

Commemorating the 15th Anniversary of the Biologics Price Competition and Innovation Act

CDER Conversations

The [Biologics Price Competition and Innovation Act](#) (BPCIA), enacted March 23, 2010, was designed to create a regulatory pathway for the approval of biosimilars. It provides a framework for FDA to approve biosimilars, ensuring they are highly similar to an FDA-approved biological product (biologic), called a reference product, with no clinically meaningful differences in safety, purity, and potency from the reference product.

Similar to the Hatch-Waxman Amendments of 1984 that paved the way for the approval of generic drugs, the BPCIA was enacted to promote competition, reduce healthcare costs, and increase access to biologic therapies by introducing biosimilar treatment options for already FDA-approved reference products.

In this CDER Conversation, Sarah Yim, M.D., director of the Office of Therapeutic Biologics and Biosimilars (OTBB) in CDER's Office of New Drugs, discusses how the BPCIA has impacted public health, biologics manufacturing, and the future of biosimilars.

How is the BPCIA important to public health?

This historic legislation's key significance was creating a pathway for biosimilar approvals where none had existed. The BPCIA also had a significant public health impact by expanding access to biologics, which provide life-saving treatments for many serious illnesses. Biological products are used to treat conditions such as diabetes, cancer, autoimmune diseases, and other chronic illnesses. The cost of treatment for some of these therapies can be expensive, and the BPCIA was a way to potentially reduce the cost through competition by allowing the development of biosimilars and interchangeable biosimilars.

The BPCIA has shaped public health by promoting innovation and competition in the biologics industry. Reference products enjoy a period of exclusivity, a twelve-year time frame when other companies are unable to obtain approval of and market a biosimilar to that biologic, to encourage innovation. Once that period ends, biosimilars to the reference product may be approved, potentially increasing competition, decreasing prices, and benefiting patients, healthcare systems, and insurers.

Provisions of the BPCIA also embody FDA's public health mission to increase access while also ensuring that patients can expect the same safety and efficacy with biosimilars. The BPCIA requires rigorous testing to confirm that biosimilars are just as safe and effective as their reference products. FDA uses comprehensive testing that compares a biosimilar's structural and functional characteristics to the reference product to ensure the biosimilar is as safe and effective as the reference product without unnecessary duplication of human testing.

How has the BPCIA impacted the biologic product industry over the last 15 years?

Prior to the BPCIA, there was not a pathway for approval of biosimilars. Now there are nearly 70 FDA approved biosimilars for 19 different reference products, since the first FDA approval of a biosimilar in 2015. Biosimilars are approved to treat a variety of serious conditions such as rheumatoid arthritis, ulcerative colitis, osteoporosis, and diabetes. With a record 18 biosimilar approvals in 2024, we're optimistic that the number of FDA biosimilar approvals will continue to grow each year as the exclusivity period ends for additional reference products, increasing the potential for biosimilar applications and approvals.

The BPCIA also contributed to the growth of the biologics industry by enabling new and existing pharmaceutical companies to begin developing and producing biosimilars. Having new companies continue to enter the biologics and biosimilars market is critical to creating a more dynamic and diverse pharmaceutical landscape and is a key factor in driving price competition and innovation. According to [IQVIA](#)®, the U.S. biologics market has grown 12.5% annually over the last 5 years and is projected to grow to as much as 129 billion in sales by 2027, suggesting the number of manufacturers entering the biosimilar market will continue to grow.

What are some challenges the BPCIA and biosimilar approvals have encountered?

Under the BPCIA, once the reference product exclusivity period ends, there may still be patent disputes between reference product manufacturers and biosimilar manufacturers that delay the marketing of a biosimilar product. Patents for many widely used biological products will expire in the next several years and we'll likely see more and more biosimilars enter the U.S. market as a direct result.

As with any new medical treatment, biosimilars have had to overcome challenges gaining acceptance and dispelling misperceptions that may exist. CDER created a robust [biosimilar education and outreach program](#) to help assure the public and health care community that biosimilars are just as safe and effective as their reference products. One sizeable hurdle we've faced with the educational program has been delineating why biosimilars are "similar to" a reference product rather "the same as" or "identical to" as we see for generic drugs. The reason is that biologics are large, complex molecules derived from living organisms that cannot be replicated exactly. This is why CDER's biosimilar education and outreach program is so important, it takes a complicated topic like this one and makes it easier to understand.

What is the future of biosimilars under the BPCIA?

The implementation of the BPCIA has paved the way for increasing numbers of biosimilars to enter the U.S. market. As the total number of biosimilar approvals increases, market competition is more likely to intensify, possibly leading to lower prices which may improve access for patients. For our part, FDA will continue to complete thorough and timely evaluations of each biosimilar application that is submitted, only approving those that meet our rigorous standards. In addition, CDER will continue outreach to increase knowledge of biosimilars through numerous new education and outreach materials, including new [curriculum materials](#) for health care professionals to help them make informed decisions when prescribing biosimilar products.

The BPCIA has created a pathway for biosimilar approvals to enhance competition, potentially reduce the cost of biologics, and increase patient access to treatments. While it has brought significant benefits, the biosimilar market still faces some challenges related to acceptance by the patients and health care professionals and delays in market entry following approval. Despite these challenges, the future of biosimilars under the BPCIA appears very promising.

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Sarah Yim, M.D.

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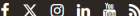
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