THE CAPITOL FORUM

Exclusive Drug Dealing

Anticompetitive Practices in the Pharmaceutical Supply Chain

Published May 2023

A special report containing articles recently **published by The Capitol Forum** as part of an ongoing project analyzing price, market share and generic formulary exclusion data to spot anticompetitive conduct.

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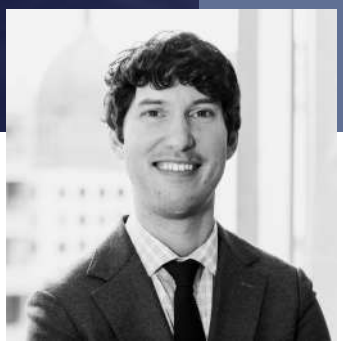


Teddy Downey
Executive Editor & CEO

In the summer of 2022, the FTC announced plans to ramp up enforcement against pharmaceutical companies and pharmacy benefit managers (PBMs), saying that payments from drug companies to PBMs in exchange for exclusionary conduct against generic competition may violate some of the most seminal pieces of antitrust legislation in U.S. history. In particular, the Agency cited Sections 1 and 2 of the Sherman Act, Section 3 of the Clayton Act, Section 5 of the FTC Act and Section 2(c) of the Robinson-Patman Act.

As part of our in-depth investigative reporting on the health care industry, The Capitol Forum has recently launched our Exclusive Drug Dealing Project, which looks at price, market share and generic formulary exclusion data to spot anticompetitive conduct in the pharmaceutical supply chain.

In this special report, we share our findings from an extensive investigation into two treatments for multiple sclerosis - Teva Pharmaceutical Industries' Copaxone and Biogen's Tecfidera - where manufacturers' efforts to exclude generic competitors appear to share similarities with anticompetitive behavior the FTC has recently identified in the insulin market.

Our ongoing project—which uses Centers for Medicare and Medicaid Services data on market share, national and state-level surveys on drug acquisition costs, and insurance plan formularies—will continue to explore exclusionary conduct in pharmaceutical markets in the coming months.

Theodore Downey

About The Capitol Forum

The Capitol Forum is the premier regulatory news organization for staying informed of regulatory developments and their impact on the market. Taking an investigative news approach, our journalists dive into the most complex issues and regulators in the United States, Europe and China, to uncover the key issues companies may face in the global regulatory environment.

CHAPTER 1

Teva's Copaxone - Introduction

Like insulin, Copaxone is an injectable treatment for a chronic health condition that has been available for decades, has undergone little meaningful innovation and continues to carry a hefty out of pocket cost for patients. In 2019, the median annual out-of-pocket cost with Medicare Part D coverage was $6,672 and a back-breaking $102,448 without insurance coverage.

Our investigation into Copaxone expands on work done by the nonprofit research firm 46brooklyn and reporters at The Columbus Dispatch. In particular, that work exposed conflicts of interest for PBMs that lead to perverse outcomes for the healthcare system.

"PBMs control the dials of price, PBMs control the levers of what's covered and what's not, and they control the grease which allows certain drugs to slide through and other ones to be essentially held up through resistance," said Antonio Ciaccia, 46brooklyn CEO and co-founder.

PBMs control the dials of price, PBMs control the levers of what's covered and what's not, and they control the grease which allows certain drugs to slide through and other ones to be essentially held up through resistance

Competitive Analysis - Price & Market Share

Teva's Copaxone (glatiramer acetate) was first approved by the FDA in 1996 as a chemical drug to treat MS.

Teva, which is primarily a generic drug manufacturer, has gone to great lengths to prevent generic competitors to Teva's branded Copaxone from both entering the market and becoming a threat to sales. Anticipating the expiration of its patent exclusivity, the company filed numerous patent infringement lawsuits and offered up multiple FDA citizen petitions. It even went as far as to sue the FDA to delay approval of a generic for its 20mg dose. At the same time, Teva developed a 40mg, three-times-a-week form of Copaxone and launched a crusade to shift patients to the new dose as a way of deterring them from switching to a generic.

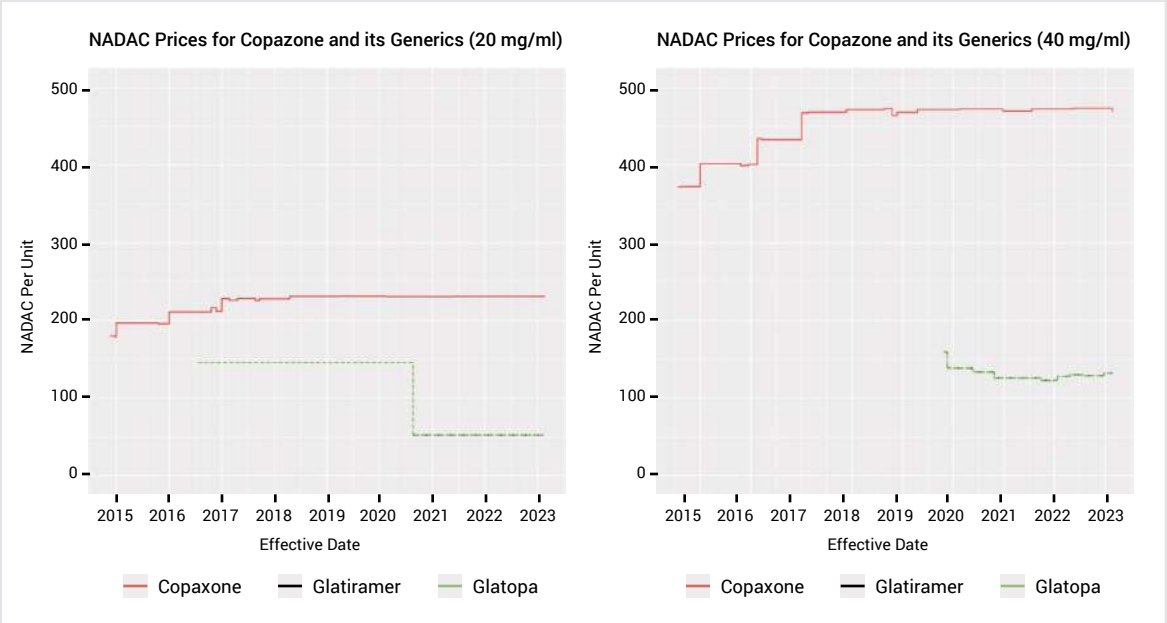
A spokesperson for Teva declined to comment.

Eventually, despite Teva's machinations to frustrate competitors, generics were able to enter the market. But it still took years for them to gain a foothold although they offered lower prices.

The first generic competitor, Sandoz's Glatopa, entered the market in 2015. In 2017, Mylan launched a second generic competitor under the name Glatiramer Acetate.

The figures below show the National Average Drug Acquisition Cost (NADAC) of Copaxone and competing generics Glatopa and Glatiramer Acetate since July 2014. The NADAC reflects the average cost per unit for an outpatient retail pharmacy to acquire the drug, based on voluntary national surveys of independent and chain pharmacies.

NADAC prices are distinct from the list price of a drug, which is set by its manufacturer; they also differ from the cost paid by wholesalers. NADAC does not reflect off-invoice discounts or rebates, but it is widely viewed as the most reliable and useful drug price data available to the public.



Source: Data.Medicaid.gov/NADAC

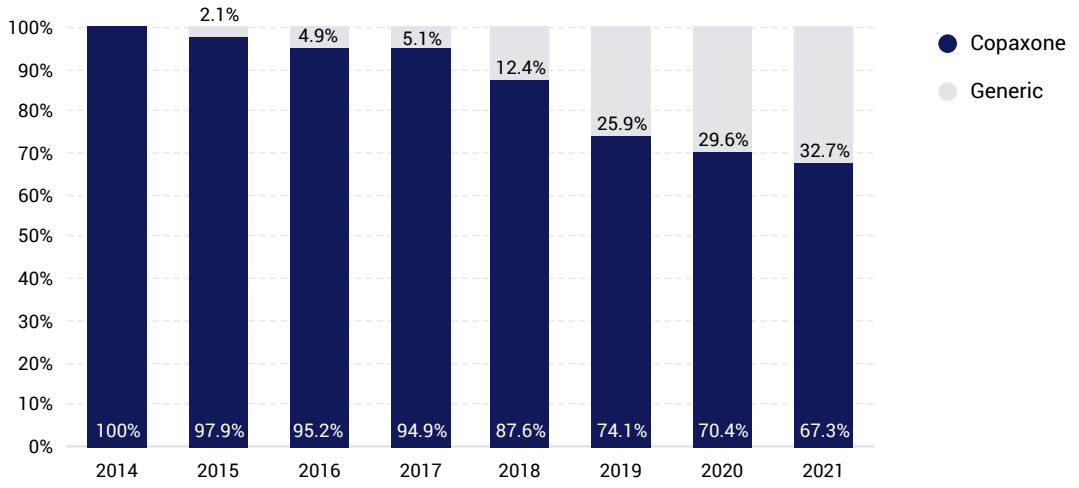
Typically, the entrance of generic competitors disrupts the market power of higher-priced brand-name drugs. "Once a generic enters the market, a brand loses 44% to 90% of its market share within the first twelve months," Rutgers Law Professor Michael Carrier wrote in a 2016 legal article calling out Teva's attempts to extend exclusivity for Copaxone.

> ***Once a generic enters the market, a brand loses 44% to 90% of its market share within the first twelve months***

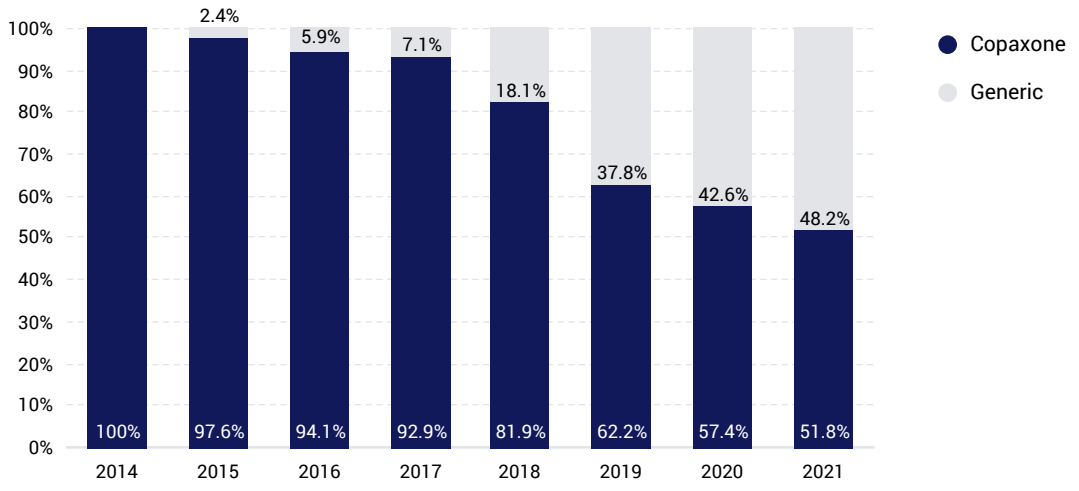
However, despite Copaxone's drastically higher cost as compared with generics, the brand's market position has remained persistently higher than it should in a typical market defined by generic substitution.

The graphs below show market share of spending and claims (utilization) under Medicare Part D for Copaxone and its generic versions from 2014 to 2021, the most recent data available. Though Copaxone's market share has diminished, it still accounted for 67.3% of spending and 51.8% of claims six years after the first generic competitor launched.

Market Share by Spending 2014 - 2021 (glatiramer acetate)



Market Share by Claims 2014 - 2021 (glatiramer acetate)



Source: Medicare Part D Spending by Drug

Since cheaper generic equivalents have been available for years, how does Copaxone maintain its dominance in terms of spending and utilization despite its high price?

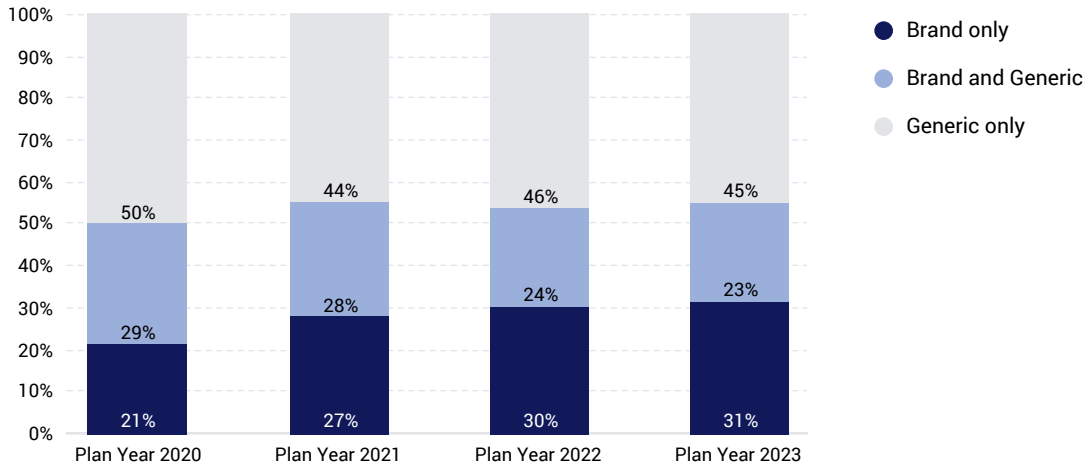
Evidence of formularies excluding generics

As the middlemen in the pharmaceutical supply chain, PBMs claim to use their negotiating power to pass rebate savings on to customers and keep drug prices in check.

But evidence compiled by *The Capitol Forum* shows that PBMs are persistently excluding generic competition from the market, resulting in higher prices and less choice for patients and the healthcare system.

The graph below reveals that although there are cheaper versions of Copaxone available, the percentage of plans that cover the more expensive brand-name product exclusively has increased to nearly one-third of Medicare plans in 2023.

Glatiramer Coverage under Medicare (2020 - 2023)



Source: CMS Prescription Drug Plan Formulary, Pharmacy Network and Pricing Information Files.
Includes Medicare Advantage plans offering drug coverage and Medicare Part D plans. Excludes Special Needs plans.

In 2023, 30.8% of all Medicare enrollees in plans offering drug coverage were in generic-excluding plans.

Of the 16 national Medicare Part D Plans (PDPs), seven covered brand-name Copaxone exclusively. Six of these generic-excluding plans are offered by CVS or Cigna, which own two of the largest PBMs: CVS Caremark and Express Scripts, respectively.

In 2023, 30.8% of all Medicare enrollees in plans offering drug coverage were in generic-excluding plans.

The chart below shows glatiramer acetate coverage by the 16 national PDPs, sorted by enrollment as of February 2023 (largest to smallest). Many of the generic-excluding plans are offered by organizations that own or contract with the three largest PBMs—Express Scripts (Cigna), Caremark (CVS Health) and OptumRx (United Health Group):

PDP Plan	*Glatiramer Acetate Coverage*	*'Big Three' PBMs*
1. SilverScript Choice	Brand only	Caremark
2. Wellcare Value Script	Generic only	Express Scripts
3. SilverScript SmartSaver	Brand only	Caremark
4. Wellcare Classic	Generic only	Express Scripts
5. AARP MedicareRX Preferred	Generic only	Optum Rx
6. Humana Walmart Value RX Plan	Both	———
7. Humana Basic Rx Plan	Both	———
8. Cigna Secure Rx	Brand only	Express Scripts
9. AARP MedicareRx Walgreens	Generic only	Optum Rx
10. AARP MeicareRx Saver Plus	Generic only	Optum Rx
11. Humana Premier Rx Plan	Both	———
12. Wellcare Medicare Rx Value Plus	Generic only	Express Scripts
13. SilverScript Plus	Brand only	Caremark
14. Cigna Extra Rx	Brand only	Express Scripts
15. Cigna Saver Rx	Brand only	Express Scripts
16. Elixir RxSecure	Brand only	———

As of February 2023, the largest stand-alone Medicare PDP was Aetna SilverScript Choice (CVS Caremark), with nearly 3 million enrollees. As the image below shows, this plan's 2023 formulary excludes generic versions of Copaxone:

Multiple Sclerosis Agents	*Drug Tier*	*Requeriments / Limits*
BETASERON	5	QL (14 EA per 28 days) PA
COPAXONE INJ 40MG/ML	5	QL (12 ML per 28 days) PA
COPAXONE INJ 20MG/ML	5	QL (30 ML per 30 days) PA
dalfampridine er	3	PA
fingolimod	5	QL (28 EA per 28 days) PA
GILENYA	5	QL (28 EA per 28 days) PA
OCREVUS	5	QL (20 ml per 180 days) PA LA
TECFIDERA STARTER PACK	5	QL (120 EA per 365 days) PA LA
TECFIDERA CPDR 120MG	5	QL (14 EA per 7 days) PA LA
TECFIDERA CPDR 240MG	5	QL (60 EA per 30 days) PA LA
VUMERITY	5	QL (120 EA per 30 days) PA LA

The third-largest national PDP, Aetna SilverScript SmartSaver (CVS Caremark), also excludes the generic from its 2023 formulary:

Multiple Sclerosis Agents	*Drug Tier*	*Requeriments / Limits*
AUBAGIO	5	QL (30 EA per 30 days) PA LA
BAFIERTAM	5	QL (120 EA per 30 days) PA LA
BETASERON	5	QL (14 EA per 28 days) PA
COPAXONE INJ 40MG/ML	5	QL (12 ML per 28 days) PA
COPAXONE INJ 20MG/ML	5	QL (30 ML per 30 days) PA
dalfampridine er	3	PA
fingolimod	5	QL (28 EA per 28 days) PA
GILENYA	5	QL (28 EA per 28 days) PA
OCREVUS	5	QL (20 ML per 180 days) PA LA

In contrast, the second-largest PDP in the U.S., Centene's Wellcare Value Script, contracts with Express Scripts rather than its in-house PBM and covers both generics but not Copaxone:

Multiple Sclerosis Agents	*Drug Tier*	*Requeriments / Limits*
BETASERON SUBCUTANEOUS KIT 0.3 MG	5^	PA-NS; QL (14 EA per 28 days)

Drug Name	*Drug Tier*	*Requeriments / Limits*
dalfampridine er oral tablet extended release 12 hour 10 mg	3	PA
fingolimod hcl oral capsule 0.5 mg	5^	PA-NS; QL (28 EA per 28 days)
GILENYA ORAL CAPSULE 0.5 MG	5^	PA-NS; QL (28 EA per 28 days)
glatiramer acetate subcutaneous solution prefilled syringe 20 mg/ml	5^	PA-NS; QL (30 ML per 30 days)
glatiramer acetate subcutaneous solution prefilled syringe 40 mg/ml	5^	PA-NS; QL (12 ML per 28 days)
glatopa subcutaneous solution prefilled syringe 20 mg/ml	5^	PA-NS; QL (30 ML per 30 days)
glatopa subcutaneous solution prefilled syringe 40 mg/ml	5^	PA-NS; QL (12 ML per 28 days)
OCREVUS INTRAVENOUS SOLUTION 300 MG/10ML	5^	PA-NS; LA
TECFIDERA ORAL 120 & 240 MG	5^	PA-NS; LA
TECFIDERA ORAL CAPSULE DELAYED RELEASE 120 MG	5^	PA-NS; LA; QL (14 EA per 7 days)
TECFIDERA ORAL CAPSULE DELAYED RELEASE 240 MG	5^	PA-NS; LA; QL (60 EA per 30 days)
VUMERITY ORAL CAPSULE DELAYED RELEASE 231 MG	5^	PA-NS; LA ; QL (120 EA per 30 days)

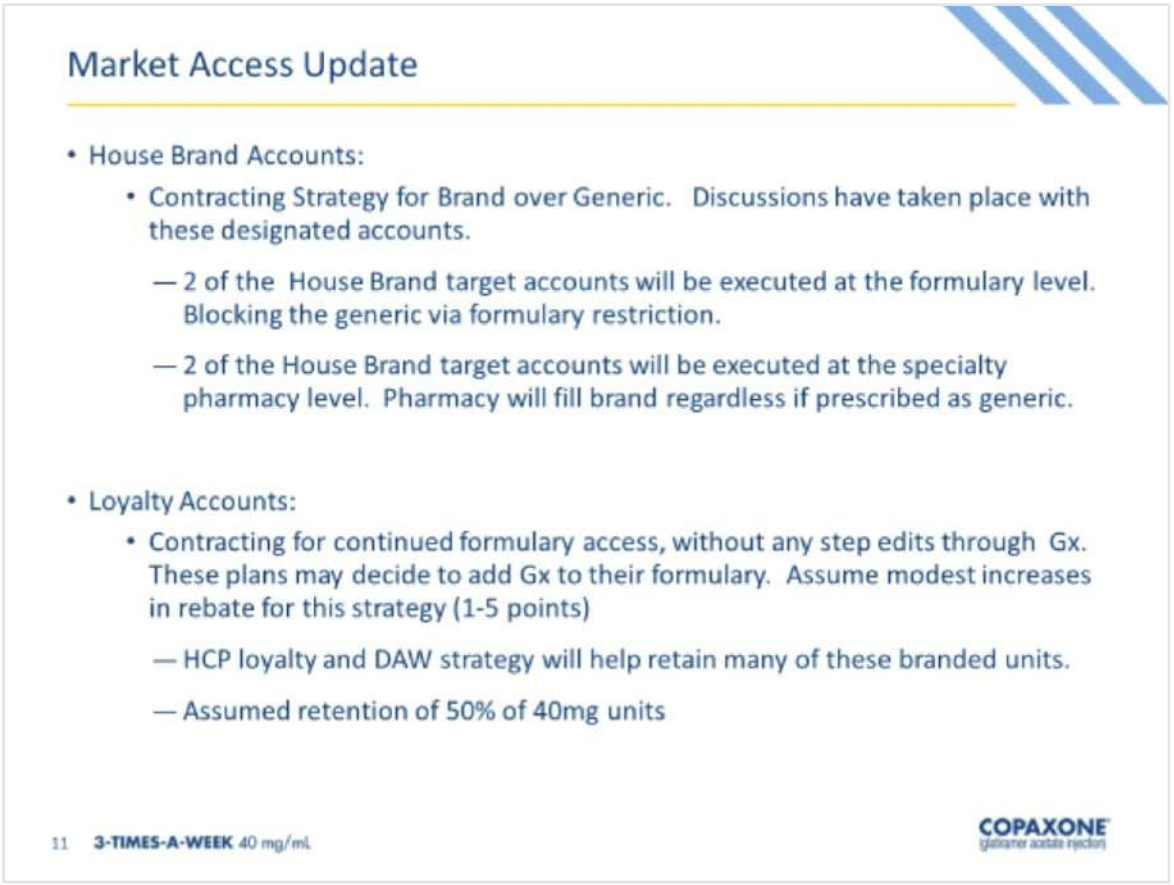
Other evidence of anticompetitive conduct

While the data show factually that PBMs exclude generics from competing with Copaxone, there is a plethora of documentation of exclusionary conduct by Teva related to its protection of Copaxone.

A 2020 investigation into drug pricing by the House Oversight Committee revealed pervasive anticompetitive behavior by drug companies and PBMs, including dealings related to Copaxone.

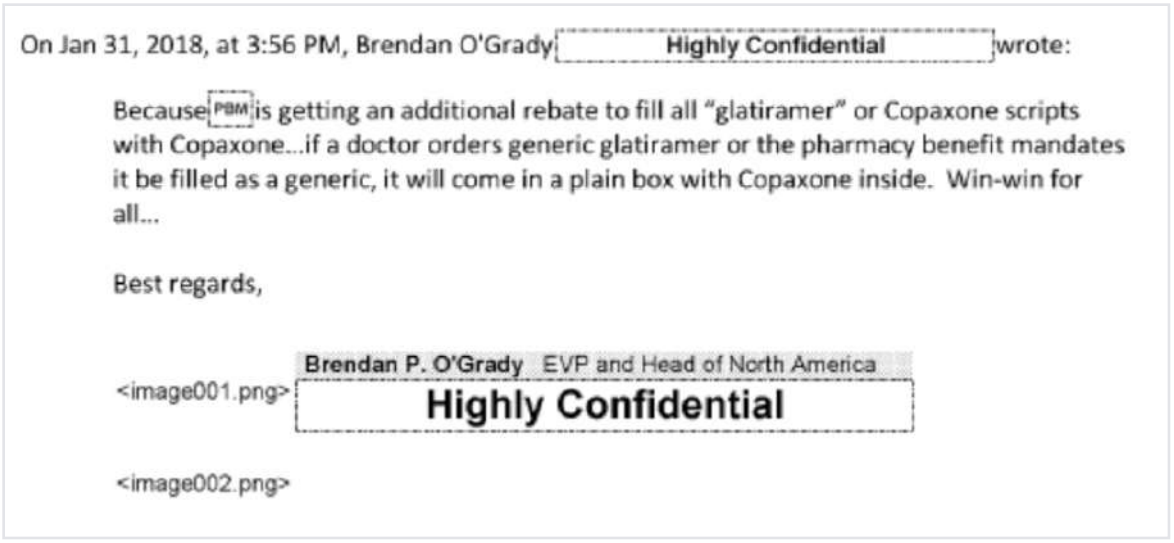
The Committee's report concluded that PBMs and Teva colluded to prevent competition from generic equivalents of Copaxone, citing Teva's internal documents and communications between executives.

Teva's rebates to PBMs were conditioned on the exclusion of generic competitors to Copaxone from formularies, and PBM-owned specialty pharmacies set policies to dispense Teva's product even when the prescription explicitly called for the generic. In fact, Teva dubbed these anticompetitive practices their "House Brand" strategy as detailed in a January 2017 internal presentation:



This one slide from the House investigation reveals several different exclusionary practices—colluding with PBMs to block generics from formularies, colluding with specialty pharmacies to exclude generics and pressuring doctors to write "dispense as written" prescriptions to effectively exclude generic substitution. In a January 2018 email thread designated "highly confidential," Teva EVP for North America Brendan O'Grady explained that, in return for a higher PBM rebate payment, the PBM would ensure the brand drug would be provided even for patients whose doctors specifically requested the generic and when generic substitution was mandated.

…in return for a higher PBM rebate payment, the PBM would ensure the brand drug would be provided even for patients whose doctors specifically requested the generic and when generic substitution was mandated.



On Jan 31, 2018, at 3:56 PM, Brendan O'Grady Highly Confidential wrote:

Because PBM is getting an additional rebate to fill all "glatiramer" or Copaxone scripts with Copaxone…if a doctor orders generic glatiramer or the pharmacy benefit mandates it be filled as a generic, it will come in a plain box with Copaxone inside. Win-win for all…

Best regards,

<image001.png> Brendan P. O'Grady EVP and Head of North America
Highly Confidential

<image002.png>

Effectively, the PBM would engage in fraudulent exclusionary conduct in exchange for a higher rebate. The email calls the situation a "win-win for all." In reality, the situation was a win for Teva and the PBM but came at the expense of increased costs to patients and the healthcare system and was a clear loss for generic competitors.

A 2019 whistleblower lawsuit filed against CVS Health by Alexandra Miller, former senior director of Medicare Part D operations at CVS, includes allegations that align with evidence in the Oversight Committee Report. The lawsuit alleges that CVS Health engaged in an illegal anticompetitive scheme to prevent Medicare beneficiaries from accessing specific generic drugs through its subsidiaries—SilverScript, Caremark PBM and CVS pharmacies. According to the lawsuit, CVS Health and its subsidiaries called the exclusionary plan the "Single Source Generic" (SSG) strategy—a vestigial misnomer in this case since generic Copaxone had been available from multiple sources since 2017.

According to the lawsuit, the redacted PBM in Teva EVP O'Grady's email above was CVS Caremark. CVS Health's SSG strategy is essentially Teva's House Brand strategy, but from the PBM's perspective.

According to the lawsuit, the exclusionary behavior was driven by higher rebates offered by manufacturers of brand-name drugs, including Teva, and made possible by the vertical integration of CVS Health.

Attorneys representing CVS Health in the Miller whistleblower case don't deny that the company excludes generics from formularies. They instead argue that CMS does not explicitly prohibit generic exclusion from formularies.

The 2019 lawsuit also alleges other exclusionary conduct, including CVS denying formulary exception requests made by beneficiaries who sought access to the generic and CVS submitting misleading billing codes to CMS. Allegedly, CVS Health repeatedly used DAW ("dispense as written") code 0, falsely indicating that the generic was dispensed or that no generic alternatives existed.

In addition, a former CVS Part D actuary for SilverScript, a confidential informant in the case, explained that the SSG strategy harmed beneficiaries and Medicare—specifically citing Copaxone as a key source of inflated costs.

Exhibits filed by CVS Health in the lawsuit show that by excluding the generic from the formularies, the out-of-pocket cost for a SilverScript PDP beneficiary of generic Glatiramer Acetate 20mg would be nearly $27,500 more annually than the out-of-pocket cost of brand-name Copaxone 20mg.

Miller, the whistleblowing former CVS executive, claims that when she raised ethical concerns with the SSG strategy, her supervisor informed her that CVS Health's senior leadership had already determined that profits from the strategy outweighed the risk of detection and subsequent government-enforcement.

CVS Health and its subsidiaries Aetna, Caremark and CVS pharmacy did not respond to requests for comment.

Teva is currently the defendant in several other cases related to its efforts to preserve the market power of Copaxone and foreclose generic competition.

Mylan, a manufacturer of the generic competitor Glatiramer Acetate, filed a lawsuit in 2021 accusing Teva of violating the Sherman Act by offering rebates that "went beyond typical, procompetitive rebating practices." According to the complaint, Teva offered rebates to PBM-owned specialty pharmacies to fill prescriptions for the generic with Copaxone—even when the generic was on the formulary. In a joint discovery plan, Teva does not deny the exclusionary conduct but instead argues that its practices are "legitimate forms of competition" which "consumers benefited from."

In July 2018, Mylan lowered the list price of its 40mg generic by 60%, with only a minimal impact on sales. In the 2021 lawsuit, Mylan said that its sales representatives were told that an exclusionary contract between Teva and a large PBM's specialty pharmacy prevented Mylan from gaining market traction with its price reduction. Teva claimed its conduct does not violate any U.S. laws.

A 2022 class action filed in New Jersey by the City of Baltimore alleges that beneficiaries of plans managed by Express Scripts PBM can only fill Copaxone through Accredo, the specialty pharmacy owned by Express Scripts. Express Scripts did not respond to requests for comment.

At least one federal enforcer also has its eye on Teva's Copaxone. In 2020, the DOJ charged Teva under the Anti-Kickback Statute of the False Claims Act with illegally paying Medicare co-pays for Copaxone through donations to third-party "independent foundations." Two organizations implicated in the case against Teva have already settled: specialty pharmacy Advanced Care Scripts Inc. for $3.5 million and The Assistance Fund for $4 million. According to a November 2022 status report meeting, the DOJ's case is expected to go to trial in September.

Antitrust scrutiny of Teva's Copaxone has not been limited to the U.S. In October of last year, the EC sent a statement of objections to Teva asserting the company violated antitrust law by attempting to delay competition for Copaxone.

Experts weigh in on potential FTC Action

In the case of Copaxone, the FTC can look at Copaxone's pricing, market share data, and formularies showing exclusion of generics, and that might be enough evidence to merit investigation of the drug for antitrust violations. But what separates Copaxone from other drugs is the extensive documentation from a Congressional investigation and extensive documentation presented in litigation.

"If the FTC is putting a target on rebating schemes that undermine a vibrant generic marketplace and the savings that it can provide the patients, Copaxone would be dead center," Ciaccia said in an interview with The Capitol Forum.

A spokesperson for the FTC declined to comment, stating that it's against agency policy to comment on specific companies or conduct.

In an interview with The Capitol Forum, Philip Longman, policy director at the Open Markets Institute, was critical of the monopsony power of PBMs and the negative impact exclusionary rebates have on consumers. "Some people used to say that PBMs are forms of legalized bribery," he said. "But strictly speaking, if we were to apply Clayton, Sherman and Robinson-Patman, they wouldn't be legal, they would just be bribery."

> ***Some people used to say that PBMs are forms of legalized bribery.***

"It looks like if you happen to belong to a health care plan that has the wrong PBM, you won't have the option of buying the generic, lower-cost, just-as-good product, and you must buy a brand," Longman said. "And that the reason why only that brand is in your formulary is because somebody paid a bribe."

Still, Robin Feldman, the Arthur J. Goldberg distinguished professor of law and director of the Center for Innovation at UC College of the Law San Francisco, cautions that exclusionary conduct by PBMs can be hard to investigate. "Rebate practices are deeply hidden secrets; even the health plans themselves and the health plans' auditors aren't given full access to the terms of the deals," Feldman said. "That's astounding, given that the PBM represents the health plan in the negotiation—so to say that its own client can't know the details of the deal is extraordinary."

But she noted that the FTC's 6(b) investigation into the PBM industry could provide insight into the industry and improve the agency's odds in antitrust litigation. "It's a rare and powerful form of investigation, because [the FTC] can require companies to not just produce documents they already have, but to create documents and evidence for them," Feldman said. "Section 6(b) investigations have formed the basis for major legislation and policy changes."

The FTC may also be emboldened by a recent decision in court on the Miller whistleblower case in which the judge ruled against Teva's motion to dismiss on March 10, 2023. The judge did not mince words in articulating the problem that collusion between pharmaceutical companies and PBMs might represent to the healthcare system: "The Government designed the Medicare Part D system to decrease costs through market competition. It did not envision a system where the Government's costs were purposefully increased by potential bad actors or merged companies who colluded and took steps at every level of the corporate Medicare reimbursement chain to profiteer at the Government's expense and prevent detection. It also did not envision a system where Medicare Part D beneficiaries, many of whom are receiving low-income subsidies, are prevented from getting critical and lifesaving prescription drugs because market-dominating affiliated companies, to extract more federal funds, conspired and denied access to less expensive, therapeutic equivalents."

CHAPTER 2

Biogen's Tecfidera - Introduction

Biogen's (BIIB) Tecfidera (dimethyl fumarate) received FDA approval in 2013 as a treatment for relapsing forms of multiple sclerosis. Biogen enjoyed several lucrative years of monopoly pricing—Tecifdera was the company's highest-revenue drug from 2015 until 2019, when it generated $3.3 billion in revenues in the U.S. alone.

As patent protection was set to expire, Biogen tried to defend Tecfidera's market exclusivity. In 2019, anticipating generics, Biogen launched another MS drug called Vumerity in what drug-pricing research firm 46brooklyn described as a "prototypical example of a product hop."

Tecifdera was the company's highest-revenue drug from 2015 until 2019, when it generated $3.3 billion in revenues in the U.S. alone.

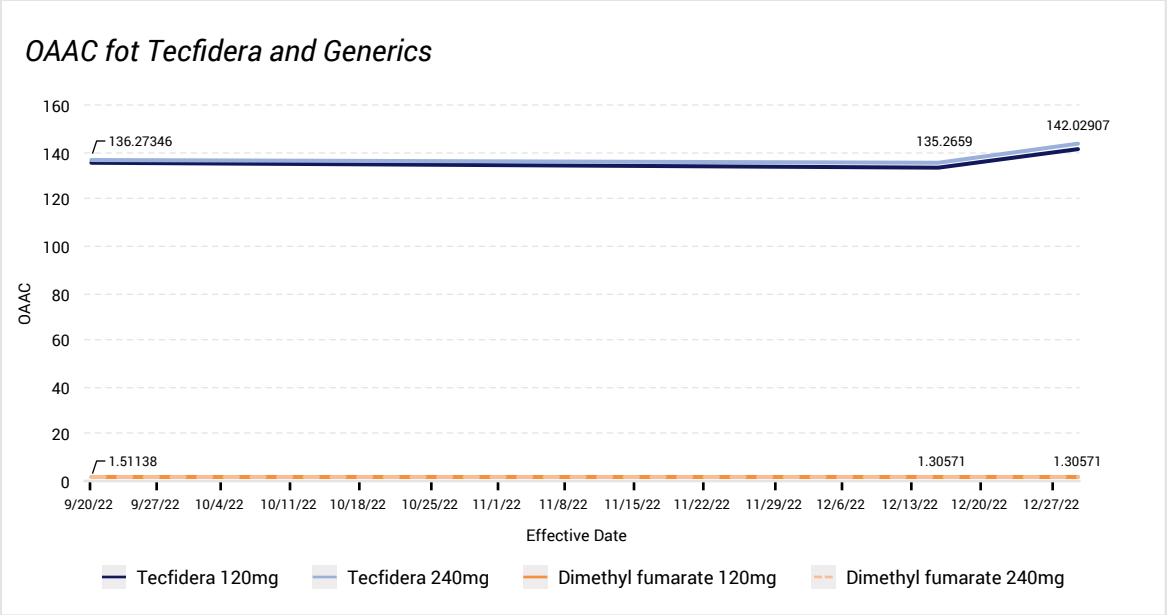
Biogen also attempted to protect its Tecfidera patent through a series of legal challenges. The company appealed a 2020 ruling favorable to generic drugmaker Mylan (now Viatris), but the appeal was denied, as was Biogen's request for a rehearing. Finally, the Supreme Court decisively acted in favor of generic competition by deciding not to hear Biogen's case.

The FDA approved the first generic version of Tecfidera, Mylan's 120- and 240-mg delayed release oral capsules of dimethyl fumarate, in August 2020. Other manufacturers followed: there are now 13 companies with generic versions of dimethyl fumarate on the market.

Competitive Analysis - Price & Market Share

Brand-name Tecfidera is not in the National Average Drug Acquisition Cost (NADAC) database—likely a result of the drug being steered to the specialty pharmacy channel. However, the state of Ohio provides a comparable measure: Ohio Average Acquisition Cost (OAAC), based on a semiannual survey of pharmacy providers. This price metric may be more comprehensive than NADAC because it includes specialty pharmacies and is compulsory.

As the graph below shows, the price differential (per capsule) is so great that it's actually difficult to see how low-priced the generics are.



Source: OAAC

Similarly, the NADAC database shows low average drug acquisition costs for generic dimethyl fumarate—about $2 for a 240 mg pill in January 2023, and $0.47 in February.

One would think that entry of cheaper generics would push the branded drug's cost down in order to compete, but pharmaceutical markets are often characterized by unique behavior; branded drugs typically compete with generics indirectly through rebates. Tecfidera is no exception.

Brand-name Tecfidera also sustained high out-of-pocket prices for patients even after generics entered the market. In 2019, the median annual out-of-pocket cost for Tecfidera was $6,595 for Medicare PDP beneficiaries—and $106,070 without insurance. Looking at 2023, The Capitol Forum estimated the median out-of-pocket cost at $7,276 for Medicare PDP beneficiaries, and $97,020 without insurance.

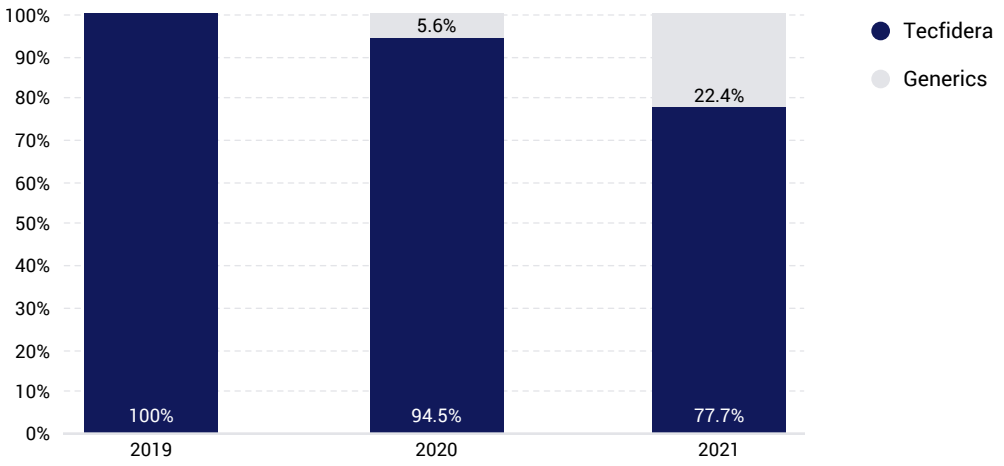
By way of comparison, for 2023, the median annual average out-of-pocket cost for generic dimethyl fumarate is $1,785 cheaper than the brand name for Medicare PDP enrollees, and $17,960 cheaper without insurance.

By way of comparison, for 2023, the median annual average out-of-pocket cost for generic dimethyl fumarate is $1,785 cheaper than the brand name for Medicare PDP enrollees, and $17,960 cheaper without insurance.

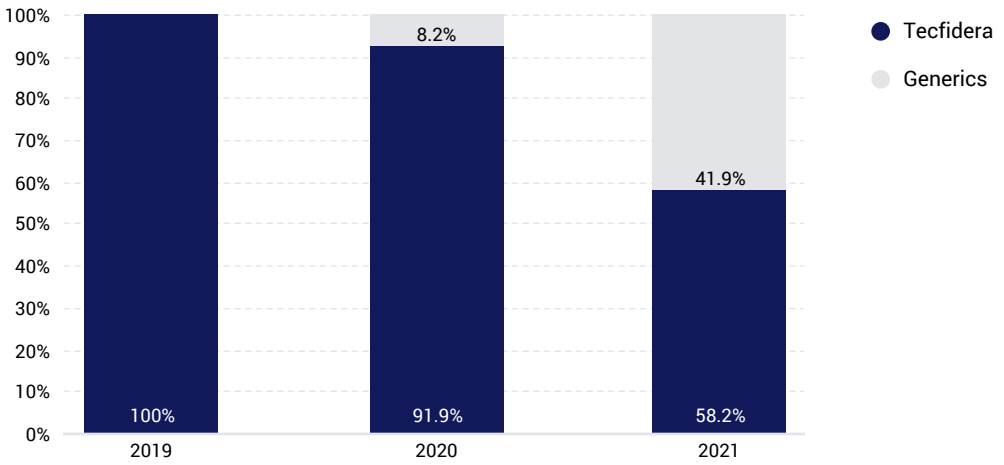
Not only has the brand-name drug sustained a high price in the face of generics with lower acquisition costs, but Tecfidera represents an outsize share of the Medicare Part D market.

When a generic enters the market, the brand-name drug is expected to lose 44% to 90% of its market share in the first year of competition, as purchasers gravitate toward cheaper versions of the drug. Tecfidera lost some ground in the Medicare Part D marketplace after generic entry, but held onto more than expected. To have the branded price remain twenty times greater for the 120mg generic and over 100x greater for the 240mg generic would, in a functioning market, decimate the market share for any other commodity.

Market Share by Part D Spending 2019 - 2021 (Dimethyl Fumarate)



Market Share by Part D Claims 2019 - 2021 (Dimethyl Fumarate)



Source: Medicare Part D Spending by Drug

Despite costing pharmacies and patients significantly more, Tecfidera has held onto a significant portion of the market in the face of generic competition.

Evidence of formularies excluding generics

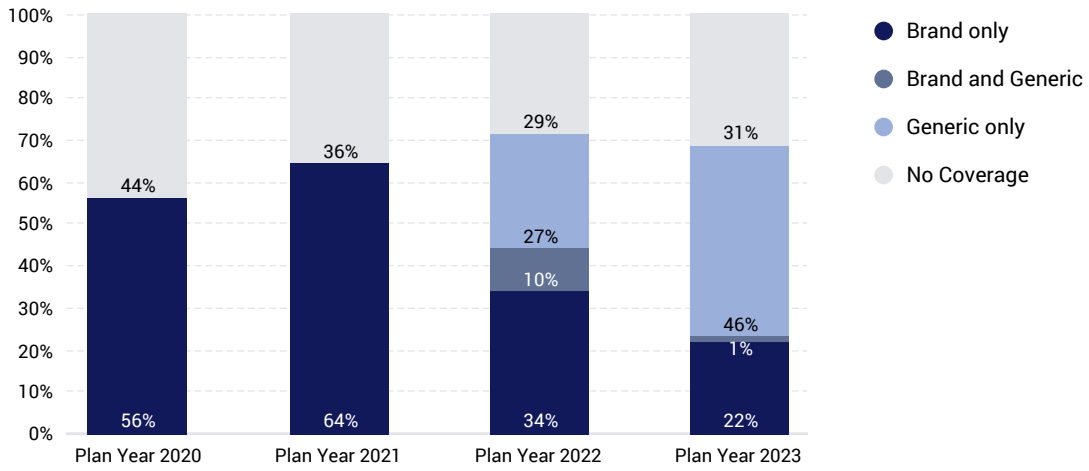
As the middlemen in the pharmaceutical supply chain, PBMs claim to use their negotiating power to keep premiums and drug prices in check.

However, PBMs are subject to certain perverse incentives. Recent scrutiny has focused on rebates paid by drugmakers, in exchange for which PBMs give brand-name drugs more favorable positions on formularies or exclude generic versions.

Because manufacturers rely on their drugs being covered by insurance plans, "PBMs have huge control over how much the sales revenue will be for specific drugs," said Ge Bai, professor at Johns Hopkins Carey Business School and Bloomberg School of Public Health. "That's how you please PBMs, you can bribe them into giving you a good position on the formulary."

The graph below shows coverage of Tecfidera and its generics in Medicare plans offering drug coverage. In 2023, 22% of plans covered brand-name Tecfidera exclusively.

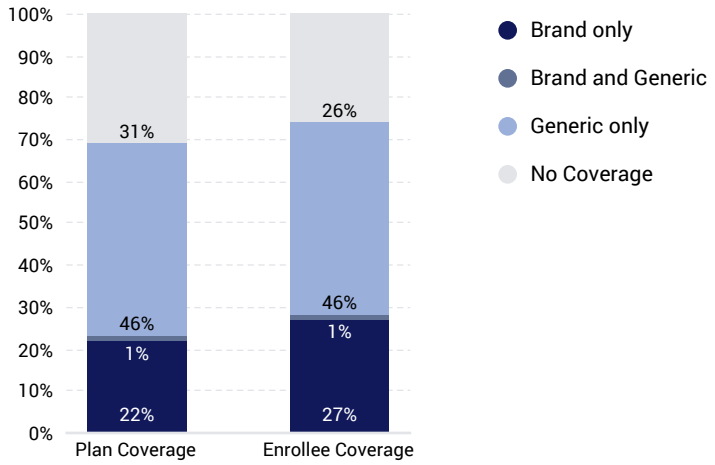
Dimethyl Fumarate Coverage Under Medicare (2020 - 2023)



Source: Medicare Part D Spending by Drug. Includes Medicare Advantage plans offering drug coverage and Medicare Part D plans. Excludes Special Needs plans; semented MA plans are aggregated.

Analyzing dimethyl fumarate access through the lens of actual patient lives paints an even starker picture: plans that exclusively cover brand-name Tecfidera account for 27% of all lives covered by all Medicare plans in Q4 2022.

Dimethyl Fumarate Coverage Under Medicare (Most Recent Data)



Source: CMS Prescription Drug Plan Formulary, Pharmacy Network, and Pricing Information Files (Q4 2022) and CMS Enrollment Files (March 2023). Includes Medicare Advantage plans offering drug coverage and Medicare Part D plans. Excludes Special Needs plans; segmented MA plans are aggregated in enrollment data.

The table below shows dimethyl fumarate coverage in 2023 for the 16 national PDPs. All the generic-excluding plans are offered by organizations who own or contract with two of the three largest PBMs—Express Scripts (Cigna) and Caremark (CVS Health).

Of the 10 national PDP plans that cover dimethyl fumarate, half exclude the generic version. In the table below, the 16 national plans are sorted by enrollment as of March 2023, largest to smallest. Generic-excluding national PDP plans account for 34% of all PDP enrollees.

> ***Of the 10 national PDP plans that cover dimethyl fumarate, half exclude the generic version.***

Plan	*Big Three PBM*	*Tecfidera Coverage*
1. SilverScript Choice	Caremark	Brand only
2. Wellcare Value Script	Express Scripts	Brand only
3. SilverScript SmartSaver	Caremark	Neither
4. Wellcare Classic	Express Scripts	Brand only
5. AARP MedicareRX Preferred	Optum Rx	Generic only
6. Humana Walmart Value RX Plan	N/A	Neither
7. Humana Basic Rx Plan	N/A	Generic only
8. Cigna Secure Rx	Express Scripts	Neither
9. AARP MedicareRx Walgreens	Optum Rx	Generic only
10. AARP MeicareRx Saver Plus	Optum Rx	Generic only
11. Humana Premier Rx Plan	N/A	Generic only
12. Wellcare Medicare Rx Value Plus	Express Scripts	Brand only
13. SilverScript Plus	Caremark	Brand only
14. Cigna Extra Rx	Express Scripts	Neither
15. Cigna Saver Rx	Express Scripts	Neither
16. Elixir RxSecure	N/A	Neither

Source: CMS Enrollment Data and Plan Formularies.

As of March 2023, the largest stand-alone national Medicare PDP was Aetna SilverScript Choice (CVS Caremark), with nearly 3 million enrollees. This plan's formulary excludes generic dimethyl fumarate:

Multiple Sclerosis Agents	*Drug Tier*	*Requeriments / Limits*
BETASERON	5	QL (14 EA per 28 days) PA
COPAXONE INJ 40MG/ML	5	QL (12 ML per 28 days) PA
COPAXONE INJ 20MG/ML	5	QL (30 ML per 30 days) PA
dalfampridine er	3	PA
fingolimod	5	QL (28 EA per 28 days) PA
GILENYA	5	QL (28 EA per 28 days) PA
OCREVUS	5	QL (20 ml per 180 days) PA LA
TECFIDERA STARTER PACK	5	QL (120 EA per 365 days) PA LA
TECFIDERA CPDR 120MG	5	QL (14 EA per 7 days) PA LA
TECFIDERA CPDR 240MG	5	QL (60 EA per 30 days) PA LA
VUMERITY	5	QL (120 EA per 30 days) PA LA

So does the formulary for the second-largest national plan, Wellcare Value Script (Express Scripts), which covers about 2.5 million enrollees:

Multiple Sclerosis Agents	*Drug Tier*	*Requeriments / Limits*
BETASERON SUBCUTANEOUS KIT 0.3 MG	5^	PA-NS; QL (14 EA per 28 days)

Drug Name	*Drug Tier*	*Requeriments / Limits*
dalfampridine er oral tablet extended release 12 hour 10 mg	3	PA
fingolimod hcl oral capsule 0.5 mg	5^	PA-NS; QL (28 EA per 28 days)
GILENYA ORAL CAPSULE 0.5 MG	5^	PA-NS; QL (28 EA per 28 days)
glatiramer acetate subcutaneous solution prefilled syringe 20 mg/ml	5^	PA-NS; QL (30 ML per 30 days)
glatiramer acetate subcutaneous solution prefilled syringe 40 mg/ml	5^	PA-NS; QL (12 ML per 28 days)
glatopa subcutaneous solution prefilled syringe 20 mg/ml	5^	PA-NS; QL (30 ML per 30 days)
glatopa subcutaneous solution prefilled syringe 40 mg/ml	5^	PA-NS; QL (12 ML per 28 days)
OCREVUS INTRAVENOUS SOLUTION 300 MG/10ML	5^	PA-NS; LA
TECFIDERA ORAL 120 & 240 MG	5^	PA-NS; LA
TECFIDERA ORAL CAPSULE DELAYED RELEASE 120 MG	5^	PA-NS; LA; QL (14 EA per 7 days)
TECFIDERA ORAL CAPSULE DELAYED RELEASE 240 MG	5^	PA-NS; LA; QL (60 EA per 30 days)
VUMERITY ORAL CAPSULE DELAYED RELEASE 231 MG	5^	PA-NS; LA; QL (120 EA per 30 days)

By contrast, the formulary for the third-largest plan, Aetna SilverScript SmartSaver (CVS Caremark), with about 1.5 million enrollees, covers neither the brand-name nor generic:

Multiple Sclerosis Agents	*Drug Tier*	*Requeriments / Limits*
AUBAGIO	5	QL (30 EA per 30 days) PA LA
BAFIERTAM	5	QL (120 EA per 30 days) PA LA
BETASERON	5	QL (14 EA per 28 days) PA
COPAXONE INJ 40MG/ML	5	QL (12 ML per 28 days) PA
COPAXONE INJ 20MG/ML	5	QL (30 ML per 30 days) PA
dalfampridine er	3	PA
fingolimod	5	QL (28 EA per 28 days) PA
GILENYA	5	QL (28 EA per 28 days) PA
OCREVUS	5	QL (20 ML per 180 days) PA LA

Why would a lower-cost drug with the same clinical efficacy be excluded from a formulary?

"That's all because of the PBM's incentive," Bai said. "One thing for sure is that in these cases, PBMs prefer the high-list price, high-rebate drugs because they benefit from it."

Dr. Mariana Socal, associate scientist at Johns Hopkins Bloomberg School of Public Health and Bai's colleague, concurred, "All of these decisions, from our perspective, we understand them as being driven or incentivized by rebate negotiations."

Spokespeople for Aetna, CVS Health, Wellcare and Express Scripts did not respond to requests for comment.

Other evidence of anticompetitive conduct

Lawsuits highlight Biogen's history of allegedly anticompetitive behavior with Tecfidera. Tecfidera pricing, and Biogen's actions to promote the drug, have drawn scrutiny from the government and private plaintiffs alike.

In 2017, noting that prices for many brand-name MS drugs had skyrocketed despite competition, Democrats from the House Committee on Oversight and Government Reform requested information on profits, rebates and pricing practices from MS drug manufacturers. Their letter to Biogen cites a 52% increase in Tecfidera's price between 2013 and 2017.

The Capitol Forum was unable to identify any subsequent activity that came of this effort.

A 2015 whistleblower lawsuit alleged that Biogen violated the False Claims Act by paying kickbacks to physicians so that they would prescribe Biogen drugs, including Tecfidera. The case was settled in 2022 for $900 million; Biogen did not admit liability.

Biogen has also come under fire for its patient assistance programs for Tecfidera. Through these programs, drugmakers help cover copays for their brand-name drugs, often using third-party or charitable foundations. This helps drugmakers retain market share, drive sales and manage public relations.

A 2017 whistleblower lawsuit brought by a former Biogen executive alleges that Biogen violated the federal Anti-Kickback Statute, state anti-kickback laws and the False Claims Act to improperly promote use of several MS drugs—Tecfidera, Avonex and Tysabri. According to the lawsuit, Biogen knowingly "seeded" use of its drugs by providing free product to uninsured patients.

Then, Biogen "swept" these patients into government programs such as Medicare Part D, a process expedited by a plethora of specialty pharmacies who are listed as defendants.

Finally, Biogen funneled donations through "charity patient assistance programs" to offset these patients' copays—and profited off the resulting Medicare claims for its drugs. A Q4 2014 analysis, cited in the lawsuit, showed an $18 "return on investment" for Tecfidera claims per $1 donated to "charity."

A Q4 2014 analysis, cited in the lawsuit, showed an $18 "return on investment" for Tecfidera claims per $1 donated to "charity".

The lawsuit also alleges that Biogen launched a large Tecfidera sweep—enrolling 3,330 patients in Medicare in the first quarter of 2015—to offset patient, doctor and investor concerns following a reported drug safety incident. (Another case alleges that Biogen executives misled investors about the safety and usage rates of Tecfidera in light of the incident, but it was dismissed.)

SEC filings show that Tecfidera earnings continued to grow between 2013 and 2020, as sales volume and drug prices crept upwards. Meanwhile, Biogen's lucrative patient assistance programs were garnering concern from the DOJ. In December 2016, Biogen was subpoenaed for information on these programs for Tecfidera, according to an SEC filing.

The DOJ intervened to settle the whistleblower suit in 2020. Biogen settled for $22 million, while specialty pharmacy Advanced Care Scripts, another defendant implicated in the lawsuit, settled for $1.4 million.

A 2021 lawsuit filed by Humana against Biogen seeks damages for overpayments in their Medicare plans incurred because of the same scheme. Exhibits in this case show claims for Biogen prescriptions filled through Humana's pharmacy, with the copays subsidized by the patient assistance programs referenced in the case against Biogen—Chronic Disease Fund Inc. and The Assistance Fund Inc.

Rx Fill Date	*Copay Foundation*	*Drug Cost*	*Copay Subsidy*
9/9/2015	Chronic Disease Fund	$6,048.73	$237.33
10/18/2015	The Assistance Fund	$6,048.73	$267.33
11/9/2015	The Assistance Fund	$6,048.73	$257.33
12/9/2015	Chronic Disease Fund	$6,048.73	$267.33
12/31/2015	The Assistance Fund	$6,048.73	$277.75
1/2/2016	Chronic Disease Fund	$6,048.73	$2,087.79
1/4/2016	The Assistance Fund	$6,048.73	$2,102.59
1/5/2016	Chronic Disease Fund	$6,048.73	$2,102.59
1/6/2016	Chronic Disease Fund	$6,048.73	$2,082.59
1/14/2016	Chronic Disease Fund	$6,048.73	$2,103.80
1/25/2016	Chronic Disease Fund	$6,048.73	$876.23
1/25/2016	The Assistance Fund	$6,048.73	$2,184.23
2/6/2016	The Assistance Fund	$6,048.73	$948.59
2/13/2016	The Assistance Fund	$6,048.73	$653.40
2/20/2016	Chronic Disease Fund	$6,048.73	$1,990.69
3/2/2016	The Assistance Fund	$6,048.73	$929.87
3/5/2016	Chronic Disease Fund	$6,048.73	$277.75
3/23/2016	The Assistance Fund	$6,048.73	$277.75

Source: Exhibit A, Humana, Inc. V. Biogen, Inc.

Biogen did not respond to a request for comment on this article.

Experts weigh in on potential FTC Action

Tecfidera could be the target of an FTC probe based on counterintuitive market behavior, according to Bai: "It seems like a good candidate for investigation because we see some abnormal placement pattern, and it's also an expensive drug," she said. "[We] see some inefficient or abnormal placement pattern that's just contrary to conventional wisdom. So that really raises the red flag for FTC to investigate. Obviously, this drug has relatively high chance."

46brooklyn CEO Antonio Ciaccia agreed: "Without a doubt, the pricing manipulation that we see on brand and generic Tecfidera are an excellent case study for drug pricing dysfunction and well within FTC's purview when it comes to examining some of the dynamics that result in patients and plan sponsors paying more than they should on medicines."

Daniel Hartung, professor at Oregon State College of Pharmacy, said the formulary exclusion of generics for Tecfidera is "worth looking into" from an anticompetitive perspective.

"It does seem problematic to me that Part D plans would be excluding, on the face, what appear to be substantially lower-priced medications in favor of very expensive medications, because there's financial incentives for them to pay for the brand—ultimately to the detriment of the federal government, and perhaps the payer or the patient, who have to pony up more out-of-pocket for a branded drug," Hartung said.

Hartung, who has studied the continued dominance of Copaxone (glatiramer acetate) after generic entry, noted that, "For this general class of medications historically, the lack of generics has been a huge source of potential reasons why the pricing is so out of whack.

The emergence of generics in this [MS] class has been a very welcome addition." He added that the "chicanery" of limiting access to generics, "is disappointing from an economic and patient perspective and access to drugs perspective."

An FTC spokesperson declined to comment on exclusionary practices surrounding Tecfidera.

A recent amicus brief filed by the FTC affirmed that "exclusion of a generic competitor harms not only that competitor, but also competition and consumers more generally."

Bai explained how rebate schemes and specialty drug tiering hurt patients. "If you're a sick patient, your problem comes because your cost-sharing, the coinsurance copayments are linked to the list price which is before any rebates," she said.

The FTC amicus brief also highlighted the impact of generic exclusion on government spending, which is certainly of concern with Tecfidera. On average, in 2021, Medicare Part D spent $69,525 per beneficiary and $8,927 per claim for Tecfidera, and $22,322 per beneficiary and $3,585 per claim for generic dimethyl fumarate.

"In looking at the Medicare dashboard, it is obvious that the drug spend for individual Part D (self-administered) specialty drugs, handled through PBMs, is much higher than the individual drug spend for Part B (provider-administered) drugs that is not handled through PBMs," said Madelaine Feldman, immediate past president of the Coalition of State Rheumatology Organizations.

High list prices for brand-name drugs are reflective of rebates paid from manufacturers to PBMs in exchange for favorable formulary placement, Bai said.

"The manufacturers are really at the mercy of PBMs," Bai said. "You're going to increase your list price, and then you increase your rebate so you have a bigger and bigger gap between the list price and net price."

Socal said rebate schemes are not observed uniformly across the branded drug landscape—or throughout an individual drug's lifetime.

"Is it fact that any high-cost drug offers a large rebate? That's not true. Companies really only offer large rebates when they have some form of meaningful competition," she said. "Before competition comes in, they're not providing rebates, maybe rebates of like 5%. All of a sudden, the competition comes and overnight now, they're giving a 70% rebate."

Beyond the FTC's enforcement statement targeting generic-excluding rebate schemes, the agency's broad inquiry into PBMs highlights additional areas of concern, including specialty drug practices.

PBMs often use specialty drug designation to steer drugs through specialty pharmacies that they own—allowing them to control prices for both branded and generic drugs and optimize for rebates. Any consideration of PBM practices should pay particular attention to the specialty drug channel, sources said.

"[The specialty drug space] is more prone to PBM control because of the affiliated pharmacy issue, and then also the dollar amount is higher," Bai said. "If the PBM tried to squeeze dollar amount from the supply chain, specialty pharmacy would be the best candidate simply because the dollar amount is higher."

Both Tecfidera and its generics are designated as "specialty" on many formularies. However, an oral medication like Tecfidera may not even belong on the specialty tier: "The whole term 'specialty' has been distorted to a big extent," Hartung said. "It used to be specialty because the drugs required special handling or needed to be refrigerated, but now it's just kind of synonymous to expensive drugs—be it oral branded, and, apparently now, generic, drugs."

The fact that data for Tecfidera is not available in NADAC is a smoking gun for this issue, according to Ciaccia.

"NADAC is a representation of retail pharmacy prices. What that means is that drugs that don't have NADAC are good candidates for drugs that are being steered out of the retail channel and into the PBM channel," Ciaccia said.

Vertical integration of PBMs, insurers, and pharmacies limits competition, especially because these anticompetitive practices can prove so lucrative, Feldman said.

"Vertical integration of PBMs, insurers, and pharmacies limits competition in the health insurance space, because these lucrative health insurance entities control the medical side of insurance, the pharmacy network, the formulary construction—and now they have employed physicians and clinics and even data analytic systems," Feldman said.

"PBMs started out adjudicating claims and figuring out how to cover expensive medicines, all good intentions. But they've evolved into money-making machines," Feldman said. "When you combine the PBM money-making machine with every other aspect of the health insurance sphere, not only is it anticompetitive with perverse incentives to put higher price drugs on the formulary—you end up with a big black box that's making lots of money with absolutely no transparency on the money trail."

Socal sees Tecfidera as a "good example" of generic-excluding rebate schemes, but noted that vertical integration may make it particularly difficult for the FTC to investigate.

"I think a very important challenge to this investigation, is that currently there's such a strong vertical integration between the PBM and the health insurer and the pharmacy, and the mail order—the specialty pharmacy—that I believe it is going to be operationally very difficult, in some cases, to obtain the full information that is needed to disentangle all of these relationships."