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Biosimilars are driving savings across the healthcare system, but will the Inflation Reduction Act hinder their potential?

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The biosimilar marketplace is realizing its potential as a critical tool to drive competition and savings in the American healthcare system. In fact, over the past 6 years, biosimilar launches have led to $21 billion in cumulative savings for Medicare, employers, patients, and other stakeholders.[1] Since the first biosimilar launched in the United States market in 2015, 42 biosimilars have been approved and 38 have been launched to compete against 11 reference biologics.[2] This competitive environment not only drives savings from the use of biosimilars themselves but also from reference products as they compete on price. As a result of the robust state of the biosimilar marketplace, the utilization of biosimilars is forecast to save more than $180 billion over the next 5 years, a more than 4-fold increase from the last 5 years.[3] While the future potential savings are substantial, these estimates vary widely and depend on a range of factors influencing market competition and uptake.

Unfortunately, just as the biosimilar marketplace was projected to fuel even greater competition and savings, this potential is now threatened by a new law that intervenes in the competitive market. The Inflation Reduction Act (IRA), signed into law in August 2022, includes drug price-setting provisions that discourage the development of biosimilar products.[4] While it is too early to assess the full impact of the IRA on the biosimilar landscape, efforts to mitigate the legislation's effects are needed to fully realize the promise of biosimilars.

Dynamic competition is driving down prices

Many biologics are physician-administered medicines reimbursed according to Medicare's average sales price (ASP) formula under the Medicare Part B benefit (see **Figure 1**). Data presented in **Table 1** demonstrate the significant decline in ASPs for both biosimilars and reference products, which have produced substantial savings for Medicare. Since ASP is a measure of what commercial insurers pay for drugs, the price also reflects savings that are occurring in the healthcare market more broadly.

Figure 1. ASP calculation

$$\text{ASP} = \frac{\text{Manufacturer's sales of drug to all purchasers in the US in a calendar quarter}}{\text{Total number of units of drug sold by manufacturer in the same quarter}}$$

In the small molecule medicine market, the introduction of generics often swiftly shifts market-share volume to generics as they compete aggressively on price; in the biologic market, the introduction of biosimilars often produces a dynamic effect. That is because lower-cost biosimilars simultaneously place downward pressure on biologic manufacturers to reduce prices of reference products in order to maintain market share. As a result, both reference products and biosimilars have decreasing ASPs, with many seeing their ASP lower by more than 45%. In fact, the prices of biosimilar drugs have been dropping by an average rate of 9% to 24% over the past few years, while the prices of the majority of reference products have lowered by an average rate of 4% to 21%.[1]

Evidence suggests dynamic competition resulting from biosimilar market entry is driving savings across Medicare and the broader health care system. A 2023 Cencora analysis of ASP trends found substantial reductions in the ASP of reference products following entry of first biosimilar (see Table 1).[1,5] For example, one reference product that dropped its price by 57% was able to withstand competition from biosimilars. In comparison, another reference product that lowered its ASP by 1% lost significant market share to biosimilars, which garnered 82% of the market by the middle of 2022.

Table 1. Trends in Medicare Part B payment rates for reference products and their biosimilars

	First biosimilar entry	Change in reference product's ASP since entry of first biosimilar (through Q3 2022)	Change in biosimilar's ASP since entry of first biosimilar (through Q3 2022)	Biosimilar's market share (Q2 2022)
Product A	2015 Q3	−1%	−60% to −73%	82%
Product B	2017 Q1	−57%	−41% to −62%	42%
Product C	2018 Q3	−36%	−38%	32%
Product D	2018 Q4	−66%	−56% to −65%	42%
Product E	2019 Q4	−14%	−52% to −63%	82%
Product F	2019 Q4	−21%	−41% to −69%	80%
Product G	2020 Q2	−13%	−44% to −58%	64%

Key: ASP – average sales price.

It is worth noting that prior to 2023, the biosimilar marketplace centered on physician-administered medicines, generally covered under managed care plans' medical benefit or the Medicare Part B benefit. But 2023 marked a pivotal moment for increased competition and projected savings with the market entry of 8 biosimilars, including 2 interchangeable products, to compete against a top-selling biologic, adalimumab, which is generally covered under the pharmacy benefit or Medicare Part D. The introduction of these pharmacy-benefit biosimilars is expected to drive additional savings in the coming years, particularly as it may be possible for those with interchangeability status to be able to negotiate formulary placement and, depending on state pharmacy laws, to be automatically substituted at the pharmacy counter without intervention from the prescriber, as is the case with many generic medicines today.

And yet, the outlook for biosimilars is under threat

Unfortunately, the IRA threatens to undermine the progress that has been made in the biosimilar marketplace. Specifically, the IRA requires the Centers for Medicare & Medicaid Services (CMS) to select certain medicines for negotiation in Medicare, including biologics, as soon as 11 years after US Food and Drug Administration approval, with a maximum fair price (MFP) set by the government going into effect 2 years after selection. Biologics eligible for selection must be in the top 100 medicines by spending in Medicare and be "single-source" at the time of selection with no "bona fide" marketed biosimilar version available.

However, the timeline for eligibility of biologics for negotiation under the IRA conflicts with existing legal and regulatory frameworks governing biologics and biosimilars in the US. Specifically, the Biologics Price Competition and Innovation Act (BPCIA), which created an abbreviated approval pathway for biosimilars in 2010, provides 12 years of data protection following the first licensure of an innovative biologic. The goal of the law, and the 12 years of market exclusivity it provides, is to maintain incentives for innovation while encouraging biosimilar market entry to drive competition and reduce costs.[6] But it also makes it unlikely for biosimilar entry to occur by the time a biologic is eligible for selection. Consequently, taking these existing legal and regulatory frameworks into account, it is likely that very few (or even zero) biologic medicines past the initial years of implementation of the IRA will be able to avoid price setting due to the presence of existing biosimilar competition.

Additionally, because the negotiation is a 2-year process, it is possible that in some cases a biosimilar competitor may be licensed and marketed after its reference biologic drug was selected but before the MFP went into effect. However, because of how CMS chose to interpret certain provisions of the IRA, the agency indicated that, depending on the timing of biosimilar marketing, the MFP may continue to apply for a selected biologic for the initial price applicability year and potentially for the following year, even if the selected biologic by then has a marketed biosimilar.

Biosimilar manufacturers face unique challenges that make the prospect of entering a market to compete against a reference product with a government-mandated MFP a significant disincentive. In particular, they face long development timelines and significant costs relative to small-molecule medicines due in large part to the complexities of biologic manufacturing. In fact, biosimilar development can take 7 to 8 years and $100 million to $250 million in investment.[7] As a result, the ability to recoup investment costs may not be possible for biosimilar manufacturers coming to market to compete against a reference product with a low government-set MFP.

To allow manufacturers with certain biosimilar products in development to come to market, the IRA allows them to apply for a "pause" in the MFP price-setting process if certain criteria are met. The pause may delay the selection of and negotiation for certain reference biologics if the Secretary of the US Department of Health and Human Services determines there's a "high likelihood" that a biosimilar will be licensed and marketed within the timeframe laid out under the law. It remains unclear whether the pause will be sufficient to allow biosimilar products to successfully come to market or to meet CMS's ill-defined "bona fide" marketing standard. The timelines and criteria used to operationalize the pause may not provide the predictability and assurances needed to justify investments in biosimilar development.

It is too early to evaluate the impact of the IRA on biosimilar competition and the future of the marketplace, but biosimilar manufacturers are certainly assessing the impact of the law on the profitability of investing in the future development of biosimilars. CMS's recent announcement of the initial list of selected drugs for 2026 seems to indicate the profitability of biosimilar market entry may be significantly impacted. In fact, 2 of the selected medicines for 2026 already have pending biosimilar competition positioned to enter the market in the years ahead. Unless those biosimilar products that reference the selected biologic medicines are able to launch and achieve the "bona fide" marketing standard by August 1, 2024, these products will be forced to compete against reference products with government-set prices.

Conclusion

Although the IRA aims to address the chilling effect of the price-setting process on biosimilar competition by allowing certain biologics to be delayed from selection and negotiation if they are facing biosimilar competition, the law falls short of creating the stability needed for biosimilar companies to invest resources in pursuing development. Investments need to generate returns, and, under this new government price-setting framework, it is unclear if it will be possible for biosimilar companies to have sufficient margins on the pricing of biosimilar products to justify the significant upfront investments required for market entry.

The federal government could have allowed the biosimilar market to lower costs for everyone and allow innovation to prosper, leading to improved health and a more sustainable healthcare system. Unfortunately, chilling biosimilar development at a time when the marketplace is poised to demonstrate the value of market competition in controlling healthcare costs is not only shortsighted, it threatens to undercut the tremendous savings that have been projected in the years ahead.

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