

# **Drug Pricing 101** If You Are Making Policy Decisions About Drug Prices Based upon List Prices, You Are Making Bad Decisions

By William Smith

## Introduction

The world of drug pricing is highly complex and, for many policy makers, highly opaque. The reason for this complexity is simple: government. Governments at the federal and state level have demanded certain discount levels for drug purchases, and those discounts vary in amount and are very complicated in their construction. Governments at the federal and state level have demanded certain discount levels for drug purchases, and those discounts vary in amount and are very complicated in their construction.

For example, in the state-federal Medicaid program, manufacturers must pay a base rebate equal to 23.1 percent of the Average Manufacturer Price (AMP) or the AMP minus the "best price" discount provided to other purchasers, whichever is greater. So,

manufacturers must not only calculate the AMP (a highly complex exercise), but they must also make certain that no other customers receive a price lower than AMP minus 23.1 percent.

In addition, some states require "supplemental Medicaid rebates" beyond the federally required discounts, and these state rebates are calculated in a variety of ways. In another example, in the Medicare Part B program, the government will reimburse for drugs based upon something called "average sales price" (plus 6 percent). There are different formulas used by governments to calculate prices in the 340B program hospital discount program and for the Veterans Administration.

If drug manufacturers make an error in their own favor when performing these highly complex calculations, they are usually subject to prosecution by the U.S. Justice Department. (It might be a worthy policy reform to have a more rational and uniform pricing system for government drug purchases. Has any policy maker considered developing a more uniform system of pricing for government purchases of drugs? Not to our knowledge.)

Therefore, preparing a comprehensive analysis of drug pricing terms and formulas would require a book-length work. However, policy makers need not fret about the inherent inability of normal human beings to understand all aspects of drug pricing because, in reality, there are really only two drug prices. First are drug "list" prices. These are the advertised prices drug makers publish each January that represent the opening bid that the companies offer to customers.

However, that opening bid is almost never the price that is actually paid. The prices that are actually paid are the "net" prices, or prices after all rebates, discounts, fees, and other incentives are given to



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customers. When formulating these discounts, the formulas require all manner of complex mathematical calculation but, in the end, all the calculations are designed to arrive at a final net price that customers actually pay. So, while the level of these rebates, fees and discounts are calculated using highly complex formulas, the reality is that there are only two drug prices: advertised list prices and net prices that customers actually pay.

In this policy brief, we hope to offer a simple guide to understanding the world of drug prices, which are so much in the news.

#### List Prices and Fake News

Each January, we can count on a slew of misleading stories about "rising drug prices." January is the month in which drug manufacturers publish their "list prices." As mentioned, list prices are not the actual prices paid by customers such as health plans. List prices are the equivalent of the sticker prices one would find on the window of a new car on a dealer's lot, exclusive of discounts or other "incentives" the car dealer or the manufacturer may offer to entice potential buyers.

Nonetheless, each January, the media reports drug list prices as if they were actual prices. Whatever their motive, the media's inability to distinguish list prices from net prices propagates the false narrative that drug prices are "skyrocketing." The examples of these misleading media stories are so many, but you can find just a few for 2023 here, here and here.

These media stories about drug prices, therefore, have an air of kabuki theater, where headlines and showmanship are more important than substance.

The reality is that these stories can be highly misleading, because, as we explained, list prices are not actual prices. So, if the list price of a drug rises by 7 percent year-over-year, one cannot know the prices actually being charged to customers without tracking the rebates, fees and other discounts provided by manufacturers for that drug during the year. Therefore, understanding the difference between list prices and net prices is the key to understanding whether drug prices are actually rising or falling.

#### List Prices v. Net Prices

When the January stories about "rising" drug prices appear, they are inevitably accompanied by a discussion of the policy solutions to drug prices. The "solutions" inevitably revolve around some type of government regulation or price control that would restrain "rising" prices. What if, however, actual drug prices are not rising? What if they are falling? If, in reality, drug prices are actually falling, reporters are not only writing misleading stories about actual prices, but also injecting policy prescriptions into the debate that are wholly unsuited to the nature of the problem.

One of the keenest analysts of drug prices and, in particular, of the important difference between list prices and net prices, is Dr. Adam Fein, who publishes the blog <u>Drug Channels</u> and also runs the <u>Drug Channels Institute</u>, a very helpful source of information on all things prescription drugs.

Fein has for a number of years pointed to a data phenomenon he has labeled the "Gross to Net Bubble." Quite simply, the gross-to-net bubble is the difference between list prices and net prices. And, more importantly, the size of the gross-to-net bubble represents the grand total of all rebates, fees, and other discounts provided by drug manufacturers to customers in order to lower list prices and make their products more attractive. During 2021, Fein <u>estimated</u> that the size of the gross-to-net bubble was \$204 billion.

If Fein's estimates are accurate, and there are many <u>reasons</u> to believe that they are, then \$204 billion is being transferred from drug manufacturers to health plans and some middlemen, such as pharmacy benefit managers (PBMs), pharmacies and wholesalers. Moreover, if Fein's estimates are correct, then all those stories about list prices that are published each January are off by a factor of more than \$200 billion.

So, while the level of these rebates, fees and discounts are calculated using highly complex formulas, the reality is that there are only two drug prices: advertised list prices and net prices that customers actually pay.

Therefore, understanding the difference between list prices and net prices is the key to understanding whether drug prices are actually rising or falling. In addition, Fein has <u>concluded</u> that when the gross-to-net bubble is factored in, then net drug prices have been dropping for an unprecedented five straight years. For 2022, Fein estimates that list prices rose at a rate of 4.9 percent while net prices dropped by 0.8 percent. Moreover, if the 8 percent inflation rate for 2022 is factored in, then net drug prices dropped by 8.7% during 2022.

Without much success, drug manufacturers have tried to point to the gross-to-net bubble to point out that drug prices have not been "skyrocketing." After relentless criticism of their insulin prices, for example, the French company Sanofi decided to issue an annual report pointing out that, while their list prices had seen increases, net prices—the actual revenue their insulin products generated—had been declining. You can find Sanofi's 2022 report <u>here</u>.

While \$204 billion in discounts is a large sum, it does not tell you about the average discounts off the list prices being offered by drug manufacturers. How deeply do drug companies discount?

To answer this question, Fein looked at 10 large pharmaceutical companies and <u>calculated</u> their average discounts off of list price. Fein found that the average reduction from the list price for these ten large companies was 52.2 percent, with the largest discounts being provided by insulin maker Novo Nordisk, which averaged discounts of 75 percent off of list price.<sup>1</sup>

Why does this gross-to-net bubble exist and why is it continually expanding? After all, while some discounts are provided to customers who are purchasing cars, they do not come anywhere near 50 percent.

Unlike discounts on cars, rebates and other discounts provided by drug makers are paid retroactively when the drug maker can confirm that the health plan has secured a certain level of sales promised in their pricing agreement. So, a drugmaker may promise to provide a 40 percent rebate on a drug if the health plan can steer 50 percent of patients who need that type of drug toward that particular company's drug. Therefore, unlike cars, these discounts cannot be provided at the point of sale, but only after the drug maker sees the quarterly sales numbers and confirms that the health plan and the PBM have delivered on their promised market share. In short, the discounts are traded for promises of market share.

The gross-to-net bubble exists because of fierce price competition within certain classes of drugs between manufacturers who are constantly required to offer more generous rebates to secure or retain market share. If a drug is in a disadvantaged position on a drug formulary, a doctor may need to fill out various paper forms to secure the drug for their patient, then that drug's market share is sure to drop. Drugs that can be prescribed without restriction tend to secure generous market share. Health plans and PBMs, therefore, secure generous rebate revenue by imposing restrictions on drugs with the least generous rebates and, on the other hand, offering easy access to drugs with generous rebates.

Specifically, the gross-to-net bubble arises when a drug manufacturer wants to secure or retain a favorable position on a drug formulary by offering a more generous rebate and one method they use for offering deeper rebates is through raising the list price. Here is how that works:

Imagine a drug company is selling a drug with a list price of \$500 per month and it secures a favorable position on a health plan formulary by providing a \$200 per prescription rebate. In return for this 40 percent discount, the company's drug has no restrictions on the health plan's formulary. No extra paperwork is required for a prescription for this drug. Therefore, at this net price of \$300 per prescription, this company's drug secures 60 percent of the market share in its therapeutic class. A competing drug company comes along and wants to capture its competitor's market share, so it offers the health plan and PBM a rebate of \$220, \$20 dollars above its competitor's rebate, and at the same net price of \$300. If 150,000 patients are taking this commonly prescribed class of drugs Unlike discounts on cars, rebates and other discounts provided by drug makers are paid retroactively when the drug maker can confirm that the health plan has secured a certain level of sales promised in their pricing agreement.

<sup>&</sup>lt;sup>1</sup> It seems that insulin makers offer some of the steepest discounts off of list prices with Novo Nordisk at -75 percent, Eli Lilly at -61 percent and Sanofi at -49 percent. And, not surprisingly, some of the most misleading media stories about drug prices have involved insulin.

and 100,000 of those patients can be steered to this new competitor's drug, that \$20 increase in rebate is worth \$2,000,000 to the health plan.

What is the original drug company going to do to keep its market share? It has two choices. One is simply to drop its net price to \$270, and provide a rebate of \$230, exceeding the bid of its competition. This, however, would result in a net price drop of \$30. But it has another choice: it can raise the list price in order to beat its competitor's rebate. If the drug company raises the list price to \$550, and keeps its net price at \$300, it can provide the health plan and PBM with a \$250 rebate per prescription, far exceeding its competitor's bid, without lowering its net price.

This is precisely what has been happening in the rebate-driven prescription drug marketplace, and it explains the growth in the gross-to-net bubble. Vast inflation in the list prices of drugs is the result of companies needing to provide more "headroom" for more generous rebates, even though net prices are remaining steady or even declining.

What, one may ask, is the problem with this? Health plans are receiving more generous rebates and drug companies are capturing market share and remaining profitable. Isn't this a way for the healthcare system to reduce drug costs?

# **The Problem for Patients**

The gross-to-net bubble may provide more and more generous rebates for health insurers and PBMs, but it is placing a greater financial burden on patients who pay cash for their prescriptions, either patients who are uninsured or those who must meet high deductibles before their insurance kicks in. With an expanding gross-to-net bubble, these patients are the big losers, as many cannot access the rebates and discounts negotiated by PBMs and health plans. One of the most urgent policy issues to be addressed under the current drug pricing regime is how to pass on rebates and discounts to patients at the pharmacy counter.

In 2022, the average deductible obligation for an insured patient was \$1763, according to the Kaiser Family Foundation. However, many patients who are insured by their employers find themselves in high deductible health plans with more than 50 percent of employer-based insurance now offered as high deductible plans. According to IRS <u>rules</u>, high deductible health plans can require out-of-pocket payments by patients of \$7050 for individuals and \$14,100 for families before insurance coverage begins.

Therefore, under the theoretical drug described above that has a list price of \$500 and a net price of \$300, when patients are meeting their deductible, they may need to pay \$500 out of their own pocket to pay for one prescription because they are paying list prices, not net prices. The gross-to-net bubble harms many patients.

## **Implications for Policy Makers**

Over the last few decades, policy makers have lived in a world where overall drug spending was escalating every year. In 1980, per capita drug <u>spending</u> was less than \$200 per patient. Spending has increased more than sevenfold, not simply due to price increases but largely due to a huge number of new drug approvals. Drugs are simply a more important part of treating patients than they used to be. During this period when drug spending was accelerating, one could point to years where list prices and net prices of drugs were also both growing significantly. In those years, drug spending was growing because of both utilization and of price.

Policy makers need to recognize that the drug spending and price growth of the 80s, 90s and early 2000s has ended. Net drug prices have dropped for five straight years, and, despite many new drug approvals, patent expirations and other factors have kept overall drug spending growth in the low single digits.

With an expanding gross-to-net bubble, these patients are the big losers, as many cannot access the rebates and discounts negotiated by PBMs and health plans. Policy makers should recognize that drug spending has not been growing at significant rates. The data on drug spending growth in recent years has been skewed by the pandemic, but the flattening of drug spending and prices is clear. During 2020, many patients were not filling their prescriptions and drug <u>spending</u> grew at less than 1 percent. Drug spending growth rebounded in 2021, rising 12.1 percent largely due to COVID vaccines and treatments. Without those COVID therapies, spending growth was 4.9 percent. To get a reasonable figure for spending growth over the last couple of years, one might combine the 2020 figure and the 2021 figure and conclude that drug spending has been growing at an annual rate of about 2–3 percent in recent years, a very modest figure compared to earlier decades. This low single-digit spending growth has been the norm for a number of years.

In short, neither drug prices nor overall drug spending are growing significantly. Yet, despite the overwhelming data, policy makers continue to explore regulatory schemes to limit drug prices or drug spending. While they explore policy options not suited to the challenges we face, policy makers are neglecting a crisis faced by many patients: out-of-pocket costs for specialty medicines. The real challenge in prescription drug affordability is health insurance benefit design that is foisting greater and greater out-of-pocket (OOP) costs onto patients in order to drive up health plan and PBM profit levels.

Growing out-of-pocket costs are not imposed upon patients who are taking generic drugs for chronic conditions but upon those patients who are facing more challenging diseases, such as cancer, cystic fibrosis and multiple sclerosis, and who are taking so-called specialty drugs, drugs that may be infused or injected.

Some insurance companies are refusing to cover specialty medicines altogether and they divert patients into so-called accumulator and maximizer programs designed to maximize patient OOP costs. A discussion of these programs is beyond the scope of this paper, but it is worthwhile to point out that health plans and PBMs are employing an aggressive strategy to maximize out-of-pocket costs for patients who require a specialty medicine.

While the political issue of "drug prices" continues to resonate with the electorate, it is our belief that this is due to the fact that some patients are being required to shell out much more money from their own pocket for drugs and they falsely believe this is due to high drug prices. It is, in fact, due to suboptimal insurance benefit design.

The mission of health insurance is to provide a financial backstop for patients if they get sick. Our insurance system is now moving to a place where sick patients with challenging diseases are being charged huge OOP sums in order to keep premiums low for the enrollees in the plan who are not facing challenging diseases. The system is moving toward a place where it imposes financial penalties upon the sick to protect the healthy and wealthy.

This OOP problem is currently the greatest challenge facing the healthcare system. Biopharmaceutical research is now producing many spectacular specialty drugs for very challenging diseases. Increasingly, those drugs are not being made available to patients who need them at an affordable cost. This challenge – not tired speeches about drug prices that could have been written 40 years ago – is what warrants the focus of policy makers. While they explore policy options not suited to the challenges we face, policy makers are neglecting a crisis faced by many patients: out-of-pocket costs for specialty medicines.



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