

*Biosimilar Access to Reduce Biologic
Spending in the United States: A Policy
Brief*

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PHCY 840

04/02/2020

INTRODUCTION:

Biosimilars have been hailed as a solution to offset the rising costs of biologic medicines, the fastest-growing category of drugs.¹ Early estimates suggested that from 2017 to 2026, biosimilar launches could save as much as \$150B with effective uptake (over 8% of total estimated biologic spending).² These cost savings would help to bend the rising cost curve of biologic drugs, a market which increased by 9.5% from 2017 to 2018 up to a total of \$125.5 billion.³ However, despite 26 FDA approvals,⁴ the market uptake of biosimilars has been slower than expected. Projected savings could be as low as \$24B.² Only 12 biosimilar products have actually launched,⁵ capturing under 2% of the biologic market. However, for the therapeutic areas that have biosimilars on the market, biosimilar market share has risen to an average 31%, indicating acceptable uptake once a product is launched.³ It would appear that the inherent barriers to market entry, such as data and market exclusivity rights of biologics, complex and closely-kept secrets of manufacturing, and steep rebate agreements between biologic manufacturers and payers are preventing greater biosimilar commercialization. This brief will focus on policy options for improving biosimilar accessibility to reduce biologic spending in the US.

A number of barriers to biosimilar access have been identified:

Payment policies disincentivize biosimilar administration. Under Medicare Part B, providers receive reimbursement for dispensing based on the average sales price (ASP) of the medicine, plus a fixed percentage.⁶ To reduce this incentive to select a higher-priced drug, the Biologics Price Competition and Innovation Act of 2009 (BPCIA) requires that the fixed percentage for biosimilars is based on the ASP of the reference product rather than their own ASP.² While this legislation was a step in the right direction, providers still achieve greater reimbursement by selecting and administering reference products, which have an ASP 15%–30% higher than that of biosimilars.⁷ This discrepancy can prevent biosimilar substitution for medicines administered in-office. Notably, private insurers often look to Medicare for guidance on payment policies.

Providers lack understanding of the efficacy, safety, and interchangeability of biosimilars. Persistent information gaps surrounding biosimilars precludes many physicians from using them in practice. When physicians, pharmacists, and other advanced practice providers responded to a survey, 74% could not adequately define biosimilars, and 40% considered them to be generic drugs.⁸ It is of little surprise then that prescribing rates are so low for these medicines – physicians will not prescribe what they do not understand or feel reasonably confident about being the best option for a patient. Important aspects for education, per the survey participants, included safety and efficacy information, followed by cost information. Knowledge in these key areas must be improved to promote efficient prescribing of biosimilars.

Reference product manufacturers employ anticompetitive strategies to subvert biosimilar access. Reference product manufacturers employ numerous schemes to stave off competition for their brand. These tactics include rebating the costs down to the point where payers cover their product over the biosimilar, disputing the interchangeability of biosimilars, and aggressively litigating and then settling with biosimilar manufacturers in “pay to delay” deals such as those keeping several Humira biosimilars from launching until 2023.⁹ Recognizing these activities, the FDA and FTC have recently pledged to disrupt anticompetitive behaviors in the biosimilar market.¹⁰ While this joint statement acknowledges

the agencies' focus on biosimilar market access, no meaningful legislation has yet been proposed for this issue.

POLICY OPTIONS:

The following policies have been identified as opportunities to promote competition in the biologics market and drive access for biosimilars. This brief evaluates these policies according to their effectiveness in reducing the costs of the biologic market, their political feasibility, and cost of implementation. These criteria will be weighted by 50%, 30%, and 20%, respectively. My rationale is that effectiveness in reducing market costs should offset/justify costs of implementation, and the most politically sound policies rarely enact meaningful change. Additionally, if a policy is highly effective and implementation costs are reasonable, then some compromise can likely be reached to make it more politically feasible.

Maintain status quo

Without any changes in policy, biosimilar uptake will remain low. Biosimilars must undergo additional clinical studies to be recognized by the FDA as interchangeable with their reference products,¹¹ which presents an additional hurdle for launching the product. Without interchangeability, patients and providers alike may hesitate to switch from the more expensive, but recognized and trusted biologic brand. Reference product manufacturers will keep prices high and funnel revenues from those products into direct-to-consumer advertising campaigns to keep brand loyalty high, as well as patent litigation to bar competitors' market access. One positive aspect of the status quo is the Food and Drug Administration and the Federal Trade Commission's recent joint statement pledging to support improved biosimilar competition.¹⁰ The joint statement listed 3 goals to regulate reference product manufacturers: (1) combating false and misleading communications about biosimilars, (2) preventing manufacturers from denying biosimilars researchers access to samples of the reference products, and (3) reviewing potentially anticompetitive patent litigation settlements. These are great sentiments, but no meaningful legislative proposals have been put forth around these goals as of yet. As the public becomes more familiar with biosimilars and clinical comfort improves, usage may gradually rise. However, this will be a slow and passive trend that is unlikely to bend the rising cost curve of the biologic market.

Maintaining the status quo would be the least effective policy option. Under status quo, nearly two thirds of approved biosimilar products have failed to launch due to lack of commercial opportunity.³ Maintaining status quo is quite feasible, since no action is required – although the recent pressure on drug pricing and cries for legislative reform suggest some disquiet would result from complete inaction on this topic. Without any substantive change required, this policy route scores quite well on cost as well.

Increase provider reimbursement for biosimilars

Currently, reference biologics and biosimilars have separate billing codes to define how providers are reimbursed for them by the Centers for Medicare & Medicaid Services under Medicare Part B. For biologics, reimbursement is set at the average sales price (ASP) of the drug +6%. For biosimilars, reimbursement is set at 100% of its ASP + 6% of the *reference* drug's ASP.⁶ Since reference products tend to have the higher ASP, providers are financially incentivized to choose them over biosimilars. In 2019, the Medicare Payment Advisory Commission (MedPAC) fielded a proposal to consolidate

reference product and biosimilar billing codes into one flat rate of reimbursement to encourage price competition between these agents.⁶

This approach is analogous to how brand and generic drugs are currently reimbursed and carries strong potential to improve prescribing rates of biosimilars. Since reimbursement rates would be equivalent, this policy would create a positive pressure on manufacturers to reduce prices to drive greater volume. In terms of political feasibility, this policy may be more difficult to enact. Reference product manufacturers have considerable lobbying power to oppose legislation like this, so without bipartisan backing, it is unlikely to be passed. This would also require significant implementation costs, as Medicare billing processes would need to be overhauled on the backend.

Expand provider understanding of biosimilar products through continuing education initiatives

One solution to combat the gap in provider education and awareness of biosimilars is to pass legislation to create a government-sponsored informational website for biosimilars and mandate biosimilar continuing education (CE) programs that correspond to the website. The *Advancing Education on Biosimilars Act* introduced in 2019 by Reps. Bucshon and Engel would create a website for both patients and providers to educate them about which biologics could be interchanged with biosimilars, and share information about how to report adverse drug events.¹² The bill would also sponsor the development of CE programs to better inform health care professionals about biosimilars.

This policy effectively addresses one of the key barriers to access for biosimilars: provider lack of understanding around efficacy, safety, and interchangeability. A well-designed and unbiased government website would provide a trusted source of information for health care professionals and the public to reference. CE programs would reinforce knowledge of biosimilars for providers. This policy would likely be feasible, since it does not impact the reimbursement of stakeholders and should be fairly cheap to implement. Most stakeholders and legislators should support the educational initiative that this policy presents.

Bar anticompetitive rebate strategies by reference product manufacturers

To address the anticompetitive rebates that reference product manufacturers negotiate with payers for exclusive market access, former FDA Commissioner Scott Gottlieb has fielded the idea of removing the “Safe Harbor” protection from the federal anti-kickback statute that permits rebating of reference products once a biosimilar competitor has launched.¹³ This would fundamentally change the biologic market landscape and wipe clean the entrenched contractual barriers to entry that biosimilars face upon launch. Rebates, negotiated as a percent discount of the list price, incentivize payers to prioritize formulary access for products that have higher list prices.¹⁴ For example, Inflectra, a biosimilar to Remicade, launched at a 15% discount to the reference product. Since most payers received a larger percentage of Remicade’s list price in rebates, they were disincentivized to put Inflectra on their formularies. Outlawing rebates in markets with biosimilars would be a bold and unprecedented move.¹⁴

Undoubtedly, the elimination of rebates would greatly improve the commercial viability of biosimilars. Of the 26 FDA-approved biosimilars, only 12 have launched in the US. This clean contractual slate would eliminate much of the first-to-market advantage that reference products hold over biosimilars. However, the unprecedented nature of such a policy presents great downsides to feasibility. The pharmacy benefit manager (PBM)/health insurance industry profits greatly from rebates. The Trump administration once considered a proposal to repeal safe harbor provisions for drug rebates across the board, but it was ultimately withdrawn.¹⁵ In terms of cost, it would take considerable funding to enforce

this new legislation, but otherwise, the government’s implementation cost would be low. However, there could be expensive litigation against the government from PBM lobbying groups down the line.

RECOMMENDATION:

	Maintain status quo	Increase provider reimbursement for biosimilars	Educate Providers about biosimilars	Bar anticompetitive practices	Wt. (%)
Effectiveness	1	3	4	5	50%
Feasibility	4	5	4	2	30%
Cost	5	2	3	3	20%
Total Score	2.7	3.4	3.8	3.7	100%

Table 1 – Policy Analysis.

Higher score = more favorable

Educating providers about biosimilars is the most viable policy option and should be prioritized by legislators seeking to improve biosimilar access. While it solves only one of several identified barriers, this policy option strikes the balance of effectiveness, feasibility, and cost. Education is a great aspect of the problem to begin solving as it is highly feasible – most stakeholders are supportive of keeping healthcare professionals informed and providing government resources that are objective and well-researched. The avenues of a website and continuing education programs are fairly affordable as well. With its targeted effectiveness and bipartisan sponsorship, the *Advancing Education on Biosimilars Act* emerges as my top recommendation for improving biosimilar market access.

It is worth noting that all of the policy alternatives considerably outperformed the status quo. These alternatives are not mutually exclusive, and ultimately, a multi-pronged solution will be needed to effectively stimulate biosimilar uptake. Compromises might need to be made – perhaps instead of banning rebates outright, for instance, the terms of such contracts should be made transparent so that biosimilars can be priced at a competitive rate. Improving provider reimbursement for biosimilars could be rendered more cost-effective if it is bundled into other legislation that requires updates to the Medicare billing system. By continuing to illuminate the key challenges in this space, legislators will be able to negotiate proposed solutions into laws that are politically feasible and still effective. For now, improving the educational resources available to patients and healthcare professionals alike is a strong step in the right direction.

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