



25 years of change: Pharmacy benefits since 2000

The rise of biologic drugs

Optum Rx[®]



As we enter the 25th year of what we used to call the “new century,” it seems fitting to look back at what’s happened in the pharmacy benefits business over that time.

From this perspective, it’s clear that there have been profound changes – especially on the pharmaceutical side – with the rise of specialty biologic drugs.

There have been other important changes. The increased use of biologic drugs has spurred the development of the biosimilars industry. And, the pharmacy benefit management industry has also changed, especially as companies race to deploy new technologies to make their services faster, more transparent, and more meaningful to members and clients.

These changes are not just academic. They form the core of what it now means to offer prescription drug coverage to millions of Americans. In this e-book we will try to summarize some of these important changes and describe their impacts today.

Pharmaceuticals

Entering the 2000s, the pharmaceutical industry had evolved a business model that featured drugs targeting very large populations. That model was very successful. For example, Lipitor® for high cholesterol, was the biggest selling drug in 2000, with a target population around of 1 billion people.¹ Accordingly, the pharmaceutical industry was the most profitable sector in the Fortune 500 for the year 2000.²

Timeline

2000

● —————
First draft of human genome

But a dramatic change in the pharmaceutical world began around the year 2010. Over a period of five or six years, drug makers faced one of the biggest waves of drug patent expirations in history.³

Manufacturers of branded traditional drugs lost billions in sales as dozens of popular products like Plavix®, Singulair®, and Lipitor reached the end of their patent protections.⁴

From mass markets to small populations

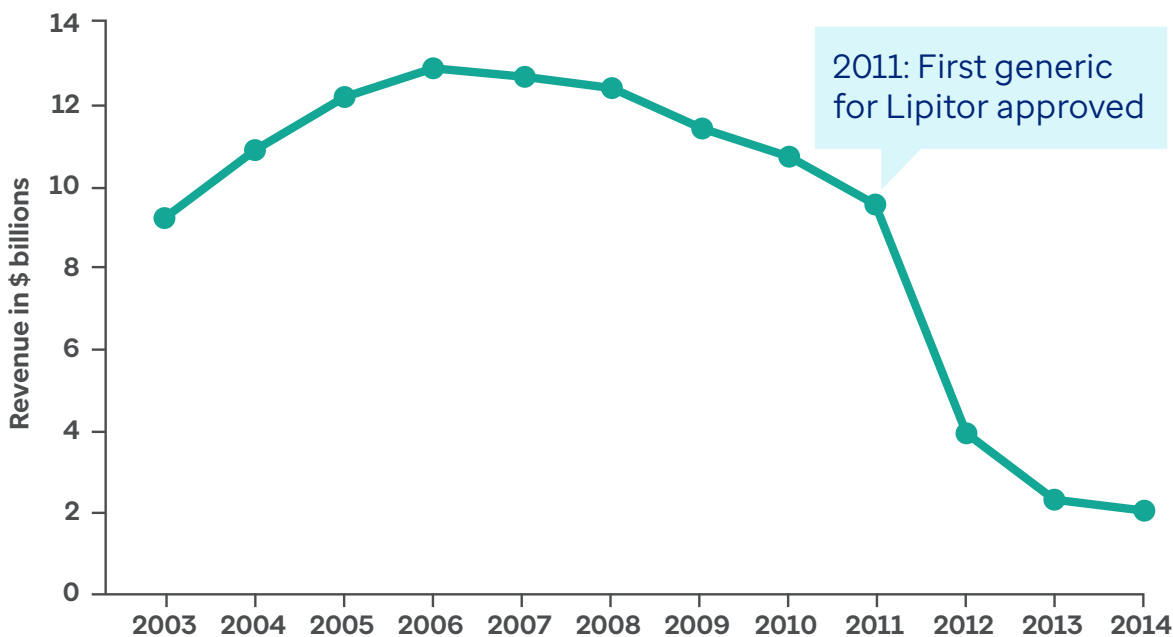
While new drugs are expensive to develop, once a new drug enters the market, tough protection from competition can mean high profits – gross profit margins can exceed 90%.⁵

But when patents run out, drug maker profits can fall substantially.

Historically, once a drug lost patent protection, generic makers are ready with cheaper generic versions. Under perfect market-competitive conditions (i.e., 5-10 competitor generics), it is not unusual for a branded drug to then lose upwards of 90% of their sales within a year or two.⁶

This is exactly what happened with the #1 selling drug of 2000, Lipitor:

Worldwide revenue for Lipitor



Optum Rx image adapted from Springerplus. [Patent cliff and strategic switch: exploring strategic design possibilities in the pharmaceutical industry](#). Published May 23, 2016.

2002



Humira® first approved

2004



FDA approves 1st monoclonal antibody

Lessons learned

As their losses accumulated over the 2010s, drug manufacturers began to grasp an important truth: **Huge sales and big target populations are great, but huge losses are not.**

As a result, drug makers began to change their strategy as they looked to replace expiring old drugs with new ones.⁷

There are actually two parts to this new drug development strategy:

- First is an increased focus on biologically-engineered drugs.⁸
- Second is to wrap each new biologic drug in multiple layers of patents to prolong the period of market exclusivity.⁹

Let's see how these factors have played out for some of the top-selling branded drugs for the years 2000 and now:

Top selling drugs in 2000

Drug Name	Indications	# Patients (worldwide)
1. Prilosec®	Acid reflux disease	1 billion+
2. Lipitor®	High cholesterol	1 billion+
3. Prevacid®	Acid reflux disease	1 billion+
4. Prozac®	Depression	280 million
5. Celebrex®	Arthritis	595 million

2000: Drug Topics. [Top 200 drugs by retail sales in 2000](#). Published March 19, 2001.

Top selling drugs in 2023

Drug Name	Indications	# Patients (worldwide)
1. Keytruda®	Various cancers	1.8 million
2. Humira®	Rheumatoid arthritis	17.6 million
3. Ozempic®	Type 2 diabetes	530 million
4. Eliquis®	Nonvalvular atrial fibrillation	53 million
5. Dupixent®	Atopic dermatitis	204 million

2023: Drug Discovery. [Best-selling pharmaceuticals of 2023 reveal a shift in pharma landscape](#). Published May 21, 2024

2005

United Healthcare buys PacifiCare

Comparing the lists a few things jump out:

For 2000, the drugs are all **traditional** in form – i.e., tablets or pills made from chemicals.

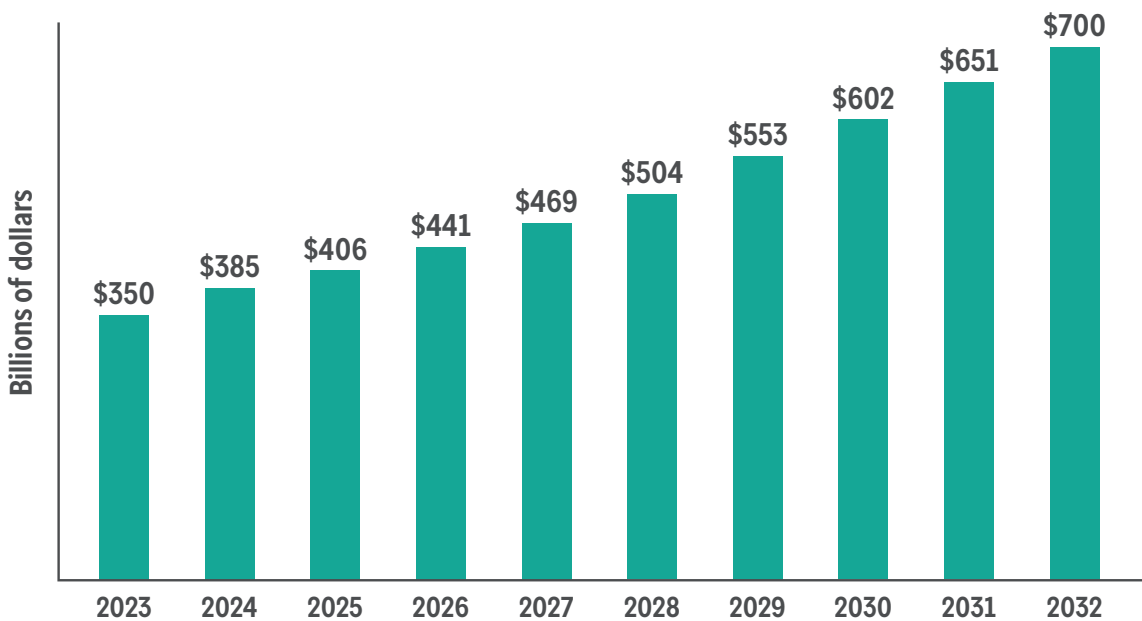
The potential markets are **huge**. The top three drugs are all for some of the most common conditions in the world.

In addition, in 2000 the per-prescription prices for these popular drugs were relatively low. At the time, Lipitor cost \$65.29 per month, (about \$119 adjusted for inflation).¹⁰ In comparison, the median annual price for new drugs was \$300,000 in 2023.¹¹

For the more recent list, only Eliquis is a traditional small-molecule drug. The rest are large protein molecules produced from living organisms. In other words, **biologic** drugs. These typically require administration as an injection or infusion.

Moving forward, we can expect to see the biologics market continue to grow – if not dominate the drug scene – for the foreseeable future:

Biologics market – 2023 to 2032



Optum Rx image adapted from: BioSpace. [Biologics Market Size to Reach USD 699.5 Billion by 2032, Impelled by Emergence of Advanced Drug Delivery Systems](#). August 8, 2024.

2006

FDA approves 1st recombinant vaccine

2007

CVS acquires Caremark

Cost consequences

These new pharma strategies have had a dramatic effect on costs. We can summarize a few of the reasons why:

- Biologic drugs are extremely expensive. The average specialty drug costs \$5,000 per year. But the price of the average new biologic drug is now \$300,000, and certain gene therapies can reach into the millions of dollars.^{12,13}
- By focusing on relatively rare conditions, drugmakers increase their chances of becoming **the only supplier** for a given patient population. **This is practically the definition of pricing power.**¹⁴
- Biologic drugs can make meaningful differences in certain rare and hard-to-treat conditions.¹⁵ As such, these treatments “... are needed by vulnerable patients who seek to improve the quality of life or to prolong life.”¹⁶
- Biologic drugs are perfect vehicles for abusive patent strategies. Their large size and complex manufacturing requirements make it relatively easy for drugmakers to prevent competitive pressure on prices. A recent study documented **\$17 billion per year in lost savings for just five biologic drugs** thanks to the use of excessive secondary patents.¹⁷

Higher costs – then even higher

With headline-grabbing prices in the millions of dollars, it’s easy to think that the launch price of new drugs is the cause of higher spending. However, that’s not actually true. Of course high launch prices matter, but in fact **most pharmaceutical revenue comes from their ability to steadily increase prices for existing drugs over a period of years.**¹⁸

This slow but steady ratcheting-up is a serious problem. For example, **patient and government spending on all biologic drugs increased by 160%** on an inflation adjusted basis between 2013 and 2021.¹⁹

These continuing price increases are far above the rate of inflation, which is bad enough.²⁰ But one unsettling aspect of these increases is that they can appear to be unsupported by any clinical rationale. The Institute for Clinical and Economic Review (ICER) has published an annual report since 2019 documenting this. The most recent report observed that, out of 10 drugs reviewed, at least half were lacking any evidence of additional benefits or reduced harm.²¹

2009

3 genes identified for Alzheimer’s disease

So it's little wonder that large pharmaceutical firms **continue to be the most profitable in the world** – even after all the changes since 2000. In fact, researchers have found that “... **large, brand-name drug manufacturers would still be the most profitable industry sector even with \$1 trillion in lower sales, all while maintaining current research investments.**”²²

Brand-name drugmakers would be the most profitable industry even with \$1 trillion in lower sales, with no loss of R&D.

In short, the strategic shifts toward biologic drugs, maximum pricing power, and continual price increases described here help explain why prescription drug prices in the U.S. are more than **400% higher** than in the rest of the world.²³

What about biosimilars?

Biosimilars, like generic drugs, may reduce the price of therapies compared to the original branded medicines. Biosimilars are biologic drugs that are highly similar to and have no clinically meaningful differences from an existing FDA-approved biologic.²⁴

However, biosimilar use has been limited by several factors, most notably the elaborate patent defenses used by brand-name manufacturers to protect their market exclusivity.²⁵

Recently we have seen more biosimilars come to market as patent protections finally begin to run out. But on the whole, the U.S. lags considerably behind other developed nations in the number of biosimilars for sale, as well as their utilization.²⁶

That said, biosimilars are putting some downward pressure on the prices of certain biologic drugs. **But increasing numbers of new specialty drugs, with their higher price tags, tends to mask or eliminate any lower costs.**²⁷

In dollar terms savings are picking up steam. In 2022 savings from the use of biosimilars amounted to about \$8.6 billion in the U.S. That amount jumped more than 30% in 2023 to \$12.4 billion.²⁸ For reference, total spending for biologics was about \$350 billion in 2023.²⁹

2011

Optum launched

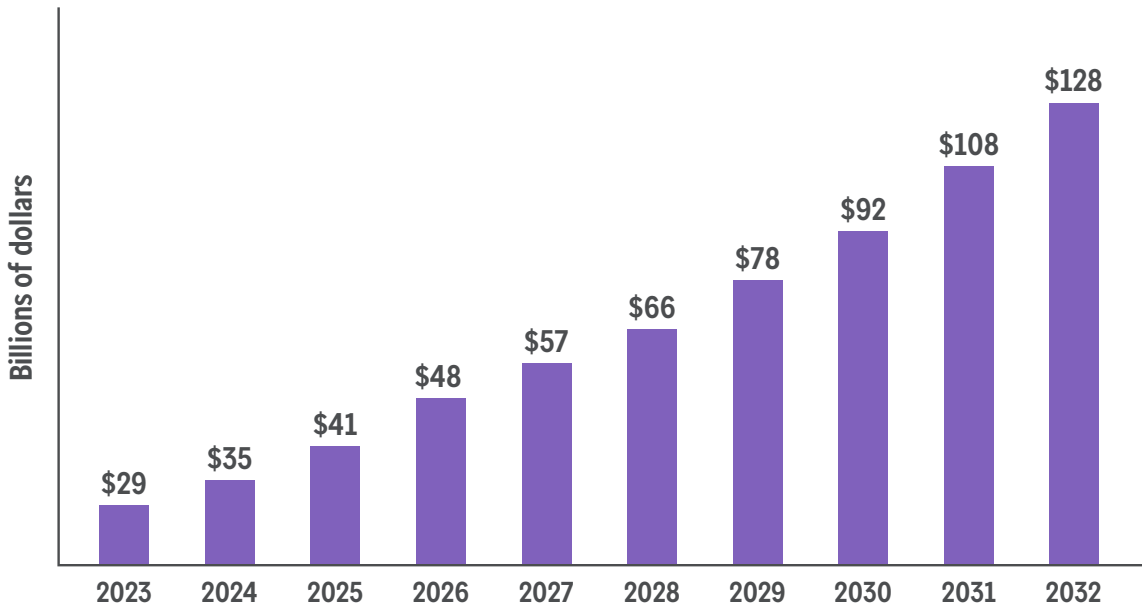
2012

Express Scripts acquires Medco

Slow growth

Today, the total biologics market worth \$350 billion. As the graph below indicates, about \$30 billion goes toward biosimilars. That's about 8%. Over the next decade, the biosimilar market is expected to grow more than 400% to \$128 billion, which is encouraging.

Biosimilars market – 2023 to 2032



Optum Rx image adapted from: BioSpace. [Biosimilars Market Size Poised to Hit USD 150.26 Billion by 2033](#). Published June 17, 2024.

Not as encouraging is that biosimilar uptake in the US has been “... less robust than expected” according to one recent study.³⁰ The study found that while biosimilar use increased from 1% in 2013 to 34% in 2022, uptake of biosimilars varies widely across patient demographics, geography, site of care, and prescriber specialty, and insurance type. It also matters which biosimilar is considered, with some seeing far more use than others.³¹

Part of the reason biosimilars continue to lag in terms of total use is that the branded drug market never stands still. Every day sees more and more biologic drugs entering and emerging from the development pipeline. Each comes with a brand new exclusivity period, and bristling with protective patents.

2012

FDA issues draft rules for biosimilar drugs

[There are other barriers to widespread biosimilar adoption.](#) Insurance coverage – or lack thereof – is a big one. Payors need to be sure that biosimilars are included in their formularies and designated as preferred. Patient and provider knowledge or misconceptions about biosimilars are also important barriers. If a physician is hesitant to use biosimilars because they don't know all their options, or don't understand how they work, they are less likely to prescribe them. Interchangeability – the freedom for pharmacies to switch to the lower-cost biosimilar form without prior permission – is perhaps one of the key stumbling blocks.

Optum Rx biosimilars strategies

Bringing biosimilars to the marketplace is one of the biggest opportunities in years to lower costs and increase accessibility for consumers. As more biosimilars come to market, Optum Rx will continue to collaborate across the health care industry. Our goal is to ensure that these products are thoroughly evaluated, so that we can make informed decisions about whether they will be added to our formulary.

Optum Rx was the first pharmacy services company to add a Humira® (adalimumab) biosimilar to its formulary at parity with the original product and the first to include both the high-list and low-list options. Optum Rx continues to bring choice and affordability to plans and patients via its biosimilar approach. Starting in January 2025, Optum Rx will prefer FDA-approved adalimumab biosimilars for patients new to therapy. In addition, Optum Rx is working with Nuvaila, a pharmaceutical commercialization business, to carry a reliable supply of two biosimilars with up to \$0 copay support for patients.

Rise of specialty medications

The rise of specialty drugs is one of the biggest changes in the pharmacy landscape over the last quarter century. Loosely defined, specialty drugs are those that often require special handling, high-touch care, limited distribution sources, and not least, high cost.³²

Specialty drugs are ~75% of the new drug pipeline.

Utilization, not price, is the leading driver of specialty spending.

2018

CIGNA acquired Express Scripts

2018

CVS acquires Aetna

In 1990 there were only 10 specialty drugs on the market. Today there are more than 400 specialty drugs, with more on the way.³³ In 2023 at least 80% of the novel drugs approved were specialty, and specialty drugs now represent approximately 75% of the 7000 the new drugs in the development pipeline.³⁴

The vast majority of specialty drugs are also biologic drugs. They continue to grow so quickly because of the highly targeted way biologics work. By altering or influencing basic biological pathways, biologics can sometimes offer improved outcomes where traditional drugs cannot.³⁰

Specialty drugs represent only one to two percent of pharmacy claims, but their very high prices means they have an impact drastically larger than that. Currently, specialty drugs account for over 50% of employers' total prescription spending.³⁶

For example, the most commonly prescribed drug in the U.S. is Lipitor (atorvastatin), which retails for around \$167 per year.^{37,38} But a recent study showed that **the average annual cost for widely used specialty drugs in the U.S. was \$84,442.**³⁹

We should note that while high drug prices are definitely a big factor in the overall cost of specialty drugs, they are not the biggest. **Actually, utilization has been, and continues to be the leading driver of specialty trend,** accounting for more than half of trend in 2023. In short, while specialty drugs continue to get more expensive, more and more people are using them.⁴⁰

Pharmacy benefits industry

Pharmacy benefit managers (PBMs) have existed since the 1950s. Their first role was mainly to serve as claims processors dedicated to just pharmacy benefits. In the years since, PBMs have grown to become an integral part of the healthcare and pharmaceutical supply chain.⁴¹

Now PBMs are intimately involved with formulary design, utilization management, building pharmacy networks, managing mail order pharmacies, and negotiating with wholesalers and manufacturers to find the lowest net costs for the drugs for their clients.⁴²

2023

First biosimilar competitor for Humira

Structurally, PBMs entered the 2000's already having assumed many of the roles they play today, as well as having established most of the principal players, including CVS Health (now including Caremark), Express Scripts (now partnered with Cigna and known as Evernorth), and the predecessor firms that would eventually become Optum Rx.⁴³

PBMs do have a direct impact on pharmacy costs and care quality – but **not** the way they are commonly portrayed. [In fact, PBMs play a vital role in controlling drug spending while improving care quality care.](#)

We can highlight some recent findings from third party resources:

- PBM purchasing volume applies leverage over product suppliers. Robust PBM buying power has helped them to **negotiate lower drug prices** and keep annual price growth low.^{44,45}
- If PBMs didn't perform utilization to control utilization, management or price negotiations, plan sponsors would likely have to do it themselves. Having PBMs do this work **contributes \$145 billion per year to the economy**, even after the cost of paying the PBMs.⁴⁶
- **PBM formularies promote quality care** through the decisions made by Pharmacy and Therapeutics (P&T) Committees. They consist primarily of independent clinicians who are charged with reviewing the scientific evidence for each drug – before any cost considerations.⁴⁷
- **PBMs promote competition among drug manufacturers.** Makers of similar products compete by granting price concessions to get on PBM formularies.^{48,49} Look specifically at the blockbuster GLP-1 weight loss drugs. Johnson & Johnson recently estimated that, as an industry, drug makers are charging about 60% less for these drugs after PBM negotiations.⁵⁰

PBM price negotiations have reduced GLP-1 prices by ~60%.

2025

43 cell and gene therapies approved in U.S.

How Optum Rx can help

The challenges to high quality, affordable pharmacy care are real, as we've seen. But at Optum Rx, we're working to make health care better.

- For our clients, we are committed to providing end-to-end transparency, from the evaluation and management of drugs to formulary guidance and choice. We also offer robust audit rights and pricing models that align with your plan's objectives.
- For members, we go beyond engagement to provide strong advocacy and protection. This includes offering the lowest available prices, copay card assistance, point-of-sale (POS) rebates, and clear guidance through prior authorizations, ensuring a smooth pathway to accessing necessary medications.
- For providers, we equip physicians with the tools they need to make better decisions at the most critical moment: When they are prescribing. We support adherence by providing tools that help members get the right medications and by adopting collaborative approaches to reduce claims costs and address clinical opportunities.

Let's dive deeper into how the power of partnership can help guide you and your members to prepare for the future, today.

To find out more about how we are helping clients manage the biggest drug spend categories, please [contact us](#).



Additional resources

[Biosimilar Interchangeability: Practical Steps to Improve Uptake](#)

[How Pharmacy Benefit Managers Add Value, Lower Costs](#)Resource

[Autoimmune, Oncology, Diabetes and Obesity Rule Drug Spending](#)



Podcasts

[Biosimilars boom: The next era](#)

[The New Drugs Plan Sponsors Need to Watch For](#)

[Preparing For the Gene Therapy Era](#)



About Optum Rx

Optum Rx is a pharmacy care services company helping clients and more than 60 million members achieve better health outcomes and lower overall costs through innovative prescription drug benefits services.

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