Biosimilars Council Policy Recommendations to Develop a Robust Biosimilars Market in the U.S.

Biosimilars have the potential to improve quality of life for patients. If the right policies are put in place to cultivate a robust market, an additional 1.2 million patients will have access to biologic medicines,[1] while also saving an estimated $54 billion[2] over the next 10 years. Congress must continue working with CMS and the FDA to ensure biosimilars can compete in the U.S. market. In addition to engaging with federal agencies, Congress should act on the following legislation that could impact patient access to biosimilars:

Increase Patient Access to Biosimilars

Co-sponsor the CREATES Act (S. 974/H.R. 2212)

Certain brand pharmaceutical companies are abusing the Food and Drug Administration's (FDA) patient safety programs and using restricted distribution schemes to delay competition while increasing the cost of prescription drugs. Biosimilar manufacturers are being prevented from purchasing at market value the samples necessary to develop and bring to market more affordable FDA-approved medicine.

Bipartisan legislation in the House and Senate, the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act, would end these anti-competitive tactics from brand pharmaceutical companies and increase patient access to biosimilars. The Congressional Budget Office estimates savings to the federal government of $3.8 billion over 10 years and even greater savings to patients at $5.4 billion annually.

More than 70 organizations – including Patients for Affordable Drugs, FreedomWorks, AARP and the Campaign for Sustainable Rx Pricing – now support the CREATES Act. We encourage you to sign on as a co-sponsor of the CREATES Act and help lower the cost of prescription drugs through competition.

Protect the Ability of the Patent Office to Review Drug Patents

Co-sponsor the PACED Act (S. 2514)

Last fall, Allergan gained national prominence for a first-of-its-kind business deal with the St. Regis Mohawk Tribe to circumvent the U.S. Patent and Trade Office's (PTO) standard review of the company's patents on dry eye treatment, Restasis®. In exchange for a one-time fee of nearly $14 million and annual royalties of $15 million, Allergan rented the sovereign immunity of the St. Regis Mohawk Tribe to extend its monopoly on Restasis. If allowed, this practice could proliferate, leading to widespread abuse of our patent system and further increase prescription drug costs for patients.

The Preserving Access to Cost Effective Drugs (PACED) Act, a bipartisan bill in the Senate maintains the PTO's ability to review patents and would prohibit Allergan's patent abuse from being replicated by other bad actors. Without congressional action on the PACED Act, a recent study found patients will pay an additional $10.7 billion for Restasis over the next 10 years. We encourage you to sign on as a co-sponsor of the PACED Act in the Senate and introduce companion legislation in the House.

References

1.The Biosimilars Council & Avalere Health. "Biosimilars in the United States: Providing More Patients Greater Access to Lifesaving Medicines". Available at: https://bit.ly/2fAWtXB. Accessed: April 20, 2018.

2. RAND Corporation. "Biosimilar Cost Savings in the United States: Initial Experience and Future Potential". Available at: https://bit.ly/2EsWDOr. Accessed: April 20, 2018.

Biosimilars: A Safe & Effective Option for Patients

In the U.S., biosimilar usage and approvals are on the rise. Access to these safe, effective treatments offers patients improved health outcomes.

What is a Biosimilar?

A biosimilar is a biologic medicine that is highly similar to a brand biologic medicine.

In the U.S., biosimilar usage and approvals are on the rise. Access to these safe, effective treatments offer patients improved health outcomes.

Biosimilar Approvals in the U.S. and E.U.

Since the passage of the BPCIA, the FDA has approved ~10 biosimilars with 60+ more in development[1,2]

In Europe, ~45 biosimilars approved in at least eight therapeutic classes[3]

Biosimilars are Safe, Effective, More Affordable & Offer Improved Patient Access.

- Comparable in safety and efficacy to their biologic counterpart
- Same mechanism of action
- Rigorous FDA testing and review; less cost to patients and the health system
- Companies that manufacture biosimilars are committed to providing safe, effective products

References

1. FDA-Approved Biosimilar Products. Available at https://bit.ly/2BQwQig. Accessed April 12, 2018.
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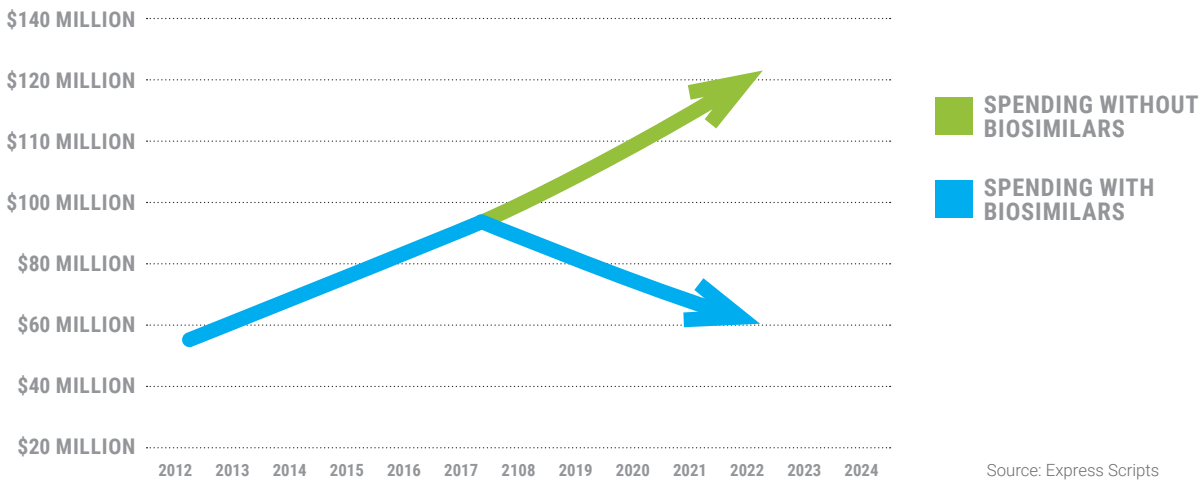
Biosimilar Savings: Impact of Biosimilars on Projected Spending for 11 Biologics



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