Margins, Myths, and Reform: What the Data Reveals About Specialty Generics

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Introduction

In the pharmaceutical industry, pharmacy benefit managers (PBMs) serve as "middle men," facilitating price negotiation, network development, and health plan delivery. For decades, PBMs have operated in this role with little federal-level regulatory or legislative oversight. In recent years, however, the conversation and criticisms surrounding PBMs and their influence on prescription drug pricing has intensified, particularly within the increasingly key segment of generic specialty drugs. While generic specialty drugs are feted as potential cost-saving alternatives to their corresponding branded therapies, they have become a flashpoint in the debate over PBM transparency, market concentration, and pricing practices.

Two landmark reports released in 2024 and 2025—one by the Congressional Budget Office (CBO)[1] and the other by the Federal Trade Commission (FTC)[2]—arrived at sharply contrasting conclusions. The CBO framed PBMs' role in generic specialty pricing as economically modest, while the FTC exposed detailed evidence of substantial markups, internal profit transfers, and potential steering behavior within vertically integrated PBM systems. Together, these analyses illuminate the tension between system-level cost neutrality and firm-level profit optimization, raising critical questions about whether current PBM businesses serve the broader goals of affordability, transparency, and fair competition in the US drug market.

Remarkably, the two-year trend for these drugs is below 0%, which is significant given that drugs in this class typically exhibit a trend of 10–15%.

Overview of FTC vs. CBO Papers

The FTC approached this analysis from a microeconomic level, focusing on three large individual PBMs that dominate the market to assess the PBM impact on drug pricing for this slice of the market. The FTC's report found that based on an analysis of 2017–2022 data, PBMs have extracted large and growing profits from generic specialty drugs, often through:

[1] Congressional Budget Office. Alternative Approaches to Reducing Prescription Drug Prices. Available at: https://www.cbo.gov/system/files/2024-10/58793-rx-drug-prices.pdf.
[2] Federal Trade Commission. Specialty Generic Drugs: A Growing Profit Center for Vertically Integrated Pharmacy Benefit Managers. Available at: https://www.ftc.gov/system/files/ftc_gov/pdf/PBM-6b-Second-Interim-Staff-Report.pdf.

- Excessive markups – Over 22 percent of specialty generics dispensed by Big 3 PBM-affiliated pharmacies were marked up by more than 1,000 percent over acquisition cost, and 63 percent exceeded 100 percent
- Revenue shifting within vertically integrated structures — The FTC found PBMs "steered" prescriptions to their affiliated specialty pharmacies and used inflated reimbursement rates to move profits downstream while avoiding medical loss ratio (MLR) limits
- Spread pricing – PBMs billed plan sponsors significantly more than they reimbursed pharmacies, earning roughly $1.4 billion in spread income across 51 specialty generics
- Aggregate profit impact – Dispensing revenue above acquisition cost reached $7.3 billion (2017–2021)

FTC conclusion: PBMs are acting in bad faith by manipulating pricing of specialty generics that should be inexpensive. The Commission argues that this is a continuing and systemic problem, not a series of isolated outliers.

The CBO examined drug pricing from a macroeconomic perspective and reached a different conclusion:

- Generic specialty drugs account for a small portion of total costs.
- Spread margins on generics (including specialty generics) are narrow compared to branded drugs. CBO estimated that PBM markups in this segment are single-digit percentages and that competition among PBMs and plan sponsors has reduced profit opportunities.

CBO's Conclusion: PBM behavior around specialty generics does not significantly distort the market or impose measurable consumer harm. Instead, the concentration of profit still lies within branded and biologic specialty markets.

The Verdict: Reconciling the Two Views

The FTC's analysis focuses on micro-level data (individual drugs and PBM internal transactions), while the CBO evaluates macro-level spending trends.

- Both perspectives are valid within their respective frameworks:
    - The FTC shows that PBMs exploit specialty generics internally to capture profits through opaque transfer pricing
    - The CBO shows that, in aggregate, those profits remain a small share of national drug spending and may not materially affect total US healthcare costs

Impact of Recent PBM Reform on Generic Specialties

Effective January 1, 2024, the administration made Point of Sale Direct and Indirect Renumeration (POS DIR) illegal via H.R. 9096 and the Inflation Reduction Act, which has had a substantial impact on the pharmaceutical industry and the way rebates are handled.

With the prohibition of POS DIR, pharmacies no longer have the same financial incentives to mark up prices. Previously, pharmacies could increase prices to offset the potential clawback of DIR, which were often assessed by drug manufacturers months after the point of sale. This practice led to higher prices for consumers, as pharmacies tried to ensure they wouldn't lose money due to retroactive fees. With the elimination of POS DIR, PBMs were no longer incentivized to price certain drugs at an inflated cost. In the months that have followed, PBMs have started to charge prices that are more reflective of the acquisition cost. Additionally, the elimination of this feature has reintroduced competition between pharmacies, which has helped reduce costs. This introduced greater incentive for payors and PBMs to pass rebates through to the actual consumer rather than keeping them for less than transparent offsets that inflated corporate profits.

Data and Methodology

Wakely conducted an analysis of the generic specialty drugs identified in the Federal Trade Commission (FTC) report. The analysis focused on the following drugs:

Fluorouracil	Abacavir	Abiraterone	Adefovir
Atazanavir	Azathioprine	Progesterone	Capecitabine
Cinacalcet	Cyclosporine	Dalfampridine	Deferasirox
Dimethyl Fumarate	Dofetilide	Efavirenz	Emtricitabine
Enoxaparin	Entecavir	Etravirine	Everolimus
Fondaparinux	Glatiramer	Tacrolimus	Imatinib
Lamivudine	Sofosbuvir	Ritonavir	Mercaptopurine
Methotrexate	Mycophenolate Mofetil	Mycophenolic Acid	Nevirapine
Octreotide	Ribavirin	Riluzole	Sildenafil
Sirolimus	Velpatasvir	Tadalafil	Tenofovir Disoproxil
Teriparatide	Tobramycin	Zidovudine	

The analysis sought to quantify pricing differentials and markups for these drugs using publicly available and CMS-restricted datasets. Each data source was cleaned, standardized, and validated prior to inclusion.

CMS Quarterly Formulary Files

The CMS Quarterly Pricing Formulary Files served as the primary source for plan-level pricing data. These files contain National Drug Code (NDC)-level observations for all Medicare Advantage Prescription Drug (MA-PD) and standalone Prescription Drug Plan (PDP) contracts.

Relevant variables extracted included:

- Contract ID and Plan ID
- NDC (11-digit) and Drug Name
- Days Supply
- Unit Cost
- Wakely Calculated Per-Unit Cost (PUC), computed as:

$$\text{PUC}_{\text{Formulary}} = \frac{\text{Total Cost}}{\text{Quantity Dispensed} \times \text{Days Supply}}$$

VRDC Prescription Drug Event (PDE) Data

To validate the accuracy and completeness of the CMS Pricing Formulary data, we extracted Prescription Drug Event (PDE) data from the CMS Virtual Research Data Center (VRDC) 100 percent sample dataset. The PDE files provide detailed transaction-level information for all Medicare prescription drug claims, including data on quantity dispensed, days' supply, and payment amounts.

We used this data to cross-check the CMS Pricing Formulary values, assessing for discrepancies or lags in reporting. The comparison did not reveal material variances between the VRDC PDE data and the CMS formulary data, supporting the reliability of the CMS pricing files for the purposes of this study.

NADAC Benchmarking

NADAC (National Average Drug Acquisition Cost) files were obtained from CMS to provide a benchmark for retail pharmacy acquisition costs. NADAC prices were joined to the CMS formulary dataset at the NDC level, and all prices were normalized to a per-unit basis to ensure comparability.

The relative markup for each drug observation was calculated as:

$$\text{Markup}_i = \frac{\text{PUC}_{\text{Formulary},i} - \text{PUC}_{\text{NADAC},i}}{\text{PUC}_{\text{NADAC},i}}$$

PBM Integration Classification

Plan identifiers were linked to PBM ownership and health plan organizational structures using a combination of public CMS crosswalks and proprietary Wakely mappings. These linkages allowed the classification of each plan into one of two categories:

0. **Non-Integrated (PBM=0):** Plans contracting with an external, independently operated PBM.
1. **Vertically Integrated (PBM=1):** Plans affiliated with a PBM owned by the same parent entity.

This classification enabled segmentation of results by integration status and supported subsequent comparative analyses between integrated and non-integrated plan types.

Results

Our analysis reveals that while some drugs are still priced above the National Average Drug Acquisition Cost (NADAC), their two-year trends (2022–2024) have shifted downward. This reduction in prices indicates a positive shift toward more affordable medication for consumers. The elimination of POS DIR has at least partially disrupted the previous pricing strategies that allowed pharmacies and PBMs to inflate drug costs. A significant portion of the low trends, and pricing changes observed below are a direct cause of the elimination of POS DIR. Below are the results of the study, which illustrate these trends in greater detail.

Exhibit 1 illustrates the two-year pricing trend for many of the specialty generic drugs analyzed. Remarkably, the two-year trend for these drugs is below 0 percent, which is significant given that drugs in this class typically exhibit a trend of 10–15 percent. For vertically integrated PBM structures (PBM Owner Flag = 1), the two- year trend was 0.6 percent, and for non-vertically integrated PBM structures (PBM Owner Flag = 0) the two-year trend was -35.1 percent. In aggregate the total two-year trend for the generic specialty drugs in the study were -11.5 percent. While two-year trends are very low for the generic specialty drugs in the study, we acknowledge a disparity between vertically integrated and non-vertically integrated PBM structures still exists.

Exhibit 1. Two-Year Trend Analysis

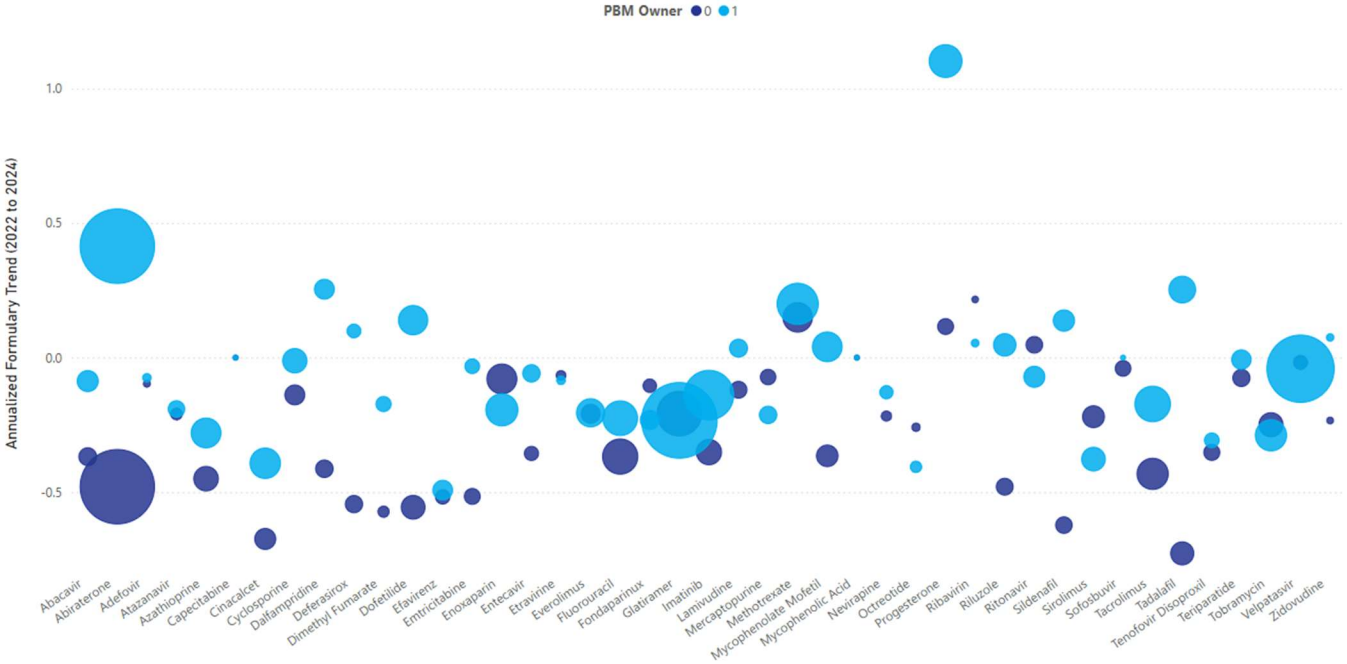


Exhibit 2 compares the prices of these drugs to NADAC for the years 2022, 2023, and 2024. The data shows that the prices in 2024 are lower compared to the previous two years. This comparison underscores the impact of the regulatory changes in reducing drug costs and the aligning prices more closely with the actual acquisition costs.

As shown below, the percent of generic specialty drugs with markup over NADAC below 20 percent for vertically integrated PBM structures has increased from 7.1 percent to 20.4 percent, and for non-vertically integrated PBM structures has increased from 7.1 percent to 11.6 percent (2022 to 2024). Similarly, the percent of generic specialty drugs with markup above 100 percent has decreased from 77.8 percent to 63.3 percent for vertically integrated PBM structures, and for non-vertically integrated PBM structures has decreased from 74.6 percent to 67.3 percent (2022 to 2024). This illustrates a positive movement of generic specialty drugs markups over NADAC. It also illustrates that vertically integrated PBM structures and non-vertically integrated PBM structures have similar distributions of price markups compared to NADAC.

Exhibit 2a. Comparison of Prices to NADAC – Vertically Integrated

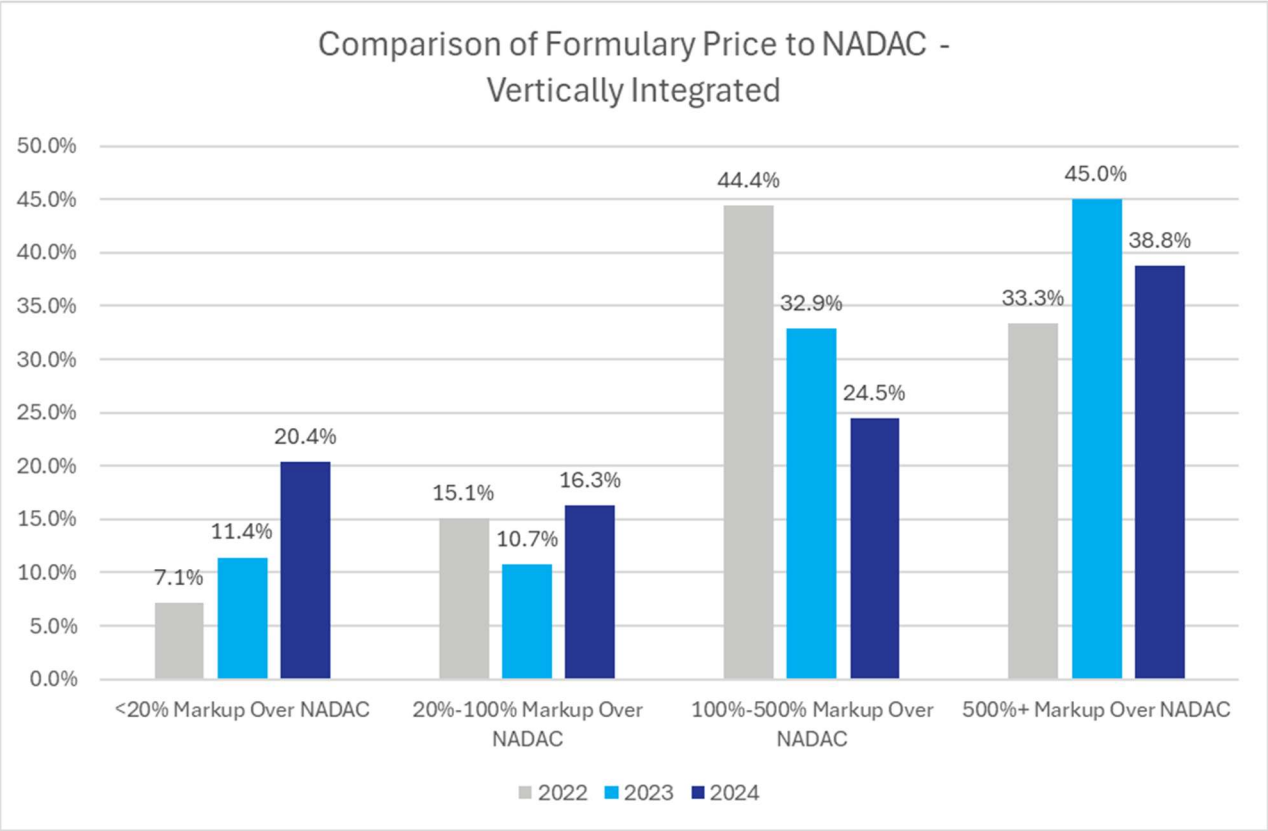
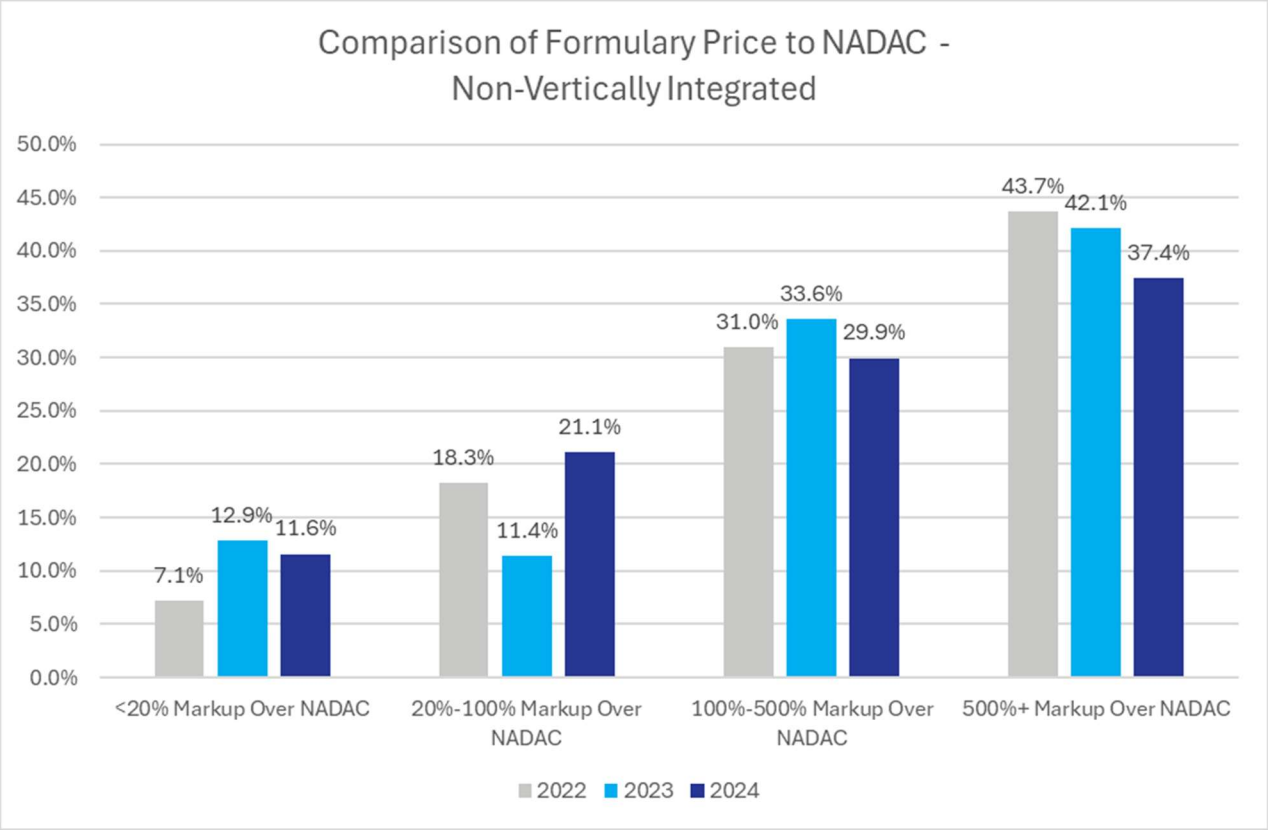


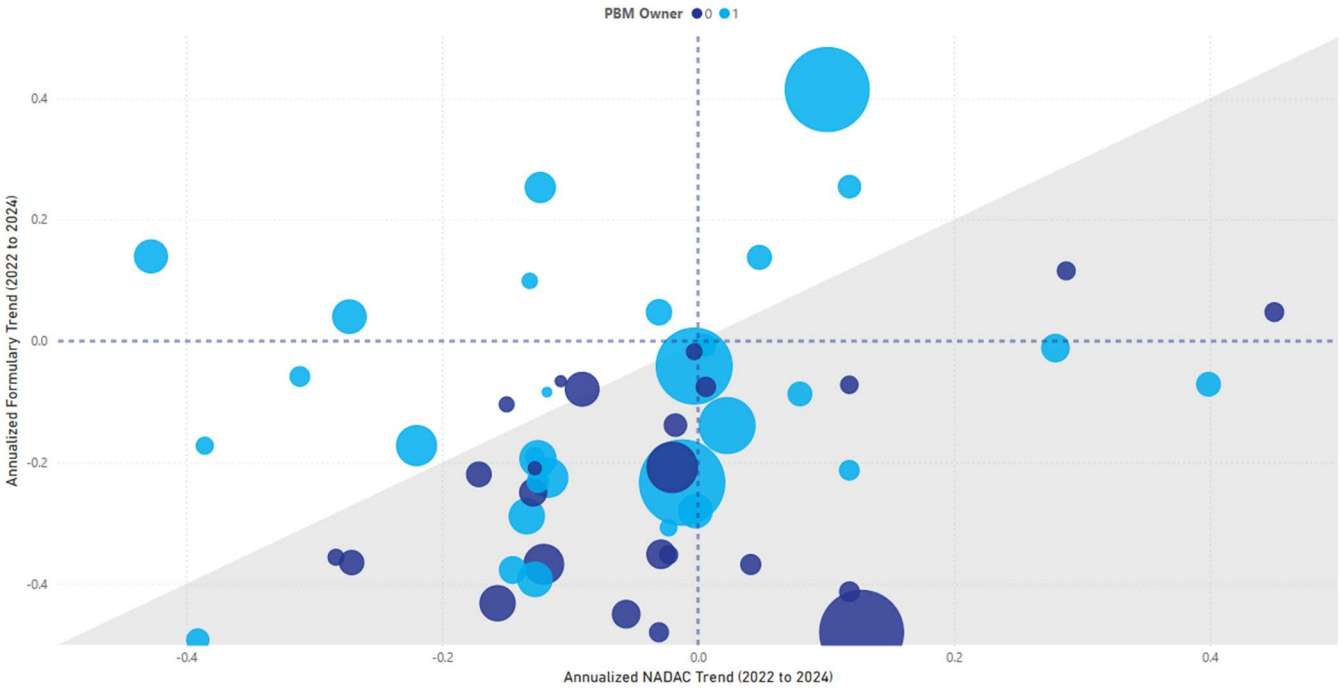
Exhibit 2b. Comparison of Prices to NADAC – Vertically Integrated



While there is certainly room for improvement (as shown in **Exhibit 2**), **Exhibit 3** illustrates a developing positive trend and demonstrates that the pricing trend for these drugs has decreased more significantly than the NADAC trend. This indicates that the reduction in prices is not merely a reflection of broader market trends but is specifically attributable to the elimination of POS DIR. The greater decrease in the pricing trend compared to the NADAC trend further validates the positive impact of the regulatory changes on drug pricing.

While there is positive movement, there are still 12 drugs from vertically integrated structures that have trends above the NADAC trend compared to 22 below the NADAC trend. This is a significant improvement but still evidence that vertically integrated structures are a source of additional markups as only three drugs for non-vertically integrated structures are above NADAC trend. Still, as seen in **Exhibit 3**, the 12 drugs above NADAC represent only 31 percent of the aggregate drug spend in this class (except Abiraterone).

Exhibit 3. Pricing Trend vs. NADAC Trend



As a result, the market has begun to respond, leading to more competitive pricing and greater transparency for many of the generic specialty drugs in the study. This trend is particularly encouraging for patients who rely on specialty generic drugs, as it enhances their access to essential treatments without the financial strain that was previously imposed by inflated prices. While the effectiveness of regulatory interventions in promoting fairer pricing practices and improving the affordability of healthcare are at least somewhat observed, we acknowledge there is still room for continued improvement.

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PBM Reform — Needed or Self-Correcting?

Cost Scale: How Much Do Generic Specialties Contribute?

- According to the CBO and CMS data, specialty generics represent a small share of the total prescription volume.
- The FTC's estimate that PBM-affiliated profits were $7.3 billion over five years implies $1.4 billion/year, not trivial but far from catastrophic systemwide where total pharmacy spend approached $600 Billion in 2023.

Arguments for Reform

- FTC evidence shows systemic steering, self-dealing, and lack of transparency
- Plan sponsors lack visibility into reimbursement rates and cannot assess fair pricing
- Current PBM incentives still reward higher gross drug prices, even on generics

Arguments for Market Correction

- Downward trend of Generic Specialties in Medicare since the passing of H.R. 9096
- Non-Traditional new entrants are creating competitive downward pressure
- Employer coalitions are demanding pass-through models, which may naturally reduce markups

Conclusion for 2026 and Beyond

Reform will likely be incremental, not revolutionary. The FTC's findings will fuel transparency and reporting rules, while market entrants may erode legacy PBM profit centers. However, without structural separation of PBMs and their specialty pharmacies, the underlying conflict of interest will persist.

Special thanks to Nick Cartossa and David Walters for contributions to this paper. Please contact Nick Cartossa at nick.cartossa@wakely.com with any questions or to follow up on any of the concepts presented here.

OUR STORY

Five decades. Wakely began in 1969 and eventually evolved into several successful divisions. In 1999, the actuarial arm became the current-day Wakely Consulting Group, LLC, which specializes in providing actuarial expertise in the healthcare industry. Today, there are few healthcare topics our actuaries cannot tackle.

Wakely is now a subsidiary of Health Management Associates. HMA is an independent, national research and consulting firm specializing in publicly funded healthcare and human services policy, programs, financing, and evaluation. We serve government, public and private providers, health systems, health plans, community-based organizations, institutional investors, foundations, and associations. Every client matters. Every client gets our best. With more than 20 offices and over 400 multidisciplinary consultants coast to coast, our expertise, our services, and our team are always within client reach.

Broad healthcare knowledge. Wakely is experienced in all facets of the healthcare industry, from carriers to providers to governmental agencies. Our employees excel at providing solutions to parties across the spectrum.

Your advocate. Our actuarial experts and policy analysts continually monitor and analyze potential changes to inform our clients' strategies—and propel their success.

Our Vision: To partner with clients to drive business growth, accelerate success, and propel the healthcare industry forward.

Our Mission: We empower our unique team to serve as trusted advisors with a foundation of robust data, advanced analytics, and a comprehensive understanding of the healthcare industry.

Learn more about Wakely Consulting Group at www.wakely.com