

ISSUE BRIEF

Tear Down This Wall

Documenting the patient costs created by anti-competitive rebate walls

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Tear Down This Wall: Documenting the patient costs created by anti-competitive rebate walls By Wayne Winegarden December 2020 A special thanks to supporters of PRI's health care policy work including Eli Lilly. Pacific Research Institute PO Box 60485 Pasadena, CA 91116 Tel: 415-989-0833 www.pacificresearch.org Nothing contained in this report is to be construed as necessarily reflecting the views of the Pacific Research Institute or as an attempt to thwart or aid the passage of any legislation. ©2020 Pacific Research Institute. All rights reserved. No part of this publication may be reproduced, stored in a retrieval

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Executive Summary

The surest sign that the current drug rebate system fails patients is its adverse impact on costs. While it would be logical to assume that rising drug rebates decrease patient costs, in fact patient costs are skyrocketing *because* rebates are growing at double-digit rates. This counterintuitive result demonstrates that fundamental reforms to the rebate system are necessary.

One of the top reform priorities should address the anti-competitive practice that is commonly referred to as a "rebate wall" or a "rebate trap". Rebate walls occur when rebates are tied to specified volume targets. When the dollar sales of a drug are large enough, which often occurs when a drug treats multiple indications, losing these dollar rebates overwhelms the potential savings that lower-priced competitive drugs can offer insurers and PBMs. In order to avoid this penalty, insurers will, essentially, block patient access to lower-priced medicines. The lack of competition between drugs causes prices to remain excessively high, which impose large costs on patients who require expensive medicines and do not benefit from the rebates. As a result, successful rebate walls worsen the drug affordability problem by denying patients access to drugs that would be just as efficacious but cost less.

The access barriers created by rebate walls prevent several types of healthy competition from occurring. One type of competition occurs when multiple brand name or biologic products that treat the same condition compete against one another. The other types of competition occur when generic medicines compete against a brand name medicine or biosimilar medicines compete against an originator biologic medicine. The empirical evidence demonstrates that all of these types of competition generate significant healthcare savings.

For instance, a 2004 study by DiMasi and Paquette noted that when brand competitors were available, those medicines were priced at a 26 percent discount relative to the price leader and a 14 percent discount relative to the class average. This is consistent with the competitive environment of hepatitis C treatments where follow-on branded drugs eventually sold for up to 69 percent less than the first-in-class drug.

A study funded by the FDA evaluated the impact on prices when generic medicines were made available to patients.² The results illustrate that even with one generic competitor, the average price for the competitive generic medicine is 61.4 percent of the price for the branded medicine prior to the generic's entry. As the number of generic competitors increase from one to two, the average generic price relative to the branded medicine fell to 46.5 percent, or less than one-half the branded medicine's price. The price discounts continue to grow as the number of competitors increase, eventually costing pennies on the dollar relative to the brand price prior to the generic's entry.

Biosimilars function like generics in the higher-cost biologics market. Due to their higher costs of production, the price discounts for biosimilars are not as large as generics, but they are still substantial. As of July 2020, the average biosimilar sells at a 30.1 percent discount compared to the price of the originator biologic prior to the introduction of the biosimilar. Zarxio offered the largest reduction in price relative to the price of the originator biologic, which was a 52.6 percent discount.

These results indicate that when rebate walls successfully block competition, they are imposing excessive and unjustifiable costs on patients. Due to the excessively complex drug pricing system coupled with the wide variance in benefit designs, the costs an individual patient will face will vary. To account for this wide variability, this analysis estimated the per drug costs imposed on patients' out-of-pocket costs from the successful implementation of a rebate wall under alternative benefit design scenarios. The analysis focuses on patients' lost savings because insurers benefit from the large dollar rebates but patients who require expensive drugs do not. Therefore, while the potential savings that insurers could be receiving from the less expensive drugs are offset by their share of the rebate savings, patients are fully exposed to these losses. Put differently, it is patients who suffer the most from the rebate wall problem and, consequently, patients who stand to benefit the most from dismantling these anti-competitive practices.

The savings are estimated for patients with employer-sponsored health insurance, patients who are on Medicare, and patients who require drugs that are infused in a clinical setting. Furthermore, the lost savings are estimated to account for the different types of competition that can be thwarted (e.g. competition from other branded or originator biologic drugs, competition from generics, and competition from biosimilar drugs). The range of savings across these alternative scenarios are summarized in Table ES 1. While there is a large variance in the lost potential savings depending upon these key factors, based on drug costs of \$10,000, \$50,000, and \$70,000, patients could be reclaiming up to tens of thousands of dollars in potential savings if rebate wall practices were eliminated.

Table ES 1Lost Savings Opportunities Caused by Effective Rebate Walls Employer-sponsored Insurance Plans and Medicare Alternative Forms of Competition

	\$10,000 LIST PRICE	\$50,000 LIST PRICE	\$70,000 List price
Employer-sponsored Plans			
Bra	nded Drug		
14% discount to class average	\$932	\$4,658	\$6,522
26% discount to price leader	\$962	\$4,810	\$6,734
1 generic competitor	\$1,428	\$7,141	\$9,997
5 generic competitors	\$3,801	\$17,564	\$24,446
10+ generic competitors	\$4,069	\$18,701	\$26,027
Originato	or Biologic Drug		
14% discount to class average	\$705	\$3,525	\$4,935
26% discount to price leader	\$728	\$3,640	\$5,096
Average biosimilar discount (30.1%)	\$843	\$4,214	\$5,900
Zarxio discount (52.6%)	\$1,473	\$7,364	\$10,310
Infu	sion Drugs		
14% discount to class average	\$747	\$3,737	\$5,231
26% discount to price leader	\$772	\$3,858	\$5,402
Average biosimilar discount (30.1%)	\$893	\$4,467	\$6,254
Zarxio discount (52.6%)	\$1,561	\$7,806	\$10,928
Medicare Part D			
Branded/Orig	inator Biologic Drugs		
14% discount to class average	\$630	\$629	\$881
26% discount to price leader	\$650	\$650	\$910
1 generic competitor	\$965	\$965	\$1,351
5 generic competitors	\$2,140	\$2,710	\$2,996
10+ generic competitors	\$2,734	\$4,385	\$5,335
Average biosimilar discount (30.1%)	\$753	\$753	\$1,054
Zarxio discount (52.6%)	\$1,315	\$1,315	\$1,841
Infu	sion Drugs		
14% discount to class average	\$534	\$2,669	\$3,737
26% discount to price leader	\$551	\$2,756	\$3,858
Average biosimilar discount (30.1%)	\$638	\$3,191	\$4,467
Zarxio discount (52.6%)	\$1,115	\$5,576	\$7,806

Beyond the direct lost savings, the access restrictions created by the anticompetitive rebate wall practices worsen patient outcomes and cause other types of healthcare spending to increase. For example, rebate walls inappropriately create access restrictions that include fail first or step therapy policies. Fail first policies require patients to first use and fail on the preferred drug before they can access another competitive product. These access restrictions can delay patient access to appropriate care. Delayed access often creates lasting healthcare consequences for patients with degenerative or progressive diseases. Compounding these problems, access restrictions are also linked to reduced patient adherence to their prescribed medicines, which is also connected to worse patient health outcomes and higher healthcare costs.

By definition of having the time to establish a large market share, drugs with high sales volumes also tend to be older, more expensive drugs while the disfavored drugs tend to be newer and lower-priced. These newer medications are not only less expensive typically, but often they are more efficacious for patients or a targeted sub-group of patients. These realities mean that by losing access to these new medicines, patients are often being denied access to more appropriate treatments.

Reducing these costs created by rebate walls should be a top policy priority. The most effective reforms fix the broader problems with the current rebate system. Due to the current opaque drug pricing system, rebates actually increase patients' share of drug costs. Requiring greater price transparency coupled with ensuring that all rebates benefit patients can correct this problem. Such reforms would remove the incentives to artificially inflate list prices and allow patients to benefit from the slower growing net prices. With respect to the problem of rebate walls, rebate reform would fundamentally change the incentives that drive the pharmaceutical market. Instead of competing based on the size of the rebates paid, drug companies would compete based on the actual market prices of medicines. With rebates no longer driving the market process, the ability to game the system via rebate wall tactics would disappear because new competitors would compete with established brands by selling their drugs at a lower net price, and insurers would be able to include these drugs on their formularies without risking losing the sizable rebate revenues.

While fundamental rebate reform is the more efficient reform option (if broad-based reform is not possible), then addressing the anti-competitive rebating practices that are generally outlawed in other markets is a second-best approach. Such reforms should prohibit, or significantly restrict, the exclusionary- and volume-based rebates that enable firms to establish anti-competitive rebate walls.

Introduction

According to the Federal Trade Commission (FTC), the agency charged with ensuring that markets are competitive, "competition in America is about price, selection, and service. It benefits consumers by keeping prices low and the quality and choice of goods and services high. Competition makes our economy work." Ensuring that competition focuses on serving the interest of consumers is essential. Competitive actions that provide consumers with better products and services at lower costs is the *sine qua non* of healthy competition, regardless of its impact on the financials of other businesses (either positive or negative).

The results from a twelve-year study of thirteen nations conducted by the McKinsey Global Institute demonstrate that consumer-focused competition is essential for securing our long-term prosperity. As summarized by former FTC Chair Deborah Majoras, the study found

...that levels of productivity made the difference between rich and poor nations. What, though, made the difference in levels of productivity? The answer, they found, was undistorted competition in product markets. In his book in which he reports the results of the study, Mr. Lewis says, "Most economic analysis ends up attributing most of the differences in economic performance to differences in labor and capital markets. This conclusion is incorrect. Differences in competition in product markets are much more important."

McKinsey also asked why the highly productive United States has higher competitive intensity than other nations. Mr. Lewis sums up the answer by saying that, in the United States, "Consumer is king." More specifically, "[t]he United States adopted the view that the purpose of an economy was to serve consumers much earlier than any other society," and we continue to "hold this view more strongly than almost any other place." He concludes that, in fact, "Consumers are the only political force that can stand up to producer interest, big government, and the technocratic, political, business, and intellectual."

Essentially, the McKinsey study documented the economic principle that businesses operating in competitive markets will consistently strive to improve their products, streamline their production processes, and/or find better ways to serve their customers. Not only does this beneficial market process improve the well-being of consumers, but it also pushes businesses to constantly find new ways to improve productivity. Vibrant productivity growth is a necessary condition for a prosperous economy that creates sustainable and broad-based improvements in people's standard of living.

Most markets in the U.S. adhere to the mantra that the "consumer is king", including a large portion of the U.S. pharmaceutical market. However, there are key segments of the prescription drug market that are rife with anti-competitive actions that distort the market process. These distortions artificially raise the prices of medicines and unjustifiably risk patients' health outcomes. While there are several anti-competitive practices, arguably anti-competitive rebate practices that collectively are referred to as a "rebate wall" or a "rebate trap" are among the most troubling.

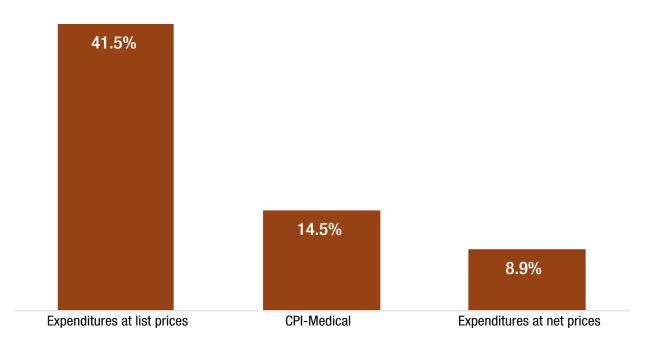
Understanding Rebate Walls

Rebates benefit consumers in most industries, but this common-sense use of rebates does not apply when patients are purchasing prescription medicines. As currently used in the pharmaceutical market, rebates have become an anti-competitive tool that increase patient costs and decrease their choices. Some of these anti-competitive practices are referred to as a rebate wall. Understanding the adverse impact created by rebate walls begins with understanding how rebates work in the pharmaceutical industry.

All drug manufacturers announce list prices (e.g. wholesale acquisition cost, WAC) for their medicines. These list prices are often mistaken for the market price, but the list prices do not account for the hundreds of billions of dollars in concessions that are paid each year in the form of discounts, rebates, and chargebacks. The list price minus the value of these concessions equals the net price, which is the actual market price.⁵

Figure 1 compares the growth in list and net prices on brand medicines as measured by IQVIA⁶ to the growth in medical care inflation as measured by the Bureau of Labor Statistics (BLS).⁷ Medical care inflation increased 14.5 percent between 2014 and 2019 – medical costs were 14.5 percent higher in 2019 compared to 2014. During the same period, drug list prices increased 41.5 percent, nearly three times faster than the growth in overall medical inflation. The net prices of drugs, or the actual market price of the drugs, were only 8.9 percent higher in 2019 compared to 2014. This means that the growth in the market price of drugs has been less than the growth in overall medical care inflation.

Figure 1
Cumulative Growth in Drug List Prices, Drug Net Prices, and Average Medical Inflation 2019 Relative to 2014



Source: IQVIA and BLS

The growth in list prices has exceeded the growth in net prices by such a wide margin because the growth in the value of rebates has been even more excessive. According to *Drug Channels*, between 2015 and 2019, concessions grew an average of 11.5 percent annually. This excessive growth is problematic because, as implemented, this rebate system incentivizes anti-competitive practices that harm patients.

Patients are harmed because they do not benefit from the large and fast-growing rebates when they purchase their medicines. Patient out-of-pocket costs are not based on the net price of medicines, which are the actual market price. Instead, the typical insurance benefit design bases patients' out-of-pocket costs (e.g. co-insurance) on the list prices of medicines, which do not reflect any rebates. Since list prices have been growing quickly in order to enable the large and fast-growing dollar value of rebates, the current rebate system is causing the out of pocket costs for patients who are prescribed expensive medicines to grow excessively. What makes this cost growth indefensible is the fact that the market price of drugs, which determines the costs for payers and the revenues for manufacturers, is growing slower than overall medical inflation.

Rebate walls contribute to this untoward situation. Manufacturers with established drugs that have large dollar sales will sometimes tie rebates to specified volume targets. The potential of losing these large rebates, and their subsequent exposure to the inflated gross prices, acts like a stick that ensures these manufacturers obtain preferential treatment for the favored medications. The large gap between spending at list prices in 2019 (\$671 billion) and the actual cost of the medicine or the spending at net prices (\$356 billion) substantiates that the rebate stick is consequential, particularly for the manufacturers of drugs that address multiple indications. This large penalty encourages insurers to block competitive drugs from the formulary or force these competitors into less favorable tiers that have more restrictions and impose higher costs on patients. The rebate wall refers to the proliferation of these anti-competitive practices.

As described by *Kaiser Health News*, the rebate wall occurs when "makers of established brands give volume-based rebates to insurers or intermediaries called pharmacy benefit managers. In return, those middlemen often leave competing generics off the menu of drugs they cover, called a formulary, or they jack up the price for patients. The result is that many can't get the cheaper drugs unless they shoulder a bigger copay or buy them with no help from insurance." ¹⁰

David Balto, former policy director at the FTC, defined rebate walls as a "means of structuring drug rebates to economically coerce insurers and pharmacy benefit managers to keep rival drugs off drug formularies. If a rival drug is granted formulary access, the manufacturer claws back the rebates, which means the payor loses millions of dollars." Instead of outright prohibition, rival drugs will sometimes gain access to the formularies, but the rebate wall grants the original drug preferential access and forces patients to first use and fail on the original drug before they can try the new rival – a system referred to as step therapy. It should be noted that step therapy requirements can be valid, so the rebate wall refers to the inappropriate use of step therapy requirements for the purpose of establishing access barriers.

Rebate walls harm patients by denying access to drugs that could potentially be more efficacious or drugs that would be just as efficacious but cost less. These adverse impacts are particularly burdensome for innovative biologics. Biologics are drugs derived from or synthesized in biological processes. These treatments have significantly improved the health outcomes for patients including cancer patients and

patients living with auto-immune diseases, such as rheumatoid arthritis (RA). Patients living with auto-immune diseases are particularly vulnerable to the rebate wall's adverse impacts because the first-in-class originator biologics are expensive and treat multiple diseases. Since the first-in-class drugs offer rebates that are difficult for new medicines to match, the rebate wall reduces the availability of competitive biologic drugs, which causes higher patient costs and lower drug adherence. Reduced drug adherence is linked to lower patient health outcomes and higher total healthcare spending.¹²

In sum, rebate walls create market distortions that accelerate the growth in healthcare inflation and decrease the quality of healthcare that patients receive.¹³

Competition Between Drugs Lowers Costs

Rebate walls worsen the problem of healthcare inflation because, regardless of the type of medicine (e.g. small molecule or biologic), the availability of competitive products create substantial cost savings. Competition in the pharmaceutical/biopharmaceutical market typically takes one of three types: (1) multiple brand name or biologic products that treat the same condition competing against one another; (2) generic medicine(s) competing against brand name medicine(s); and (3) biosimilar medicine(s) competing against originator biologic medicine(s).

Starting with brand name competition, several studies have documented the savings potential created when the drug pricing environment encourages brand-on-brand competition. However, other studies claim that these "follow-on" competitors (as these subsequent branded competitors are sometimes called) do not meaningfully reduce drug prices. Sarpatwari et al. (2019), for instance, reviewed 10 studies that evaluated brand on brand competition's impact on prices. ¹⁴ The authors concluded "that policies to promote brand-brand competition in the US pharmaceutical market, such as accelerating approval of non-first-in-class drugs, will likely not result in *lower drug list prices* absent additional structural reforms."¹⁵

As their conclusion demonstrates, Sarpatwari et al. (2019) focused on drug list prices as the measure of market prices. As documented in the above section, list prices exclude the large and growing rebates and other concessions paid by manufacturers that meaningfully reduce the actual market prices of the drugs. In fact, once these concessions are included, the list price growth trends will significantly diverge from the growth in actual market prices. This point was emphasized more than a decade ago by Guha et al. (2008),

The unique structure of the pharmaceutical industry implies that the most commonly available pricing data, which do not reflect patient co-payments, rebates paid to insurers and PBMs, or the effective price discounts provided by free samples, are poorly measured for branded drugs. Such data imperfections can lead to erroneous conclusions about the nature and amount of competition between drugs within a therapeutic category.¹⁶

When actual market or transaction prices are examined, the expected finding that more competition leads to lower overall costs holds. For instance, DiMasi and Paquette (2004) examined the impact from branded competition using market prices finding that "for 20 new entrants to existing classes that were

introduced in the US from 1995 to 1999, 80% were launched at a discount to the price leader and 65% were launched at a discount to the average price for the class (actual transaction prices for a very large pharmacy benefit manager were used). The average percentage change was a 26 percent discount relative to the price leader and a 14 percent discount relative to the class average. The presence of multiple drugs in a class also gives managed care leverage in extracting rebates for drugs in the class. These additional cost reductions were not included in the data obtained for the study."¹⁷

Treatments that cure hepatitis C are a recent demonstration of the price lowering benefits from branded competition (or the competition created by follow-on drugs). When Sovaldi was released, it was the first well tolerated cure for hepatitis C that offered revolutionary benefits; however, its \$84,000 price tag was also controversial. Despite these controversies, there are also sound arguments supporting this price point because a well-tolerated cure significantly improves patient health outcomes and reduces systemic costs, on net, by avoiding the need for other healthcare expenditures that often include liver transplants that cost upwards of \$300,000 plus the annual \$40,000 in costs to cover the anti-rejection drugs.

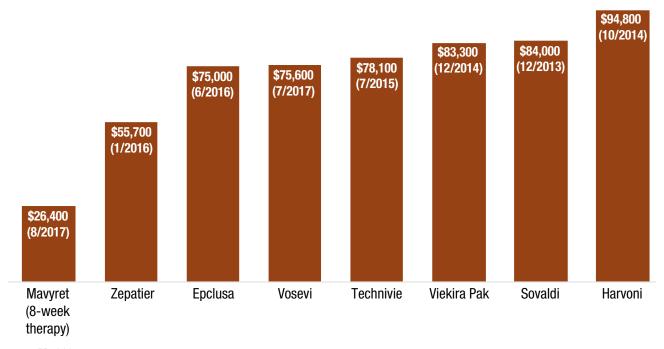
Regardless of this price's appropriateness, the introduction of several follow-on drugs materially changed the environment. The process took time, but there are now multiple drugs that work in different ways competing at different price points. Overviewing this process, Saag (2017) noted that when

the 'Me three' regimens [came along] they set a lower price. The market began to evolve but it was hard to determine what the true cost of drug regimen was owing to complexity of 'rebates' and discounts off of listed price.

Enter Mavyret (glecaprevir/pibrentasvir, AbbVie) and it appears that AbbVie has learned a lesson about the role of drug pricing as a discriminator in a competitive marketplace. Their new pan-genotypic, once daily, 8- to 12-week regimen was priced less than two-thirds of the initial pricing of Harvoni, just a few years earlier.¹⁸

Figure 2 presents the wide cost variability of current treatments as reported by *Healthline*, along with the FDA approval date for each drug in parentheses. Figure 2 demonstrates that branded (or me-too) competition meaningfully impacted the costs for hepatitis C drugs and, as a result of brand-on-brand competition, effective cures for the disease are currently being sold up to 69 percent cheaper than the first-in-class drug.¹⁹

Figure 2
Estimated Treatment Cost for Alternative Hepatitis C Cures, 2020



Source: Healthline.com

Another type of drug competition occurs when generics – lower-priced versions of formerly exclusive drugs – enter the market. The reduction in drug costs enabled by generic competition is well documented. A 2019 study of this issue funded by the FDA summarized these benefits stating that,

greater competition among generic drug makers is associated with lower generic drug prices, according to a new analysis using two different sources for wholesale prices. We show that generic drug prices after initial generic entry decline with additional competition using both the average manufacturer prices (AMP) reported to the Centers for Medicare and Medicaid Services (CMS) and invoice-based wholesale prices reflecting pharmacy acquisitions from IQVIA's National Sales Perspective database (NSP).²⁰

Figure 3 summarizes the FDA's results based on the AMP data. The FDA's results illustrate that, even if there is only one competitor, generic competition significantly lowers prices. With one generic competitor, the average price for the competitive generic medicine is 61.4 percent of the price for the branded medicine prior to the generic's entry. As the number of generic competitors increases from one to two, the average generic price relative to the branded medicine fell to 46.5 percent – less than one-half. The price discounts continue to grow as the number of competitors – a measure of the intensity of competition – increases eventually costing pennies on the dollar relative to the brand price prior to the generic's entry.

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Figure 3Median Generic Prices Relative to Brand Prices Before Generic Entry



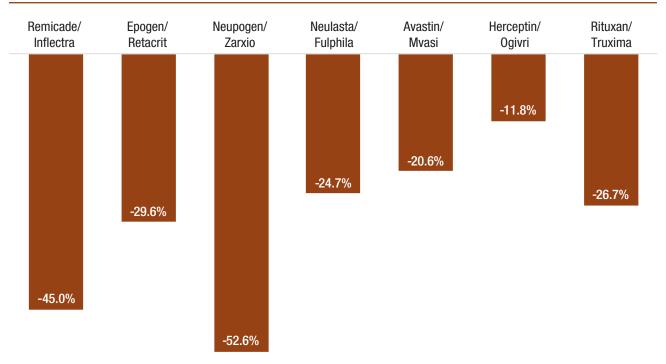
Source: FDA

The last type of competition occurs when biosimilars compete against originator biologic medicines. Anti-competitive practices, like the rebate wall, impose particularly large costs in the biologics market because these high innovation drugs are costly to produce and, as a result, are typically expensive. Due to these high costs, U.S. dollar sales of biological drugs in 2018 were 32.3 percent of total drug sales, or the highest share of total spending among the OECD countries.²¹

In addition to the originator competition discussed above, biosimilar products offer patients lower-cost alternatives to originator biologics. In this way, biosimilars create a competitive environment for originator biologics that is similar to the competitive environment generics create for branded medicines. Due to their higher costs of production, the price discounts are not as large for biosimilars compared to generics, but they are still substantial, see Figure 4.

Figure 4 compares the prices as of July 2020 for the lowest-priced biosimilar compared to the price of the originator biologic prior to the introduction of the biosimilar. Each biosimilar was introduced at a different date with the biosimilars Inflectra (prices down 45.0 percent), Retacrit (prices down 29.6 percent), Zarxio (prices down 52.6 percent), and Fulphila (prices down 24.7 percent) being available the longest. As Figure 4 demonstrates, when biosimilars enter the market to compete with originator biologics, prices decline.

Figure 4
Current Biosimilar Prices Relative to Originator Prices Before Biosimilar Entry
Prices as of July 2020



Source: FDB MedKnowledge

The Rebate Wall Negatively Impacts Drug Costs

Rebate walls thwart competition causing patient out-of-pocket (OOP) costs to be higher than they would be under a competitive environment. The analysis focusses on patient OOP costs because insurers benefit from the large dollar rebates, but patients who require expensive drugs do not. Even though insurers devote a large portion of the savings toward lowering insurance premiums, these savings benefit all beneficiaries indicating that the patients funding these costs (those who require expensive medicines) bear the full brunt of the costs but only receive a small portion of the savings. Therefore, while the potential savings that insurers could be receiving from the less expensive drugs are offset by their share of the rebate savings, patients are exposed to the vast majority of these losses. Put differently, it is patients who suffer the most from the rebate wall problem and, consequently, patients who stand to benefit the most from dismantling these anti-competitive practices.

Due to the excessively complex drug pricing system coupled with the wide variance in benefit designs, how the costs are manifested will differ across patient groups. Patients with drug prescription plans with higher co-insurance rates pay higher out-of-pocket costs from a successful rebate wall compared to patients with lower co-insurance rates. Whether patients are covered under Medicare versus private plans will also matter, as will whether the drug is infused in a clinical setting versus sold over a pharmacy counter.

To account for this wide variability across these different patient populations, the following analyses summarize, on a per drug basis, the impact on patient out-of-pocket costs from the successful implementation of a rebate wall for patients with different insurance coverage. Additionally, the analyses account for the differences in the potential lost savings when a rebate wall prevents competition from other branded or originator biologic drugs, as well as when a rebate wall prevents competition from generic or biosimilar drugs.

The scenarios are evaluated for patients with employer-sponsored health insurance, patients who are on Medicare, and patients who require drugs that are infused in a clinical setting. For ease of exposition, the sources, assumptions, and detailed calculations that support the estimates visualized in Figures 5 through 9 are presented in the Appendix. It should also be emphasized that these calculations demonstrate the types of costs that patients are bearing when rebate wall tactics are successful. The scenarios evaluated are not intended to be a comprehensive analysis of all of the costs.

With these caveats, it is clear from the calculations that each instance of a successful rebate wall imposes large costs on patients regardless of the type of competition thwarted or the type of insurance covering the patient.

Figure 5 presents the lost savings for patients with the average employer-sponsored benefit design who are taking a branded drug with list prices of \$10,000, \$50,000, and \$70,000. These list prices generally represent the range of "high-cost" medicines. Figure 5 demonstrates that increased branded competition could reduce out of pocket (OOP) expenditures between \$932 and \$962, for a drug with a \$10,000 list price and between \$6,522 and \$6,734 for a drug with a \$70,000 list price. Effective generic competition could generate even greater savings – reducing OOP expenditures between \$1,428 and \$4,069 and \$9,997 and \$26,027 for a drug with a \$70,000 list price.

Figure 5
Lost Potential Savings for Employer-Sponsored Insurance
When Rebate Walls Block Alternative Forms of Competition Against Branded Drugs:
Alternative List Prices



The potential lost savings for patients with the average employer-sponsored benefit design who is taking an originator biologic with \$10,000, \$50,000, and \$70,000 list prices that is protected by a rebate wall are presented in Figure 6. The estimated savings that are lost vary slightly because biologic drugs tend to have different co-pays and co-insurance rates compared to preferred branded drugs. Overall, increased originator biologic competition could generate between \$705 and \$728 in OOP savings for a biologic with a \$10,000 list price and \$4,935 and \$5,096 for a biologic with a \$70,000 list price. Biosimilar savings, on the other hand, could generate between \$843 and \$1,473 in OOP savings and \$5,900 and \$10,310 for biologics with a \$10,000 and \$70,000 list price, respectively.

Figure 6Lost Potential Savings for Employer-Sponsored Insurance When Rebate Walls Block Alternative Forms of Competition Against Originator Biologic: Alternative List Prices



Figure 7 presents the lost savings for patients with employer-sponsored health insurance who require an infusion drug. Increased originator biologic competition could generate between \$747 and \$772 in OOP savings for a biologic with a \$10,000 list price and \$5,231 and \$5,402 for a biologic with a \$70,000 list price. The lost potential OOP savings from biosimilar competition are estimated to be between \$893 and \$1,561 and \$6,254 and \$10,928 for biologics with a \$10,000 and \$70,000 list price, respectively.

Figure 7
Lost Potential Savings When Rebate Walls Block Alternative Forms of Competition Against Infusion Originator Biologics
Employer Sponsored Plans: Alternative List Prices



Figure 8 details the potential savings for patients' OOP costs under Medicare Part D's excessively complex standard benefit. Based on the structure of the standard benefit, the potential OOP savings are less than under the employer-sponsored benefit design yet still substantial. For an originator biologic drug with a \$10,000 list price, potential savings between \$630 and \$1,315 are lost from a successful rebate wall, while for a branded drug with a \$10,000 list price the lost potential savings from rebate wall tactics range between \$630 and \$2,734. Based on a \$70,000 list price, the potential OOP savings range between \$881 and \$1,841 for an originator biologic drug and between \$881 and \$5,335 for a branded drug.

Figure 8Lost Potential Savings in Medicare Part D When Rebate Walls Block Alternative Forms of Competition: Alternative List Prices



Figure 9 evaluates the impact on OOP costs for patients with Medicare who require originator biologics that must be delivered in a clinical setting. These figures demonstrate that patients covered either by Medicare Advantage programs or with traditional Medicare but without Medigap insurance could save between \$534 and \$1,115 in OOP costs for a biologic with a \$10,000 list price. For a biologic with a \$70,000 list price, the lost savings potential range between \$3,737 and \$7,806.

Figure 9
Lost Potential Savings When Rebate Walls Block Alternative
Forms of Competition Against Infusion Originator Biologics Medicare Advantage/No
Medigap: Alternative List Prices



Figures 5 through 9 demonstrate that rebate walls that successfully thwart competition unjustifiably increase total drug spending for patients. Further, these lost savings exist regardless of the type of competition thwarted – whether it is branded competitors, originator biologic competitors, generic competitors, or biosimilar competitors. The existence of these lost savings demonstrates the importance of prohibiting the anti-competitive contracting practices that enable these adverse outcomes.

The Rebate Wall's Negative Impact on Healthcare Costs, Outcomes, and Innovation

In addition to the direct increase in drug costs created by rebate walls, the access restrictions created by these anticompetitive practices will harm patient outcomes and lead to increases in other types of healthcare spending.

For example, a typical rebate wall barrier will inappropriately place competitor products on less favorable tiers that require patients to fail first on the preferred drug (i.e. step therapy) before they can access the competitive product. Another barrier imposes excessive prior authorization requirements before a patient can access the medicine. Such requirements create unnecessary access delays that create lasting healthcare consequences, particularly for patients with degenerative or progressive diseases.

There is also a growing literature that links access restrictions to reduced patient adherence to their drugs. It is well documented that reduced patient adherence to their medicines causes worse health outcomes and higher overall healthcare costs. Boytsov et al. (2019) examined the impact from access restrictions on patients with rheumatoid (RA) or psoriatic arthritis (PsA) and found that,

RA patients whose insurance plans required a stepped approach...for the treatment of their disease had 17–19 percent lower odds of treatment effectiveness compared with patients who did not have access restrictions or whose access restrictions only included PA [prior authorization]. Examination of the components of treatment effectiveness revealed that differences in effectiveness between groups were driven by differences in medication adherence as those with step therapy requirements had 18–19 percent lower odds of adherence compared with PA only or no restrictions. Among PsA patients, the decrease in the odds of treatment effectiveness associated with step therapy requirements was 25–27 percent, driven by 27–29 percent lower odds of medication adherence for PsA patients with step therapy. These associations were weakened and lost statistical significance when patients with PA and patients with step therapy were combined into a single cohort, indicating that step therapy is a stronger deterrent to treatment effectiveness than PA alone.

Formulary restrictions may also be leading to higher utilization of healthcare resources. In this study, ER visits and inpatient admissions due to infections were higher among RA patients with access restrictions than those patients without access restrictions.²²

Beyond the explicitly imposed access restrictions, drugs that impose higher costs on patients, or are less efficacious than necessary, are also associated with lower overall drug adherence rates. For example, a 2019 Kaiser Family Foundation survey found that,

about three in ten of all adults (29 percent) report not taking their medicines as prescribed at some point in the past year because of the cost. This includes about one in five who report that they haven't filled a prescription (19 percent of total) or took an over-the-counter drug instead (18 percent of total), and about one in ten who say they have cut pills in half or skipped a dose.

In addition, three in ten (29 percent) of those who report not taking their medicines as prescribed say their condition got worse as a result of not taking their prescription as recommended (eight percent of total). Lower drug adherence reduces patients' health outcomes and raises systemic healthcare costs.²³

By definition of having established a large market share, drugs with high sales volumes tend to be older more expensive drugs while the disfavored drugs tend to be newer and priced lower. These newer medications are not only less expensive typically, but they are also often more efficacious for patients or a targeted sub-group of patients. Losing access to these medicines will, consequently, deny patients access to more appropriate treatments.

As a final impact, successful rebate walls also have a deleterious impact on innovation. It takes 10 to 15 years, and \$2.6 billion (\$2.9 billion including post-marketing costs) to develop one new treatment, including the cost of failures. ²⁴ Developing a new biosimilar takes 7 to 8 years, and costs between \$100 million and \$250 million. ²⁵ Once a drug has received approval that it is clinically efficacious, the medicine must then generate revenues that are sufficient to cover these capital costs. Market impediments, such as the rebate wall, make it more difficult for these innovators to achieve this goal and, consequently, make it more difficult for innovators to obtain the necessary capital to invest in the innovations of tomorrow. The lost innovation means opportunities to improve patient health outcomes and reduce overall healthcare expenditures have been lost as well.

Conclusion: Consumer-Driven Competition Is the Solution

As the Introduction documented, when competition encourages firms to serve the needs of customers (or in this case patients), many beneficial outcomes result. In the case of the biopharmaceutical market, patients will benefit from higher quality healthcare services and declining costs. The broader economy benefits as well because the drive to better serve patients accelerates productivity growth, which is essential for improving our standard of living.

Markets that are not transparent, like the pharmaceutical and biopharmaceutical markets, are susceptible to distortions that turn competitive tools that typically serve the interests of consumers into anti-competitive market barriers. FTC Chairman Majoras concurred with this concern stating that while there are relatively few findings of actual monopoly power, competitive actions that could raise competitive concerns include "exclusive dealing, predatory and other forms of pricing, refusals to deal, tying, bundling, rebates, product design, misleading and deceptive conduct, and abuse of government processes, as well as variations on and among each."²⁶

Rebate walls are consistent with the competitive concerns raised by Chairman Majoras. When rebate wall practices successfully create competitive barriers, concessions that are supposed to benefit patients have the actual impact of raising prices, decreasing patients' adherence to their medicines, and reducing the overall quality of healthcare.

The most effective way to address the problem of rebate walls is to fix the broader problems with the current rebate system. Because the current drug pricing system is opaque, patients do not benefit from the vast sums of rebates paid every year. In fact, by driving up the list prices of medicines, rebates are inequitably increasing patients' share of drug costs.

Requiring greater price transparency coupled with ensuring that all rebates must benefit patients can correct this problem. Such reforms would remove the incentives to artificially inflate list prices and allow patients to benefit from the slower growing net prices.

With respect to the problem of rebate walls, rebate reform would fundamentally change the incentives that drive the pharmaceutical market. Instead of competing based on the size of the rebates paid, drug companies would compete based on the actual market prices of medicines. With rebates no longer driving the market process, the ability to game the system via rebate wall tactics would disappear. New competitors would be able to compete with established brands by selling their drugs at a lower net price, and insurers would be able to include these drugs on their formularies without risking the sizable rebate revenues. It is important to emphasize that, in order for rebate reforms to succeed, the spirit of these reforms must be adhered to. This means that other potential competitive obstructions, such as using fees or other concessions as a tool to lock-in share for the market leader, must also be prohibited. Loopholes that enable other obstructions to replace the rebate wall will not achieve the goal of competition based on each drug's net price.

While fundamental rebate reform is the more efficient option, if broad-based reform is not possible, then addressing the anti-competitive rebating practices that are generally outlawed in other markets is a second-best approach. Such reforms should focus on effectively defining the exclusionary- and volume-based rebates that enable firms to establish anti-competitive rebate walls, and prohibit these practices. The goal from these reforms should be ensuring that the rules governing anti-competitive practices in the pharmaceutical markets conform with the standards applied in other markets.

By removing unwarranted barriers, fundamental rebate reforms (or targeted reforms that eliminate the practice of rebate walls if fundamental reforms are not possible) will help establish a competitive drug market where companies compete against one another by finding better ways to serve patients (e.g. the customer), not health industry middlemen as they do today. As the findings of the McKinsey Global Institute demonstrated, competitive markets that focus on serving customers result in rising productivity and declining prices. For the U.S. pharmaceutical and biopharmaceutical industries, this means an environment where new and better medicines continue to be created while the overall cost of healthcare becomes more and more affordable.

Appendix

The patient out-of-pocket costs were estimated based on a cost breakdown analysis for a drug purchased over the pharmacy counter based on the benefit designs for the average employer-sponsored plans and patients with Medicare Part D. The costs for patients receiving infusion biologic drugs were evaluated based on the average employer-sponsored plans and Medicare Part B insurance coverage. In order to calculate patient out-of-pocket costs, the cost savings for the other payers is also calculated and presented.

PATIENT WITH EMPLOYER-SPONSORED INSURANCE

The employer-sponsored insurance scenarios evaluate the impact on payers and patients based on assumed drug list prices of \$10,000, \$50,000, and \$70,000. The costs of the drug are distributed between the insurer and patient based on the average drug benefit design for an employer-sponsored health benefit as reported by the Kaiser Family Foundation (KFF).²⁷ The patient out-of-pocket costs assume any applicable deductibles have been met, and the copayment and coinsurance rates reflect the averages for the employer plans with three or more tiers. The specific tier assumptions vary depending on whether the drug is a biologic, branded, biosimilar, or generic drug.

Lost savings when the rebate wall thwarts competition between branded drugs

As the impact on the prices of hepatitis C drugs demonstrated, competition between branded drugs creates substantial savings opportunities. Consequently, when anti-competitive rebate wall practices thwart branded competitors from offering patients choices, significant healthcare savings are foregone. How large are these lost potential savings? Based on the results from DiMasi and Paquette (2004), greater branded competition could reduce prices by between 14 percent (relative to the class average) and 26 percent (relative to the price leader). Such a price decrease would meaningfully reduce overall costs including patient out-of-pocket costs.

To visualize these potential savings, the analysis evaluated the payer and patient costs for two follow-on branded competitors relative to the payer and patient costs for the original branded medicine. The original branded medicine has assumed list prices of \$10,000, \$50,000, and \$70,000. One of the branded competitors is assumed to set its list price at 26 percent below the original branded drug's price. The other branded competitor is assumed to set its list price at 14 percent below the average of these two competitors. To ensure that there is fair competition (i.e. there are no rebate wall obstructions), all three branded drugs are assumed to be preferred drugs on the plan's formulary, indicating they would likely be Tier 3 drugs. According to KFF, the average employer-sponsored health benefit for a Tier 3 drug required a \$62 co-pay and 37 percent co-insurance rate.

When estimating the potential cost reductions that could be gained if rebate wall practices were eliminated it is important to account for the large dollar concessions that reduce the expenditures of insurers, but do not impact the out-of-pocket costs for patients. According to IQVIA, total drug spending measured at list prices was \$671 billion in 2019, with net drug spending equaling \$356

billion or 53.1 percent of the list price. This is the discount used to determine the payer's costs for all three branded medicines.²⁹

Finally, it is assumed that the patient purchases the medicine monthly for the entire year. This assumption causes patient co-pays to be higher, but its co-insurance costs to be lower. Assuming that the medicine is only purchased once during the year will decrease the patient co-pay and increase their co-insurance cost. However, the differences in the costs between the alternatively priced drugs are not changed so the overall potential savings are not impacted by this assumption.

Based on these assumptions, Table A1 summarizes the total costs (at list and net prices), payer costs, and out-of-pocket costs associated with the alternative branded competitors. Table A2 summarizes the potential savings competitive branded medicines could generate. These tables demonstrate that successful rebate wall practices are denying patients the ability to substantially reduce their out-of-pocket costs. Based on the assumptions applied in this analysis, for a \$10,000 branded drug, patients could save between \$932 and \$962, or a cost reduction between 22.3 percent and 23.1 percent. For a \$70,000 branded drug, patients could save between \$6,522 and \$6,734, or a cost reduction between 24.7 percent and 25.5 percent.

Table A1Alternative Total, Payer, and Out-of-Pocket Cost Scenarios Between Competitive Branded Drugs

	COST AT LIST Price	COST AT NET Price	PAYER Costs	TOTAL OOP	CO-PAYMENT	CO-INSURANCE	
		\$10,000 List Price					
Original branded competitor	\$10,000	\$5,306	\$1,137	\$4,169	\$744	\$3,425	
14% discount to class average	\$7,482	\$3,970	\$733	\$3,237	\$744	\$2,493	
26% discount to price leader	\$7,400	\$3,926	\$719	\$3,207	\$744	\$2,463	
			\$50,000 Lis	st Price			
Original branded competitor	\$50,000	\$26,528	\$7,559	\$18,969	\$744	\$18,225	
14% discount to class average	\$37,410	\$19,848	\$5,538	\$14,310	\$744	\$13,566	
26% discount to price leader	\$37,000	\$19,630	\$5,472	\$14,159	\$744	\$13,415	
			\$70,000 Lis	t Price			
Original branded competitor	\$70,000	\$37,139	\$10,770	\$26,369	\$744	\$25,625	
14% discount to class average	\$52,374	\$27,787	\$7,940	\$19,847	\$744	\$19,103	
26% discount to price leader	\$51,800	\$27,483	\$7,848	\$19,635	\$744	\$18,891	

Table A2Potential Total, Payer, and Out-of-Pocket Savings
Offered by Competitive Branded Drugs

	DOLLAR SAVINGS			PERCENTAGE SAVINGS		
	Total Net	Payer	00P	Total Net	Payer	00P
			\$10,000	List Price		
14% discount to class average	\$1,336	\$404	\$932	-25.2%	-35.6%	-22.3%
26% discount to price leader	\$1,379	\$417	\$962	-26.0%	-36.7%	-23.1%
			\$50,000	List Price		
14% discount to class average	\$6,680	\$2,021	\$4,658	-25.2%	-26.7%	-24.6%
26% discount to price leader	\$6,897	\$2,087	\$4,810	-26.0%	-27.6%	-25.4%
	\$70,000 List Price					
14% discount to class average	\$9,351	\$2,830	\$6,522	-25.2%	-26.3%	-24.7%
26% discount to price leader	\$9,656	\$2,922	\$6,734	-26.0%	-27.1%	-25.5%

Lost savings when the rebate wall thwarts competition from generic drugs

While a rebate wall's negative impact on branded competition denies patients potential savings, the lost savings potential is even larger when these practices thwart generic competitors. To estimate the lost savings potential when the rebate wall thwarts generic competitors, two modifications to the previous assumptions are required. First, the prices for the potential generic drugs that are prevented from competing will be significantly lower than the prices of branded competitors. The 2019 FDA study cited above provides an estimate of the potential price reductions. Since the 2019 FDA study linked the size of the discount to the number of generic competitors, the savings are evaluated based on the rebate wall thwarting competition of one (38.6 percent discount to the branded drug), five (85.6 percent discount to the branded drug) potential generic competitors.

The other modification is the assumed tier for the generic drugs since generics are typically placed on a different formulary tier than a branded medicine. Consequently, the payer and out-of-pocket costs for the scenarios where there are five and ten plus competitors are based on the average employer-sponsored plan's tier 1 benefit design of an \$11 co-pay and 18 percent co-insurance rate. Since the expected price reduction that results when only one generic competitor enters the market is less, the generic drug under this scenario is assumed to be a tier 3 drug.³¹

Based on these assumptions, Table A3 summarizes the costs and Table A4 summarizes the potential savings. These tables demonstrate that when successful rebate wall practices thwart generic competition, patient out-of-pocket costs are multiples higher than they could otherwise be. Based on the assumptions applied in this analysis, patients could save between \$1,428 and \$4,069, or experience a cost reduction between 38.6 percent and 98.1 percent.

Table A3Alternative Total, Payer, and Out-of-Pocket Cost Scenarios Generic Drugs Competing Against Branded Drugs

	COST AT LIST PRICE	COST AT NET PRICE	PAYER COSTS	TOTAL OOP	CO-PAYMENT	CO-INSURANCE			
		\$10,000 List Price							
Original branded competitor	\$10,000	\$5,306	\$1,137	\$4,169	\$744	\$3,425			
1 generic competitor	\$6,140	\$3,258	\$517	\$2,741	\$744	\$1,997			
5 generic competitors	\$1,440	\$764	\$397	\$367	\$132	\$235			
10+ generic competitors	\$100	\$100	\$0	\$100	\$100	\$0			
			\$50,000	List Price					
Original branded competitor	\$50,000	\$26,528	\$7,559	\$18,969	\$744	\$18,225			
1 generic competitor	\$30,700	\$16,288	\$4,460	\$11,828	\$744	\$11,084			
5 generic competitors	\$7,200	\$3,820	\$2,416	\$1,404	\$132	\$1,272			
10+ generic competitors	\$500	\$500	\$232	\$268	\$132	\$136			
			\$70,000	List Price					
Original branded competitor	\$70,000	\$37,139	\$10,770	\$26,369	\$744	\$25,625			
1 generic competitor	\$42,980	\$22,803	\$6,432	\$16,371	\$744	\$15,627			
5 generic competitors	\$10,080	\$5,348	\$3,425	\$1,923	\$132	\$1,791			
10+ generic competitors	\$700	\$700	\$358	\$342	\$132	\$210			

Table A4Potential Total, Payer, and Out-of-Pocket Savings
Offered when Generic Drugs Compete Against the Original Branded Drug

		DOLLAR SAVINGS			RCENTAGE SAVIN	IGS			
	Total Net	Payer	00P	Total Net	Payer	00P			
		\$10,000 List Price							
1 generic competitor	\$2,048	\$620	\$1,428	-38.6%	-54.5%	-34.3%			
5 generic competitors	\$4,542	\$740	\$3,801	-85.6%	-65.1%	-91.2%			
10+ generic competitors	\$5,206	\$1,137	\$4,069	-98.1%	-100%	-97.6%			
		\$50,000 List Price							
1 generic competitor	\$10,240	\$3,099	\$7,141	-38.6%	-41.0%	-37.6%			
5 generic competitors	\$22,708	\$5,143	\$17,564	-85.6%	-68.0%	-92.6%			
10+ generic competitors	\$26,028	\$7,327	\$18,701	-98.1%	-96.9%	-98.6%			
			\$70,000	List Price					
1 generic competitor	\$14,335	\$4,338	\$9,997	-38.6%	-40.3%	-37.9%			
5 generic competitors	\$31,791	\$7,345	\$24,446	-85.6%	-68.2%	-92.7%			
10+ generic competitors	\$36,439	\$10,412	\$26,027	-98.1%	-96.7%	-98.7%			

Lost savings when the rebate wall thwarts competition between biologic drugs

The same benefits created when branded drugs compete against one another also apply when originator biologics compete against one another. However, the size of these benefits will vary even if the original biologic medicine sells at the same assumed list prices as the original branded medicine because employer-sponsored plans often place biologics on a separate tier (tier 4 or specialty tier) with different benefit designs.

According to KFF, the average employer-sponsored health benefit for a tier 4/specialty tier drug required a \$116 co-pay and 28 percent co-insurance rate.³² This benefit design difference leads to slight differences in the costs and savings that patients can see from eliminating rebate wall practices, which are summarized in Tables A5 and A6. Specifically, while competition between similarly priced originator biologics provides the same dollar and percentage savings as branded competition, payers benefit slightly more from the savings under the average specialty tier benefit design for an employer sponsored plan. Despite this difference, it is clear that when rebate wall practices thwart originator competition, patient costs are unnecessarily increased.

Table A5Alternative Total, Payer, and Out-of-Pocket Cost Scenarios Between Competitive Originator Biologic Drugs

	COST AT LIST PRICE	COST AT NET PRICE	PAYER Costs	TOTAL OOP	CO-PAYMENT	CO-INSURANCE		
		\$10,000 List Price						
Originator biologic	\$10,000	\$5,306	\$1,503	\$3,802	\$1,392	\$2,410		
14% discount to class average	\$7,482	\$3,970	\$872	\$3,097	\$1,392	\$1,705		
26% discount to price leader	\$7,400	\$3,926	\$852	\$3,074	\$1,392	\$1,682		
			\$50,000 I	List Price				
Originator biologic	\$50,000	\$26,528	\$11,525	\$15,002	\$1,392	\$13,610		
14% discount to class average	\$37,410	\$19,848	\$8,371	\$11,477	\$1,392	\$10,085		
26% discount to price leader	\$37,000	\$19,630	\$8,268	\$11,362	\$1,392	\$9,970		
			\$70,000 I	List Price				
Originator biologic	\$70,000	\$37,139	\$16,536	\$20,602	\$1,392	\$19,210		
14% discount to class average	\$52,374	\$27,787	\$12,120	\$15,667	\$1,392	\$14,275		
26% discount to price leader	\$51,800	\$27,483	\$11,976	\$15,506	\$1,392	\$14,114		

Table A6Potential Total, Payer, and Out-of-Pocket Savings
Offered by Competitive Originator Biologic Drugs

	DOLLAR SAVINGS			PERCENTAGE SAVINGS		
	Total Net	Payer	00P	Total Net	Payer	00P
			\$10,00	0 List Price		
14% discount to class average	\$1,336	\$631	\$705	-25.2%	-42.0%	-18.5%
26% discount to price leader	\$1,379	\$651	\$728	-26.0%	-43.3%	-19.1%
			\$50,00	0 List Price		
14% discount to class average	\$6,680	\$3,154	\$3,525	-25.2%	-27.4%	-23.5%
26% discount to price leader	\$6,897	\$3,257	\$3,640	-26.0%	-28.3%	-24.3%
	\$70,000 List Price					
14% discount to class average	\$9,351	\$4,416	\$4,935	-25.2%	-26.7%	-24.0%
26% discount to price leader	\$9,656	\$4,560	\$5,096	-26.0%	-27.6%	-24.7%

Lost savings when the rebate wall thwarts competition from biosimilar drugs

Just as generics are low-cost drugs that compete with branded drugs, biosimilars are lower-cost biologics that compete with originator biologics. Due to biologics' greater complexity, the cost savings are not as high as generics, but are substantial, nonetheless. The lost potential savings when rebate wall practices thwart biosimilar competition is evaluated based on the average biosimilar discount as of July 2020 (30.1 percent) and the widest biosimilar discount as of July 2020 (52.6 percent).

With respect to the formulary design, there are sound reasons for biosimilars to have a preferred formulary tier, but often this is not the case. Consequently, for conservative purposes, biosimilars are assumed to be on an employer-sponsored plan's specialty tier; plans that offer lower co-pays or co-insurance rates for biosimilars would offer patients even greater out-of-pocket savings potential. Tables A7 and A8 summarize the lost savings potential that occurs when rebate wall practices discourage biosimilar competition.

Table A7Alternative Total, Payer, and Out-of-Pocket Cost Scenarios Biosimilars Competing Against Originator Biologics

	COST AT LIST PRICE	COST AT NET PRICE	PAYER Costs	TOTAL OOP	CO-PAYMENT	CO-INSURANCE
			\$10,000	List Price		
Originator biologic	\$10,000	\$5,306	\$1,503	\$3,802	\$1,392	\$2,410
Average biosimilar discount (30.1%)	\$6,990	\$3,709	\$749	\$2,959	\$1,392	\$1,567
Zarxio discount (52.6%)	\$4,740	\$2,515	\$185	\$2,329	\$1,392	\$937
			\$50,000	List Price		
Originator biologic	\$50,000	\$26,528	\$11,525	\$15,002	\$1,392	\$13,610
Average biosimilar discount (30.1%)	\$34,950	\$18,543	\$7,755	\$10,788	\$1,392	\$9,396
Zarxio discount (52.6%)	\$23,700	\$12,574	\$4,936	\$7,638	\$1,392	\$6,246
			\$70,000	List Price		
Originator biologic	\$70,000	\$37,139	\$16,536	\$20,602	\$1,392	\$19,210
Average biosimilar discount (30.1%)	\$48,930	\$25,960	\$11,257	\$14,703	\$1,392	\$13,311
Zarxio discount (52.6%)	\$33,180	\$17,604	\$7,311	\$10,293	\$1,392	\$8,901

Table A8Potential Total, Payer, and Out-of-Pocket Savings
Offered when Biosimilars Compete Against the Originator Biologic

	DOLLAR SAVINGS			PERO	INGS	
	Total Net	Payer	00P	Total Net	Payer	00P
			\$10,000	List Price		
Average biosimilar discount (30.1%)	\$1,597	\$754	\$843	-30.1%	-50.2%	-22.2%
Zarxio discount (52.6%)	\$2,791	\$1,318	\$1,473	-52.6%	-87.7%	-38.7%
			\$50,000	List Price		
Average biosimilar discount (30.1%)	\$7,985	\$3,771	\$4,214	-30.1%	-32.7%	-28.1%
Zarxio discount (52.6%)	\$13,954	\$6,590	\$7,364	-52.6%	-57.2%	-49.1%
	\$70,000 List Price					
Average biosimilar discount (30.1%)	\$11,179	\$5,279	\$5,900	-30.1%	-31.9%	-28.6%
Zarxio discount (52.6%)	\$19,535	\$9,225	\$10,310	-52.6%	-55.8%	-50.0%

PATIENTS COVERED BY MEDICARE PART D

The Medicare Part D scenarios evaluate the impacts based on assumed drug list prices of \$10,000, \$50,000, and \$70,000. The Medicare Part D standard benefit is a complex system that, as of 2021, includes:

- a standard deductible of \$445 that is covered by the patient;
- an initial coverage limit of \$4,130 where the patient covers 25 percent of the costs and the plan (insurer) covers 75 percent of the costs;
- a coverage gap that begins at \$4,130 and runs until total spending has reached \$10,048 where the patient covers 25 percent of the costs, the insurer covers 5 percent of the costs, and manufacturers must cover 70 percent of the costs; and,
- a catastrophic phase for costs in excess of \$10,048 where the patient covers 5 percent, the insurer covers 15 percent of the costs, and Medicare covers 80 percent of the costs.³³

The allocation of costs changes when the cost of a medicine exceeds the catastrophic phase. To estimate the cost distribution the drug purchases were assumed to occur once a month for the entire year.

Using the \$10,000 list price for the first branded drug or originator biologic as the example, the \$10,000 list price requires an \$833 monthly payment. In the first month, the patient would initially cover these costs until the \$445 annual deductible is met. Once met, the costs are then distributed based on the initial coverage percentages (25 percent patient, 75 percent insurer) until the coverage gap threshold is crossed. Costs are then distributed based on the coverage gap percentages (25 percent patient, 5 percent insurer, and 70 percent manufacturer).

While the drug with a \$10,000 list price would not cross the catastrophic phase threshold, drugs with a \$50,000 and \$70,000 list prices do. For these expenditures, the costs are distributed based on the catastrophic phase percentages (5 percent patient, 15 percent insurer, 80 percent Medicare). It should be noted that the insurer and Medicare costs are reported on a gross basis, but like the employer-sponsored plans, insurers receive rebates on the drugs dispensed. Given Medicare Part D's complex benefit design that includes Medicare serving as a "reinsurer" for costs in excess of \$10,048, the Medicare Part D plans receive rebates on the gross costs of the drugs even though Medicare will cover a substantial share of the expenditures for the most expensive drugs, which will be subject to the profit limitations established by Medicare. Due to this uncertainty, the insurer and Medicare costs are evaluated at list prices.

Table A9 presents the cost distribution, savings, and percentage savings that are blocked when rebate walls successfully thwart competition for a branded/originator biologic with a \$10,000 list price. The potential savings lost to the rebate wall varies based on the type of competition that is thwarted, and includes lost OOP savings,

- from branded/originator biologic competition between \$630 and \$650;
- from biosimilar competition between \$753 and \$1,315; and,
- from generic competition between \$965 and \$2,734.

Table A11 summarizes the savings based on a branded drug/originator biologic with a \$70,000 list price. The lost OOP savings in this scenario includes,

- between \$881 and \$910 from branded/originator biologic competition;
- between \$1,054 and \$1,841 from biosimilar competition; and,
- between \$1,351 and \$5,335 from generic competition.

Table A9Cost Breakdown, Lost Savings, and Lost Savings Percentage
Due to Successful Rebate Wall Barriers - Based on \$10,000 List Price

	SPENDING AT LIST PRICES	INSURER COSTS	OOP COSTS	MANUFACTURER DISCOUNT
Biologic/Branded drug w/\$10,000 list price	\$10,000	\$3,057	\$2,834	\$4,109
		Branded/Ori	iginator Competition	
14% discount to class average	\$7,482	\$2,931	\$2,204	\$2,346
26% discount to price leader	\$7,400	\$2,927	\$2,184	\$2,289
		Biosimi	lar Competition	
Average biosimilar discount (30.1%)	\$6,990	\$2,907	\$2,081	\$2,002
Zarxio discount (52.6%)	\$4,740	\$2,794	\$1,519	\$427
		Generi	ic Competition	
1 generic competitor	\$6,140	\$2,864	\$1,869	\$1,407
5 generic competitors	\$1,440	\$746	\$694	\$0
10+ generic competitors	\$100	\$0	\$100	\$0
		Dol	lar Savings	
		Branded/Ori	ginator Competition	
14% discount to class average	\$2,518	\$126	\$630	\$1,763
26% discount to price leader	\$2,600	\$130	\$650	\$1,820
		Biosimi	lar Competition	
Average biosimilar discount (30.1%)	\$3,010	\$150	\$753	\$2,107
Zarxio discount (52.6%)	\$5,260	\$263	\$1,315	\$3,682
		Generi	ic Competition	
1 generic competitor	\$3,860	\$193	\$965	\$2,702
5 generic competitors	\$8,560	\$2,311	\$2,140	\$4,109
10+ generic competitors	\$9,900	\$3,057	\$2,734	\$4,109
		Percei	ntage Savings	
		Branded/Ori	ginator Competition	
14% discount to class average	-25.2%	-4.1%	-22.2%	-42.9%
26% discount to price leader	-26.0%	-4.3%	-22.9%	-44.3%
		Biosimi	lar Competition	
Average biosimilar discount (30.1%)	-30.1%	-4.9%	-26.6%	-51.3%
Zarxio discount (52.6%)	-52.6%	-8.6%	-46.4%	-89.6%
		Generi	ic Competition	
1 generic competitor	-38.6%	-6.3%	-34.1%	-65.8%
5 generic competitors	-85.6%	-75.6%	-75.5%	-100.0%
10+ generic competitors	-99.0%	-100.0%	-96.5%	-100.0%

Table A10Cost Breakdown, Lost Savings, and Lost Savings Percentage Due to Successful Rebate Wall Barriers
Based on \$50,000 List Price

	TOTAL SPEND AT GROSS PRICES	INSURER COSTS	MEDICARE	00P	MANUFACTURER DISCOUNT
		_	Dollar Spending	_	
Biologic/Branded drug w/\$70,000 list price	\$50,000	\$9,052	\$31,962	\$4,843	\$4,143
		Brand	ded/Originator Com	petition	
14% discount to class average	\$37,410	\$7,164	\$21,890	\$4,214	\$4,143
26% discount to price leader	\$37,000	\$7,102	\$21,562	\$4,193	\$4,143
		E	Biosimilar Competit	on	
Average biosimilar discount (30.1%)	\$34,950	\$6,795	\$19,922	\$4,091	\$4,143
Zarxio discount (52.6%)	\$22,553	\$3,960	\$10,922	\$3,528	\$4,143
			Generic Competition	n	
1 generic competitor	\$30,700	\$6,157	\$16,522	\$3,878	\$4,143
5 generic competitors	\$7,200	\$2,917	\$0	\$2,134	\$2,149
10+ generic competitors	\$459	\$0	\$0	\$459	\$0
			Dollar Savings		
		Brand	ded/Originator Com	petition	
14% discount to class average	\$12,590	\$1,889	\$10,072	\$629	\$0
26% discount to price leader	\$13,000	\$1,950	\$10,400	\$650	\$0
		E	Biosimilar Competit	on	
Average biosimilar discount (30.1%)	\$15,050	\$2,258	\$12,040	\$753	\$0
Zarxio discount (52.6%)	\$27,448	\$5,093	\$21,040	\$1,315	\$0
			Generic Competition	n	
1 generic competitor	\$19,300	\$2,895	\$15,440	\$965	\$0
5 generic competitors	\$42,800	\$6,135	\$31,962	\$2,710	\$1,994
10+ generic competitors	\$49,541	\$9,052	\$31,962	\$4,385	\$4,143
			Percentage Saving	S	
		Brand	ded/Originator Com	petition	
14% discount to class average	-25.2%	-20.9%	-31.5%	-13.0%	0.0%
26% discount to price leader	-26.0%	-21.5%	-32.5%	-13.4%	0.0%
		E	Biosimilar Competit	on	
Average biosimilar discount (30.1%)	-30.1%	-24.9%	-37.7%	-15.5%	0.0%
Zarxio discount (52.6%)	-54.9%	-56.3%	-65.8%	-27.2%	0.0%
			Generic Competition	n	
1 generic competitor	-38.6%	-32.0%	-48.3%	-19.9%	0.0%
5 generic competitors	-85.6%	-67.8%	-100.0%	-55.9%	-48.1%
10+ generic competitors	-99.1%	-100.0%	-100.0%	-90.5%	-100.0%

Table A11Cost Breakdown, Lost Savings, and Lost Savings Percentage Due to Successful Rebate Wall Barriers
Based on \$70,000 List Price

	SPENDING AT GROSS PRICES	INSURER COSTS	MEDICARE	00P	MANUFACTURER DISCOUNT				
	Dollar Spending								
Biologic/Branded drug w/\$70,000 list price	\$70,000	\$12,052	\$47,962	\$5,843	\$4,143				
	Branded/Originator Competition								
14% discount to class average	\$52,374	\$9,409	\$33,861	\$4,962	\$4,143				
26% discount to price leader	\$51,800	\$9,322	\$33,402	\$4,933	\$4,143				
	Biosimilar Competition								
Average biosimilar discount (30.1%)	\$48,930	\$8,892	\$31,106	\$4,790	\$4,143				
Zarxio discount (52.6%)	\$31,440	\$4,789	\$18,506	\$4,002	\$4,143				
		0	Generic Competiti	on					
1 generic competitor	\$42,980	\$7,999	\$26,346	\$4,492	\$4,143				
5 generic competitors	\$10,080	\$3,064	\$26	\$2,847	\$4,143				
10+ generic competitors	\$509	\$0	\$0	\$509	\$0				
	Dollar Savings								
		Brande	Branded/Originator Competition						
14% discount to class average	\$17,626	\$2,644	\$14,101	\$881	\$0				
26% discount to price leader	\$18,200	\$2,730	\$14,560	\$910	\$0				
	Biosimilar Competition								
Average biosimilar discount (30.1%)	\$21,070	\$3,161	\$16,856	\$1,054	\$0				
Zarxio discount (52.6%)	\$38,560	\$7,263	\$29,456	\$1,841	\$0				
	Generic Competition								
1 generic competitor	\$27,020	\$4,053	\$21,616	\$1,351	\$0				
5 generic competitors	\$59,920	\$8,988	\$47,936	\$2,996	\$0				
10+ generic competitors	\$69,491	\$12,052	\$47,962	\$5,335	\$4,143				
	Percentage Savings								
		Branded/Originator Competition							
14% discount to class average	-25.2%	-21.9%	-29.4%	-15.1%	0.0%				
26% discount to price leader	-26.0%	-22.7%	-30.4%	-15.6%	0.0%				
	Biosimilar Competition								
Average biosimilar discount (30.1%)	-30.1%	-26.2%	-35.1%	-18.0%	0.0%				
Zarxio discount (52.6%)	-55.1%	-60.3%	-61.4%	-31.5%	0.0%				
		0	Generic Competiti	on					
1 generic competitor	-38.6%	-33.6%	-45.1%	-23.1%	0.0%				
5 generic competitors	-85.6%	-74.6%	-99.9%	-51.3%	0.0%				
10+ generic competitors	-99.3%	-100.0%	-100.0%	-91.3%	-100.0%				

PATIENTS RECEIVING INFUSION DRUGS

The infusion drug scenarios evaluate the impact based on an average sales price (ASP) of \$10,000, \$50,000, and \$70,000 for both Medicare Part B and employer-sponsored insurance. The total cost for the infusion drug is based on the Medicare statutory reimbursement of ASP plus 6 percent and the average employer-sponsored plan benefit design or Medicare Part B coverage. Patients covered by traditional Medicare with a Medigap plan would not face any out of pocket costs, but patients without Medigap plans, or patients with Medicare Advantage with the most popular coverage plans are assumed to face co-insurance costs of 20 percent. The drugs for patients with employer-sponsored insurance are assumed to be placed on the specialty drug tier with the average benefit structure of a \$116 co-pay and 28 percent co-insurance rate. Tables A11 – A13 presents the estimated costs and savings based on these assumptions.

Table A11
Cost Breakdown and Lost Savings
Due to Successful Rebate Wall Barriers
Based on \$10,000 List Price for Infusion Drugs

					SAVINGS				
	Commercial Insurance		No Medigap Insurance/ Medicare Advantage		Commercial Insurance		No Medigap Insurance/ Medicare Advantage		
	Payer	00P	Payer	00P	Payer	00P	Payer	00P	
Biologic w/\$10,000 list price	\$7,548	\$3,052	\$8,322	\$2,278					
14% discount to class average	\$5,627	\$2,304	\$6,186	\$1,745	\$1,922	\$747	\$2,135	\$534	
26% discount to price leader	\$5,564	\$2,280	\$6,117	\$1,727	\$1,984	\$772	\$2,205	\$551	
Average biosimilar discount (30.1%)	\$5,251	\$2,158	\$5,769	\$1,640	\$2,297	\$893	\$2,552	\$638	
Zarxio discount (52.6%)	\$3,534	\$1,490	\$3,861	\$1,163	\$4,014	\$1,561	\$4,460	\$1,115	

Table A12Cost Breakdown and Lost Savings
Due to Successful Rebate Wall Barriers
Based on \$50,000 List Price for Infusion Drugs

	Commercial Insurance		No Medigap Insurance/ Medicare Advantage		SAVINGS				
					Commercial Insurance		No Medigap Insurance/ Medicare Advantage		
	Payer	00P	Payer	00P	Payer	00P	Payer	00P	
Biologic w/\$10,000 list price	\$38,076	\$14,924	\$42,242	\$10,758					
14% discount to class average	\$28,468	\$11,187	\$31,565	\$8,089	\$9,609	\$3,737	\$10,676	\$2,669	
26% discount to price leader	\$28,155	\$11,065	\$31,218	\$8,002	\$9,922	\$3,858	\$11,024	\$2,756	
Average biosimilar discount (30.1%)	\$26,590	\$10,457	\$29,479	\$7,568	\$11,486	\$4,467	\$12,762	\$3,191	
Zarxio discount (52.6%)	\$18,004	\$7,118	\$19,939	\$5,183	\$20,072	\$7,806	\$22,302	\$5,576	

Table A13Cost Breakdown and Lost Savings
Due to Successful Rebate Wall Barriers
Based on \$70,000 List Price for Infusion Drugs

	Commercial Insurance		No Medigap Insurance/ Medicare Advantage		SAVINGS				
					Commercial Insurance		No Medigap Insurance/ Medicare Advantage		
	Payer	00P	Payer	00P	Payer	00P	Payer	00P	
Biologic w/\$10,000 list price	\$53,340	\$20,860	\$59,202	\$14,998					
14% discount to class average	\$39,888	\$15,628	\$44,255	\$11,262	\$13,452	\$5,231	\$14,947	\$3,737	
26% discount to price leader	\$39,450	\$15,458	\$43,768	\$11,140	\$13,890	\$5,402	\$15,434	\$3,858	
Average biosimilar discount (30.1%)	\$37,260	\$14,606	\$41,334	\$10,532	\$16,081	\$6,254	\$17,867	\$4,467	
Zarxio discount (52.6%)	\$25,239	\$9,931	\$27,978	\$7,193	\$28,101	\$10,928	\$31,223	\$7,806	

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