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ISSUE BRIEF

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# Competition in the U.S. Therapeutic Biologics Market

We conducted a targeted literature review to identify key features of competition in the therapeutic biologics market, with special focus on unbranded products.

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## KEY POINTS

- Spending on biologics—large, complex molecules made from a living source—has been increasing over time and now represents nearly half of all U.S. prescription drug spending.
- Biosimilar competition for biologics is limited. Only 19% of biologics without patent protection have a marketed biosimilar—a highly similar version of the original biologic that is manufactured by a different entity than the one who produces the original biologic.
- Even when competition exists, biosimilar prices are modestly lower than those of the original biologic (25% less at most), and after a year, less than 40% of sales have shifted away from the original biologic.
- Just over half of biologics with competition have an unbranded version available–either as unbranded biologics or unbranded biosimilars. While these unbranded versions are identical to the branded versions (be it a biologic or a biosimilar) except for having a lower price, they are sold by the same manufacturer as the branded versions for purposes of market share retention and negotiating position with pharmacy benefit managers. Therefore, they should not necessarily be included in measurements of competition in these markets.

## BACKGROUND

Biologics—large, complex molecules made from living sources[1]—have revolutionized clinical practice and markedly improved patient outcomes, turning debilitating conditions into ones that are managed (e.g., psoriasis, rheumatoid arthritis, Chron's disease), and offering disease course modification where options had previously been limited or nonexistent (e.g., multiple sclerosis, non-Hodgkin's lymphoma). During the past five years, about 28% of novel approvals[i] by the Food and Drug Administration (FDA) were for biologics[3].

Typically, biologics have high prices that are, in part, attributed to their potential benefits and the complexity of their development and manufacturing. As of 2023, biologics accounted for nearly half of U.S. prescription drug spending[4] and this proportion continues to grow[5].

Competition is the primary mechanism by which prescription drug prices are reduced in the United States. Competition comes from either another drug that competes for market share within the disease area, or from a copy of the drug that competes directly with the original product. Creating an identical copy of a biologic is

[i] "Novel" drugs are new drugs never before been approved or marketed in the U.S.[2]

not possible due to the complexity of the molecule and manufacturing process. Instead, a biosimilar version that is highly similar to the original biologic with no clinically meaningful differences can be made. Biosimilars are licensed by FDA via an abbreviated[ii] pathway created by the Biologics Price Competition and Innovation Act (BPCIA) of 2010. Biosimilars cannot be substituted at the pharmacy[6] without the intervention of the health care provider[iii]. For this reason, they also generally have their own brand name.

Currently, there are 226 marketed biologics in the United States. Of these 226 biologics, 62 have lost patent protection making them eligible for biosimilar competition. However, only 12 out of the 62 biologics (19%) without patent protection have a marketed biosimilar[iv].

The term unbranded is used to describe biologics or biosimilars that are identical to the branded product (be it a biologic or biosimilar) but which are marketed without the brand name on the labeling. They are produced by the original drug manufacturer, or a third party licensed by them, and do not require any additional marketing authorization beyond what the original product obtained. Thus, the biologics market is not limited to just the original biologics and their biosimilars but includes unbranded originals and unbranded biosimilars. Among biologics with biosimilars, 25% had at least one unbranded version on the market.

In contrast to biologics, the market for small molecule drugs[v] has the original brand and an identical copy called a generic. Generics are approved via an abbreviated pathway[vi] created by the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act). Because the generic and original small molecule drugs are identical, they can be substituted at the pharmacy without the intervention of a health care provider, and generally do not have their own brand name. The small molecule version of unbranded exists only for the original and is called an authorized generic. Only 6% of small molecules with a generic also have an authorized generic[8].

In this issue brief, a targeted literature review was conducted to evaluate market share and pricing for biosimilars as compared to generic drugs and the impact of unbranded biologics on competition. This work provides a foundation for understanding competition in the biologics market for future policy work related to drug affordability, transparency, and patient choice.

## BIOLOGIC MARKET REACTION TO COMPETITION

This section compares the market for generic drugs and biosimilars. While the nature of the molecules—large versus small—and the separate legislative and regulatory frameworks described above make the comparison a limited one, there is no better alternative. Both sets of products are intended for treating patients and obtaining desired health outcomes at lower prices compared to the originator products (i.e., brand drug and original biologic).

Several points can be made that show the large difference between the markets:

- At 12-months after a generic drug enters the market, the generic will capture about 75% of market share. At three years after entry, generics generally have 90% of the market share[9]. In comparison, at

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[ii] Abbreviated as compared to the approval requirements and process for a new biologic.

[iii] It is possible for a biosimilar sponsor to request from FDA to be an interchangeable (351(k)(4)). This would allow it to be substituted at the pharmacy level. Interchangeable biosimilars must demonstrate that switching between the original product and the biosimilar does not decrease effectiveness or increase risks.[7] Current FDA draft guidance is set to eliminate this process, however, further details are not finalized. For this brief the three molecules with marketed interchangeable biosimilars have been included with biosimilars.

[iv] Source for number of biologics that have lost patent protection is IQVIA's 2025 "Assessing the Biosimilar Void in the U.S" report[4].

[v] Drugs whose molecule is small (under 1,000 Daltons), are chemically synthesized, and can be copied exactly.

[vi] Abbreviated (Food, Drug & Cosmetic Act, Section 505(j)) as compared to the approval for a new drug application (Section 21 Code of Federal Regulations, Part 314).

12-months following market entry, biosimilars at most have 40% of market share, and at three years, on average 52% (with some having less than 15% and others reaching 80%)[10].

- For most small molecules, the first generic enters at a heavily discounted price (median discount of 40%)[11]. For biologics, a similar generalization cannot be made; the discounts for biosimilars range from only 5-25% [12].

- For both small molecules and biologics, the higher the number of competitors, the lower the price of the generics or biosimilars. The median price for the 10th generic entering the market is 90% lower than the brand price[11]. For biologics, there is only one case (adalimumab) where there are 10 biosimilars. As of the launch of the 10th, three of the biosimilars had a discount of about 85%[13].

Some of the disparities in prices at launch between generics and biosimilars are likely due to the difference in their costs to develop. While the specific molecule will determine the actual costs, which may vary greatly, generic drug development typically costs between $2 million and $10 million and takes 2 to 3 years[14, 15]. In contrast, biosimilar development ranges from $100 million to $300 million and takes 7 to 9 years[16]. It should be noted that these costs do not apply to unbranded products, which have no regulatory obligations beyond what the original product has fulfilled.

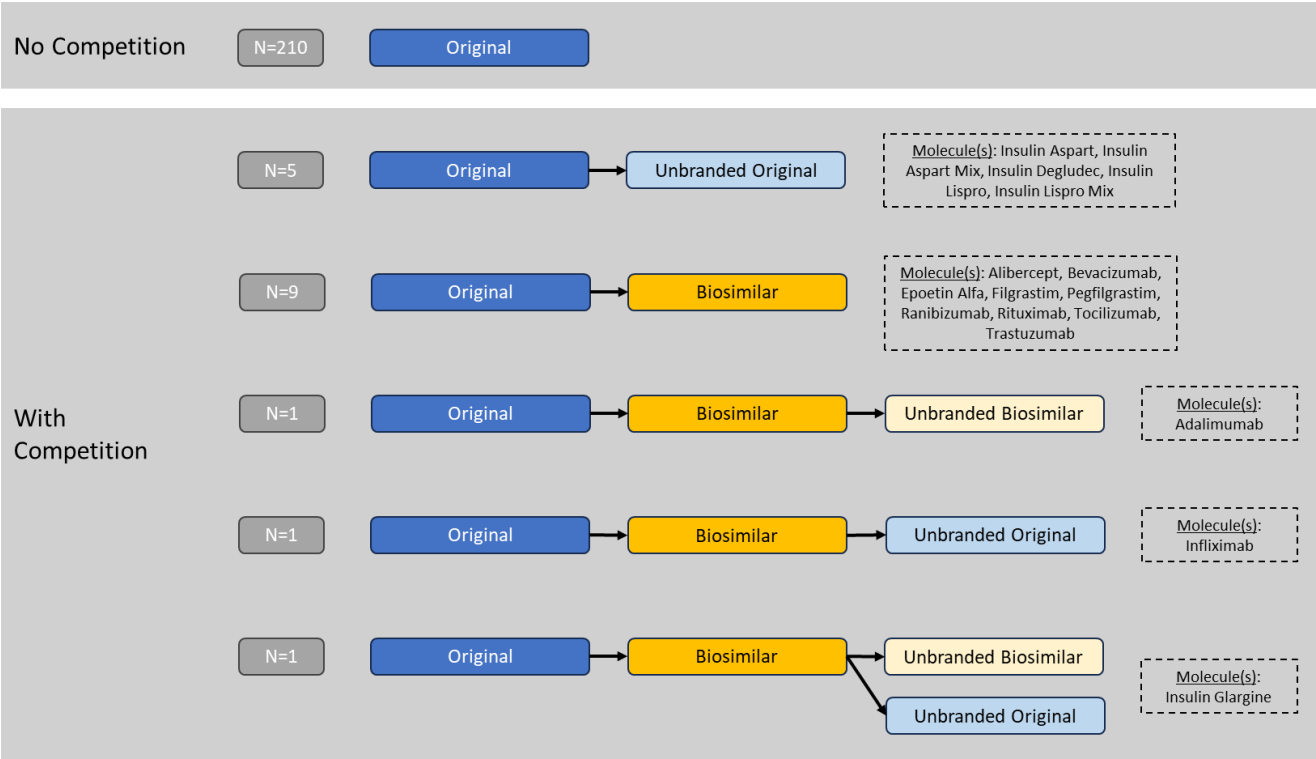
## UNBRANDING AND DUAL PRICING

While the BPCIA was designed to facilitate competition through biosimilars, biologic manufacturers have introduced unbranded versions of their products, leading to a dual pricing scenario. Just over half of biologics with competition (53%) have an unbranded version available (**Error! Reference source not found.** and 2). While the unbranded versions offer the same branded product at a lower price, they should not necessarily be considered a competitor product (e.g., likely to reduce spending on the molecule) because they have the same manufacturer.

In the biologics market, there are two main reasons for having dual prices: market share retention and improved negotiating positions with intermediaries and/or insurance plan sponsors. For purposes of market share retention, a manufacturer may introduce an unbranded product in anticipation of loss of exclusivity of the original biologic[17-19]. In these cases, the manufacturer sells its product without a brand name (at a lower price) so that current patients switch to the lower priced product they manufacture before the biosimilar enters the market. Since the biosimilar manufacturer has to make up for its development costs, it may be unable to lower its price to that of the unbranded product.

The pathway for using dual pricing to improve negotiating positions is less straightforward. Manufacturers generally set a list price that balances net profitability with varying rebate schemes. Pharmacy benefit managers (PBMs) use list prices to negotiate with both manufacturers and plan sponsors, benefiting from higher list prices as they can secure larger manufacturer rebates while guaranteeing rebates to sponsors – all while maintaining their own profits[20, 21]. This dynamic creates pressure on manufacturers to keep list prices high, yet may also result in the loss of price-sensitive plan sponsors and patients (i.e., those facing mostly out-of-pocket costs since these are based on list price, the under or uninsured). As a result, a manufacturer may decide to continue selling the high-priced original, and to offer the unbranded lower-priced original to the price-sensitive market.

**Figure 1: Therapeutic Biologic Molecules According to Whether There Is Competition**




Notes: N = number of unique molecules for each scenario. Competition is defined as when the market consists of the original biologic for that molecule, plus at least one additional entrant. Therapeutic biologics included are those found in the FDA's Purple Book[vii] and regulated by the FDA's Center for Drug Evaluation and Research (CDER) including monoclonal antibodies, therapeutic proteins and immunomodulators. Type of competitor was determined using Purple Book's license type (351(a) is an original biologic, 351(k) is a biosimilar) and the IQVIA National Sales Perspective's (NSP)[viii] product name (the lack of a brand name indicated an unbranded product).

Under the assumption that consumers will prefer lower prices, particularly if it is for the exact same product, it could be expected that low-priced unbranded products would dominate sales. However, evidence suggests that despite the presence of unbranded biologics, they do not have a larger market share. One example is insulins, where unbranded versions have been available since 2019, priced at 50% of the brand price[22], but with a market share of just under 10%[21]. More broadly, in 2024, over 94% of biologics sales volume was for the original manufacturer (original plus unbranded original), with on average 86% being for the original higher priced version. Furthermore, just among the 17 molecules with competition, 94% of sales volume was for original manufacturer, with on average 87% being for the original high price version (**Error! Reference source not found.**).

Unbranding is considered a growing trend for biologics, raising the question about what role, if any, they are playing in prices remaining high, spending not decreasing, and/or in disincentivizing further competition. The question of disincentivizing development is particularly salient given that only 10% of biologics whose patents are expiring in the coming decade have a biosimilar in development[4].

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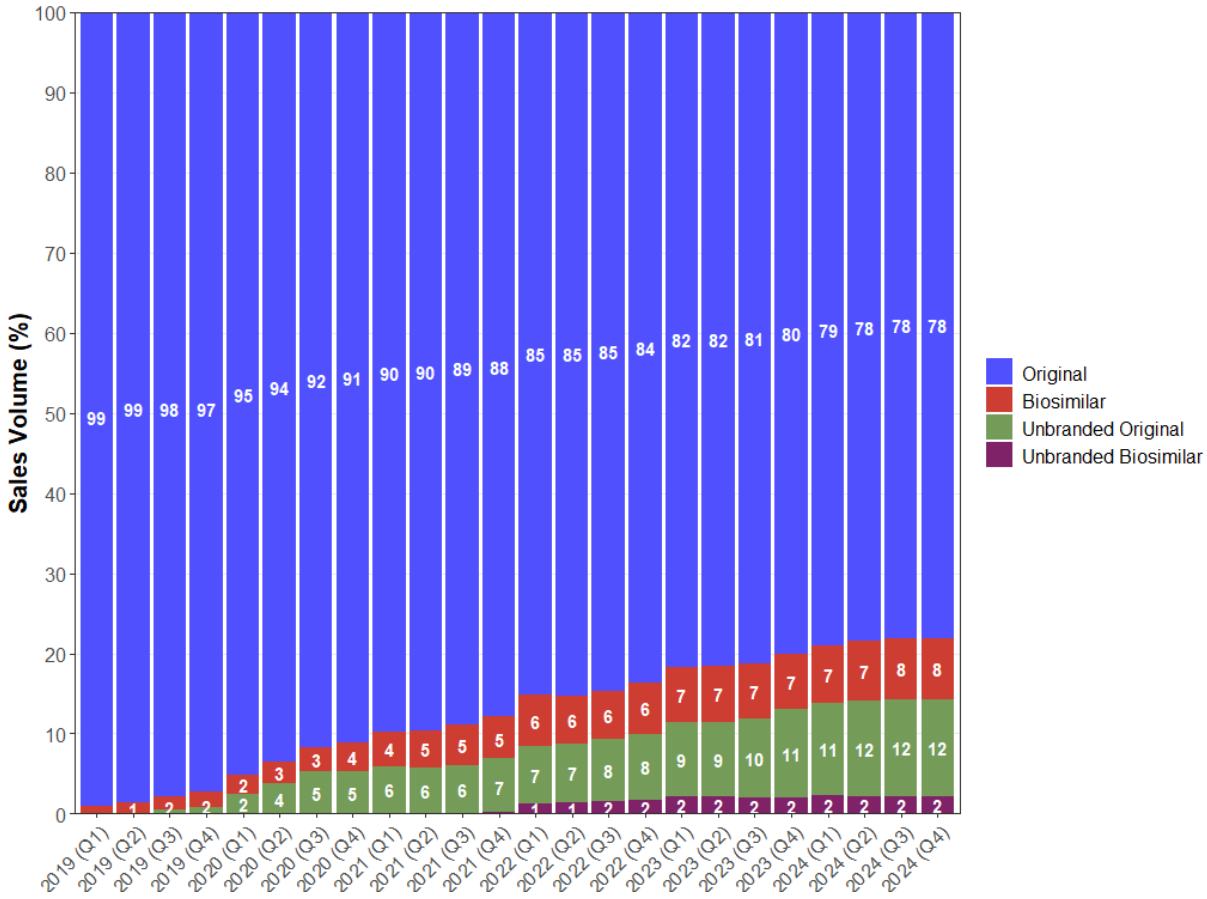
[vii] Database with all FDA-licensed (approved) biological products regulated by the Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) including licensed biosimilar and interchangeable products, and their reference products. For this brief, only CDER products were included (CBER regulated allergenic, cellular and gene therapy, hematologic, and vaccine products were excluded).

[viii] IQVIA NSP's dataset is a nationally representative database covering over 90 percent of all U.S. drug sales. Sales data are reported monthly by distribution channel (e.g., chain pharmacy, clinic, non-federal hospital, etc.). Metrics include each drug's brand status (brand, generic, branded generic), market launch date, molecule type (small molecule, original biologic, biosimilar), dosage form, therapeutic class, and sales information.

**Figure 2: Market Share by Sales Volume for Therapeutic Biologics with Competitors from 2019-2024**




Notes: Market share determined by sales volume from IQVIA NSP's data and measured using eaches (number of single items such as vials, syringes, or bottles, contained in a shipping package and purchased by providers). Type of competitor was obtained as described for **Error! Reference source not found.**. Percentages shown are only those above 1% (rounding to the nearest integer).

## CONCLUSION

Innovation in the biologics space shows no indication of slowing down and the benefits these therapeutics offer may be not only unique but life changing. Policymakers should therefore understand how patients can be afforded not just choice, but affordable choices as well, while allowing for innovation to continue. The findings described in this issue brief demonstrate that unbranded versions of biologics do not appear to be an accessible choice for patients (or at least are not being utilized as such), nor should they be considered innovation.

To fully understand this market and the implications for patients, we are limited by the lack of transparency regarding rebates and discounts. Some policy tools have been created to facilitate this including ongoing efforts such as the requirement that health plans provide consumers with the "actual prices" that their health plans or their PBMs pay for prescription drugs, a commitment made under Executive Orders "Improving Price and Quality Transparency in American Healthcare to Put Patients First"[ix] and reiterated in "Making America Healthy Again by Empowering Patients with Clear, Accurate, and Actionable Healthcare Pricing Information"[x]. Analyses using the new data from the increased transparency should be undertaken to understand what

[ix] Executive Order 13877 of June 24, 2019.
[x] Executive Order 14221 of February 25, 2025.

additional policy levers can benefit the American people.

To ensure that Americans have choice, policymakers should encourage increased competition in this market. To understand the possible levers, a comprehensive review of challenges to biosimilar development and market entry is warranted. For instance, among legal scholars the main challenge posited is the stepwise nature of the established patent disclosure and challenge process[23, 24]. From an economic perspective, the lack of biosimilars in the development pipeline and that those in development are only for products with over $1 billion in annual sales[4], suggests that the issues are with the costs of development and/or lack of market size. Further work should aim to understand these perspectives so that policymakers can determine what policies would lead to increased competition.

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