WHITE PAPER: PART 2

FAILURE TO LAUNCH

Barriers to Biosimilar Market Adoption

$2.2 Billion in Lost Savings

September 2019

Failure to Launch

Barriers to Biosimilar Market Adoption

Executive Summary

America's health care system is eager for biosimilars, especially in light of mounting evidence that they deliver increased patient access and savings by providing competition for costly brand-name biologics.[1] Biosimilars are lower-priced versions of brand medicines that have been projected to save as much as $54 billion over the next 10 years for a range of debilitating and life-threatening diseases.[2] Widely available in the European Union and around the globe, and with more than 20 now approved by the U.S. Food and Drug Administration (FDA), biosimilars hold the potential to be an integral component of efforts to reduce the high cost of brand-name biologics and enhance patient access.

Unfortunately, significant barriers stand in the way of biosimilar success, leaving America's patients and payers to lose out. In Part I of this series, "Failure to Launch: Patent Abuse Blocks Access to Biosimilars for America's Patients," the Association for Accessible Medicines' (AAM) Biosimilars Council found that delayed launch of biosimilars due to patent thickets has cost the U.S. health care system an astounding $7.6 billion in lost savings since 2015.

However, savings are also being missed as a result of barriers to adoption. Based on a review of U.S. biosimilar launches, the Biosimilars Council found that despite significant price discounts, few of the nine biosimilars available to patients have been able to garner significant market share.[3] This is a direct result of anti-competitive market access tactics by brand-name companies, along with inadequate incentives for their use and insufficient information for patients. Taken together, these post-market barriers have slowed biosimilars adoption, adding upwards of $2.2 billion in potential lost savings since 2015 to the $7.6 billion.

In total, brand-name biologic company anti-competitive tactics and perverse market access barriers have **cost America's patients nearly $10 billion since 2015**. Patients, taxpayers and the overall health care system are bearing the costs.

This white paper will provide an explanation of the perverse mixture of brand-name biologic companies' anti-competitive market access tactics and inadequate incentives that have cost the U.S. health care system billions of dollars in lost savings.

1 Davio, K. (2019, April 17). PBM Says Its Biosimilars Strategy Led to 86% Use of Biosimilar Infliximab. Retrieved from https://www.centerforbiosimilars.com/news/pbm-says-its-biosimilars-strategy-led-to-86-use-of-biosimilar-infliximab

2 Mulcahy, A. W., Case, S. R., & Hlavka, J. P. (2017, October 23). Biosimilar Drugs May Reduce U.S. Health Spending by $54 Billion. Retrieved from https://www.rand.org/pubs/perspectives/PE264.html

3 As of September 4, 2019, there are nine biosimilars commercially available. This paper analyzes lost savings for biosimilars at the end of 2018. See Methodology for more detail.

U.S. Biosimilars Market Overview

Brand-name biologics are the most significant driver of prescription drug spending in the United States. Since 2014, brand-name biologic drugs have accounted for more than 90 percent of prescription drug spending growth. They now account for 36% of total prescription drug spending.[4] This burden is disproportionally shouldered by taxpayers and the federal government. Indeed, in just Medicare Part B, brand-name biologics account for more than two-thirds of drug spending and represent the top 10 highest-expenditure products in the program.[5]

Recognizing the need for competition in this space, Congress passed the Biologics Price Competition and Innovation Act (BCPIA) in 2010 to spur biosimilar competition and reduce drug spending on expensive brand-name biologics.

Early experience demonstrates the promise and challenges of biosimilar medicines. Biosimilars are available for nearly half the list price of brand-name biologics, and their net cost is nearly 20 % less – creating valuable savings for patients and the U.S. health care system.[6] Patient out-of-pocket cost is often based on a percentage of the list price of a drug, meaning that biosimilars provide patients with a significantly lower cost burden than brand-name biologics, leading to increased adherence and better patient outcomes. Further, payers that have preferred biosimilars over the brand-name biologic have been able to realize significant savings for their members and patients.[7]

Not only do biosimilars provide a more affordable option for patients and the health care system, they also lower the price of the brand-name biologic as a result of competition. As an example, Remicade has lowered its net price in Medicare Part B by 23% since biosimilars entered the market. In comparison, At the same time, Remicade biosimilars have continued to discount further in order to compete and are currently priced roughly 20% below Remicade's discounted net price.[8] This dynamic enforces the conclusion from a 2017 study that found 1.2 million patients in the U.S. could gain access to biologic medicines by 2025 because of biosimilar competition. The report also suggests that women and lower-income and elderly individuals would particularly benefit from access to biosimilar medicines.[9]

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4 IQVIA Institute for Human Data Science. (2019, May 9). Medicine Use and Spending in the U.S. Retrieved from https://www.iqvia.com/institute/reports/medicine-use-and-spending-in-the-us-a-review-of-2018-and-outlook-to-2023

5 MedPAC. (2019, April 30). Payment policy for prescription drugs under Medicare Part B and Part D. Retrieved from http://www.medpac.gov/docs/default-source/congressional-testimony/04_30_2019_medpac_drug_testimony_for_eandc.pdf?sfvrsn=0

6 AAM Analysis of IQVIA WAC Data July 2019; Centers for Medicare and Medicaid Services. (2019, July). 2019 ASP Drug Pricing Files. Retrieved from https://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/downloads/2019-July-ASP-Pricing-File.zip

7 Davio, K. (2019, April 17). PBM Says Its Biosimilars Strategy Led to 86% Use of Biosimilar Infliximab. Retrieved from https://www.centerforbiosimilars.com/news/pbm-says-its-biosimilars-strategy-led-to-86-use-of-biosimilar-infliximab

8 Centers for Medicare and Medicaid Services. (2019, July). 2019 ASP Drug Pricing Files. Retrieved from https://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/downloads/2019-July-ASP-Pricing-File.zip

9 Biosimilars Council. (2017, September). Biosimilars in the United States: Providing More Patients Greater Access to Lifesaving Medicines. Retrieved from http://biosimilarscouncil.org/wp-content/uploads/2019/03/Biosimilars-Council-Patient-Access-Study.pdf

Unfortunately, a myriad of roadblocks has prevented biosimilars from generating the level of savings in the U.S. that policymakers have anticipated. Since 2015, when the first biosimilar was launched, through the end of 2018, marketed biosimilars have saved the U.S. health care system $882 million, well short of the projected $54 billion in savings over 10 years.[10] Reasons for this shortfall include delayed launch due to patent thickets and slow adoption related to patient and provider unfamiliarity with this innovative class of medicine.

A closer examination of seven of the biosimilars that were commercially available at the end of 2018 reveals significant anti-competitive market barriers to biosimilar adoption. Together with misaligned Medicare policies that fail to encourage use of lower-cost biosimilars, these factors have prevented the biosimilars market from taking hold in the U.S. and from fully realizing the potential for savings.

Obstacles to Biosimilars Adoption

> **"Manufacturers are using several schemes to hamstring biosimilar competition…the net result is a lopsided playing field that disincentivizes biosimilar developers from making the sizable investment in bringing such products to market."**
>
> **–Former FDA Commissioner, Scott Gottlieb, M.D.**

Payer

The use of "rebate traps" by brand-name manufacturers has been well-documented. In these cases, brand-name companies threaten to remove rebates that they provide to payers unless the biosimilar is effectively excluded from the market. This may go so far as to threaten the rebates on a basket of products in the event that the contracted entity utilizes a biosimilar in place of the reference product.[11]

While a biosimilar is entering at a significant discount from the brand-name product, the "rebate trap" forces the health plan to choose to block biosimilar use or pay the full price for the brand-name product. At that point, it becomes economically unfeasible for a payer to cover a biosimilar with the loss of significant rebate dollars from the brand-name company.

Despite the biosimilar costing patients and Medicare less, the payer is financially incentivized to exclude the biosimilar and continue to use the brand biologic given the uncertainty of biosimilar uptake and the certainty of the brand-name biologic pulling its rebate.

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10 IQVIA Institute for Human Data Science. (2019, May 9). Medicine Use and Spending in the U.S. Retrieved from https://www.iqvia.com/institute/reports/medicine-use-and-spending-in-the-us-a-review-of-2018-and-outlook-to-2023

11 Goldman, A. (2018, June 7). Walgreen and Kroger sue Johnson & Johnson over Remicade, Allege Antitrust Violation. Retrieved from https://www.keionline.org/28114

"Rebate Trap" Illustrated in Medicare Part D

Spending for a beneficiary who takes one prescription drug	**Brand** with list price of $60,000, 25% rebate	**Biosimilar** with list price of $30,000, 25% rebate
Gross drug spending		
Beneficiary cost sharing	$5,489	$3,989
Coverage gap discount	$2,069	$2,069
Covered benefits	$52,442	$23,942
Subtotal	**$60,000**	**$30,000**
Allocation of rebates and fees assuming 80% reinsurance		
Medicare reinsurance (at 80%)	$4,000	$2,000
Plan liability	$11,000	$5,500
Subtotal	**$15,000**	**$7,500**
Net effect		
Beneficiary cost sharing	$5,489	$3,989
Medicare reinsurance after rebates	$37,729	$15,729
Plan liability after rebates and reinsurance	**-$287**	**$713**

MedPAC 2017 Report to Congress

Provider

Medicare Part B reimbursement policies do not encourage providers to prescribe and administer lower-cost treatments. Rather, the Part B program pays providers the same add-on (+6% of the brand net price) whether they administer a lower-priced biosimilar or higher-cost brand-name biologic. While this ensures that providers are not penalized for using a lower-cost biosimilar, it also means that providers have no incentive to use the lower-cost option. Additionally, the brand-name biologic's add-on is +6% of its own net price. This payment system thus incentivizes the brand-name company to increase its price in order to increase its own add-on, further increasing patient out-of-pocket costs.

Patient

Patients are responsible for 20% of the cost of a drug in Part B. As an example, Remicade costs roughly $3000 per administration, making the patient out-of-pocket cost $600 per administration. The recommended treatment for Remicade is three administrations, meaning a patient would face nearly $2000 in out-of-pocket costs in just two months.

Patients pay less for biosimilars compared to brand-name biologics because biosimilars' net price are, on average, 20% lower than their respective brand-name biologics' net price.[12] However, patients do not seek out biosimilars from their providers because the difference in their cost-sharing is rarely communicated to the patient or the provider.

Misinformation

Intentional misinformation disseminated by brand-name manufacturers undermines confidence in these FDA-approved products across these stakeholder groups and serves as one of the largest barriers to biosimilar uptake. This misinformation is intended to sow doubt among patients and prescribers regarding biosimilars' safety and efficacy, as well as construct regulatory, policy and legal roadblocks to competition.

Fortunately, groups like the International Coalition of Medicines Regulatory Authorities (ICMRA), which is made up of the heads of 29 medicines regulatory authorities from every region in the world (including the FDA), have begun to make significant strides to address misperceptions related to biosimilars.[13] However, much more needs to be done in the way of education to ensure health care providers, patients and stakeholders broadly understand that biosimilars are just as safe and effective as their branded counterparts.

12 Centers for Medicare and Medicaid Services. (2019, July). 2019 ASP Drug Pricing Files. Retrieved from https://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/downloads/2019-July-ASP-Pricing-File.zip

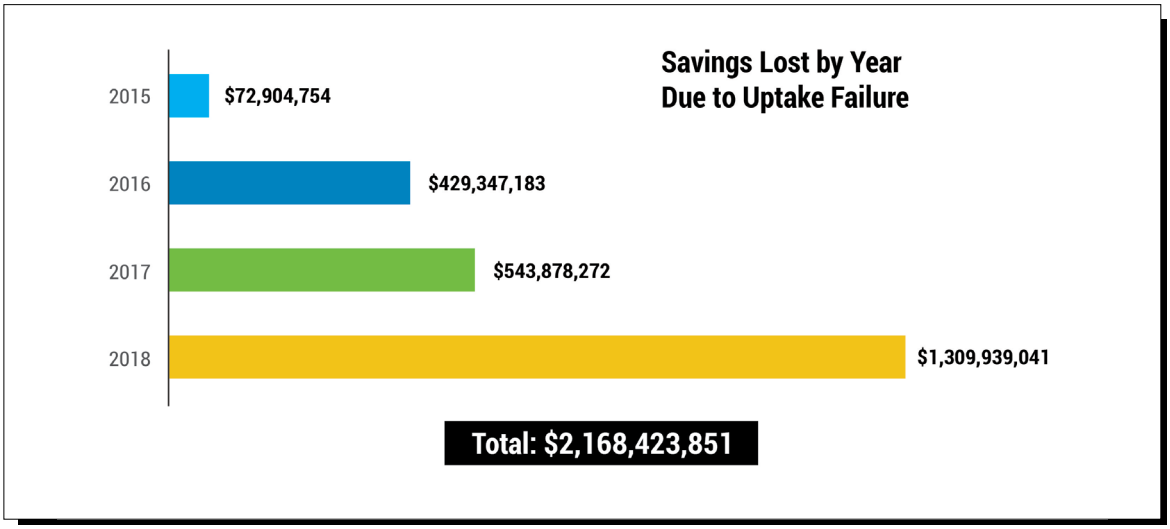
13 International Coalition of Medicines Regulatory Authorities. (2019, August). ICMRA statement about confidence in biosimilar products (for healthcare professionals). Retrieved from http://www.icmra.info/drupal/sites/default/files/2019-07/ICMRA_statement_about_confidence_in_biosimilar_product_HCP.PDF

Key Findings

In order to quantify the savings lost due to slow biosimilar adoption, the Biosimilars Council took seven marketed biosimilars that were available at the end of 2018, as well as discounts from their respective brand-name biologics, and calculated the savings that would accrue if utilization and uptake increased modestly to less than half of the total market.

The Biosimilars Council found the U.S. health care system has foregone $2.2 billion in potential additional savings since 2015 from for these seven products.

When combined with the lost savings from brand-name manufacturers' patent "thickets" that have blocked the launch of other FDA-approved biosimilars, the U.S. health care system has lost nearly $10 billion in savings from 2015 until the end of 2018.



AAM Analysis

Solutions

In order to foster a successful biosimilars marketplace, the role of rebating or discounting schemes in blocking biosimilars market access should be reduced after a biosimilar medicine is launched, especially when it involves exclusionary contracting that obstructs price competition. Additionally, given these barriers, incentives are needed to ensure this innovative class of medicine flourishes.

Medicare Part D

Three of the top selling brand-name biologics in Medicare Part D—Lantus, Humira and Enbrel—accounted for nearly $10 billion in Part D spending in 2017.[14] Medicare Part D could be improved to ensure that rebate or discount-driven utilization management does not further block uptake of lower-priced biosimilars once launched. Ensuring lower cost-sharing and preferred formulary placement for biosimilars will help expand patient access to needed medicines and realize significant savings to the Part D program.

To address these challenges, Medicare Part D could be updated to:

- Ensure lower-priced biosimilar medicines are automatically covered on Part D formulary tiers immediately after launch;
- Ensure that Part D plans place biosimilars on separate, rather than the same, formulary tiers to lower patient cost-sharing as compared to brand drugs and;
- Provide for Part D plans to establish a specialty tier for biosimilars above the CMS specialty threshold (more than $670 in 2020).

These policy updates would support greater patient access to lower-priced biosimilars, lower the out-of-pocket costs for America's patients and avoid the confusion currently experienced by Medicare's providers and beneficiaries. Such a shift would promote savings for the Medicare Part D program as more patients use lower-cost biosimilar medicines and help create a robust biosimilar market in the U.S.

Medicare Part B

To encourage biosimilar utilization, Medicare Part B could also be improved to promote the use of these lower-cost alternatives to expensive brand-name biologics. Specifically, the program could be updated by:

- Waiving the cost-sharing for patients in Part B when a biosimilar is administered and;
- Implementing a "shared-savings" model for biosimilars that allows providers and the Part B program to share in the savings when a lower-cost biosimilar is prescribed instead of the reference biologic.

14 Centers for Medicare and Medicaid Services. (2019, March 14). Medicare Part D Spending Dashboard. Retrieved from https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD.html

Waiving Cost-Sharing for Biosimilars in Part B

Recent research from IQVIA shows that patient abandonment increases significantly once a patient's out-of-pocket cost exceeds $50.[15] Other studies also find that physicians are increasingly sensitive to patient concerns relating to cost and other factors.[16] Given the high cost of brand-name biologics, and beneficiaries' out-of-pocket responsibility within Part B, the reduction or elimination of cost-sharing for biosimilars is likely to affect both patient and provider prescribing behavior.

Thus, removing the cost-sharing for patients using biosimilars would influence providers by increasing their patients' desire to avoid the financial barriers they may experience using a brand-name biologic. Moreover, as patients are made aware of the elimination of any additional out-of-pocket cost for the biosimilar, demand for biosimilars should dramatically increase their utilization.

"Shared-Savings" Program

A "shared-savings" program in Medicare would help create a financial incentive for providers to administer biosimilars over the brand-name biologic and guarantees additional savings to Medicare Part B. Under this program, providers would share in the savings generated by the difference in net price for the biosimilar, compared to the net price of its brand-name biologic, when the biosimilar's net price is lower than the brand-name net price. This creates a direct, traceable financial incentive for providers to administer the less costly biosimilar.

Additionally, the Medicare Part B program can realize savings under this proposal by splitting the savings realized by prescribed biosimilars with the provider. Unlike other proposals, Medicare Part B would be largely guaranteed to see savings from this proposal, as the shared savings payments to providers are only available when the biosimilar net price is less than the brand-name biologics'.

15 IQVIA Institute for Human Data Science. (2019, May 9). Medicine Use and Spending in the U.S. Retrieved from https://www.iqvia.com/institute/reports/medicine-use-and-spending-in-the-us-a-review-of-2018-and-outlook-to-2023

16 Mostofian, F., Ruban, C., Simunovic, N., & Bhandari, M. (2015, January). Changing physician behavior: what works? Retrieved from https://www.ncbi.nlm.nih.gov/pubmed/25880152

Summary

This analysis highlights that significant and costly barriers to biosimilar adoption remain even after successfully navigating anti-competitive patent thickets and entering the market. The anti-competitive rebating tactics by brand-name biologic companies combined with the absence of strong provider reimbursement incentives and insufficient patient information on biosimilars cost the U.S. health care system $2.2 billion from 2016 to 2018 in lost savings from lower-than-expected biosimilar adoption rates. Combined with patent abuse that block biosimilars from getting to the market, these barriers have cost the U.S. health care system a total of $9.8 billion in savings since 2015. Only by creating incentives for biosimilar uptake and use can the biosimilars marketplace thrive and these savings be fully realized.

Policymakers must take steps to ensure the viability of this market for America's patients. Without competition from biosimilars, brand-name biologics will continue to drive up prescription drug spending at an unsustainable rate and keep life-altering treatment out of the hands of patients.

$9.8B 2015-2018 lost savings for the U.S. health care system

Methodology

To conduct the analysis, AAM used seven marketed FDA-approved biosimilars available at the end of 2018 to examine foregone savings. The products are listed below.

For purposes of the analysis, AAM assumed a 30% price discount for biosimilar products relative to their reference biologic. This assumption was selected to conform with previous AAM analyses of potential biosimilars.[17]

Similarly, AAM assumed an uptake assumption of 40% for individual biosimilars. This uptake assumption is assumed to remain constant during the presence of two biosimilars (for example, biosimilar uptake of 40% is split between both biosimilars). When there are assumed to be three biosimilars in the market, the total uptake assumption for all the available biosimilars is assumed to be 50%.

The data on pricing were purchased by AAM from IQVIA and provide national sales and pricing information for the selected products and their reference biologics from 2012 through the present.

17 QuintilesIMS. (2017, May). The Impact of Biosimilar Competition in Europe. Retrieved from https://www.medicinesforeurope.com/wp-content/uploads/2017/05/IMS-Biosimilar-2017_V9.pdf

Biosimilar (Approval Year)	Reference Product	2015 Lost Savings	2016 Lost Savings	2017 Lost Savings	2018 Lost Savings
Zarxio* (2015)	Neupogen	$72,904,754.16	$68,656,732.68	Excluded from Analysis	Excluded from Analysis
Inflectra* (2016)	Remicade		$477,315,440.10	$327,637,513.56	$261,679,714
Erelzi (2016)	Enbrel		$284,471,546.12	$949,060,552.20	$956,669,903
Amjevita (2016)	Humira		$406,184,048.79	$979,820,830.62	$957,604,549
Renflexis* (2017)	Remicade			216,240,758.95	$261,679,714
Cyltezo (2017)	Humira			$323,340,874.10	$957,604,549
Mvasi (2017)	Avastin			$87,935,906.07	$364,691,201
Ogivri (2017)	Herceptin			$27,935,363.04	$187,645,400
Ixifi (2017)	Remicade		Excluded from Analysis	Excluded from Analysis	Excluded from Analysis
Retacrit* (2018)	Epogen/Procrit				$185,375,327
Fulphila* (2018)	Neulasta				$253,633,969
Nivestym* (2018)	Neupogen				$16,986,517
Hyrimoz (2018)	Humira				$957,604,549
Udenyca* (2018)	Neulasta				$253,633,969
Herzuma (2018)	Rituxan				$187,645,400
Truxima (2018)	Herceptin				$534,841,850
Total Lost Savings by Year		**$72,904,754.16**	**$1,236,627,767.69**	**$2,911,971,798.54**	**$6,337,296,610**
Total Lost Savings					**$9,818,724,453.08**

* A currently marketed biosimilar

AAM Analysis

Biosimilars Council
A Division of AAM

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