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Paper 03

Towards Fair Competition in the Pharmaceutical Industry:

Evaluating Remedies for *In re Insulin Pricing Litigation*

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This paper evaluates remedies for the FTC's recent suit against the "Big Three" Pharmacy Benefit Managers (PBMs). We begin by introducing the relevant markets and describing the role of PBMs in the pharmaceutical and health care value chain. We then briefly introduce the FTC's complaint and the alleged anticompetitive conduct. Assuming a finding of liability, we then discuss potential remedies and assess these from an economic and legal standpoint. We also identify policy solutions that could be imposed by non-court actors. We conclude by recommending the remedies and solutions best positioned to mitigate the competitive harm outlined in the FTC's complaint.

Market Structure and Role of PBMs

The commercial ecosystem that fills the gap between drug manufacturers, health plans, and patients is the most complicated and obscure in the healthcare industry, and possibly in the American economy. The distribution of physical products through the retail supply chain is linear and relatively uncomplicated: drug manufacturers sell their products to wholesalers, wholesalers resell the drugs to pharmacies, then pharmacies dispense the drugs to patients.[1] The flow of payments, on the other hand, is much more complex. This complexity is exacerbated by a web of rebates involving manufacturers, wholesalers, pharmacies (mail-order and retail), other retailers, health plan sponsors, patients, and PBMs.[2]

PBMs act as intermediaries between pharmacies, health plan sponsors, pharmaceutical manufacturers, and drug wholesalers in this flow of payments.[3] It is important to note that PBMs are not intermediaries in the *physical* flow of products from manufacturer to consumer; unlike wholesalers, they do not buy drugs from one party and distribute them to another. Rather, they act as contracting agents (on behalf of insurers and plan sponsors) that seek to manage drug expenditures by managing supply costs and utilization. Supply cost management involves negotiating with drug manufacturers and pharmacies for manufacturer rebates, pharmacy reimbursement rates, and pharmacy dispensing fees.[4] Utilization management involves developing and managing a formulary and pharmacy network.[5]

[1] T. Angerhofer, R. Blair & C. Durrance, *Antitrust Policy in Healthcare Markets* 210 (Cambridge Univ. Press 2022).

[2] *Id*., at 211.

[3] T. Joseph Mattingly II, David A. Hyman & Ge Bai, P*harmacy Benefit Managers: History, Business Practices, Economics, and Policy*, 4 JAMA HEALTH FORUM E233804 (Nov. 3, 2023), https://jamanetwork.com/journals/jama-health-forum/fullarticle/2811344 (last visited June 13, 2024).

[4] LAWTON ROBERT BURNS, THE HEALTHCARE VALUE CHAIN: DEMYSTIFYING THE ROLE OF GPOS AND PBMS, 374-375 (Springer 2022).

[5] *Id.*

In 2025, PBMs managed prescription drug benefits for 289 million Americans,[6] and at least 80 percent of all prescriptions written in the U.S. were processed by a PBM.[7] PBMs are responsible, *inter alia*, for handling claims processing, formulary design, utilization management, constructing pharmacy networks, and contracting with wholesalers and manufacturers.[8] They determine which drugs will be covered, which pharmacies the drugs may be dispensed at, the price that must be paid by the patient and plan sponsor, and (controversially) how much the manufacturer will remunerate the PBM for steering patients to use the manufacturer's drug. PBMs thus play an integral role in structuring the flow of payments through the pharmaceutical supply chain.

Specifically, PBMs design and manage a portion of the insurance plan called the "health plan drug benefit," which determines how and to what extent the plan covers the purchase of prescription medications. The drug benefit is distinct from the medical benefit, which covers medical procedures. PBMs manage drug benefits either for plan sponsors directly, by contracting with the sponsors themselves, or indirectly, by contracting with an insurer who manages sponsors' medical and drug benefits. This management of prescription drug benefits involves several core, related services:

> **Formulary and Plan Design:** Formulary design is the most important service provided by a PBM. A formulary "specifies which drugs the PBM will cover and the associated patient-level costs when the drug is dispensed."[9] Formularies use a tiered system for covered drugs, which they use to steer patients to preferred drugs. Formularies may simply include two tiers that distinguish preferred and non-preferred drugs, or they may have 3+ tiers that allow for more sophisticated incentive structures.[10] PBMs steer patients to preferred drugs (i.e., drugs on lower tiers) by offering incentives such as lower out-of-pocket costs.[11] Tier placement thus influences consumer behavior, and drug manufacturers are incentivized to compete for (1) inclusion in formularies and (2) favorable tier placement within those formularies. An individual drug's tier placement may be influenced by any number of considerations (e.g., safety and efficacy, ease of use, adherence factors,

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[6] PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION, *The Value of PBMs*, https://www.pcmanet.org/value-of-pbms/ (last visited May 12, 2025).

[7] DRUG CHANNELS BLOG, *The Top Pharmacy Benefit Managers of 2023: Market Share and Trends for the Biggest Companies—And What's Ahead* (April 9, 2024) https://www.drugchannels.net/2024/04/the-top-pharmacy-benefit-managers-of.html (last visited May 12, 2025).

[8] *Id*; *See also*, DRUG CHANNELS INSTITUTE, *The 2024 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, https://www.drugchannels.net/2024/03/now-available-2024-economic-report-on.html, (last visited May 12, 2025).

[9] *Id*., at 4.

[10] *Id*., at 3 (Consider, for example, a hypothetical three-tiered formulary. Drugs in Tier 1 would be the most preferred drugs, while drugs in Tier 3 are the least preferred. Thus, a PBM might design the formulary such that patients face the highest out-of-pocket costs for using Tier 3 drugs and the lowest out-of-pocket costs for using Tier 1 drugs. Out-of-pocket costs for Tier 2 drugs, then, would fall somewhere in between).

[11] *Id*.

preferences of plan sponsors, etc.), but among the most significant is cost.[12] Drug manufacturers and wholesalers thus offer rebates and discounts to compete for formulary inclusion and favorable tier placement.

Retail Network Management (or Pharmacy Network Management): Once a PBM has designed a formulary (i.e., decided which drugs will and will not be covered, and for what price), it is then responsible for creating a pharmacy network (i.e., determining which pharmacies these formulary prices will apply at).[13] PBMs and health plans benefit from selective contracting via pharmacy networks because they stimulate price competition among pharmacies.[14] Pharmacies are willing to accept the lower prices from selective contracting in exchange for the sales volume that comes from network inclusion.[15]

Rebate Negotiation: The third core service of a PBM is rebate negotiation, or deciding how much drug manufacturers will pay PBMs for arranging (by way of formulary design, plan design, and retail network management) the purchase of their drugs by beneficiaries, and how much of this payment is passed through to plan sponsors. PBMs generally use one of three contracting strategies to generate profits, each of which is dependent upon their ability to negotiate rebates and discounts with drug manufacturers, wholesalers, and pharmacies.[16] The first strategy, rebate retention contracting, involves an arrangement wherein the plan sponsor pays a drug's list price and the PBM is entitled to a percentage of the rebate it negotiates with the manufacturer.[17] The second strategy, spread pricing contracting, involves an arrangement wherein the plan sponsor pays a fixed amount for each drug, and the PBM keeps the difference between what it receives from the plan sponsor and what it agreed to pay pharmacies for dispensing the drug.[18] This difference is referred to as the "spread."[19] The third strategy involves an arrangement wherein the plan sponsor pays the PBM an administrative fee for access to the special pricing (net of all discounts and rebates) it negotiates.[20]

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[12] *Id*.

[13] *Id*.

[14] Dennis Carlton et al., *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied Against Pharmacy Benefit Managers* (Oct 2024), at 26 – 27, https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921 (last visited May 12, 2025).

[15] *Id*.

[16] T. Joseph Mattingly II, David A. Hyman & Ge Bai, *Pharmacy Benefit Managers: History, Business Practices, Economics, and Policy*, 4 JAMA HEALTH FORUM E233804 (Nov. 3, 2023) at 5, https://jamanetwork.com/journals/jama-health-forum/fullarticle/2811344 (last visited June 13, 2024).

[17] *Id*.

[18] *Id*.

[19] *Id*.

[20] *Id*.

PBMs are motivated by the economic logic of selective contracting: dealing only with certain suppliers while excluding others in order to obtain more advantageous contractual terms.[21] In health care, selective contracting usually refers to arrangements that incentivize beneficiaries to purchase health care services or drugs from a limited number of providers or vendors.[22] In other words, health plans "steer" beneficiaries to purchase their drugs from a particular manufacturer or pharmacy by making it cheaper for them to do so, thereby increasing expected sales volume for that manufacturer or pharmacy. The threat of formulary exclusion or unfavorable tier placement incentivizes a drug manufacturer to offer discounts (in the form of rebates) on drugs, and the threat of network exclusion incentivizes a pharmacy to offer discounts on drugs and lower dispensing fees. Manufacturers and pharmacies are willing to provide these per-unit discounts because higher volume means higher revenue. This simple theory of selective contracting explains how PBMs can represent sponsors by counterbalancing the market power of manufacturers, driving down prices for the entire ecosystem. But a closer look at the details of contracting decisions, the money flow through the ecosystem, and the financial incentives faced by PBMs complicates this picture.

The flow of products through the retail supply chain is straightforward. As mentioned above, drugs move from (1) manufacturers to (2) wholesalers to (3) retail pharmacies, mail-order pharmacies, and other retailers to (4) consumers. The flow of payments through this same ecosystem is much more complex.[23] Manufacturers set a list price for their drugs known as the wholesale-adjusted cost (WAC). No one ever pays the WAC for a drug; instead, it is used as a benchmark to set other prices. When a wholesaler buys a drug from a manufacturer, they pay the average manufacturer price (AMP). AMP is WAC minus a discount given to wholesalers in the form of rebates. Pharmacies that purchase these drugs from wholesalers pay a price benchmarked indirectly to WAC: WAC plus a markup (which is known as the average wholesale price (AWP)) minus discounts and rebates. When a drug is purchased by a beneficiary at a pharmacy, the beneficiary pays whatever portion of the final price listed at the pharmacy is detailed in their plan's cost-sharing agreement.

But the insurer's payment to the pharmacy is not as simple as that of the beneficiary. The purchase of a drug at a pharmacy triggers a process of "adjudication" in which a set of preexisting contractual relationships between the PBM, pharmacy, and insurer (negotiated largely by the PBM) determine how they square up financially after the purchase. PBMs' selective contracts with

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[21] Joanna Shepherd, *Selective Contracting in Prescription Drugs: The Benefits of Pharmacy Networks*, 15 MINN. J.L. SCI. & TECH. 1027 (2014).

[22] Gregory Vistnes, Hospitals, Mergers, and Two-Stage Competition, 67 ANTITRUST L.J. 671 (2000); Shepherd, Joanna, *Selective Contracting in Prescription Drugs: The Benefits of Pharmacy Networks*, MINN. JL SCI. & TECH. 15, 1027 (2014); Dennis Carlton *et al*, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied Against Pharmacy Benefit Managers*, https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921 (last visited June 13, 2024).

[23] LAWTON ROBERT BURNS, THE HEALTHCARE VALUE CHAIN: DEMYSTIFYING THE ROLE OF GPOS AND PBMS, 377 (Springer 2022).

pharmacy networks determine how much insurers owe them, with the price set as AWP minus a percentage discount plus a flat dispensing fee per drug. Both the percentage discount and the dispensing fee for each particular drug are variable and are negotiated in the contract between PBM and pharmacy. Any positive difference between the amount the PBM charges the sponsor for a particular drug minus the amount paid to the PBM by the pharmacy is known as the "spread." Some PBM-insurer contracts provide for pass-through pricing instead of spread pricing, meaning that the sponsor is charged exactly how much the PBM pays the pharmacy, passing through all price concessions to the insurer or plan sponsor. Spread pricing figures prominently in most arguments about PBMs' anticompetitive conduct.

Drug manufacturers also pay retrospective rebates to the PBMs. These rebates, calculated as a percentage of WAC, usually depend on the purchasing behavior of beneficiaries, or framed differently, the PBM's success at steering consumers to purchase the manufacturer's drug. Predetermined PBM-manufacturer contracts dictate the level of discount PBMs receive for certain levels of spending from plan beneficiaries, and PBM-insurer/plan sponsor contracts dictate what percentage of these rebates are passed through. These rebates are offered to PBMs in exchange for preferred placement on the formularies of the PBM's plan sponsors for the manufacturer's drugs. Importantly, the disparity between list cost and net price (basically, the rebate amount) has skyrocketed in recent years.[24] Rebate agreements between manufacturers and PBMs, especially in the absence of complete or near-complete pass-through, are the centerpiece of anti-competitive accusations against the PBMs.

I. The FTC's Complaint

On September 20, 2024, the FTC filed an administrative complaint against the "Big Three" PBMs: Caremark, ESI, and Optum, alleging a wide array of anticompetitive practices.[25] The complaint followed a lengthy staff report on PBMs, which found, amongst other things, that horizontal and vertical concentration had given the largest PBMs power to control prescription drug access and price, and that this market structure had resulted in diminished competition, misaligned incentives, and higher drug prices.[26] The complaint alleged a violation of Section 5 of the FTC Act.

The FTC alleged that the proliferation of rebate agreements between manufacturers and PBMs created incentives for both to raise list prices and rebates in tandem, resulting in larger profits for both entities and skyrocketing out-of-pocket costs for the many beneficiaries whose

[24] Federal Trade Commission, *Complaint, In the Matter of Caremark Rx, LLC et al.*, Docket No. 9437 (Sept. 20, 2024) (public redacted version), https://www.ftc.gov/system/files/ftc_gov/pdf/d9437_caremark_rx_zinc_health_services_et_al_part_3_complaint_public_redacted.pdf, ¶ 129 (hereinafter FTC Complaint).

[25] FTC Complaint.

[26] U.S. FED. TRADE COMM'N, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* (Interim Staff Report, Office of Policy Planning, July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

payments are tied to these list prices. The FTC focused specifically on the staggering increases in the list price of insulin that accompanied the rise of rebate agreements: from 1999 to 2017, the list price of Humalog increased from $21 to $274, a jump of over 1,200%.[27] The list of anticompetitive actions undertaken by the PBMs includes the creation of highly exclusionary formulary designs, demands for ever-increasing manufacturer rebates that necessitated list price hikes, and disadvantaging unbranded, low-WAC versions of the same drugs produced by the same manufacturers. This last anticompetitive strategy resulted in beneficiaries purchasing a much more expensive version of the exact same drug to preserve higher rebates. The PBMs profited from the rise in prices across the sector, while patients with high out-of-pocket costs bore the brunt of the increase.

The FTC's complaint proposed remedies for this anticompetitive conduct, including prohibiting the PBMs from (1) disadvantaging low-WAC versions of drugs made by the same manufacturers, (2) accepting any rebates or discounts benchmarked to WAC or list price, and (3) designing a drug benefit plan that benchmarked out-of-pocket costs to the list price of a drug rather than net cost.[28] Currently, the administrative proceeding is in the pre-trial phase, with evidentiary hearings likely to begin in 2026.[29]

II. Remedies

Assuming that the court finds PBMs liable, the FTC is empowered with broad latitude to craft appropriate behavioral and structural remedies. Generally, the purposes of antitrust remedies are as follows: (1) unfetter a market from anticompetitive conduct; (2) terminate the illegal conduct; (3) deny to the defendant the fruits of its statutory violation; and (4) ensure that there remain no practices likely to result in anticompetitive conduct in the future.[30]

In light of these goals, we first summarize the remedies toolkit available to the FTC (section A), then discuss potential legal remedies (B-E). Next, we propose policy solutions that could achieve the same goals, but outside this court proceeding (F-G).

A. Remedies Toolkit

The complaint alleges that the PBMs' conduct constitutes an unfair method of competition in violation of section 5(a) of the FTC Act.[31] The allegation builds upon the FTC's 2022 policy statement, which viewed the mandate of the FTC Act as extending beyond the scope of the

[27] FTC Complaint.

[28] FTC Complaint.

[29] Paige Minemyer, "FTC Chair Ferguson Changes Course on Recusal from PBM Insulin Case," *Fierce Healthcare* (Apr. 4, 2025), https://www.fiercehealthcare.com/regulatory/ftc-pauses-lawsuit-against-pbms-over-insulin-pricing (last visited May 20, 2025).

[30] United States v. Microsoft Corp., 253 F.3d 34, 103 (D.C. Cir. 2001); Steven Salop, *What Is An Effective Remedy in the Google Case*, PROMARKET (September 6, 2024), available at https://www.promarket.org/2024/09/06/what-is-an-effective-remedy-in-the-google-search-case/ (last visited May 20, 2025).

[31] FTC Complaint, ¶ 261

Sherman and Clayton acts and wanted to resuscitate the use of section 5 to act against other forms of unfair conduct with a tendency to negatively affect competitive conditions.[32]

The Commission's authority to issue remedial orders flows from section 5(b) of the FTC Act.[33] The chief limitation is that the FTC's remedies must avoid being overly broad and must bear a reasonable relation to the illegal conduct.[34] Though section 5 violations encompass a broader set of behaviors than the Sherman Act, the four purposes of remedies identified by the court in *U.S. v. Microsoft* for section 2 monopolization case (as enumerated above) remain relevant.

The FTC has developed a robust toolkit to remedy anticompetitive conduct. The FTC can issue cease-and-desist provisions prohibiting certain forms of conduct and can impose civil penalties on parties that subsequently violate the order.[35] Importantly, the prohibited conduct can go beyond the conduct that has been expressly identified as illegal, in order to "effectively . . . close all roads to the prohibited goal."[36] The FTC can also issue notice or reporting obligations to monitor the effectiveness of remedies, and can require companies to institute compliance programs to reduce the probability of recurrence.[37]

The FTC primarily monitors compliance with remedies through self-reporting by respondents. FTC orders routinely contain a requirement that the respondent file periodic reports demonstrating compliance.[38] The FTC can also appoint third-party monitors when remedies involve complex or ongoing relationships between colluding parties, particularly in the context of mergers.[39]

B. Cost Benchmarking Remedies

Cost-benchmarking remedies govern how PBMs and manufacturers may use a drug's WAC (also called list price) to agree on price and rebates. These remedies vary in their intensity. Some constrain the ways PBMs and manufacturers may use the list price as a benchmark for

[32] Policy Statement Regarding the Scope of Unfair Methods of Competition Under Section 5 of the Federal Trade Commission Act, Commission File No. P221202, https://www.ftc.gov/system/files/ftc_gov/pdf/P221202Section5PolicyStatement.pdf (last visited May 20, 2025).
[33] 15 U.S.C § 45.
[34] FTC v. Nat'l Lead Co., 352 U.S. 419, 428 (1957); Fixer Upper: Using the FTC's Remedial Toolbox to Restore Competition, Remarks of Ian Conner, Director, Bureau of Competition, February 8, 2020.
[35] 15 U.S.C § 45(l); A Brief Overview of the Federal Trade Commission's Investigative, Law Enforcement, and Rulemaking Authority, May 2021, https://www.ftc.gov/about-ftc/mission/enforcement-authority (last visited May 20, 2025).
[36] FTC v. Ruberoid Co., 343 U.S. 470, 473 (1952).
[37] Fixer Upper: Using the FTC's Remedial Toolbox to Restore Competition, Remarks of Ian Conner, Director, Bureau of Competition, February 8, 2020.
[38] Roberta Baruch and Bruce Hoffman, Bureau of Competition, Compliance Reports: Reinforcing a commitment to effective orders, March 11, 2019, https://www.ftc.gov/enforcement/competition-matters/2019/03/compliance-reports-reinforcing-commitment-effective-orders (last visited May 20, 2025).
[39] FTC, Negotiating Merger Remedies, https://www.ftc.gov/advice-guidance/competition-guidance/negotiating-merger-remedies (last visited May 20, 2025).

bargaining, while others seriously limit the ability of PBMs and manufacturers to engage in rebate schemes entirely, narrowing the distinction between list and net price.

1. Prevent the Exclusion of Identical Low-WAC Drugs

One potential limited WAC remedy can be found in the FTC's complaint. The FTC wants to prevent the respondent PBMs and Group Purchasing Organizations (GPOs) from "excluding or disadvantaging low WAC versions of high WAC drugs made by the same manufacturers whenever the Respondent covers the high WAC drug on a formulary."[40] This solution stems from concerns about PBMs' preferential coverage of high-WAC, high-rebate drugs over identical low-WAC, low-rebate versions. The FTC's complaint details how the largest insulin manufacturers became worried about public criticism over high list prices.[41] The manufacturers could have lowered list prices, but they worried that PBMs would disadvantage their drug if they unilaterally lowered rebates. Instead, they introduced low-WAC, unbranded versions of the same drugs already covered on the PBMs' formularies. But PBMs continued to favor the high-WAC drugs on their formularies, in many cases exclusively, because their contracts with plan sponsors rewarded rebate dollars rather than net cost of medicines. This choice meant that beneficiaries (and possibly insurers and sponsors too) were on the hook for higher out-of-pocket costs benchmarked to the list price.[42]

This remedy is a limited one because it only changes PBMs' behavior when a lower-WAC version of a drug is offered by the same manufacturer. Nevertheless, it still offers meaningful relief for beneficiaries in crucial drug markets, such as that for insulin, and it comes with few drawbacks. This remedy prevents PBMs from pursuing their misaligned incentives by prohibiting them from excluding cheaper products. This results in more competition unless manufacturers respond to the remedy by discontinuing these unbranded products.

Prohibiting the exclusion of identical low-WAC drugs would also result in a redistribution of costs from consumers to PBMs. A decrease in large rebates from favored high-WAC drugs would reallocate rebate funds from PBMs and insurers/sponsors to manufacturers who might consequently reduce list prices. Lower list prices would, all else equal, reduce costs for beneficiaries and plan sponsors/insurers and lower revenue for manufacturers. Thus, the net effect of ameliorating this market failure is to redistribute money from PBMs to consumers (with an ambiguous effect on plan sponsors/insurers). Lastly, this remedy would in theory have no negative effects on static or dynamic efficiency (in other words, output or innovation) within the healthcare ecosystem.

2. Link Out-of-Pocket Costs to Net Price, Not List Price

[40] FTC Complaint.

[41] FTC Complaint.

[42] *Authorized Generic Drugs 'Insufficient' to Improve Affordability in Medicare Part D*, Healio (Oct. 20, 2021), https://www.healio.com/news/endocrinology/20211020/authorized-generic-drugs-insufficient-to-improve-affordability-in-medicare-part-d (last visited May 20, 2025).

Another WAC remedy in the FTC's complaint would prohibit the PBMs from designing "a benefit plan that bases patients' deductibles or coinsurance on the list price, rather than the net cost after rebates."[43] This remedy is intended to prevent situations in which out-of-pocket costs are not reflective of a drug's net price. If a patient's insurance plan ties their out-of-pocket costs to the list price of a drug (usually through coinsurance) then patients end up paying huge amounts untethered to the net cost of the drug.[44] In fact, as the complaint points out, sometimes, patients end up paying even more than the drug's WAC minus rebates, meaning that their insurer paradoxically turns a profit when the patient purchases the drug.

Similar to the remedy described above, linking out-of-pocket costs to net price addresses the principal-agent misalignment between the PBM contracting on behalf of the insurer and the beneficiary. The insurer makes money with an increase in list price, the beneficiary (in many cases) loses money. The solution is to prohibit the latter from losing money due to net price-list price disparities in any case at all. Specifically, out-of-pocket costs for the beneficiary must only be benchmarked to the net price after rebates and discounts, not the list price before them. Solving this market failure will result in better outcomes for beneficiaries without reducing efficiency. The solution redistributes rebate funds from PBMs and sponsors/insurers to beneficiaries and holds them to a fairer price that is now attached to the true overall price of the drug. Of course, some of these gains to beneficiaries might be clawed back in the form of higher premiums.[45] But even if insurers raised premiums to account for the entirety of their loss, the solution would still result in a fairer and more equitable distribution of insurance costs across consumers. Lastly, manufacturers are largely unaffected by this fix, so incentives for innovation and production are unchanged.

3. Mandate Complete Rebate Pass-Through

A third remedy (found in the Lower Health Care Costs Act) would require PBMs to pass through all price concessions from manufacturers—rebates, fees, alternative discounts, etc.—to plan sponsors/insurers.[46] This remedy tackles the same principal-agent misalignment in which PBMs desire higher WAC and rebates, some of which they keep, rather than passing them through to insurers/plan sponsors. Currently, PBMs retain roughly 10% of rebates, although that number varies by the insurer/sponsor.[47] The FTC's complaint details how the perverse incentives produced by the rebate model lead to higher costs for vital drugs such as insulin. Mandating pass-through would ameliorate the misalignment between PBMs and their clients, likely resulting in lower net costs for sponsors and insurers than the current equilibrium. This remedy could potentially drive

[43] FTC Complaint.

[44] Mulcahy et al., *Prescription Drug Prices, Rebates, and Insurance Premiums*, RRA1820-3 (RAND Corp. Dec. 3, 2024), https://www.dol.gov/sites/dolgov/files/ebsa/laws-and-regulations/laws/no-surprises-act/2024-appendix-prescription-drug-prices.pdf (last visited May 20, 2025).

[45] *Id.*

[46] S. 1895, Lower Health Care Costs Act, 116th Cong. (2019), https://www.congress.gov/bill/116th-congress/senate-bill/1895 (last visited May 20, 2025).

[47] Kristi Martin, *What Pharmacy Benefit Managers Do, and How They Contribute to Drug Spending* (Explainer, Commonwealth Fund Mar. 17, 2025), https://doi.org/10.26099/fsgq-y980 (last visited May 13, 2025).

down drug prices. Since PBMs could no longer directly benefit from rebates, they would not be incentivized to push manufacturers for higher rebates and manufacturers would not feel compelled to artificially inflate WAC.

This solution could have downsides. Because PBMs would no longer directly profit from larger rebates and discounts, they have less incentive to strike these bargains.[48] However, PBMs would compete to negotiate lower net costs, as this would allow them to contest their rivals' sales. Additionally, plan sponsors could design contracts with PBMs that incentivize lowering the net cost of drugs. Horizontal concentration and differentiation in the PBM market complicate this picture, though, and might limit the degree to which contestation drives down net prices. Ultimately, complete pass-through would shift the focus of PBM competition from ever-larger rebates (which only partially benefit sponsors and insurers) to formulary design and net cost and administrative fees. And complete pass-through might also have salutary effects on price competition amongst manufacturers: some economic analyses predict that it would cause manufacturers to compete more vigorously on the basis of list price when selling to PBMs and insurers. [49]

In summary, this remedy lessens incentive misalignment between PBMs and insurers/sponsors and creates the conditions for competition among PBMs to drive down net costs. However, it does not prevent beneficiaries from paying high and economically unjustified out-of-pocket costs at the point of sale.

4. Limit Rebates to the Point of Sale

A fourth remedy, proposed by the FTC, would prohibit manufacturers' from receiving kickback rebates after the sale of a drug, instead limiting all price concessions to the point of sale.[50] This remedy was proposed in the Drug Price Transparency Act which has received bipartisan support.[51] This remedy is similar to mandating total-pass through of all rebates to sponsors/insurers, but with a few key differences. First, discounts in this case would be applied directly to the cost of the drug which the beneficiary pays. In this, it essentially combines the two previous remedies: linking out-of-pocket costs to net price and mandating complete rebate pass-through.

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[48] Academy of Managed Care Pharmacy, *Pharmaceutical Manufacturer Rebates* (Legislative & Regulatory Position), AMCP, https://www.amcp.org/legislative-regulatory-position/pharmaceutical-manufacturer-rebates (last visited May 12, 2025).

[49] Neeraj Sood, PhD, Rocio Ribero, PhD, Martha Ryan & Karen Van Nuys, PhD, *The Association Between Drug Rebates and List Prices* (White Paper, USC Schaeffer Ctr. for Health Policy & Econ. Feb. 11, 2020), https://schaeffer.usc.edu/research/the-association-between-drug-rebates-and-list-prices/ (last visited May 12, 2025).

[50] FTC Complaint.

[51] S. 1131, Drug Price Transparency Act of 2023, 118th Cong. (2023), https://www.congress.gov/bill/118th-congress/senate-bill/1131 (last visited May 12, 2025).

Second, point-of-sale discounts provide for total transparency about the net cost of the drug to the insurer/sponsor after PBM-negotiated discounts. However, such transparency might make manufacturers less likely to offer generous rebates to a single PBM, as other PBMs could quickly note the price concession and demand the same.[52] For this reason, this remedy is a less attractive option than the previous two remedies individually or combined. A potential solution to this problem could be to require pharmacies to charge patients the negotiated price *or less*. This would preserve the benefit of passing on savings to consumers without making negotiated prices entirely public. This challenge could alternatively be avoided through a *partial* point-of-sale rebate structure, in which some undisclosed but sizable portion of the negotiated rebate applies at the point of sale. The remainder could be paid directly to health plans and used to lower costs by decreasing copays or cost sharing obligations.[53] Because the exact portion of rebates passed on to consumers would not be publicly disclosed, third parties would not gain access to PBMs' competitively sensitive information.

This remedy also makes it more difficult for a manufacturer and PBM to contract on conditional discounts. These are discounts that grow as the PBM shifts more share to the product, and they cannot be calculated until after shares are known. Point of sale pricing would in this case have to use an estimate of the final price or an upper bound.

5. Prohibit Spread Pricing

A final remedy (included in the Lower Health Care Costs Act) would prohibit spread pricing, or billing sponsors/insurers more than the amount paid for a drug by a PBM to a pharmacy.[54] The market failure addressed by this remedy is one of opaque pricing and contracting on behalf of the PBMs, that is, it is often difficult for insurers/sponsors to determine how much a PBM is paying on their behalf for a specific drug and demand not to be charged more than that amount.[55] Often, these spreads can be quite large. A recent study examined 45 high-utilization generic drugs in Medicare Part D and found that of the $22.50 per subscription paid on average by Part D, PBMs captured $9.18 in gross profit while pharmacies and wholesalers together earned

[52] Cong. Budget Off., *Alternative Approaches to Reducing Prescription Drug Prices* (Oct. 2024), https://www.cbo.gov/publication/60812 (last visited May 12, 2025).

[53] Joanna Shepherd, Pharmacy Benefit Managers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs, 38 YALE LAW AND POLICY REVIEW 357, 394.

[54] S. 1895, *Lower Health Care Costs Act*, supra note 46. This proposal is importantly distinct from mandating rebate pass-through. The spread pricing remedy involves the contractual relations between PBMs and insurers, and it prevents PBMs from charging insurers more than the amount paid to the pharmacy when a drug is dispensed. The pass-through remedy restricts what PBMs may do with the rebates given to them by manufacturers. Even if PBMs were required to pass through all manufacturer rebates, they could still charge insurers more than the amount paid to PBMs for dispensing. The spread pricing remedy stops that from happening.

[55] Noah Tong, *Pharmacies and Wholesalers, Not Just PBMs, Rely on Spread Pricing*, *Fierce Healthcare* (Oct. 20, 2023), https://www.fiercehealthcare.com/payers/pharmacies-and-wholesalers-not-just-pbms-rely-spread-pricing (last visited May 12, 2025).

$6.58.[56] PBMs may favor high-cost drugs over identical low-cost drugs on formularies to earn a larger spread.[57]

The fix is to prevent this practice entirely. The benefit is better alignment between PBMs and insurers/sponsors, as all price concessions are passed through to insurers/sponsors. The downside is that if PBMs cannot keep any of the discounts they gain from pharmacies, they may be less incentivized to obtain or increase those discounts. To the extent that transparency and horizontal competition in the PBM market hold, this may not be an issue, as PBMs will still compete on the basis of net cost to steal rivals' customers. Research on state Medicaid spread pricing bans found evidence of huge savings, with managed Medicaid cost per prescription dropping by 21.7% on average.[58] This indicates that spread pricing bans effectively target PBM rent-seeking without substantially diminishing their incentives to seek discounts. However, additional pricing transparency would be needed to ensure that PBMs do not simply raise other opaque fees to compensate for their loss.[59] Distributionally, this remedy will redistribute funds from PBMs to sponsors/insurers.

C. Transparency and Disclosure Remedies

The FTC has identified the lack of transparency between PBMs and payers as another source of dysfunction in the current market. PBMs often refuse to share drug-level rebate and fee amounts or net cost information, leaving payers without a clear understanding of negotiated prices.[60] PBMs may also re-categorize the rebates they receive as fees to avoid disclosure obligations.[61] In fact, the Department of Health and Human Services found that most health plans were not aware of the contract terms that determine the rebates they receive.[62]

As a result of this lack of transparency, contract negotiations between PBMs and payers often center around absolute rebate amounts, rather than more specific metrics.[63] Structuring contracts around absolute rebate amounts further incentivizes PBMs to prioritize high rebates. In addition to distorting PBM's incentives, this lack of transparency "precludes the payers' ability to make fully informed decisions and better protect their patients."[64] For example, payers cannot adequately evaluate the cost-effectiveness of their PBM's formulary, cannot assess whether they

[56] *Id*.
[57] T. Joseph Mattingly II, David A. Hyman & Ge Bai, *Pharmacy Benefit Managers: History, Business Practices, Economics, and Policy*, 4 JAMA HEALTH FORUM E233804 (Nov. 3, 2023), https://jamanetwork.com/journals/jama-health-forum/fullarticle/2811344 (last visited May 20, 2025).
[58] Eric Yde, *Regulating Vertical Relationships in Prescription Drug Markets: Evidence from Medicaid* (Dec. 2023) (paper presented at the 2024 ASSA Annual Meeting of the American Economic Association, Jan. 5–7, 2024, San Antonio, Tex.), https://www.aeaweb.org/conference/2024/program/paper/HBD4iAak (last visited May 20, 2025).
[59] Tong, *supra* note 55.
[60] FTC Complaint, ¶ 175.
[61] Shepherd, *supra* note 53, at 381.
[62] FTC Complaint, ¶ 176.
[63] FTC Complaint, ¶ 171.
[64] FTC Complaint, ¶ 201.

are receiving a correct portion of the rebates, and do not have access to drug-level utilization and spending patterns.[65]

Accordingly, a potential remedy includes increasing PBMs' disclosure obligations to payers regarding the total amount and structure of rebates they receive from manufacturers. For example, the Creating Transparency to Have Drug Rebates Unlocked (C-THRU) Act of 2017 would have required PBMs to disclose their rebates to payers, as well as the share of rebates that they retained.[66] It would also have required PBMs to post aggregated information on the website of the Centers for Medicare & Medicaid Services in order to allow payers to evaluate the effectiveness of their services.[67]

Proponents of this remedy assert that increased transparency would allow plan sponsors to more effectively serve the interests of their employees by enabling them to evaluate the quality of the PBM's services and empowering them to negotiate for a larger share of PBMs' rebates.[68] However, others have opposed such reforms, claiming that increased disclosure requirements may have the unintended effect of raising drug prices by reducing PBM's ability to negotiate with manufacturers. If rebate terms are made public, manufacturers may lose their incentive to compete by providing generous rebates because their competitors will be able to discern their rebate arrangements and outbid them. They may also hesitate to provide generous rebates to one PBM because then the other PBMs will demand the same.[69] Finally, the disclosure of this competitively sensitive information may allow for tacit collusion among manufacturers.[70] If executed improperly, disclosure requirements may not be the optimal channel to align incentives.

D. Rebuttable Presumption of Illegality

PBMs' use of rebate retention and spread pricing as a form of compensation is at the heart of the issues outlined in the FTC's complaint. However, this race for higher rebates has additional negative externalities for competition in pharmaceutical markets that are not mentioned in the FTC complaint.

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[65] House Committee on Oversight and Accountability, *The Role of Pharmacy Benefit Managers in Prescription Drug Markets*, p. 27 ("Lack of transparency and the complexity of rebates and fees can make it difficult for plan sponsors to assess whether they are fully benefiting from all price concessions that PBMs negotiate on their behalf.*")*.

[66] Summary of The Creating Transparency to Have Drug Rebates Unlocked (C-THRU) Act, https://www.finance.senate.gov/imo/media/doc/CTHRU%20One%20Pager.pdf (last visited May 20, 2025).

[67] Summary of The Creating Transparency to Have Drug Rebates Unlocked (C-THRU) Act, https://www.finance.senate.gov/imo/media/doc/CTHRU%20One%20Pager.pdf (last visited May 20, 2025).

[68] Shepherd, *supra* note 53, at 382.

[69] Shepherd, *supra* note 53, at 384.

[70] Shepherd, *supra* note 53, at 385.

One such negative externality is that the race for higher rebates creates the conditions necessary for drug manufacturers to foreclose the entry of a nascent competitor. Consider, for example, the conduct at issue in *Sanofi-Aventis U.S., LLC v. Mylan, Inc.*[71] Mylan, Inc. is the manufacturer of EpiPen, the dominant epinephrine auto-injector in the United States.[72] In 2013, Sanofi-Aventis launched a competing epinephrine auto-injector, Auvi-Q. At the time, Mylan controlled 90% of the U.S. epinephrine auto-injector market (i.e., filled 90% of prescriptions). Upon entry, Auvi-Q faced an uphill battle: EpiPen had been on the market for decades and had built up significant goodwill among allergists and patients alike, even becoming a household name. PBMs would likely be reluctant to completely exclude EpiPen from their formulary because many patients prefer the drug they are familiar with. Excluding the leading EpiPen would make the PBM's plan appear to be of lower quality in the eyes of consumers. Put simply, this lawsuit alleged that the manufacturer of EpiPen leveraged this so-called "non-contestable share" (or, concretely, the fact that some percentage of patients will not be willing to switch from EpiPen to Auvi-Q) to demand that PBMs steer a large percentage of their members to EpiPen. To defect, the PBM would have to forgo rebates on all EpiPens, resulting in reduced compensation for PBMs that tie their compensation to rebate size. The result of these restrictive "loyalty rebate" contracts was that Sanofi failed to scale Auvi-Q and had to withdraw the drug from the market. Absent the contracting strategies that incentivize PBMs to chase rebates, the PBMs might have been able to leverage the entry of a new player, Auvi-Q, to command better price terms from the incumbent, EpiPen, and perhaps even expand patient choice by offering Auvi-Q a more favorable formulary placement. In other words, PBMs would not be phased by rebates being conditioned on "loyalty" if their compensation structure did not rely so heavily on it.

It is clear that harm caused by rebate-based PBM compensation strategies extends beyond the market for insulin. The far-reaching harm caused by rebate retention and spread pricing support the proposal for remedies that promote, or even mandate, the disentanglement of PBM compensation and rebate size.

The court should consider imposing a rebuttable presumption, which holds that contracts in the pharmaceutical industry involving rebate-based compensation arrangements are presumed to be anticompetitive in the absence of evidence clearly showing otherwise. This includes, but is not limited to, contracts involving PBMs, plan sponsors, retailers, group purchasing organizations, and drug manufacturers. The success of such a rebuttable presumption would rely upon its broad applicability in the pharmaceutical industry. Consider, for example, the fact that the Big 3 PBMs have spun off their contract negotiating arms into separate, affiliated entities known as "rebate aggregators" in recent years;[73] a rebuttable presumption that applies only to PBMs may not be

[71] Sanofi-Aventis U.S., LLC. v. Mylan, Inc., 44 F.4th 959 (10th Cir. 2022).

[72] Epinephrine auto-injectors are self-administered medical devices used to treat life-threatening allergic reactions.

[73] U.S. Fed. Trade Comm'n, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies (Interim Staff Report, Office of Policy Planning, July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf (last visited on May 20, 2025).

sufficiently broad to adapt to such market changes. Properly applied, this proposed remedy would force PBMs to abandon rebate-based contracting in favor of fixed dollar amount fees, thereby encouraging drug manufacturers to compete on net price (rather than rebate size) for formulary inclusion and favorable tier placement. Furthermore, PBMs would be prohibited from using guaranteed minimum rebates in negotiations with plan sponsors, thus encouraging competition among PBMs on other price and non-price dimensions. Finally, as an added bonus, this remedy would confront the loyalty rebate system, thereby lowering barriers to entry and spurring innovation.

The court may hesitate to declare a rebuttable presumption of illegality for *all* contracts in the pharmaceutical industry involving rebate-based compensation arrangements because doing so might be interpreted as judicial overreach. If the court finds liability and does not pursue this rebuttable presumption as part of the remedy, then the FTC should consider utilizing its rulemaking authority pursuant to section 6(g) of the FTC Act to do so.

E. Divestiture

All the major insurers in the US — Aetna, Cigna, UnitedHealth Group, Humana, and Blue Cross Blue Shield — are vertically integrated with five of the six largest PBMs in the United States.[74] Together, these account for over 80% of all prescription drug claims.[75] Today, the vast majority of small companies (i.e., companies with fewer than 1,000 employees) purchase plan-integrated PBM services, rather than seeking a separate contract with a PBM.[76] Companies of this size employed 88% of private sector employees in the United States.[77] Between 2019 and 2023, the percentage of small companies that purchased plan-integrated PBM services shrunk from approximately 88% to 73%.[78] Industry experts suggest that this may reflect reluctance for smaller companies to engage with the large vertically integrated PBMs, and the rise of smaller, more transparent PBMs that use pass-through pricing, rather than spread pricing or rebate retention.[79]

Given this amount of vertical integration, we must seriously consider divestiture as a potential remedy. Industry experts have aptly posed the following question: "if plan sponsors are so unhappy with the Big Three PBMs, why don't they restructure their PBM contracts?"[80] While

[74] FTC Report, p. 24

[75] Drug Channels Blog, *The Top Pharmacy Benefit Managers of 2023: Market Share and Trends for the Biggest Companies—And What's Ahead* (April 9, 2024), https://www.drugchannels.net/2024/04/the-top-pharmacy-benefit-managers-of.html (last visited May 12, 2025).

[76] *Id* at p. 148

[77] United States Bureau of Labor Statistics, *Employment by size of establishment, private industry*, https://www.bls.gov/charts/county-employment-and-wages/employment-by-size.htm (last visited May 12, 2025).

[78] Drug Channels Report at p. 148

[79] Drug Channels Report at p. 148 & 172

[80] Drug Channels Blog, *If Plan Sponsors Are So Unhappy with Their PBMs' Transparency, Why Won't They Change the Model?*, (October 15, 2024) https://www.drugchannels.net/2024/10/if-plan-sponsors-are-so-unhappy-with.html#:~:text=Smaller%20PBMs%20win%20big%20on,affect%20plan%20sponsors'%20perceived%20satisfaction (last visited May 20, 2025).

some have suggested plan sponsors' warped incentive to internalize rebates received from PBMs (rather than passing the savings onto beneficiaries at the point of sale) is to blame,[81] the FTC's complaint states that "some health insurers reportedly do not permit their clients to comparison shop for PBM services; rather, the client must use the PBM affiliated with the health insurer."[82] If true, then the vertically integrated PBMs face diminished incentive to compete on price and non-price dimensions, including rebate transparency. This lack of incentive for vertically integrated PBMs supports the proposal for insurer divestiture.

Despite this, divestiture alone is insufficient to address the harms alleged in this case. While vertical integration indubitably reduces incentive for integrated PBMs to offer competitive terms, it cannot be blamed in isolation for the harm described in the FTC's complaint. The D.C. Circuit explained in the 2001 *Microsoft* decision that "structural relief … require[s] a clearer indication of a significant causal connection between the conduct and creation or maintenance of market power."[83] In other words, "divestiture should be applied to unitary companies … only when 'tailored to fit the wrong creating the occasion for the remedy.'"[84] Thus, regardless of its potential benefits, the courts are unlikely to mandate divestiture because the "wrong" in *this* case is more directly a result of PBMs' rebate- and list price-based contracting practices, not the vertically integrated PBM structure. These anti-competitive contracting practices can be more precisely targeted using behavioral remedies such as those described in the preceding sections.

F. ERISA Insurance Definition Changes

Not all fixes for PBMs' anticompetitive practices are legal remedies that could be imposed by courts. Legislative and executive actors can also play a role in promoting competition. The final two solutions focus on policy action from these actors. One fix for the most egregious instances of PBM misconduct is for the Department of Labor to use its rulemaking authority under the Employment Retirement Income Security Act of 1974 (ERISA) to stipulate that plans that

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[81] Dennis Carlton et al., *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied Against Pharmacy Benefit Managers*, https://compass-lexecon.files.svdcdn.com/production/files/documents/PBMs-and-Prescription-Drug-Distribution-An-Economic-Consideration-of-Criticisms-Levied-Against-Pharmacy-Benefit-Managers.pdf?dm=1728503869 (last visited May 20, 2025); Drug Channels Blog, *If Plan Sponsors Are So Unhappy with Their PBMs' Transparency, Why Won't They Change the Model?* (October 15, 2024) https://www.drugchannels.net/2024/10/if-plan-sponsors-are-so-unhappy-with.html#:~:text=Smaller%20PBMs%20win%20big%20on,affect%20plan%20sponsors'%20perceived%20satisfaction (last visited May 20, 2025).

[82] FTC Complaint at p. 24.

[83] Thomas Barnett, *Section 2 Remedies: A Necessary Challenge*, https://www.justice.gov/archives/atr/file/519221/dl (last visited May 20, 2025); United States v. Microsoft Corp., 253 F.3d 34, 106 (D.C. Cir. 2001).

[84] Spencer Weber Waller, THE PAST, PRESENT, AND FUTURE OF MONOPOLIZATION REMEDIES, ANTITRUST LJ 76 (2009), at 11.

systematically charge a beneficiary more than the market value to access care cannot qualify as health insurance plans under ERISA and receive pre-tax treatment.

The ERISA, amongst other things, created minimum federal standards for private health insurance plans offered by insurers.[85] Employers are not required to offer their workers health insurance, but if they do (and if they want the benefit to qualify for pre-tax treatment), they must meet ERISA's minimum standards.[86] The rulemaking authority to specify which plans and entities can qualify for this pre-tax treatment is vested in the Department of Labor.[87]

This context is relevant to a specific kind of anticompetitive strategy facilitated by the PBMs' opaque pricing and rebate scheme. As explained above, patients with large coinsurance or deductibles often pay huge out-of-pocket costs at the point of sale that are untethered to the net cost of the drug. In the most egregious instances, patients end up paying more than the drug's net price. In other words, they pay more for the drug than it costs. Health insurance is, in theory, a payment up front in order to pay less than market value when the beneficiary needs to access care. But in these peculiar instances, the beneficiary's insurance ends up receiving a transfer of money (or net gain) upon purchase rather than the opposite. This remedy involves a simple argument: health care plans that charge beneficiaries more to access care than the net price for that care should not qualify as an "insurance" provider in any meaningful sense of the word because instead of insuring the beneficiary against his loss, the insurer is making money off of the loss.

The Department of Labor has the rulemaking authority to stipulate that plans which (either systematically or on average) charge a beneficiary more than the net price to access care cannot qualify as health insurance plans under ERISA and receive pre-tax treatment. However, the public attention of a trial can increase the likelihood of regulatory action.

G. Mandatory Fiduciary Duty

A comprehensive policy solution could be the imposition of a mandatory fiduciary duty on PBMs akin to the duties imposed on investment fiduciaries and corporate managers in for-profit contexts. Fiduciary duty generally encompasses two core obligations: a duty of loyalty, to act in the best interests of the client and avoid self-dealing, and a duty of care, to act with informed diligence and prudence.[88] Unlike ordinary contractual obligations, where each party may pursue its own interests at arm's length, fiduciary status requires the PBM to treat the client's interest as paramount and subordinate its own.[89] In this framework, a PBM would be legally obligated to act

[85] Employee Retirement Income Security Act of 1974, Pub. L. No. 93-406, 88 Stat. 829 (1974) (codified as amended at 29 U.S.C. §§ 1001–1461 (2018)).

[86] U.S. Dep't of Labor, Employee Benefits Security Administration, *ERISA* (2025), https://www.dol.gov/general/topic/health-plans/erisa (last visited May 12, 2025).

[87] *Id.*

[88] Restatement (Third) of Trusts §§ 77–78 (Am. L. Inst. 2007); Tamar Frankel, *Fiduciary Law*, 71 CAL. L. REV. 795, 829–31 (1983).

[89] 15 U.S.C. § 80b-6; Shepherd, *supra* note 53, at 387–89

in the best interests of the health plan and its beneficiaries, placing patient and plan welfare above its own profit motives.

Fiduciary vs. Contractual Obligations

Under current law, PBMs may engage in profit-maximizing conduct—such as retaining rebates or using spread pricing—so long as the plan contract does not prohibit it.[90] Fiduciary designation would invert this presumption: any self-enriching conduct would be presumptively prohibited unless affirmatively justified as aligned with the client's best interests. This standard parallels the rules governing investment advisers and corporate directors, who must avoid conflicts or demonstrate that their decisions meet exacting fairness standards.

Contract law presumes symmetry in bargaining and knowledge, but in the PBM market, sponsors lack the visibility and leverage to detect and discipline opportunism. Information asymmetries, vertical integration, and complex rebate structures impede oversight.[91] Fiduciary duty addresses these problems directly, obligating PBMs to act loyally and prudently regardless of the client's capacity to monitor behavior.

Addressing Opacity and Conflicts

Transparency is often offered as a solution to PBM misaligned incentives. However, meaningful transparency in this market has proven difficult, if not impossible, to achieve. PBMs manage formularies, negotiate rebates, and set cost-sharing terms in a structurally opaque environment. Employers and patients often cannot tell whether the PBM is acting in their interest or steering them toward higher-cost drugs to increase retained rebates. The most salient conflict arises from manufacturer rebates, which can induce PBMs to prefer expensive therapies over lower-cost therapeutic equivalents.

Fiduciary duty provides an enforceable, ex ante constraint on this behavior. A fiduciary PBM would be legally required to structure decisions—such as formulary placement and rebate negotiation—around the financial and clinical benefit to the client. If a PBM chose a high-rebate drug over a lower-cost equivalent, it would bear the burden of showing that the decision was in the best interest of the plan.[92] Courts and regulators could evaluate PBM conduct against a general loyalty standard: did the PBM act for the benefit of the plan and patients, or did it place its own revenue first?

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[90] U.S. Gov't Accountability Off., GAO-21-176, Prescription Drugs: Rebates and Fees Continue to Create Conflicts of Interest and Misaligned Incentives for PBMs 7–10 (2021), https://www.gao.gov/assets/gao-21-176.pdf (last visited May 20, 2025).

[91] Fed. Trade Comm'n, Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies 1–3 (2005), https://www.ftc.gov/sites/default/files/documents/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report/050906pharmbenefitrpt.pdf (last visited May 20, 2025).

[92] In re Walt Disney Co. Derivative Litig., 906 A.2d 27, 53–55 (Del. 2006).

Duty of Loyalty – Best Interest in Practice

Implementing a fiduciary duty would require operational changes to PBM practice. All third-party compensation—rebates, administrative fees, pricing spreads—would need to be disclosed and, absent explicit justification, remitted to the plan. This mirrors the fiduciary obligations of investment advisers, who must disclose and avoid conflicts or secure informed consent.

Beyond disclosure, fiduciary PBMs would be required to demonstrate affirmatively that their decisions prioritize client benefit.[93] For example, if a PBM selects a preferred insulin, it must document the rationale, showing that the choice optimizes clinical outcomes, adherence, and affordability. Internal deliberations, emails, and committee minutes would need to reflect patient-centric rather than profit-driven considerations. If the record revealed that a high-rebate drug was chosen to hit revenue targets rather than deliver net value, that would constitute a breach of loyalty.

Duty of Care – Process and Diligence

The duty of care obligates PBMs to maintain professional rigor in decision-making. PBMs must convene appropriate clinical committees, assess relevant data—including biosimilar pricing and therapeutic equivalence—and monitor patient outcomes. A PBM that fails to consider lower-cost alternatives or rubber-stamps manufacturer proposals would risk violating this standard.

This reflects the business judgment rule in corporate law: directors must inform themselves of material facts and act with deliberation and care. Similarly, fiduciary PBMs would be expected to establish internal governance structures, audit rebate and pricing decisions, and document the rationale behind drug coverage policies.

Enforcement and Evidentiary Standards

Fiduciary obligations are enforceable through litigation and regulation. Once a plaintiff establishes a conflict or apparent disloyalty, the burden shifts to the PBM to prove that its actions were consistent with fiduciary obligations. Remedies may include injunctive relief, disgorgement of rebates, or monetary damages. For instance, if a PBM prefers a high-rebate insulin, it must show that the product delivered superior clinical outcomes or lower net cost—not merely that it generated revenue.

Legal implementation could occur through ERISA amendment, regulatory reinterpretation, or common law evolution. Standing could extend to plan sponsors and potentially beneficiaries. As with trust and investment law, fiduciary status creates affirmative duties that function independently of the plan's ability to negotiate or monitor the PBM's behavior.

Structural and Behavioral Implications

[93] Compliance Programs of Investment Companies and Investment Advisers, Investment Advisers Act Release No. 2204, 68 Fed. Reg. 74714, 74716 (Dec. 24, 2003).

A fiduciary standard would prompt both structural reform and cultural change. PBMs would need to shift to transparent, fee-based compensation models, address internal conflicts (such as affiliated pharmacies), and implement compliance protocols. Compensation systems might evolve to reward cost savings or clinical outcomes rather than rebate volume.

Behaviorally, PBMs would need to reorient their institutional priorities. Manufacturers would no longer be revenue partners but counterparties. The plan and its members would become the clients. Internally, rebate contracting teams and formulary managers would need to align decisions with plan value, not PBM profitability. Regulators and plan sponsors could support this realignment through audits, disclosure rules, and fiduciary attestations.

The mere possibility of fiduciary litigation—with discovery obligations and burden shifting—would encourage PBMs to maintain thorough records and adopt client-first processes.[94] In this way, fiduciary duty does not require perfect oversight to improve outcomes. It imposes a legal baseline that corrects incentives and constrains self-dealing regardless of transparency limits.

III. Conclusion

Not all the remedies discussed above are effective, well-targeted solutions for the problems laid out in the FTC's complaint. Some are unlikely to be ordered by a court, and others have second-order costs that may outweigh first-order benefits. Divestiture fits into the former category. It's overbroad and burdens far more commercial activity than is necessary to remedy the alleged competitive harm. At the same time, a divestiture does not sufficiently disincentivize or disallow PBMs' anticompetitive contracting practices. Similarly, the proposal for constraining all rebates to the point of sale falls under the latter category (where second-order costs outweigh first-order benefits). Limiting discounts and rebates to the point of sale could constrain the ability of PBMs to obtain price concessions from manufacturers, as other PBMs could easily note the discount and demand the same.

The ideal antitrust remedy terminates (and prevents the recurrence of) the unlawful conduct, restores competitive conditions to the market(s) harmed, and compensates victims.[95] With these guiding principles in mind, we recommend that the court orders the following remedies:

- Prohibit the use of list price or rebate size for determining any form of compensation in the pharmaceutical industry (including, but not limited to, rebate retention contracting, guaranteed minimum rebates, and linking a patient's out-of-pocket costs to list price rather than net price);
- Prohibit PBMs from excluding or disadvantaging low WAC versions of high WAC drugs made by the same manufacturers whenever the PBM covers the high WAC drug on a formulary; and

[94] FRANK H. EASTERBROOK & DANIEL R. FISCHEL, THE ECONOMIC STRUCTURE OF CORPORATE LAW 90–93 (1991).
[95] A. Douglas Melamed, *Afterword: The purposes of antitrust remedies*, 76 ANTITRUST LJ 359 (2009).

- Prohibit spread pricing.

The benefits of these remedies have been discussed at length. Additionally, we recommend increasing transparency regarding PBMs' negotiated contracts with manufacturers via disclosure obligations to empower plan sponsors to better evaluate their PBM's performance and compare it to others. However, these disclosure requirements should be carefully fashioned to protect PBMs' ability to obtain rebates from manufacturers and to guard against tacit collusion.

Finally, some broader policy changes could improve competition in this space. First, sponsors and insurers should be prohibited from offering 'insurance' that systematically charges beneficiaries above market price for drugs under ERISA. A more comprehensive fix would impose fiduciary duty on PBMs vis-à-vis its clients (health plans and beneficiaries). As explained above, enforcing this obligation requires clients to know how PBMs have been contracting with manufacturers and pharmacies. Thus, any imposition of a fiduciary duty on PBMs should be accompanied by rigorous disclosure requirements, carefully fashioned to preserve their ability to obtain rebates from manufacturers. Together, these legal and policy solutions could restore competition in this sector.