Understanding Biosimilars: A Balanced Analysis

Center Forward Basics

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Overview

Biologics are complex medicines derived from living organisms and have revolutionized the treatment of chronic and life-threatening conditions, including cancer, autoimmune diseases, and diabetes. Their effectiveness, however, often comes with high financial costs, potentially adding to barriers to access for many patients. To address these challenges, the **Biologics Price Competition and Innovation Act (BPCIA)** of 2010 introduced a regulatory framework for **biosimilars**—biologics that are highly similar to and have no clinically meaningful differences from an FDA-approved **reference product**.

Biosimilars have gained traction as a tool to promote competition, reduce healthcare costs, and expand treatment options. They remain a focal point of policy debates as stakeholders work to understand the market impact of this new class of medicines and the associated reimbursement and regulatory policies impacting a biosimilar market. This Basic will provide an overview of biosimilars, explore their role in healthcare, and examine perspectives of various stakeholders.

What Are Biosimilars?

Biosimilars are biologic medicines that have no clinically meaningful differences to an existing FDA-approved reference product's clinical efficacy and safety profile. Outside of Humira, and a couple of other self-administered drugs like insulin, the majority of biosimilars are for physician administered drugs. Unlike small-molecule **generics**, whose active pharmaceutical ingredients (API) are chemically identical to their branded counterparts, biosimilars cannot be exact copies due to the complexity of the organic protein molecules themselves upon which the biological medication is made up of. Instead, biosimilars are considered "highly similar" to the reference product with no clinically meaningful differences in safety, purity, or potency. Like baking two loaves of bread from the same recipe, no loaf is an exact copy of the other, but both produce the same type of bread. In this case, each batch of biologics is made with a mix of ingredients, including living sources. Because living sources have slight variations, each batch is not an exact copy, but the final product provides the same treatment benefits. Biosimilars tend to more expensive than generics to produce.

To receive FDA approval, biosimilar manufacturers must demonstrate similarity to the reference product through rigorous analytical, nonclinical, and clinical studies. Some biosimilars achieve an additional designation of "**interchangeability**," allowing pharmacists to substitute them for reference products without prescriber authorization, subject to state laws.

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Center Forward brings together members of Congress, not-for profits, academic experts, trade associations, corporations and unions to find common ground. Our mission: to give centrist allies the information they need to craft common sense solutions.

Key Definitions:

- **Biologic**: A medicine made from living organisms
- **Biologics Price Competition and Innovation Act (BPCIA)**: A 2010 U.S. law creating a regulatory pathway for approving biosimilars
- **Biosimilar**: A biologic medicine highly similar to an FDA-approved biologic (reference product) with no clinically meaningful differences in safety, purity, or effectiveness
- **Reference Product**: The original FDA-approved biologic against which a biosimilar is compared to ensure biosimilarity
- **Generics**: Medicine created to be the same (bioequivalent) as an existing brand-name drug in chemical compounds and all performance characteristics
- **Interchangeable Biosimilar**: A biosimilar meeting additional FDA requirements allowing it to be substituted for its reference product without the intervention of a prescriber
- **Uptake**: The rate at which a newly

Market Dynamics and Regulatory Framework

The biosimilar market operates within a unique framework that seeks to balance innovation with competition. The FDA's approval process ensures biosimilars meet safety, efficacy, and quality standards, fostering confidence among providers and patients. The FDA collaborates with biosimilar manufacturers every five years as part of the Biosimilar User Fee Act reauthorization, which allows industry and regulators to improve the biosimilar approval process.

The BPCIA also preserved incentives for innovator products by including 12 years of data exclusivity to reference biologics to ensure continued investments in innovative biologics. Market dynamics in the U.S. continue to evolve and differ from generics, as biosimilars require more nuanced strategies for **uptake**. Factors such as physician and patient awareness, reimbursement policies, cost of the biosimilar, and payer incentives are crucial in determining market success.

introduced drug is adopted by providers and patients

Key Statistics:

- As of the November of 2024, the FDA has approved 61 biosimilars
- Europe has approved 66 biosimilars to date
- More than 100 biosimilars are in development in the U.S.
- In 2025, more than 35 biologics are expected to be deemed eligible for biosimilar competition

The Case for a Robust Biosimilar Market

A strong biosimilar market has transformative potential for healthcare affordability and access. By fostering competition, the introduction of biosimilars drive down the costs of both the biosimilars and the reference biologics they compete against. This dynamic has yielded substantial savings for patients and the healthcare system. Studies suggest biosimilars could save the U.S. healthcare system up to $181 billion over the next five years.

Additionally, biosimilars expand treatment options for patients with chronic and life-threatening conditions such as cancer, autoimmune disorders, and diabetes. Finally, supporters also argue that the greater adoption of biosimilars can alleviate financial pressures on public programs like Medicare, making them more financially sustainable in the long term.

Challenges

Biosimilars can face hurdles in gaining market traction. Regulatory requirements for interchangeability further complicate their adoption, with some stakeholders questioning whether the distinction between interchangeable and non-interchangeable biosimilars is necessary. This distinction also causes confusion for providers. Although the prescribing of biosimilars has improved as more physicians gain experience with them, there are still concerns to address including reimbursement and potential patient abrasion when switching to a biosimilar. Additionally, those in favor of biosimilar competition highlight misaligned incentives facing payers who seek lower net costs for drugs vs list prices - that can lead to preferring high-rebate products over biosimilars
with lower list prices.

Developing a biological medicine requires significant time and financial investment, often exceeding a billion dollars and a decade of research. Proposals like reduced data exclusivity could disincentivize pharmaceutical companies from pursuing groundbreaking biologic research. In that same vein, the IRA may also impact research and development into biosimilars given the uncertainty of bringing to market a biosimilar for a brand drug that may have already had its price set by the Medicare program. Finally, some of the rapid price decreases for biosimilars could impact the long-term stability of the market and cause manufacturers to exit. Together, it is argued these challenges could limit the potential savings and accessibility promised by biosimilars. As the healthcare landscape evolves, these dynamics highlight the need for careful consideration of the long-term stability of biosimilar competition.

Context and Case Studies

The policy landscape surrounding biosimilars reflects competing priorities between innovation, affordability, and access. One key debate centers on whether to eliminate the FDA's interchangeability designation, which some argue creates unnecessary

hurdles and adds additional costs to development without additional safety benefits, while others point out the FDA already has the authority to waive additional clinical studies to grant interchangeability without need for new authorities from Congress. In a secondary debate, some advocate reforms to the 340B program and PBM practices alleging their role in distorting market incentives and increasing costs for patients. In contrast to those views, others suggest allowing development and use of more balanced—or value based—pricing and reimbursement approaches that support adequate incentives for innovation while fostering more balanced competition that lowers net drug costs overall. Meanwhile, the Inflation Reduction Act's (IRA) Medicare Drug Price-Negotiation Program's provisions have sparked concerns about their potential to discourage biosimilar development, as manufacturers may struggle to recover investments if the brand product has already been subjected to the IRA's price negotiation process. Policymakers must continue to weigh these complex trade-offs, seeking a balanced approach to fostering competition while preserving incentives for innovation.

Real-world examples underscore both the promise and challenges of biosimilar uptake. For instance, the introduction of biosimilars for Humira, a widely used treatment for autoimmune diseases, has been met with substantial savings in Europe but slower uptake in the U.S. due to provider hesitation, interchangeability status/regulations, and payer dynamics. Some PBMs are already implementing new ways to successfully increase biosimilar uptake for Humira under existing market incentives/conditions. For example, one PBM offers plan sponsors a formulary design removing Humira (adalimumab) altogether while preferring its newly available biosimilars instead. Clients adopting this approach have seen 96% of all member adalimumab prescriptions filled with biosimilar versions—saving them over $908M so far, while their enrollees pay $0 cost-sharing for these medications. In contrast to the generally slow uptake of Humana biosimilars compared to Europe, biosimilars in the U.S. for oncology treatments have demonstrated robust market penetration, leading to meaningful cost reductions in Medicare Part B. These case studies highlight the variability in biosimilar adoption, efforts to increase uptake, and the importance of addressing systemic barriers to fully realize their cost-saving potential.

Outlook and Conclusion

The biosimilar market is poised for growth, with numerous products in the pipeline and increasing adoption by healthcare providers. To fully realize their potential, safety, efficacy, incentives for biologic innovation, equitable market entry, and effective uptake must be ensured. Through careful consideration and thoughtful implementation, some believe biosimilars represent a promising solution to the twin challenges of rising healthcare costs and access disparities. While they have delivered substantial savings and expanded treatment options, their full impact depends on a balanced approach between policy and market dynamics.

Link to Additional Resources

- Alliance for Safe Biologic Medicines: Myth vs. Fact
- Amgen: Biosimilars
- Amgen: Fast Facts About Biosimilars
- America First Policy: Federal Barriers Make Biologic Drugs Unaffordable
- Association for Accessible Medicines: The U.S. Generic & Biosimilar Medicines Savings Report
- Biotechnology Innovation Organization: Biosimilar Primer
- Cencora: U.S Biosimilar Landscape
- Center For Medicare and Medicaid Services: Frequently Asked Questions Inflation Reduction Act Biosimilars Temporary Payment Increase
- Chrons and Colitis Foundation: Biosimilars - What You Should Know
- Coalition for Sustainable Prescription Drug Pricing Resources: Fact Sheet
- Department of Health and Human Services: Biosimilar Cost and Use Trends in Medicare Part B
- Food and Drug Administration: Biosimilars - What Patients Need to Know
- Food and Drug Administration: What is a Biosimilar Medication
- Food and Drug Administration: Biosimilars
- Food and Drug Administration: Biologic Product Innovation and Competition
- Food and Drug Administration: Review and Approval
- Food and Drug Administration: User Fee Amendments
- Food and Drug Administration: 9 Things to Know About Biosimilars and Interchangeable Biosimilars
- Food and Drug Administration: Biosimilar Product Information
- Incubate Coalition: Looking Back and Looking Ahead
- PhRMA: The U.S. Biosimilars Market Continues to Increase Competition and Savings, but Reforms are Needed to Realize its Full Potential
- PhRMA: Biologics and Biosimilars
- Sidley: Medicare Announces Final Rule on Part D Biosimilar Formulary Substitutions, Including Noninterchangeable Biosimilars