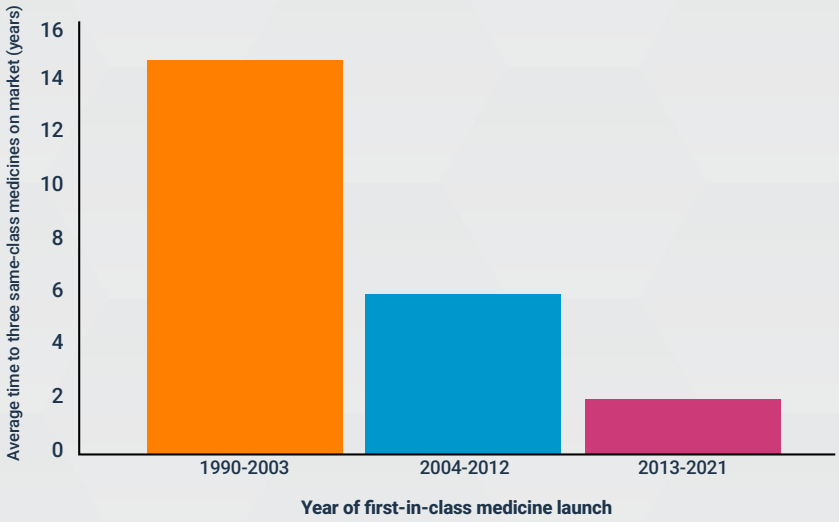
America's IP System Balances Innovation and Affordability, but Middlemen in the Pharmaceutical Supply Chain Harm Access

Competition between brands, and from low-cost generics and biosimilars gives U.S. patients more medicine choices than anywhere else in the world while also keeping medicine costs a small and stable 14% of health care spending. Every generic and biosimilar exists because it started out as a brand medicine and these medicines represent 90% of the prescriptions filled today. That is because our IP system requires innovators to publicly share in their patents information about their inventions, paving the way for these lower cost options to reach the market. On average, brand drugs face generic competition after just 13 years on the market.[1]

Brand-to-brand Competition Reduces Costs: No company has a monopoly on treating a disease. Patents drive competition by encouraging manufacturers to develop alternative ways to address diseases relative to brands that are already on the market. As a result, most new medicines already have at least one competitor on the market at the time of market entry or will have one shortly after. Biopharmaceutical competition is also accelerating: Two decades ago, it took 16 years on average for a first-in-class medicine to have two competitors – now it takes an average of two years. Today, the top drug classes are highly competitive. In 2024, 16 of the top 30 drug classes had more than four approved medicines.[2] Payers leverage this competition to negotiate discounts and rebates which can lower the price of brand medicines by as much as half.[3]

Average Time for Three Same-Class Medicines to Go to Market Decreased by 13 Years

Competitive dynamics within specific drug classes have driven discounts and rebates in a number of therapeutic areas.



Brand-to-brand Competition Reduces Costs[4]

CGRP Inhibitors
(first treatments designed to prevent **migraines**)
2018 → 2023: **-52%**

PCSK9 Inhibitors
("a game-changer" in **high cholesterol** management)
2015 → 2023: **-85%**

DAAs
(**Hepatitis C** cure rates approaching 100%)
2013 → 2023: **-86%**

SGLT2s
(managing not only **Type 2 diabetes** but providing heart and kidney benefits)
2014 → 2023: **-57%**

GLP-1s for the treatment of obesity
(Transforming the treatment of a wide range of chronic diseases)
2021 → 2023: **-47%**

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Policymakers must protect U.S. innovation and IP while confronting insurer and PBM practices that block access to affordable medicines and put profits ahead of patients.

After more than two decades of horizontal and vertical consolidation, the three largest PBMs have come to wield enormous control over which medications patients can access and the degree to which they are affordable. PBMs, insurers and pharmacies are increasingly part of the same health care conglomerates with the three largest of these entities controlling 80% of the market today.[5] PBMs are often compensated based on the list price of medicines, which may encourage them to reward medicines with higher list prices and larger rebates, while discouraging coverage of lower-cost alternatives.

Due to these misaligned incentives, PBMs and insurers routinely block access to generics and biosimilars. For example:

- New generics that launched in 2016 were covered in Part D just 22% of the time. Nine years later, these same generics were still covered only 54% of the time.
- In the commercial market, new generics that launched in 2016 were covered just 46% of the time that year. It wasn't until nine years after these products launched that coverage reached 86%.[6]
- The role that PBMs are playing in slowing the adoption of generics in the market today is also apparent in the 900% increase in commercial formulary exclusions among the three largest PBMs since 2014.
- Similarly, while the availability of biosimilars competing for coverage under the pharmacy benefit has increased dramatically over the past few years, 37 biosimilars have been excluded in 2025 from the commercial formulary of at least one of the three largest PBMs—representing a 164% increase since 2022 alone.[7]

Our IP framework fuels both innovation and affordability by paving the way for lower cost biosimilars. But if PBMS block access to those products by excluding them from formularies that careful balance breaks.

Sources:

1 Grabowski, H., Long, G., Mortimer, R., & Bilginsoy, M. (2021). Continuing trends in U.S. brand-name and generic drug competition. Journal of Medical Economics, 24(1), 908–917. https://doi.org/10.1080/13696998.2021.1952795

2 McKinsey Analysis. (2025). A New Era of Biopharmaceutical Innovation. PhRMA. https://innovation.org/wp-content/uploads/2025/02/PhRMA-InnovationReport.pdf.

3 MedPac, Report to Congress, 2023.

4 PhRMA Analysis of SSR Health Data

5 Fein A. The 2025 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. Drug Channels Institute, March 2025.

6 AAM, The U.S. Generic & Biosimilar Medicines Savings Report, 2025 (AAM) – September 2025