The Flawed Design of Medicare Part D: A Copaxone Case Study



Pop quiz: Are generic drugs cheaper than brand drugs?

If you are new to the intricacies of U.S. drug pricing (and therefore, applying common sense to your answer) your initial reaction probably is, "Of course! There is nothing at all distinctive about a generic drug. It is ... well ... generic. Brands are protected by patents and exclusivity, which of course makes them more expensive."

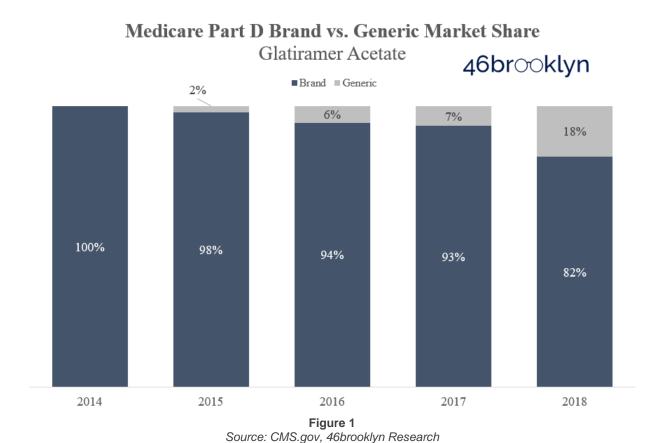
Unfortunately, logic does not prevail when it comes to prescription drug pricing in the U.S. The answer to the question of whether generic drugs are cheaper than brand drugs is actually, "it depends."

It depends on how many <u>rebate dollars</u> the brand drugmaker is willing to offer to a <u>pharmacy benefit manager (PBM)</u> to secure formulary placement viz-a-viz its generic competition. It also depends on what insurance card you have in your wallet. If you're on your employer's plan, rebates may be the only distorting factor. But if you are one of the 47 million seniors enrolled in plans that provide the Medicare Part D drug benefit, which one is cheaper for you depends less on the drug's cost and more on the byzantine Part D cost-sharing math, which as we will illustrate in this report, can make a brand cheaper than its generic equivalent **before** factoring in rebates.

Zombie Brands

Between rebates and the complex Part D cost share structure, the U.S. has created a new class of drugs – we'll call them **zombie brands**. A zombie brand is a brand drug that has lost its patents and market exclusivity, but <u>somehow just keeps on selling</u>. You can throw as many generics at it as you want, and it may be leaking rebate dollars from every orifice, but it just keeps lumbering along, sucking up as much utilization and cash as possible.

Copaxone (glatiramer acetate) – a medication used to treat certain types of multiple sclerosis (MS) – is a zombie brand. But it's not just your normal run-of-the-mill zombie brand. Teva's Copaxone – approved way back in 1996 – is the king of zombie brands, with more than \$1.2 billion in 2018 Medicare Part D sales. That would be impressive for any brand. But it's even more impressive if you consider that Copaxone's first generic competitor, Sandoz's Glatopa hit the market in 2015, followed by Mylan in 2017. Even with the added competition, these generics had no chance. Teva still captured 82% of overall 2018 glatiramer claim volume in Part D despite cheaper (identical) generic options (Figure 1).



Contrast this with Celebrex (celecoxib), a popular anti-inflammatory drug used for treatment of rheumatoid arthritis, osteoarthritis, and short-term/acute pain.

Much like Copaxone, Pfizer sold more than \$1 billion worth of Celebrex into Part D in 2014, right as it was facing its patent cliff. But unlike Copaxone, the much-easier-to-replicate Celebrex died a swift and painless death. It sold just \$32 million into Part D in 2018 and gave up all but 1% of its market share to generic competition (**Figure 2**).

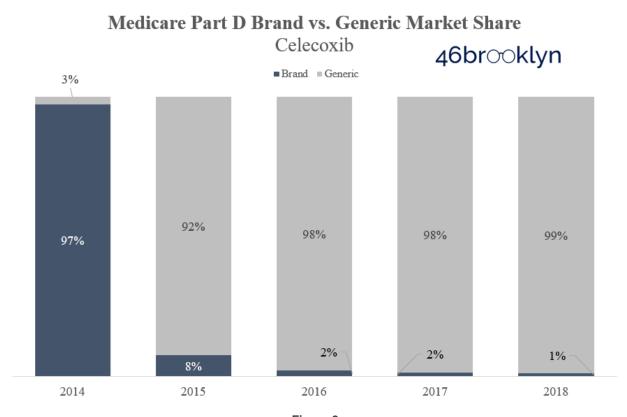


Figure 2
Source: CMS.gov, 46brooklyn Research

To be fair, the difference between **Figures 1 and 2** can largely be explained by the fact that the generic marketplace for Copaxone developed at a glacially slow pace, especially relative to Celebrex, in which no less than eight generic drugmakers piled into the market in the first year. With Copaxone, Sandoz brought its generic version, Glatopa, to market in June 2015, priced it at a relatively meager 15% discount to Copaxone ... and that was it for roughly two years. Mylan's glatiramer eventually came to market in October 2017 and priced their version at – surprise! – **the exact same price** (to the penny) as Glatopa (**Figure 3**). It wasn't until Mylan's price cut in June 2018 that things got interesting. Sandoz followed with their own price cut in November 2019, putting both the generics at much more impressive 70%+ discounts to brand-name Copaxone.

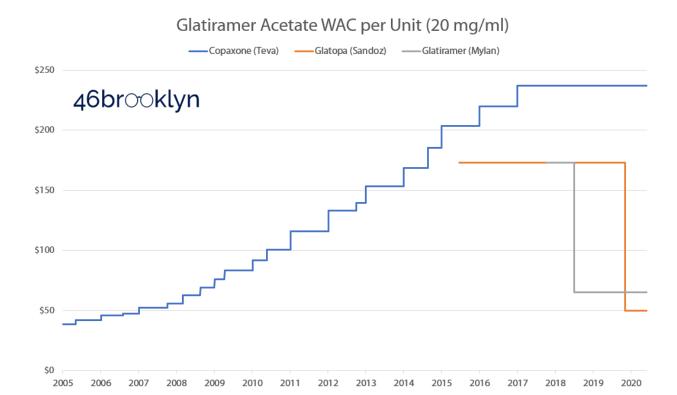


Figure 3
Source: Elsevier Gold Standard Drug Database

So now that the generics are cheaper, Teva should start to lose market share in Part D, right? Don't hold your breath. As we'll show in this report, unless something is done to fix the multi-faceted (and worsening) distortions embedded deep within Medicare Part D, this zombie drug problem is just getting started.

Currently, there are only a handful of non-biologic specialty generic drugs on the market that are impacted by the dynamics we'll review in this report. But as more brand-name specialty drugs face their patent cliff over the next few years, this will change, bringing a wave of specialty generic drugs to market. Make no mistake, these specialty generics have the potential to materially lower U.S. drug expenditures. But if nothing else, this Copaxone case study is the canary in the coal mine, suggesting that they'll instead struggle to gain traction in Part D, even if they are priced at a significant discount. The remainder of this report details the distortions in Part D that will reduce uptake of all specialty generic drugs and analyzes potential solutions for how to fix them.

THE WARPED INCENTIVES INTRODUCED BY THE PART D COST SHARE

For a good overview of the Medicare Part D program as a whole, <u>Kaiser Family Foundation is a great starting point</u>, but in order to set the table for this Copaxone story, we'll review some of the basics. Part D's costs are split between four parties – the patient, the plan, the drugmaker, and the government. The percentage that each party pays depends on where that patient is in the cost share structure – deductible, initial coverage limit (ICL), coverage gap, or catastrophic.

It starts out simple enough. In **deductible phase**, the patient pays 100% of the bill (\$435 in 2020). When the patient has met his or her deductible, they enter the **initial coverage limit (ICL)**, where the plan kicks in and covers 75% of the bill, leaving 25% for the patient.

That continues until the patient makes it into the **coverage gap** (which in 2020, kicks in after \$4,020 of total drug spend). In 2006, when Part D first brought retail pharmacy benefits to Medicare, the coverage gap (a.k.a. "donut hole") was also quite simple. The patient paid 100% of their drug costs in the gap. Simple, but painful!

Clearly, this needed some tweaking. So, starting in 2011 (with the Affordable Care Act, or ACA), the wheels were put in motion to gradually reduce the patient's costs in the donut hole, with the patient's share slated to fall to 25% in the 2020 plan year. The patient's cost share ended up getting reduced to this level one year early, thanks to the 2018 Bipartisan Budget Act (BBA).

The Race to Catastrophic

Clearly, we need to explain exactly how these policy changes backfired. But to do so, we need to venture into the deep, dark Part D cost share waters. We know what you are thinking, "Have fun with that, I'm out." But give it a shot. We'll try to make it fun by using an analogy.

Think of the Medicare Part D cost share as a race. We'll call it the "Race to Catastrophic" (**Figure 4**). In this race, the finish line is the patient's out of pocket (OOP) threshold, which in the 2020 plan year is \$6,350. **Catastrophic coverage** is the finish line, because it's the phase of the Part D benefit where the beneficiary *only* has to pay 5% of their drug costs. It gets no cheaper than that, at least not in Part D.



Figure 4
Source: 46brooklyn Research

All throughout the year, **our nation's seniors are racing along through their cost share to get to catastrophic coverage**. They run through the deductible phase all by themselves without receiving any assistance, meaning that even though many drugs have varying degrees of discounts and rebates, the patient is stuck paying those dreaded sticker prices.

Once the patient reaches their deductible and move into their ICL phase, the plan starts chipping in some money for their drugs, but plan dollars don't count towards a senior's out-of-pocket (OOP) threshold – only their own money counts in this race. So, our nation's seniors are still running alone, putting one dollar in, and getting one dollar closer to that finish line.

A bit down the proverbial road (at \$1,331.25 of out of pocket expense, to be exact), a senior will reach the coverage gap, which we **depict as a fork in the road**. For a multi-source drug (i.e. a drug with both brand and generic options available) like Copaxone, they now have a choice on how to get to the OOP "finish line" – traverse the precarious generic drug dirt road, or breeze across the Brand-Name Drug Superhighway.

So which route should our seniors take? Consider that for as long as our seniors are out there "running" in the coverage gap, they are paying 25% for each

prescription they fill. The longer they are out there, the more this adds up. So, if there was a shortcut that got them to their OOP threshold faster, why not take it?

The Brand-Name Drug Superhighway

This shortcut, which we call the **Brand-Name Drug Superhighway**, was the idea hatched by Medicare intended to fix the punitive donut hole: simply shift part of the bill in the coverage gap from the patient to the manufacturer. This is what the ACA started to do in 2011. For brand-name drugs, it lowered the patient's share from 100% to 50% and gave the other half to the drug manufacturer.

But that change alone didn't create the shortcut. What did was the ACA's gifting of these new brand-name drug manufacturer discounts to a patient's OOP. This immediately created the shortcut. Now the patient was getting \$2 of credit towards their OOP for every \$1 they spent on brand-name drugs in the coverage gap, accelerating their progress towards catastrophic coverage. Again, the less time out on the road, the less money a patient will spend.

Under ACA's original plan, by 2020 a patient would have received \$3 in credit for every \$1 they spent in the donut hole. A sweet deal for sure.

But it got even better. As we already noted, the BBA came in and gave seniors this credit one year early. But the BBA didn't just give seniors \$3 of credit for every \$1 in brand-name drug spending. It gave them **\$3.80** in credit for every \$1 in brand-name drug spending.

You may be wondering how the BBA conjured up such cost share sorcery? It did so by not only lowering the patient share to 25%, but increasing the drugmaker share to 70% (rather than making the plans cover the difference). As a result, if a patient chooses a brand drug, they get credit for \$0.95 of each dollar spent. \$0.95 divided by \$0.25 (again, the patient's share) is 3.8.

Thanks to this speed boost, seniors taking brand-name drugs started cruising through the coverage gap, sailing towards the relative peace and tranquility of their 5% cost share in catastrophic coverage. But we must reiterate, **this highway was only available if they chose to take a brand name drug**. If they chose a less expensive generic, they had to take the circuitous, scenic route, and slowly amble along (with no assistance at all) towards the finish line (**Figure 5**).

Total Credit a Beneficiary Receives Towards OOP Threshold For Each Dollar Spent in the Coverage Gap



Figure 5
Source: Q1Medicare.com, 46brooklyn Research

"Sending the wrong pricing signal"

For those of you who follow drug pricing research, does this all sound familiar? It should, because in July 2019, Stacie Dusetzina and her team at Vanderbilt put out a masterful piece entitled, "Sending the Wrong Price Signal: Why Do Some Brand-Name Drugs Cost Medicare Beneficiaries Less Than Generics." In her report, she very clearly shows how the manufacturer coverage gap discount was producing brands in Part D that were far cheaper for patients than their generic equivalents.

One of the drugs on her list was zombie-king Copaxone, which she found would save patients \$1,072 a year versus its cheaper generic competitor. That's right. Only in America can a drug that costs Medicare \$87,000 per year be *less expensive* for a patient than a drug that costs Medicare \$50,000 per year. And the entire reason why is because if you choose Copaxone, you hop on the Brand-Name Drug Superhighway (sponsored by manufacturers like Teva) and coast to the finish line, whereas if you choose the generic, you have to hoof it through the woods all on your own.

Don't be fooled. Plans are also saving \$ on the brand.

But patients aren't the only ones benefiting from this coverage gap math magic. Nope, plans are saving serious dough by going with the brand version as well.

Let's walk through the math, starting with brand-name Copaxone.

According to <u>CMS' Medicare Part D formulary and pricing data</u>, the median unit price paid by Part D plans for Copaxone in Q1 2020 was \$496.99. Note that this is for the more common 40 mg/ml strength. We worked the math for the 20 mg/ml strength (not shown) and it arrives at the same conclusion.

With Copaxone 40 mg/ml dosed three times a week, a year's supply will run Medicare \$77,530 for one patient. Now we just need to figure out how to divvy it up among the different payers. Easier said than done, but after banging our heads against our computers for some time, we were able to sort it all out (**Figure 6**). Note that the math in Figure 6 assumes the standard Part D deductible (\$435), ICL (\$4,020), and cost share arrangement (25% patient share in ICL and gap). It also assumes a non-LIS (low income subsidy) beneficiary.

Copaxone (Teva) - 40 mg/ml							
Median Part D Cost per Unit (Q1 2020) Cost per Year (Cost per unit x 3 x 52)	\$496.99 \$77,530	46br⊙oklyn					
	Patient	Plan	Manufacturer	Medicare (Reinsurance)	Total Drug (Running Total)	Medicare True Out of Pocket	
Deductible	\$435.00	\$0.00	\$0.00	\$0.00	\$435.00	\$435.00	
ICL	\$896.25	\$2,688.75	\$0.00	\$0.00	\$4,020.00	\$1,331.25	
Coverage Gap	\$1,320.72	\$264.14	\$3,698.03	\$0.00	\$9,302.89	\$6,350.00	
Catastrophic	\$3,411.38	\$10,234.13	\$0.00	\$54,582.04	\$77,530.44	\$9,761.38	
Total	\$6,063.35	\$13,187.03	\$3,698.03	\$54,582.04			

Figure 6
Source: CMS.gov, 46brooklyn Research

Deductible and ICL are easy to explain. The patient simply takes the first \$435 of the bill for their first Copaxone prescription. Recall though that this drug costs \$497 every three days, so the deductible doesn't even cover their first day of treatment. As such, **the patient immediately kicks over into ICL on their first Copaxone fill**, where they pay 25% of the bill up to a total drug cost of \$4,020. That's another \$896.25, leaving the plan to cover \$2,688.75.

Given Copaxone's cost, the patient will blow through not only deductible but also the ICL on the first fill (which should last four weeks) and move into the gap. Our patient is at \$1,331.25 total OOP at the start of the gap, and they have to get to \$6,350. That means they have to spend \$5,018.75 before they can bask in the 5% cost share sunlight of catastrophic coverage. Not to worry though. If our patient chooses to take the brand, Teva's going to cough out \$3,698.03 in the

gap, all of which counts towards the patient's OOP. That leaves the patient with only \$1,320.72 out of the \$5,018.75 to pay in the gap before they've reached the finish line. That, folks, is the math behind the superhighway shortcut.

But take a look at what the Part D plan pays in the gap: \$264. We're not missing a zero here. That's all the plan pays – the equivalent of just over half a dose of Copaxone. Thanks to the cost share, from deductible through the gap, the plan only was required to lay out \$2,952.89 – a measly 32% of the pre-catastrophic total drug cost. Said differently, the plan was allowed to shift the financial burden of payment from themselves to the next groups in line: the drug manufacturer and the Federal Government.

Finally, we make it across the finish line. But since a year's worth of Copaxone costs more than a Tesla Model X, the spending is far from over. The \$68,000+ that's still owed is divvied up between the patient (5%), the plan (15%), and the Federal Government, which foots 80% of the bill through "reinsurance" (originally designed to protect plans from excessive costs, but is now a primary payer of Part D drug costs). Overall, the feds get stuck with a \$54,582 bill for Copaxone. Mind you, this is not free money. Higher reinsurance in one year will, all things equal, put upward pressure on premiums the next year.

Medicare Part D Copaxone Cost Share

Based on 2020 plan design and median Part D plan Copaxone cost

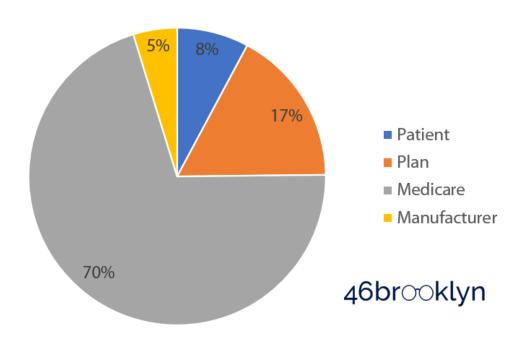


Figure 7
Source: CMS.gov, 46brooklyn Research

Overall, **Figure 7** shows how the \$78k yearly Copaxone bill is split between the four payers. The plan only ends up paying \$13,187, or 17% of Copaxone's annual costs. Oh, and then they likely collect prescription drug rebates on top of that, which if they are more than 17%, will end up offsetting any plan expense on the drug.

Now let's perform the same math for the generic. The Part D-reported unit price for Mylan's glatiramer acetate was \$303.22 in Q1 2020, a 39% discount to the brand. That equates to an annual cost of \$47,302. **Figure 8** shows how this cost this divvied up among the payers.

Glatiramir Acetate (Mylan) - 40 mg/ml							
Median Part D Cost per Unit (Q1 2020) Cost per Year (Cost per unit x 3 x 52)	\$303.22 \$47,302	46brooklyn					
	Patient	Plan	Manufacturer	Medicare (Reinsurance)	Total Drug (Running Total)	Medicare True Out of Pocket	
Deductible	\$435.00	\$0.00	\$0.00	\$0.00	\$435.00	\$435.00	
ICL	\$896.25	\$2,688.75	\$0.00	\$0.00	\$4,020.00	\$1,331.25	
Coverage Gap	\$5,018.75	\$15,056.25	\$0.00	\$0.00	\$24,095.00	\$6,350.00	
Catastrophic	\$1,160.37	\$3,481.10	\$0.00	\$18,565.86	\$47,302.32	\$7,510.37	
Total	\$7,510.37	\$21,226.10	\$0.00	\$18,565.86			

Figure 8
Source: CMS.gov, 46brooklyn Research

Both the deductible and ICL phases are exactly the same as the brand. The patient still enters the gap having spent \$1,331.25. **And they still have to spend a total of \$6,350 to exit the gap.** But oh no! What happened to the superhighway? Sadly, it's closed for you, dear senior, because you chose the "cheaper" generic option. Hand over a full \$5,018.75 to get yourself out of the gap. Oh, and don't forget your compass. We don't want you to get lost on that long generic journey.

Our seniors are not alone in their coverage gap misery when it comes to expensive generic drugs. The plans are right there in trenches with them. That's because, unlike with brand drugs, plans actually have to **pay up** for generic drugs in the coverage gap – they are responsible for 75% of the bill. And they have to keep paying 75% as their beneficiary trudges along the generic dirt road. This adds up to a plan share of >\$15,000 in the coverage gap alone for glatiramer – more than they had to pay for all coverage phases for Copaxone.

Medicare Part D Glatiramer Cost Share

Based on 2020 plan design and median Part D plan Glatiramer cost

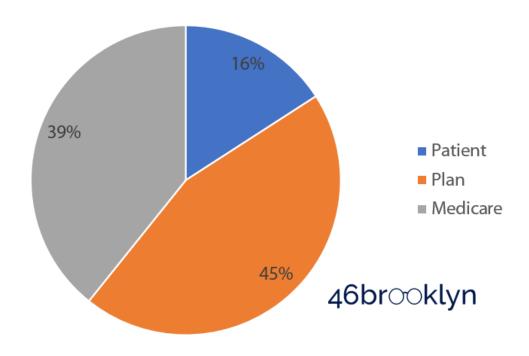


Figure 9 Source: CMS.gov, 46brooklyn Research

When it's all said and done, as shown in **Figure 9**, the Part D plan has to pay over \$21,000 (43% of total cost) for the generic, while patient's annual bill is over \$7,500 (26% of total cost).

That's \$8,039 *more* for the generic for the plan (not even accounting for any brand-name Copaxone rebates they forego), and \$1,447 *more* for the generic for the patient. The payer that saves money by dispensing generic glatiramer is the Federal Government, who's reinsurance bill gets slashed by over \$36,000 (**Figure 10**). Too bad the feds don't have a say in which one the Part D "free market" chooses to cover.

Annual Savings by using Copaxone over Glatiramer

Based on 2020 plan design and median Part D plan copaxone cost



Figure 10 Source: CMS.gov, 46brooklyn Research

With incentives like these for Part D plans, is it any wonder that federal reinsurance has increased from \$10 billion in 2010 to over \$45 billion in 2019?

The drugmaker also loves the Superhighway

Let's talk about the brand-drug manufacturer – in this case, Teva. What do you suspect their thoughts are on this coverage gap arrangement? On cursory glance, they have to pay 70 percent of the bill in the gap! That should teach them a lesson, right?

Completely wrong. Here's why.

Recall, that Teva has to pay \$3,698 for a year's worth of Copaxone for a Part D patient. That works out to be 4% of the total annual list price. **Four percent**. When we are talking about rebates on brands with generic competition, 4% is practically nothing. It's a rounding error.

Recall that the median cost in Part D for Mylan's glatiramer is 39% less than Teva's Copaxone. It follows then that absent these wacky Part D cost share distortions, **Teva would have to cough up at least a 39% rebate to compete on price with Mylan's generic**. But instead, thanks to this coverage gap math experiment, a brand drugmaker now gets to chip in a minuscule 4% "discount" and absolutely trounce the generic's economics with the payers that matter: the patient and the plan. Then the drugmaker can turn to the plan and hand over a nice big rebate goose egg. Why pay any more than that? The brand drugmaker already won thanks to the coverage gap.

Talk about a policy change backfiring.

Copaxone plan coverage in Part D

It's now clear that plans have the strong incentive to choose the brand over the generic, despite the generic's list price cost advantage. So, did they? As shown in **Figure 11**, exactly half of all plans took the bait in 2020, despite the availability of two significantly cheaper generic options.

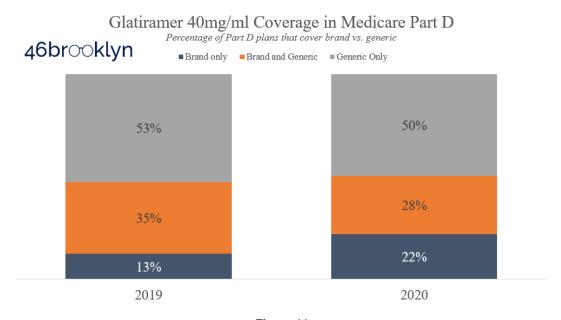


Figure 11
Source: CMS.gov, Elsevier Gold Standard Drug Database, 46brooklyn Research

It gets worse though. Take a look at the blue series. This shows the percentage of all unique plans that said, "to hell with the generics, we're only going to make brand-name Copaxone available." This actually *increased* from 13% in 2019 to 22% in 2020, officially making Copaxone the <u>Benjamin Button</u> of brand-name drugs.

You may be wondering why the number of plans that exclusively covered the brand increased in 2020. It's likely because starting in 2020, the patient's OOP threshold was increased from \$5,100 to \$6,350. This effectively made the coverage gap ~25% bigger. Using our race analogy, it made the donut hole portion of the race 25% longer for patients and plans. The longer the race is, the more valuable the shortcut (i.e. superhighway) becomes.

Long story short, this increase to the patient OOP threshold made brand-name Copaxone more attractive to both plans and patients relative to generic glatiramer (**Figure 12**). And not just by a little. The savings a plan could achieve with a brand (that had negotiated median generic glatiramer pricing) increased

from \$3,506 in 2019 to \$8,039 in 2020. That's a 129% increase in plan savings just for choosing brand-name Copaxone over generic glatiramer.

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		Patient		
	2019	2020	YoY Change	YoY Change (%)
Copaxone	\$5,759	\$6,063	\$304	5%
Glatriramer	\$6,599	\$7,510	\$911	14%
Copaxone Savings	\$840	\$1,447	\$607	72%

		Plan		
	2019	2020	YoY Change	YoY Change (%)
Copaxone	\$13,207	\$13,187	(\$20)	0%
Glatriramer	\$16,713	\$21,226	\$4,513	27%
Copaxone Savings	\$3,506	\$8,039	\$4,533	129%

Medicare (Reinsurance)								
	2019 2020 YoY Change YoY Change (%)							
Copaxone	\$55,740	\$54,582	(\$1,158)	-2%				
Glatriramer	\$23,990	\$18,566	(\$5,424)	-23%				
Copaxone Savings	(\$31,750)	(\$36,016)	(\$4,266)	13%				

Figure 12
Source: CMS.gov, 46brooklyn Research

EVEN WHEN PLANS CHOOSE THE GENERIC, MONEY IS GETTING SKIMMED

There is a different way to interpret **Figure 11** – despite how strong the economic incentives are to cover brand-name Copaxone in 2020, half of all plans chose not to do it! We just walked you through the math clearly illustrating why the brand will save money versus the generic – both for the patient and the plans – and more than half the plans are doing the opposite? What gives?

Well, you have to realize that just because the median Part D plan is paying \$303 per dose for generic glatiramer, it doesn't mean that's what generic glatiramer actually costs. It turns out that pharmacies can buy generic glatiramer for somewhere around the drug's Wholesale Acquisition Cost (WAC), which in 2020 is \$163 per dose for Mylan's version and \$125 per dose for Sandoz's version. Most pharmacies will be able to get an even better deal than this after accounting for the rebates they'll receive from their wholesaler on generic glatiramer (but not on brand-name Copaxone).

The disconnect between Part D's price and pharmacy acquisition cost is driven by the fact that here in the U.S., **generics are priced by PBMs** (for their clients, in this case Part D Plan Sponsors) based on a contractual discount to <u>Average Wholesale Price (AWP)</u> – a completely different price benchmark altogether – which is also set by the drugmaker.

For generic glatiramer (both versions), the **AWP** is \$524 per dose today. In other words, the median Medicare Part D plan is getting an impressive 42% discount off AWP. Sounds great right? Until you realize that this "42% off deal" is yielding a price that is *at least* 86% to 142% higher than the drug's acquisition cost. This is the magic that is AWP – the root cause of generic drug overpayments for payers and patients and the core tool used by PBMs to execute their arbitrage-based business models.

How much would the generic have to cost to save money?

In an attempt to find some rationale to explain why so many plans are choosing the generic – despite evidence that it's a poor financial decision – let's for a moment forget how much Part D is reporting generic glatiramer costs. At what price will the generic be cheaper than the brand for patients and plans? To figure this out, we performed a quick sensitivity analysis on our model and arrived at the answer. In 2020:

- To save the patient money, generic glatiramer has to cost less than \$147 per dose.
- To save the plan money, generic glatiramer has to cost less than \$116 per dose.

So maybe, just maybe, our focus on the median price is hiding a gaggle of plans that have reined in their PBM and negotiated fair generic glatiramer prices that are saving their members money? It was at least worth checking.

Very few Part D plans have generic glatiramer priced correctly

Sadly, we didn't find that to be the case. In **Figure 13**, we racked and stacked the generic glatiramer negotiated prices of 3,200+ unique plans (excluding special needs plans) in 2020. The y-axis is the cost of generic glatiramer reported by CMS for each unique plan, and the x-axis is the cumulative percentage of plans in descending order (so it looks like a ski slope rather than hiking up a mountain).

The way to read the chart is to select a price on the y-axis, draw a horizontal line over to the edge of ski slope, and then drop a vertical line down to the x-axis.

That will tell you the percentage of plans that turned in a negotiated price **at or below** your chosen price.

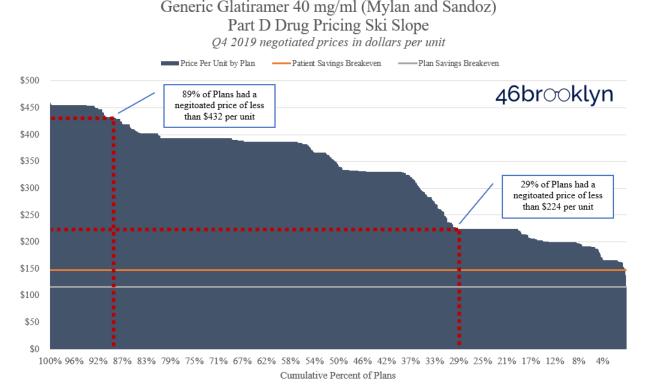


Figure 13
Source: CMS.gov, 46brooklyn Research

As shown in the chart, we now know that in Q4 2019, 89% of all Part D plans negotiated a generic glatiramer price at or below \$432 per unit. Meanwhile, only 29% of all Part D plans negotiated a price at or below \$224 per unit. Again, a pharmacy really shouldn't be paying any more than \$150 after rebates for this drug, while some could be paying under \$100 per unit.

Considering that one the major selling points of insurance companies and PBMs is the idea that their size, scale, and expertise can help leverage lower costs, it makes you wonder that if you can get the median Part D plan to shell out two to three times glatiramer's actual acquisition cost, what else could you dupe them into buying? A \$85 pet rock? A \$33,000 Ford Pinto? A \$400 Vince Neil Cameo message? 5 cents for a Van Halen III CD?

So, how many plans were able to secure prices that saved their members and/or themselves money? Sadly, the number is so small, we can't even measure it in percentage points anymore. Rather we'll just tell you the number of plans. Out of the 3,200+ unique plans that covered glatiramer, just nine secured pricing at or below the patient brand/generic breakeven (\$147), while **just two unique plans** (surprisingly, both Cigna plans) negotiated pricing at or below the plan brand/generic breakeven (\$116).

Do plans even care about generic glatiramer's price?

To recap, so far we have proven that brand-name Copaxone is cheaper for both the median plan and the patient. We then went on to prove that even when the generic is exclusively covered (more than half the time), the majority of plans and their PBMs have it priced in the stratosphere relative to its actual cost, resulting in overcharges not only for their patients, but also for themselves.

From the viewpoint of an economist, on its surface this is a real head-scratcher. The market appears to be broken. Plans have no incentive to cover the generic even at a fair cost, so why are so many covering it at a price multiple times higher?

Low income subsidy

One possible explanation that we looked into (and somewhat, but not completely, debunked) is the impact of the <u>low income subsidy (LIS)</u> program. In this program, LIS beneficiaries pay just about nothing for their drugs (aside from a small copay at times), so whenever they owe money (say in deductible or ICL) the low income subsidy steps in and foots the bill. This has the effect of "<u>airlifting</u>" the plan through the coverage gap (plans pay nothing in the gap for LIS beneficiaries) and dropping them into catastrophic. Without having to pay anything in the gap, Part D economics get flipped on their head, making even a wildly overpriced generic cheaper than its equivalent brand (**Figure 14**).

Annual Plan Expense on Glatiramer 40 mg/ml per LIS Beneficiary							
46brooklyn Brand Brand Generic @ \$303 Brand less Generic							
Deductible	\$0.00	\$0.00	\$0.00				
ICL	\$2,688.75	\$2,688.75	\$0.00				
Coverage Gap	\$0.00	\$0.00	\$0.00				
Catastrophic	\$10,234.13	\$3,481.10	\$6,753.03				
Total	\$12,922.88	\$6,169.85	\$6,753.03				

Figure 14
Source: CMS.gov, 46brooklyn Research

While this was a good theory, we didn't find plans that covered only generic glatiramer to have a higher prevalence of LIS beneficiaries than plans that also (or only) covered Copaxone (in fact, we found the opposite). So, while this could partially explain the sheer amount of mispriced generic glatiramer coverage in Part D, there must be another factor at play here.

We propose an entirely different hypothesis altogether. Maybe this is not the plan's decision to begin with? Of course, it's technically supposed to be, but we are starting to wonder how many plans scrutinize formularies presented to them by their PBMs. Possibly, plans do not have enough skin in the game in Medicare Part D to push back on the behemoth PBMs, and are simply accepting whatever the PBMs want them to cover? Or maybe the partnering up of the largest plans and PBMs (Express Scripts/Cigna, CVS/Aetna, Optum/United) has removed the incentive for plans to push back on prices proposed by... well... themselves?

Let's at least pull on this thread a bit. If this were true, we need to understand the game from the PBM's vantage point. Which drug would **they want** the plan to cover? Brand Copaxone, or generic glatiramer?

Specialty pharmacy "steering" in Medicare Part D

The answer is, in this case, a way overpriced generic glatiramer. Recall that PBMs pretty much all have their own specialty pharmacies. Express Scripts has Accredo. Optum has Briova. CVS Caremark has, well, CVS. A specialty pharmacy that buys generic glatiramer at \$125 per dose and sells it at \$303 per dose (again, the Part D median price in 2020 Q1) will make **nearly \$28,000 in profit** per patient per year.

The first part is simple. All the PBM has to do is set the price in its contract with each plan, likely as a discount off of the specialty generic drug's seriously inflated Average Wholesale Price (AWP). The actual price of generic glatiramer is irrelevant in the plan contract. All that matters is the discount to AWP (which again is \$524 per dose for both versions of generic glatiramer and hasn't changed since the generics were brought to market).

With the inflated price set for generic glatiramer, the pharmacy that dispenses the claim is now set to reap windfall profits. How convenient that all major PBMs have their own affiliated specialty pharmacies!

In commercial (or Medicaid managed care) plans, a PBM can contractually mandate which pharmacy fills your specialty drugs, setting it as their own if they so choose. Excessive profits collected on specialty drugs by pharmacies affiliated with plans and PBMs was a central finding of 46brooklyn co-founders' consulting research performed using Florida's Medicaid claims data. Longtime 46brooklyn readers will recall that we found similar trends in Ohio's Medicaid state utilization data as well. PBMs can't do that in Part D, which has any-willing-provider rules. But as MedPAC wrote all the way back in 2017, "PBMs may get around this rule by instituting fees that discourage pharmacy participation."

That statement could refer to one of two games played by PBMs. One way they discourage participation is through the notorious <u>Direct and Indirect</u>

<u>Remuneration (DIR) fees</u>, the <u>exponentially growing clawbacks PBMs take from pharmacies on Part D claims</u>. These punitive DIR fees, which are responsible for

a litany of <u>pharmacy closures</u>, as well as many successive exclamation points and errant capital letters from pharmacists on Twitter, pressure many community pharmacies to opt out of preferred network contracts and instead move to standard networks, which then sets up perfectly for the second PBM game.

The second game involves tinkering with the copays and pricing in preferred and standard pharmacy networks. As we will show, preferred pharmacy networks can be designed to lure patients to a PBM's preferred pharmacies with discounted copays on cheap "loss leader" maintenance generics. Once the preferred pharmacy has the patient, all they have to do is wait for them to bring in a prescription for a specialty drug to cash in on this scheme.

Take Aetna for example. We've found them to be on the extreme end of copay differentiation between preferred and standard pharmacies. To illustrate, let's conjure up a NYC-based senior that is taking three ultra-cheap and very common maintenance generic drugs:

- 1. Losartan (generic Cozaar) to manage blood pressure
- 2. Rosuvastatin (generic Crestor) to lower cholesterol
- 3. Omeprazole (generic Prilosec) to help with their indigestion

According to <u>Plan Finder</u>, if this senior got its prescription benefits through Aetna Medicare Elite Plan (Plan ID: H5521-120-0) and tried to fill them at a standard in-network pharmacy like <u>Manhattan Apothecary</u>, it would cost them \$50 per month. This same cocktail of prescriptions would cost \$7.32 per month down the street at a preferred (and in this case, Aetna-affiliated) CVS pharmacy.

What is our senior to do? Unless they have easy accessibility or considerable loyalty to Manhattan Apothecary, they would likely transfer their prescriptions to CVS.

Don't get us wrong, \$7.32 for these three drugs is a fantastic deal. If you purchased all three together using <u>GoodRx</u>, you'd pay nearly \$27. The problem is what happens if our senior gets very sick.

To illustrate, let's say that our senior has sadly just been diagnosed with chronic myelogenous leukemia. Thankfully, <u>miracle drug Gleevec</u> is not only available to help, but is available in generic form. They head to their new CVS pharmacy to fill their first prescription and get stuffed with a bill for \$2,486. Amazingly, this drug would have been *cheaper* if they just stayed at Manhattan Apothecary. Plan Finder quotes a first fill price of \$2,357 at this **standard** pharmacy, which is \$129 cheaper than the **preferred**, Aetna/Caremark-affiliated CVS pharmacy. So, they ironically end up shelling out more money on this specialty generic by switching to a preferred pharmacy.

But that's a sideshow compared to the main-event takeaway. Want to know how much this drug really costs? Just surf over to GoodRx where you'll find that your

local pharmacy will charge you **just over \$200**, or less than a tenth of Aetna's "negotiated price."

And that's how this game works. MedPAC was on the right track by <u>saying</u>, "PBM-owned specialty pharmacies may face mixed incentives." Although we would disagree that they are mixed. **The incentives seem quite clear to us**. There is nothing at all stopping a vertically-integrated health care behemoth like CVS/Caremark/Aetna from putting their thumb on the scale in the pharmacy marketplace and printing money off seniors in Medicare Part D by:

- 1. Tinkering with the plan design to lure patients into its pharmacies with cheap maintenance generics;
- 2. Waiting for the patient to bring in a specialty generic prescription;
- 3. Having its PBM slap a 10x markup on the drug;
- 4. And finally, pocketing a few grand on the fill.

Sadly, with the data we have, we cannot completely quantify the magnitude of this indirect PBM/plan-affiliated pharmacy steering for specialty generics like generic Gleevec and generic Copaxone. But the proof that drug prices and pharmacy networks are being manipulated to benefit the vertically integrated plan is all sitting on Plan Finder, buried in examples like the one highlighted above. Explore for yourself. We sincerely hope that government officials and the collective research community invests more time into assessing the magnitude of any and all conflicts of interest in the supply chain that may be unnecessarily enriching corporations at the expense of their beneficiaries, and Medicare in general.

Not all Part D plans are created equal

Before we wrap up, we thought it would be beneficial to take a tour of some of the common household-name Part D plan sponsors to see if they are on "Team Copaxone" or "Team Glatiramer." As such, we collected all information on glatiramer coverage for all unique plans managed by 10 of the largest Part D plan sponsors and presented it in **Figure 15**. It's worth noting that these 10 insurance companies together have over 35 million Part D enrollees – nearly 80% of the entire program!

First, a quick orientation to **Figure 15**. Each column presents a different plan group name. Take AARP to start, who has both Medicare Advantage (MA) and "stand-alone" Part D Plan (PDP) options ("coverage options"). We present three columns for each coverage option, for both Copaxone and generic glatiramer:

- "% of Plans" shows how many plans are covering the specified drug.
- "Avg Tier" is the average tier on which the plans that cover each drug have placed it.

"Avg Price" is the average price across all plans in the group.

As an example, based on this chart, we can very quickly see what AARP has chosen to do – it only covers the generic, has placed it on Tier 5, and priced it at an average of \$312 for their PDP plans and \$343 for their MA plans.

46brooklyn	Copax	one (Brand) - Q	24 2019	Glatriamer (Generic) - Q4 2019		
400100Ktyll	% Plans	Avg Tier	Avg Price	% Plans	Avg Tier	Avg Price
AARP (MA)	0%	N/A	N/A	100%	5	\$343
AARP (PDP)	0%	N/A	N/A	100%	5	\$312
Aetna (MA)	100%	5	\$492	0%	N/A	N/A
Anthem (MA)	88%	5	\$488	100%	5	\$395
Anthem (PDP)	0%	N/A	N/A	100%	5	\$393
Blue Cross (MA)	60%	5	\$480	92%	5	\$266
Blue Cross (PDP)	31%	5	\$482	89%	5	\$272
Cigna (MA)	100%	5	\$504	0%	N/A	N/A
Cigna (PDP)	67%	5	\$500	33%	5	\$206
Humana (MA)	100%	5	\$510	100%	5*	\$223
Humana (PDP)	100%	5	\$511	100%	5	\$224
Kaiser Permanente (MA)	100%	5	\$503	100%	2	\$241
SilverScript (PDP)	100%	5	\$498	0%	N/A	N/A
UnitedHealthcare (MA)	0%	N/A	N/A	100%	5	\$342
WellCare (MA)	0%	N/A	N/A	100%	5	\$404
WellCare (PDP)	0%	N/A	N/A	100%	5	\$396

 $^{^*}$ One Humana MA Plan (HumanaChoice Value H2029-001) has generic glatiramer on Tier 2

Figure 15

Source: CMS.gov, 46brooklyn Research

Now that you're familiar with the table, spend a moment or two letting it all sink in. It's quite a beautiful mess, isn't it? Here are a few of our key takeaways:

- Plans are showing a bias towards covering brand-name Copaxone in Medicare Advantage, but less so in PDP (Anthem, Cigna).
- The three plans that have chosen to cover Copaxone only are all owned by, or own a PBM (Aetna-CVS, Cigna-Express Scripts, SilverScript-CVS).
- Meanwhile, the same PBM that owns two of the plans mentioned in the above bullet has set generic glatiramer's price at an astonishing \$390+ per dose for two of its very large non-affiliated clients (Anthem, WellCare)
- Only three companies reported generic glatiramer prices below \$250 per dose (Cigna, Humana, and Kaiser Permanente), two of which operate using exclusively in-house PBMs (Humana, Kaiser Permanente).
- Only one plan has placed generic glatiramer on the ~\$10-20 copay Tier 2, which is typically reserved for non-preferred generic drugs (Kaiser Permanente). All others still have generic glatiramer on the ~25-35% coinsurance Tier 5, which is typically reserved for specialty drugs.



How to Fix this Mess

While this story is about Copaxone, it is a cautionary tale that should apply to all non-biologic specialty drugs (which the <u>CBO found to be over half of all specialty drugs</u>). In the coming years, more and more specialty drugs will go generic, expanding the impact of this unfortunate Part D mess from the multiple sclerosis community to many other patients suffering from complex disease states. If there is no change to how Part D works, non-biologic specialty generics will struggle to make a dent in brand-name drug market share, leading to inflated drug spending for years on the therapies these drugs are designed to treat.

But we have reason to be hopeful. There has been increasing energy over the past year to completely reform the Part D cost share. Provisions to revamp the cost share are currently included in different pieces of major drug pricing legislation sitting in the House (HR-3) and the Senate (S-2543). Both versions eliminate the coverage gap altogether, shifting considerable financial burden to the plan, and both cap patient out-of-pocket costs once they hit the catastrophic phase. The version outlined by MedPAC is shown in **Figure 16**.

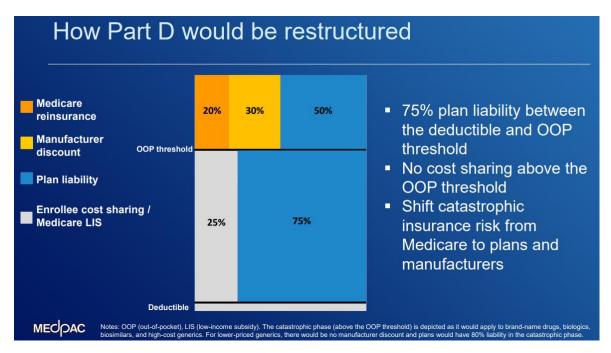


Figure 16 Source: MedPac

We went ahead and modeled out MedPAC's proposed cost share changes for Copaxone (**Figure 17**), and it's a tsunami of a change.

As we show below, MedPAC's recommendations not only completely eliminate the warped incentive to prefer brand-name Copaxone, but they also severely punish plans who offer brands or allow PBMs to overcharge for generics. Any plan that chooses to dispense brand-name Copaxone in MedPAC's new Part D

world is going to get stuffed with an annual \$48,922 bill for it, almost 4x what they are paying right now. If they continue to accept the going Part D inflated price for generic glatiramer of \$303 per dose, they'll pay \$30,875, which is still 2.3x what they are paying for the brand today. Meanwhile, patients are completely insulated from the plan's decision, paying \$3,100 (the new OOP threshold) either way. Plus, they'll benefit indirectly from lower premiums in future years driven by the plummet in the federal government's reinsurance payments.

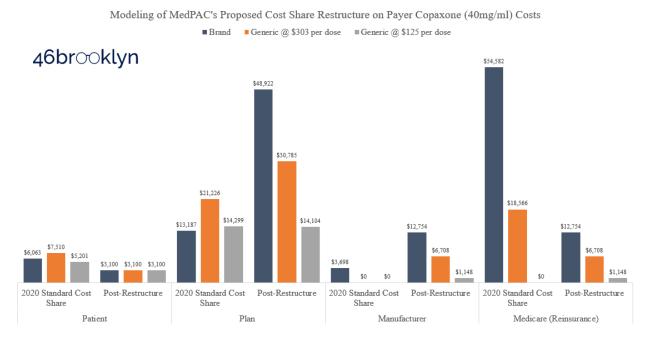


Figure 17
Source: CMS.gov, MedPac, 46brooklyn Research

Plans may initially be terrified of this change. But the basis for such concern is weak, in our view. Note that **Figure 17** also shows that if plans held their PBMs accountable to providing fair pricing for generic glatiramer (~\$125 per dose), they would pay \$14,104 for the drug – only \$917 more than they are paying for brand-name today per patient per year. So, the only plans that need to be terrified are those that choose to keep their heads buried in the sand on generic pricing ... and of course, any plans that own their own PBMs and are knowingly manipulating generic pricing to recognize fat profits in their own affiliated pharmacies.

Aren't aligned incentives beautiful?

But this is about more than cost and incentives. It's about restoring trust in a broken program. Part D, with its many incremental changes over its 14 years of life, has become beyond complex.

And in its complexity, it has become fragile. It has become weak. It has become sick.

And just as fragile, weak, and sick gazelles are easy prey for tigers, Part D is easy prey for ever-expanding health care conglomerates.

But unlike a gazelle, Medicare has the power to change its fate. It's time for Medicare to wake up, realize it's the tiger (not the gazelle), and fully fix the perverse incentives in Part D. Patients with complex illnesses and expensive drugs have needlessly suffered enough with drug prices that are far higher than they should be. We can't let this problem cascade to other patient groups, destroying their hope that low-cost specialty generics will one day come to market and significantly lower their medication costs. Our seniors deserve better.

As you may have noticed, to best tell this story, we not only needed to purchase a considerable amount of data from CMS, but also - for the first time - worked with an immensely talented free-lance artist (<u>Janelle Anderson</u>) to create really slick custom artwork.

First off, if you were as blown away by **Figure 4** as we were, and are in the market for custom infographics to tell a story, reach out to Jannelle (@janelleoart on Instagram)!

Second, all of this data and art costs money! We want to extend our heartfelt gratitude to the Mark Cuban Foundation, whose generous donation is allowing us to both expand our data arsenal and venture beyond the written word into new, and hopefully more effective, ways (like custom artwork and infographics) to educate the public on drug pricing.

For questions or comments contact 46brooklyn Research at info@46brooklyn.com

or

P.O. Box 512 Dayton, OH 45401

