

Biosimilars are Overcoming Challenges of a Turbulent, Unfriendly Marketplace

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With total spending on U.S. cancer care projected to rise 34 percent from 2015 to 2030 to \$245 billion, biosimilars can play a role in helping reduce those costs. Biosimilars are newcomers to the pharmaceutical market, and they have already gained a strong footing. A biologic is a drug that is derived from living organisms or contains components of living organisms, whereas a biosimilar is a nearly identical but organically less complex copy of the referenced biologic.

After specified novel biologics receive U.S. Food and Drug Administration (FDA) approval, manufacturers can develop and submit biosimilars for approval as well. To be successful, the biosimilar manufacturer must demonstrate that its product has no clinically meaningful difference from its referenced biologic in terms of safety and effectiveness. The FDA uses an abbreviated drug approval pipeline for biosimilars that is meant to expedite their market entry and reduce the cost of their development. However, even

after obtaining FDA approval, patents for biologics must expire before biosimilars can launch, a problem made clear to several biosimilar companies. Only around 60 percent of the 31 biosimilars approved since 2015 have made it to the market.

Due to their shorter development time, biosimilars are approximately 15 percent to 20 percent cheaper than their more commonly prescribed reference biologics. Biosimilars' manufacturers pass a portion of their cost savings on to patients through decreased market costs, and they have potential to save billions in claims. Their presence on the drug market also creates competition with expensive biologics, potentially lowering costs for everyone. And biosimilars can provide treatment alternatives for patients with complex needs who may require timely, accessible, and affordable treatment options that biologics cannot provide. In recognition of this, the FDA expanded the biosimilar category to include 90 additional molecules in March 2020.

Unfair Business Practices

The volume of new FDA-approved biosimilars fell sharply in 2020 to just three approved drugs—a stark contrast from the year before, in which the FDA approved 10 new biosimilars. Since 2015, the year in which the first biosimilar earned FDA approval, the number of approvals has risen each year—until 2020. This is likely due at least in part by researchers across the globe turning their attention to vaccine development in the wake of the COVID-19 pandemic.

In addition to the global pandemic, ongoing lawsuits from referenced biologics' manufacturers suing biosimilar manufacturers are having a negative impact on the development and approval of new biosimilars. Biologics' pharmaceutical companies have motive to disrupt the entry of new, cheaper treatment options into the market. Small biosimilar manufacturers often do not have the resources of biologic manufacturers to fight frivolous lawsuits. Court-imposed delays and legislative fees are expensive, which dissuades smaller companies from continuing work in the biosimilars market. Brand-name biologics also leverage their discounts and rebates to maintain marketplace advantage. Additionally, payers are moving slower than expected toward adding biosimilars to their preferred drug list. This is partly caused by legacy contracts with brand-name biologics. These methods are very effective—consider that congress created the biosimilar approval

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pathway in 2010. Since much of this litigation is founded on dubious claims and weighed down in bureaucratic red tape, President Biden recently issued an executive order that challenges unfair business practices in the biosimilars market.

Legislative Solutions

Biden's July 9, 2021, executive order (EO) on promoting competition in the American economy includes a provision that requires the Department of Health and Human Services (HHS) to make the FDA biosimilars approval framework more transparent and easier to follow. What that will mean exactly remains unclear until HHS makes public its specific recommendations. HHS leadership has reported that it will be months before their plan is finalized and made public.

That said, the EO requires HHS to promote the entry of biosimilars into the pharmaceu-

tical marketplace. The order draws its authority from the Advancing Education in Biosimilar Act of 2021 (S.164). The EO echoes this law, which has in effect expanded the regulatory responsibilities of the HHS secretary by mandating the prioritization of biosimilars and enhancing a biosimilars education page on the FDA's website, which contains comprehensive provider and patient resources and education.

In another attempt to promote the use of biosimilars, in April 2021, Reps. Kurt Schrader (D-OR) and Adam Kinzinger (R-IL) introduced into congress the BIOSIM Act (H.R.2816) to increase provider reimbursement for biosimilars, thus making them more attractive for providers to prescribe to their patients. Providers are currently reimbursed for biosimilars based on the average sales price of the drug +6 percent. This bill would increase reimbursement for biosimilars by 2

percent for five years, giving providers additional motivation to prescribe less expensive biosimilars to their patients. Recent research indicated that physicians are trusted by their patients, with most reporting that if asked by their physician to utilize a biosimilar they would.

Taken together, Biden's EO, the BIOSIM Act of 2021, and the recently passed Advancing Education on Biosimilars Act have set the stage for a market that embraces the cost-savings potential of biosimilars. ACCC will continue to advocate for and monitor the policy landscape as it relates to biosimilars. Share your drug cost and access concerns by emailing: bmccreery-cullifer@acc-cancer.org.



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