

Since Congress enacted the Biologics Price Competition and Innovation Act (BPCIA) in 2010, biosimilars have been viewed as an important way to bolster competition and increase options for patients. The BPCIA created an abbreviated approval pathway for biosimilars while maintaining 12 years of data protection for innovative biologics, balancing the goal of reducing costs with the need to maintain incentives for the development of new

innovative biologics. This framework has provided more choices for patients, increased access to lifesaving medicines and lowered health care costs through additional competition in the marketplace. While the BPCIA is just a decade old, it's clear it is achieving its policy goals and that the benefits of the BPCIA on innovation and competition are being realized. Here are three things you should know about the biosimilar market.

First, though the biosimilars market is still relatively new, the successful implementation of the U.S. regulatory pathway has allowed the biosimilar landscape to advance faster than the EU biosimilar market had in a comparable period of time.

Current data show that while the U.S. has not had a biosimilar market in place as long as the EU, the U.S. market has significantly evolved and is rapidly gaining ground. In fact, the U.S. biosimilar market has advanced faster than the EU biosimilar market had in a comparable period of time.

In the five years following the EU's first biosimilar approval, there were a total of 11 approved biosimilars. By contrast, the U.S. approved 28 biosimilars in the five years following its first approval. As of November 2020, there are 18 biosimilars on the market in the U.S. competing against 7 reference biologics with 10 additional FDA approved biosimilars due to come to market over the next several years.ⁱ The dynamics of the current U.S. market are more akin to the 2014 EU market, when there were also 18 approved products on the market.^{ii,iii,iv} This is largely due to the regulatory certainty that has been provided by the successful implementation of the biosimilar pathway. In the last several years, the U.S. Food and Drug Administration (FDA) has finalized critical guidance providing additional clarity for biosimilar manufacturers.

The rich pipeline of potential biosimilar and interchangeable products currently in development as well as current market experience indicates that there is still significant potential for cost savings in the United States market. In FY2020, there were 104 programs enrolled in the Biosimilar Product Development (BPD) Program.^v In addition to products for oncology, immunology, and multiple sclerosis, since the successful addition of the transition products to the biosimilar pathway in March 2020 it is now possible for manufacturers to develop biosimilars for diseases including diabetes, respiratory distress syndrome, fertility conditions, Cushing's syndrome, deep vein thrombosis, Gaucher disease and many more.^{vi,vii}

Second, biosimilars are achieving significant market uptake and are increasingly leading to cost savings.

The introduction of biosimilars is increasingly leading to cost savings in the U.S. market.^{viii} Many innovator medicines now compete with multiple biosimilar versions, with one biologic medicine currently facing competition from 5 biosimilars.^{ix} The absolute savings from biosimilars vary with larger savings realized from

more recent launches competing against more costly products. As of July 2020 the difference between the originator and the mean Average Sales Price (ASP) of their biosimilars ranged from 8.1% to 45.1% lower than the originator products (including insulins).ⁱ In the Medicaid program, discounts increased by between 20.1 and 35.2 percentage points.ⁱⁱ Annualized savings from biosimilars reached \$6.5B in the second quarter of 2020,^{xii} and savings are modeled to exceed \$100 billion in aggregate over the next five years.^{xiii}

Biosimilars are also achieving significant market uptake, with the three most recently-launched biosimilars in 2019 achieving between 20% and 42% of market share within their first year.^{xiv} These trends suggest that uptake by doctors and patients of the coming wave of biosimilars will occur much more quickly than occurred for biosimilars launched earlier, in part due to increased education, awareness and experience among health care providers and patients.^{xv}

And finally, to continue to foster a robust biosimilar market, the following steps should be taken:

- ✦ Ensure the long-term stability of the Biosimilar User Fee Act (BsUFA) program through financial transparency, efficiency, and accountability.
- ✦ Increase focus on provider and patient education including the development and dissemination of evidence-based materials on the full range of treatment options, including biosimilars.
- ✦ Address barriers to appropriately structured alternative payment models, particularly in Medicare, that have the ability to increase competition among innovator and biosimilar products.
- ✦ Ensure the successful implementation of meaningful rebate reforms that remove barriers to biosimilar uptake and promote access and competition.

In enacting the BPCIA a decade ago, U.S. policymakers rightly sought to balance increased competition with policies that support the United States' leading role in finding new treatments for patients. By allowing the market to continue to evolve and enacting policies that support this evolution, we'll continue to see biosimilars' benefits for patients and society.

ⁱ PhRMA analysis of FDA, Biosimilar Product Information, <https://www.fda.gov/drugs/biosimilars/biosimilar-product-information>; IQVIA Institute Report (2020). Biosimilars in the United States 2020 – 2024. Retrieved from https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/iqvia-institute-biosimilars-in-the-united-states.pdf?_=1606843358393.

ⁱⁱ PhRMA analysis of EMA. "Biosimilar medicines." Accessed December 2020. Retrieved from https://www.ema.europa.eu/en/medicines/field_ema_web_categories%253Aname_field/Human/ema_group_types/ema_medicine/field_ema_med_status/authorised-36/ema_medicine_types/field_ema_med_biosimilar/search_api_aggregation_ema_medicine_types/field_ema_med_biosimilar.

ⁱⁱⁱ Article 10(4) Directive 2001/83/EC of the European Parliament and of the council of 6 November 2001 (OJ L311 p67), as amended; in particular by Directive 2004/27/EC (OJ L136 p34).

^{iv} Crespi-Lofton, J (2017). The growing role of biologics and biosimilars in the United States: Perspectives from the APhA Biologics and Biosimilars Stakeholder Conference. Journal of the American Pharmacists Association. Vol. 57 (e15 – e27).

^v U.S. FDA. BsUFA Background and Reauthorization Process. November 19, 2020. Available at: <https://www.fda.gov/media/143986/download>.

^{vi} U.S. FDA (2020, March 23). Insulin Gains New Pathway to Increased Competition [Press release]. Retrieved from <https://www.fda.gov/news-events/press-announcements/insulin-gains-new-pathway-increased-competition>.

^{vii} IQVIA Institute Report (2020). Biosimilars in the United States 2020 – 2024. Available at: https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/iqvia-institute-biosimilars-in-the-united-states.pdf?_=1606843358393.

^{viii} Fein, Adam. (2020). The Booming Biosimilar Market of 2020. Drug Channels. Retrieved from <https://www.drugchannels.net/2020/10/the-booming-biosimilar-market-of-2020.html>.

^{ix} Ibid.

^x IQVIA Institute Report (2020). Biosimilars in the United States 2020 – 2024. Retrieved from https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/iqvia-institute-biosimilars-in-the-united-states.pdf?_=1606843358393.

^{xi} San-Juan-Rodriguez A, Gellad WF, Good CB, Hernandez I. (2019) Trends in List Prices, Net Prices, and Discounts for Originator Biologics Facing Biosimilar Competition. JAMA Netw Open. 2(12):e1917379. Available at: [doi:10.1001/jamanetworkopen.2019.1737](https://doi.org/10.1001/jamanetworkopen.2019.1737).

^{xii} Ibid.

^{xiii} IQVIA Institute Report (2020). Biosimilars in the United States 2020 – 2024. Retrieved from https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/iqvia-institute-biosimilars-in-the-united-states.pdf?_=1606843358393.

^{xiv} Ibid.

^{xv} Fein, Adam. (2019). We Shouldn't Give Up on Biosimilars – And Here Are the Data to Prove It. Drug Channels. Retrieved from <https://www.drugchannels.net/2019/09/we-shouldnt-give-up-on-biosimilarsand.html>.