Members of the House Health and Commerce Committees,

Senator Mann and I are running a set of three drug marketplace reform bills, this session. They were first heard in the Senate Commerce Committee last week, and they'll be heard in the House Health Committee, this week (and re-referred to Commerce, knock-on-wood). Understanding the objective of these bills requires a somewhat deeper understanding of the role that PBMs play in the value chain and their relationship with both manufacturers and health plans. To get the gist of what's going on, here, you'll first want to read this Wall Street Journal article:

https://www.wsj.com/health/healthcare/same-drug-two-prices-why-the-higher-price-prevails-d24038c8?st=oPcv2U&reflink=desktopwebshare_permalink

It's about a five-minute read and your initial reaction will be: **WTF?**

So, how did we get here?

Once upon a time Pharmacy Benefit Management (PBM) was a boring business specializing in processing drug claims for health insurance companies. Then in 1990, Congress carved out a safe harbor exemption from the federal anti-kickback statute that allowed drug manufacturers to offer rebates to the purchasers of their drugs in hopes that this would inject more price competition in the drug marketplace. There were some unintended consequences.

The PBM companies saw a business opportunity and approached the health plans with a business proposition: "Since we understand this side of the business much better than you do, we can negotiate much better deals with the manufacturers than you can and, in fact, we're so confident of this that we're willing to be compensated by taking a share of the savings that we win for you." In the beginning, the concessions were modest. The PBM might win a 10% rebate and pass 8% on to the health plan. Except that every January, right after the health plan year began and the drug formularies were locked in for the year, the drug manufacturers would raise their prices by 12% to assure themselves of a net price increase. The next year, the rebate would be 15%, 12% was passed along the health plan and, in January the manufacturers would raise their prices by 17%. This went on for years and every year the manufacturers got a net increase in price and the PBMs got a bigger slice of rebate dollars but the health plans and their members were actually worse off.

Eventually, the health plans caught on and demanded basic changes in the relationship. From then on, the health plans received substantially all the rebate revenues and the PBMs were instead paid transaction fees for conducting the negotiations and processing the claims. (They've since invented new revenue streams – we'll leave that for part 3.) Henceforth, the PBMs were compelled to negotiate exemptions from the manufacturer's January price increases on behalf of their health plans. However, by the time the cycle was broken, the average drug price had doubled and the average rebate had reached about 50%. (Dr Adam Fein refers to this as the "Gross to Net Bubble".) (Note: When I first hypothesized

that this is what had happened, each of the major PBMs personally confirmed to me that this was *exactly* what had happened.)

So now you're thinking that, surely, these huge rebates must be finding their way back to the patients taking these drugs in the form of lower prices at the pharmacy, right? If you're thinking this, you would be wrong! Instead of passing the rebate savings along to patients in the form of lower drug prices, the plans decided to pocket the savings for themselves and use them to buy down the cost of premiums for their memberships at-large. In the case of employer-sponsored ERISA plans, a Milliman study found that employers were pocketing 70% of the rebates to buy down their share of plan contributions. What was worse, the PBMs and plans didn't exempt *their members* from the manufacturers' January surprise price increases. So, if you're a patient taking one of these expensive drugs with an inflated list price you might be paying a co-insurance payment of 25% of the inflated full list price of the drug – you might even be paying more than your health plan is paying for the drug (net of the rebate).

Now, go back and re-read the Wall Street Journal Article, again, and connect the dots, because something else that's really pernicious has crept into the equation: The health plans have become so addicted to the rebates that, when offered the choice between a high-price/high-rebate drug and a low-price/low-rebate drug, *they're choosing PBM formularies with the high price drugs instead of PBM formularies with the low-price drugs*. The PBMs are taking most of the blame for this sad state of affairs, but it's really the plans that are driving this behavior. The result is that sick patients who need lifesaving drugs are paying higher prices so that the healthy can pay lower premiums. In many cases the sick patients who need the drugs can't afford to take them, so "drug regimen adherence" and patient health suffer.

And then there's this: *there is no longer any incentive for competitive manufacturers to enter the market with cheaper generic and biosimilar drugs*. If formulary placement is based solely on the size of the rebate, the incentive is to ***raise*** the price to that you can pay a larger rebate to buy your way onto the formulary. Why spend millions to develop a new low-price generic drug if the PBMs and plans are going to prevent you from selling it? This is why you see manufacturers offering the same drug in a high-price/high-rebate version and a low-price/low-rebate version and why we're seeing the high price version being the one that the PBMs and plans usually choose.

The three bills that will be before the House Health Committee on Wednesday attack this in different ways.

HF1652/SF1806 says that a health plan can't force you to switch drugs in the middle of a plan year because they're now getting a bigger rebate from the manufacturer of a competitive drug. If you chose your health plan because the drug that works for you was on that plan's formulary during open enrollment, then the health plan should be required to allow you to keep taking that drug though the end of the plan year. It's already illegal for a health plan to take away a medical benefit during the plan year. Why is it legal for lifesaving drugs?

HF1075/SF1877 says that your health plan and PBM must use the rebates that they received when you bought your drug to buy down your price at the pharmacy counter in the form of a “Point of Sale Rebate”. This is now done in several states. Minnesota-based OptumRx is a PBM that pioneered POS Rebates and promoted them to its health plan clients (who said “no thanks, we’d rather keep the rebates for ourselves”). All the big PBMs have confirmed to me that they already have the capability to implement POS rebates seamlessly (most of them use the Optum RxClaim drug claim processing system). This is all done automatically and invisibly in the system – the patient and pharmacist don’t have to do anything special. When POS rebates were implemented in Arkansas, a follow-up study by Milliman found no perceptible increase in health insurance premiums. This bill has been through the Mandate Review process. Commerce determined that it did not constitute a mandate subject to defrayal.

HF1076/SF1876 is a novel approach not yet adopted by any other state. It says that, when there are high-price and low-price drug equivalents in the market, the PBMs and plans have to include the low-price drugs in their formularies and construct their formularies so that the drugs with the lowest prices *to the patient* receive the best placement in their formularies. One of the objectives with this approach is to redirect competition away from rebates towards lower prices.

Both HF1075 and HF1076 will exempt plans where patients pay modest copays for their drugs (instead of percentage co-insurance payments based upon high list prices).

I’m still looking for co-authors on these three bills.

Finally, if the Wall Street Journal article wasn’t sickening enough for you, this New York Times article will surely put you over the top:

“Drugmakers including Purdue Pharma paid pharmacy benefit managers not to restrict painkiller prescriptions, a New York Times investigation found.”

https://www.nytimes.com/2024/12/17/business/pharmacy-benefit-managers-opioids.html?unlocked_article_code=1.4k4.HTZt.Lj0ENodLMTlB&smid=em-share

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https://www.wsj.com/health/healthcare/same-drug-two-prices-why-the-higher-price-prevails-d24038c8

Same Drug, Two Prices: Why the Higher Price Prevails

Patients are paying hundreds of dollars more for a prescription than they would if their health plan chose to cover a lower-priced twin

By Peter Loftus Follow *and Jared S. Hopkins* Follow

Nov. 8, 2023 5:30 am ET

The way medicines are paid for in the U.S. has become so convoluted that some drugmakers are setting two prices for the same drug—and many health plans are choosing to cover the more expensive version.

The decisions mean some patients are paying hundreds of dollars more in out-of-pocket charges to fill a prescription for an identical medicine made by the same company.

Take the widely used insulin Humalog. Eli Lilly sells the drug for $274 a vial, as well as an identical but unbranded version for $25. Half as many Americans have insurance coverage for the less expensive product as for the higher-priced brand, which accounts for 61% of prescriptions.

Kevin Favro, who has Type 1 diabetes, sometimes rationed supplies of Humalog or used expired vials because the drug cost him so much under his health insurance plan. Earlier this year, he paid $630 out of pocket for a 100-day supply to meet his plan's deductible.

"I think it's disgusting how much we have to pay for it," said Favro, a 33-year-old lawyer in Irvine, Calif. After recently discovering he could pay less if he just bought the lower-priced duplicate himself through Amazon.com's online pharmacy, Favro is now paying $105 for a 125-day supply of vials.

For years, doctors and patients have criticized drugmakers for their high prices. The companies have responded, in part, by listing at least 10 drugs at a lower

Kevin Favro switched from taking Humalog for his Type 1 diabetes to a lower-priced duplicate through an online pharmacy. PHOTO: KEVIN FAVRO

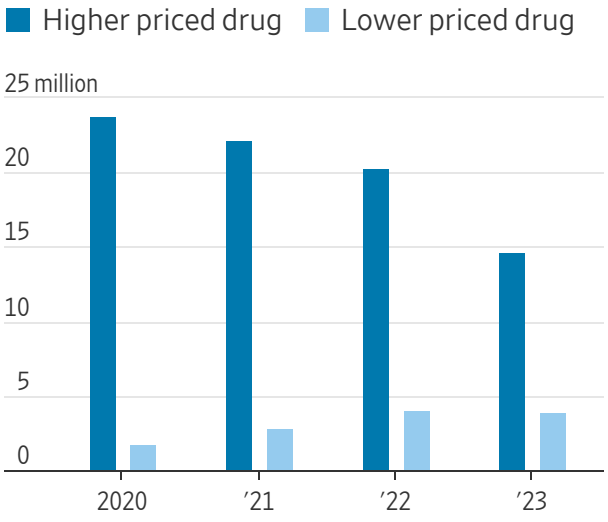
price.

Yet some drugmakers are also keeping the higher price they had been charging. Others are introducing a new drug with two prices simultaneously—one high, one low. And many health plans are choosing the more-expensive version, according to data analysis conducted for The Wall Street Journal.

The reasons reflect how the drug-payment system doesn't work like most markets.

Pricey Preferences

How prescription volumes differ between the higher- and lower-priced options for certain insulins and copies of AbbVie's Humira



Note: 2023 is through Sept. 30
Source: Iqvia

Health-insurance plans that pay for many medicines often use middlemen, called pharmacy-benefit managers, to negotiate how much the plans will pay. Usually, the PBMs ask for rebates from manufacturers in exchange for putting a drug on their list of covered medicines, called a formulary.

A higher-priced drug can result in a bigger rebate to the PBM. Drugmakers say they have to keep offering the costlier versions to gain a favorable spot on the formulary because the PBMs prefer the higher rebates and fees with costlier drugs. The manufacturers say their drugs' lower-priced twins do appeal to hospitals and health systems that pay for the medicines themselves.

PBMs say the rebates can substantially lower the plans' final costs for drugs. Some plans use the rebate money to help keep a lid on premiums for all their members.

For patients like Favro, whose health plans require a deductible or coinsurance, the rebates offer little help because their plans often peg out-of-pocket charges to the drug's list price.

"Patients are overpaying," said Stacie Dusetzina, professor of health policy at Vanderbilt University School of Medicine. "If you have to pay based on the list price, you're probably pretty worried about this."

She said patients should ask their doctors or pharmacists if a lower-priced option is available. There are also services, like GoodRx, that people can use to find the best prices for drugs.

For a sample of the two-priced medicines, about 78% of prescriptions dispensed in September were for the more expensive versions, according to an analysis for The Journal done by prescription tracker Iqvia Holdings.

The analysis included certain insulins and copycat versions of AbbVie's arthritis, skin and gut disorder drug Humira.

Pharmacy-benefit managers say drug companies set their own prices, and plans sometimes choose to cover the higher list price version of a drug because manufacturers' rebates make them cheaper even than the versions with lower list prices.

"We make decisions on what is the lowest net cost to a plan sponsor," said Harold Carter, chief pharma trade relations officer at Cigna Group's Express Scripts. The PBM also offers services aimed at capping out-of-pocket costs for individual patients.

Eli Lilly sells two versions of insulin drug Humalog: one for $274 a vial and an identical but unbranded version for $25. PHOTO: PABLO SALINAS/ASSOCIATED PRESS

Lilly had raised the list price of its Humalog insulin for many years through 2017, drawing criticism from patients and politicians. Yet Lilly said rising rebates paid to PBMs ate up the price increases, and its revenue from the product actually dropped.

In 2019, Lilly introduced the lower-priced, unbranded version, initially at a 50% discount to Humalog. Later Lilly cut the no-name product's price further—most recently to $25 in May.

The company introduced the lower-priced unbranded version to help patients who face high out-of-pocket costs. Lilly has said insurance coverage for the cheaper, unbranded version is lower than for branded Humalog because middlemen still prefer the higher fees and rebates associated with the higher-list-price Humalog.

Express Scripts, one of the country's largest PBMs, added the unbranded version to its list of preferred drugs only after Lilly cut the price all the way down to $25 this spring.

"It makes more sense to have a lower-price version out there, but I think the complexities of the U.S. payer system are what makes this kind of funky," said Stephen Pagnotta, a commercial official at drugmaker Boehringer Ingelheim.

In July, the company rolled out its immune disease drug Cyltezo. In October, Boehringer added a lower-priced version. Now, a two-pack of Cyltezo lists for

$6,577 and $1,350.

Cyltezo is among a handful of drugs that are copycats, or biosimilar versions, of Humira, a widely used brand-name therapy. Humira, from the company AbbVie, was among the world's top-selling drugs before losing patent protection earlier this year.

Humira is priced at $6,922 for a two-pack, or roughly $90,000 a year. It commanded roughly 99% of prescriptions compared with its biosimilar rivals through the end of September, according to Iqvia, even though versions of Cyltezo and some other copycats are priced lower.

All of Cyltezo's prescriptions are for the higher-priced version, Pagnotta said. Boehringer is talking with health plans about adding the less expensive twin to formularies.

Another of the Humira copycats, Amjevita from Amgen, lists for $40,500 or $85,494 a year. Amgen said it set two prices because some drug-benefit managers sought the rebates that come with higher list prices, while it also wanted to ensure patients could get the drug.

More than half of Amjevita's prescriptions filled were for the lower-priced option, Iqvia said.

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Further Reading

Eli Lilly Plans to Spend $27 Billion on New U.S. Plants