionary rebates that prevent competition in the form of lower-cost drugs may constitute unreasonable agreements in restraint of trade under Section 1 of the Sherman Act; unlawful monopolization under Section 2 of the Sherman Act; or exclusive dealing under Section 3 of the Clayton Act.
- Inducing prescription drug middlemen to include higher-priced drugs on formularies and exclude lower-cost alternatives so as to increase costs to payers and patients may violate the prohibition against unfair methods of competition or unfair acts or practices under Section 5 of the FTC Act.
- Paying or accepting rebates or fees in exchange for excluding the lower cost drugs on the formularies may constitute commercial bribery under Section 2(c) of the Robinson-Patman Act, which prohibits compensating an intermediary to act against the interests of the party it represents in the transaction.

The FTC recognizes that drug manufacturers, PBMs and health plans are free to negotiate good-faith rebates and fees for legitimate services for the benefit of payers and patients. But when those agreements venture into the realm of foreclosing competition from lower-cost generics and biosimilar alternatives, the agency intends to investigate and, where appropriate, bring enforcement actions under the aforementioned laws.<sup>12</sup>

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<sup>7</sup> *Id.*

<sup>8</sup> "Federal Trade Commission." June 16, 2022. *Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower-Cost Drug Products* at 3.

<[https://www.ftc.gov/system/files/ftc\\_gov/pdf/Policy%20Statement%20of%20the%20Federal%20Trade%20Commission%20on%20Rebates%20and%20Fees%20in%20Exchange%20for%20Excluding%20Lower-Cost%20Drug%20Products.near%20final.pdf](https://www.ftc.gov/system/files/ftc_gov/pdf/Policy%20Statement%20of%20the%20Federal%20Trade%20Commission%20on%20Rebates%20and%20Fees%20in%20Exchange%20for%20Excluding%20Lower-Cost%20Drug%20Products.near%20final.pdf)> (accessed June 24, 2022).

<sup>9</sup> *Id.* at 1.

<sup>10</sup> "Federal Trade Commission." June 16, 2022. *FTC to Ramp Up Enforcement Against Any Illegal Rebate Schemes, Bribes to Prescription Drug Middleman That Block Cheaper Drugs*. <<https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-ramp-up-enforcement-against-illegal-rebate-schemes>> (accessed June 22, 2022).

<sup>11</sup> *Id.*

<sup>12</sup> "Federal Trade Commission." June 16, 2022. *Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower-Cost Drug Products* at 4-5.

## Vega Economics Offers Extensive Knowledge and Experience in the Drug-Pricing Arena

Vega's team and experts have in-depth knowledge of the economic issues surrounding drug pricing, PBMs, and related areas. As enforcement in this area expands, Vega can offer substantive assistance to our clients whether they need guidance on how to navigate these new waters or require assistance because state or federal authorities have involved them in legal matters.

For more information about our experience or experts, contact us at [experts@vegaeconomics.com](mailto:experts@vegaeconomics.com).

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[https://www.ftc.gov/system/files/ftc\\_gov/pdf/Policy%20Statement%20of%20the%20Federal%20Trade%20Commission%20on%20Rebates%20and%20Fees%20in%20Exchange%20for%20Excluding%20Lower-Cost%20Drug%20Products.near%20final.pdf](https://www.ftc.gov/system/files/ftc_gov/pdf/Policy%20Statement%20of%20the%20Federal%20Trade%20Commission%20on%20Rebates%20and%20Fees%20in%20Exchange%20for%20Excluding%20Lower-Cost%20Drug%20Products.near%20final.pdf) (accessed June 24, 2022).

