

Impediments to a Stronger Biosimilars Market:

AN INFlixIMAB CASE STUDY

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An Infliximab Case Study

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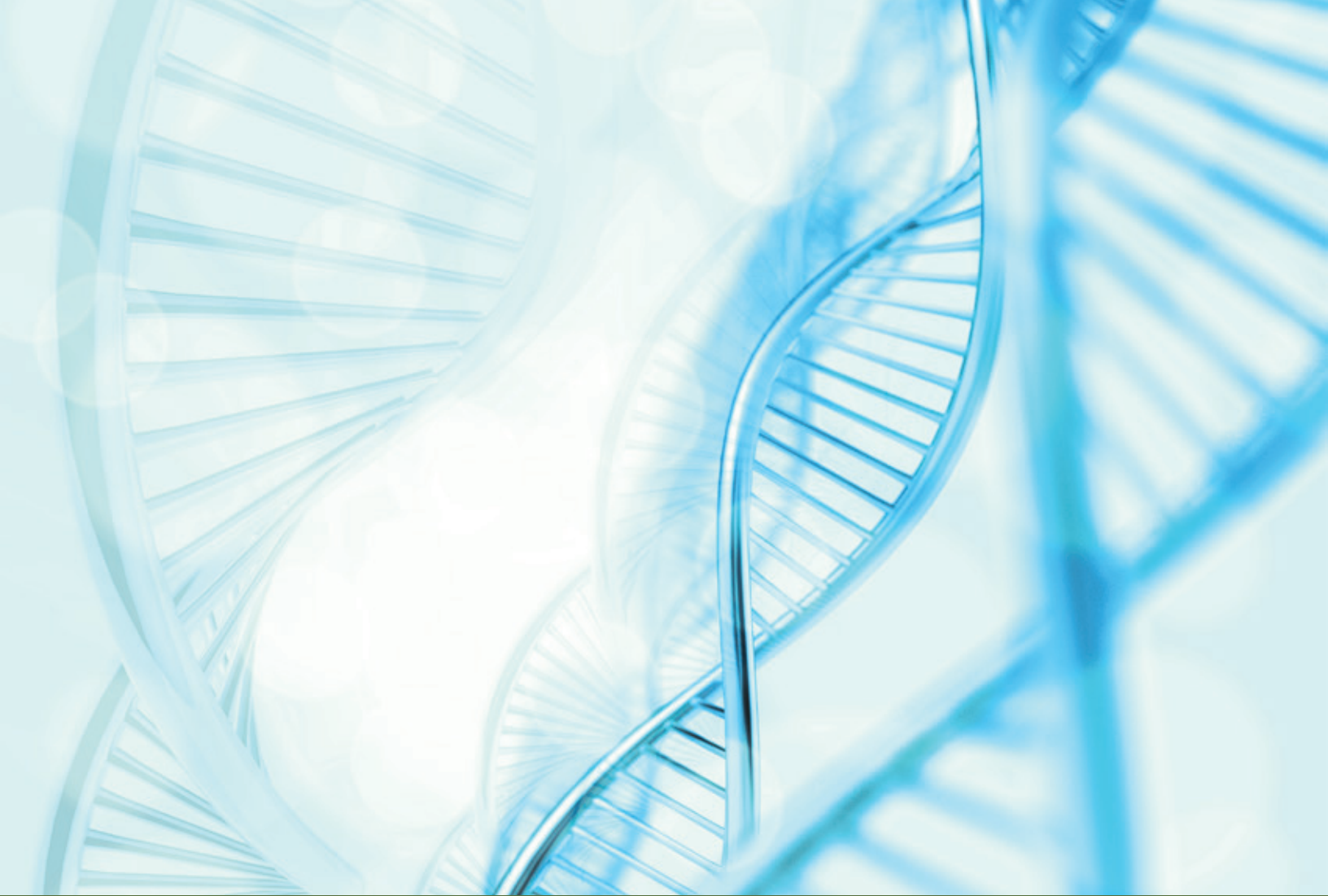


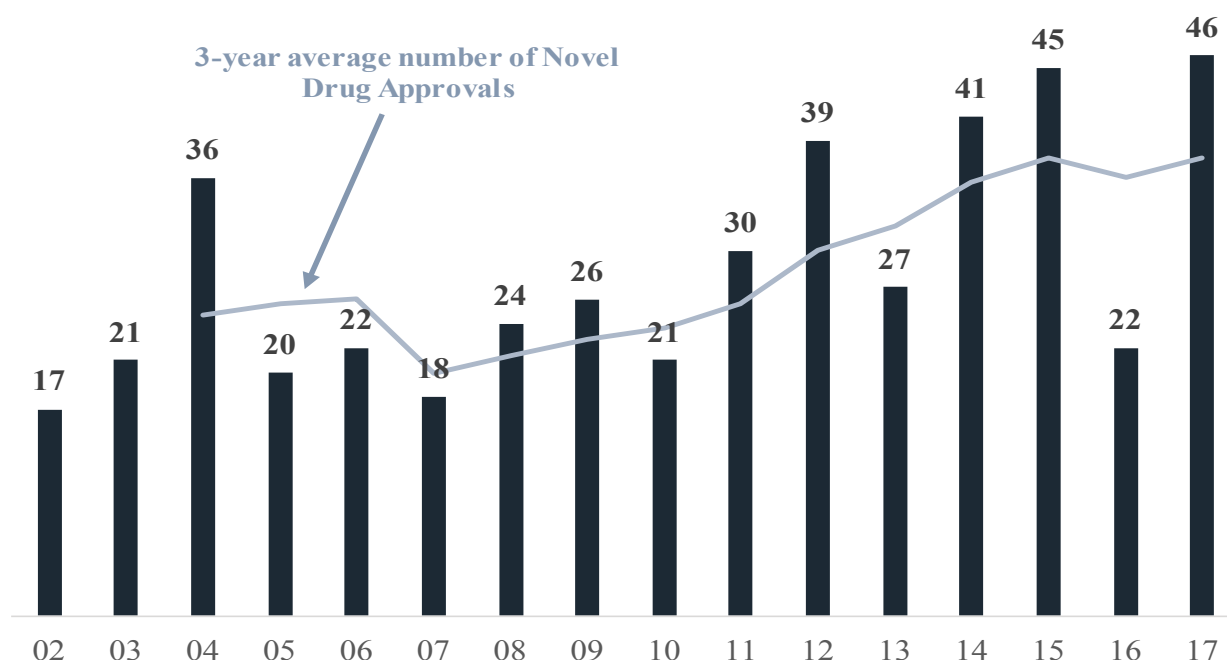
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Introduction

For the past several years, the number of new drug innovations in the U.S. has been historically high and growing. In 2017 alone, there were 46 new novel drug innovations, including new treatments for cancers, Parkinson's disease, and serious skin infections, see Figure 1.¹

FIGURE 1
NUMBER OF NOVEL DRUGS APPROVED BY THE FDA BY CALENDAR YEAR, 2002 - 2017



Source: Center for Drug Evaluation and Research, Food and Drug Administration

Creating new novel therapies is critically important for improving patient health, but it is equally important to ensure that the pharmaceutical market is competitive to promote drug affordability. Simultaneously incenting new innovations and a competitive market for medicines requires a careful balance, which has been struck reasonably well for chemically-based medicines (although important deficiencies exist); and, this careful balance has been fostered, in large part, by the Hatch-Waxman Act. The Hatch-Waxman Act lowered the excessive regulatory approval costs that manufacturers of generic medicines faced, and for manufacturers of branded medicines Hatch-Waxman extended patent terms and clarified patent rights.

Because the Hatch-Waxman Act struck the right balance between incenting pharmaceutical innovation and promoting a competitive drug market, the U.S. is now both the global leader in developing new drugs – 57 percent of all new drugs are developed in the U.S. – and has the largest generic sector compared to all other OECD countries.² In fact while the share of total generic pharmaceuticals was only 13 percent prior to the passage of the Hatch-Waxman Act in 1984,³ as of 2016, generics were 89 percent of all prescriptions filled.⁴ And, the systemic savings created by generic medicines are impressive and have played an important role in reducing pricing pressures on chemically-based pharmaceuticals.

According to the FDA,

when multiple generic companies market a single approved product, market competition typically results in prices about 85 percent less than the brand-name. According to the IMS Health Institute, generic drugs saved the U.S. health care system \$1.67 trillion from 2007 to 2016.⁵

Unlike chemically-based medicines, the U.S. health care system has not yet struck the right balance for the relatively newer biologic medicines. According to IMS Institute for Healthcare Informatics, the global biologic market was “worth \$46 billion in 2002 [and] is projected to grow to \$390 billion by 2020, by which time biologics will account for up to 28 percent by value of the global market for pharmaceuticals.”⁶

While new biologic medicines have been an important contributor to the surge in innovation illustrated in Figure 1, the growth in the biosimilar market has been less impressive. Biosimilar medicines are like generic medicines in that they create a more competitive environment that offers providers and patients more treatment options at better prices. Biosimilars differ from generic medicines in fundamental ways, however.

Unlike generic medicines, which are chemically identical to the innovative product, the size and complexity of biologic molecules make it impossible to make an identical biological molecule. Due to these differences, biosimilars’ price discounts are expected to be smaller than the price gap for generics. Nevertheless, greater use of biosimilar medicines has the potential to reduce the pricing pressures for biologic medicines. Since biosimilars are still new in the U.S. market, the actual price discounts are not yet known with certainty; but, based on industry expectations, biosimilars should reduce prices by around 30 percent.⁷ While smaller than the 85 percent discount for generics estimated by the FDA, such savings are still substantial.

“ Since biosimilars offer large potential health care savings, but have failed to be widely prescribed, it is important to understand the causes behind the slower than expected uptake of biosimilars.

Despite this potential, the market uptake of biosimilars has been slower than expected.⁸ Without a higher uptake of biosimilars, the downward pressure on pharmaceutical prices that these medicines should create will be smaller, causing overall health care spending to be higher than necessary. The costs on employer-based plan sponsors and Medicare will be higher than necessary, consequently, as will be patient co-pays and deductibles. Further, higher drug spending could force patients to reach coverage maximums faster, creating possible patient access issues. There are also important policy implications. Due to the decreased biosimilar uptake, the pressure to implement ill-considered policies, such as price controls or drug importation, will be greater.

Since biosimilars offer large potential health care savings, but have failed to be widely prescribed, it is important to understand the causes behind the slower than expected uptake of biosimilars. The purpose of this analysis is to identify the barriers inhibiting wider adoption of biosimilars and then quantify the potential savings to employer-based plans and Medicare if these barriers were reduced.

The potential savings are estimated based on the alternative biologic and biosimilar prices for the drug infliximab. This analysis illustrates that the potential savings from the infliximab biosimilars are, in fact, large, indicating that significant overall health care savings should arise from eliminating the identified barriers in the biosimilars market.

Barriers Obstructing Cost Savings Potentials

Perhaps the most troubling market access barrier for biosimilars is the pricing practices of the broader health care reimbursement system that dis-incentivizes lower-cost biosimilars. Specifically, biologics and biosimilars are typically purchased via the “buy-and-bill” process where providers purchase medicines, and then bill the payers (either a commercial insurance company or the government) once the medicines have been administered to the patients. These reimbursements are typically based on the average sales price (ASP) of the medicine, plus a percentage mark-up over the ASP.

The Department of Health and Human Services (HHS) Office of Inspector General defines ASP as “a manufacturer’s sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that same quarter. The ASP is net of any price concessions, such as volume discounts, prompt pay discounts, cash discounts, free goods contingent on purchase requirements, chargebacks, and rebates other than those obtained through the Medicaid drug rebate program.”⁹ It is, effectively, the transaction price of the drug to the health care system.

Most commercial payers base the percentage mark-up on the ASP of the actual drug being administered (whether it is the biologic or the biosimilar). The biosimilar’s ASP is less than the biologic’s, however, meaning that providers will lose money when they prescribe a biosimilar medicine instead of its reference biologic medicine – the same percentage mark-up on a lower priced biosimilar provides less revenues to the provider than if a higher-priced biologic medicine had been prescribed. As these differences in repayment can be large, the current reimbursement system is biased in favor of the more expensive biologic medicines.

In a study that quantified these impacts, Reddan et al. (2017) noted that “to date, the uptake of the first biosimilars has been modest. One critical factor limiting provider use of biosimilars appears to be the “buy-and-bill” reimbursement model for infused therapies. While the Centers for Medicare & Medicaid Services (CMS) incentivizes biosimilar use through differential reimbursement, private payers generally do not. As a result, adoption of lower-cost biosimilars in today’s reimbursement model leads to a reduction in practice profits for most providers.”¹⁰

Quantifying these disincentives, Reddan et al. (2017) estimated that “the weighted average gross margin loss ranges from \$9 per unit vial in a physician office setting, to \$43 in an outpatient hospital, and \$79 in a 340B hospital. While this impact may seem minimal, it could add up – a hospital treating 50 patients using two vials of drug per month stands to lose over \$50,000 per year. Considering a single brand such as Remicade, which was used to treat over 130,000 Americans in 2016, broad adoption of a biosimilar could decrease profit by as much as \$100 million across providers. The loss stands to grow as multiple biosimilars come to market and decrease profit across additional brands.”¹¹

As referenced by Reddan et al. (2017), and in recognition of these disincentives, Medicare uses a slightly different reimbursement system. Instead of basing the provider reimbursement on the price of the prescribed drug, Medicare bases the percentage mark-up on the biologic’s ASP regardless of whether the biologic or biosimilar is prescribed. Consequently, providers receive the same dollar mark-up from Medicare whether they prescribe biosimilars or biologics, reducing this financial dis-incentive against biosimilars.

There are other market practices that further disincent the use of biosimilars. One of these market practices is the fail first, or step therapy, policies that are commonly included in insurance plans. Typically, the purpose of fail first policies is to require patients to use lower-priced generic medicines first, then, only if the generic medicines fail to sufficiently help the patients, can a more expensive branded medicine be prescribed. As applied to biosimilars, however, fail first policies work in reverse. In this case, the insurance clauses will only allow patients to use the less expensive biosimilars if they first failed on the more expensive biologics. Thus, as currently applied, fail first policies bias the market against less expensive biosimilars.

Additionally, current biologic contracting practices link the rebates insurers receive on reaching pre-established minimum volume-thresholds; or, the rebates connect biologic sales with rebates on other medical devices. These contracting practices creates another reimbursement disincentive that biases the market against lower priced biosimilars.

Then there is the FDA. Just like generic drugs, biosimilars must obtain FDA approval before they can be prescribed to patients. An entirely new approval system for biologics is necessary because biologic medicines are developed from living entities that are much more complex than their chemical counterparts. The FDA (as of May 2018) has not yet provided the industry with finalized regulatory guidance, which creates unnecessary regulatory uncertainty.

The problems created by this regulatory uncertainty has been noted by the Council of Economic Advisors (CEA), which linked regulatory uncertainty to slower biosimilar development. Specifically, the CEA noted that the "...guidelines for demonstrating biosimilarity were only finalized in 2015, five years after passage of the BPCIA [Biologics Price Competition and Innovation Act], in part reflecting the complexity of this problem. The FDA has indicated it will not finalize guidelines on demonstrating biosimilar interchangeability for another two years or more. *Speeding up the issuance of final guidelines could add certainty and attract additional biosimilar applicants.* If these guidelines are relatively easy and inexpensive to adhere to, it could spur interchangeable applications and approvals, which could result in more effective competition with the reference biologic and lower prices."¹²

Speeding up the issuance of final guidelines could add certainty and attract additional biosimilar applicants.

It is important to note that the interchangeability issue referenced by the CEA is more of an excuse than an actual barrier because the interchangeability designation is only relevant for drugs purchased through pharmacies, not drugs administered by doctors who can change the prescription at their discretion. Instead, the meaningful barrier is the lack of regulatory clarity cited by the CEA that discourages the use of biosimilars.

There is growing evidence that this regulatory confusion is impacting medical outcomes. For instance, a *Drug Topics* report illustrates that due to the regulatory confusion, the views of health care professionals with respect to Remicade contradicts the growing body of evidence. Specifically, while the report noted

that “physicians and consultants have expressed concerns about switching patients from branded drugs to biosimilars”,¹³ this contradicts infliximab’s evolving clinical effectiveness evidence. For example, a

new clinical study, sponsored by the Norwegian government, involved nearly 500 patients at 40 sites across Norway who had stable [results] on infliximab treatment for at least six months. The patients had chronic inflammatory diseases, including Crohn’s disease, ulcerative colitis, rheumatoid arthritis, spondyloarthritis, psoriatic arthritis, or chronic plaque psoriasis.

In the 50 percent of patients switched to the biosimilar infliximab (CT-P13), the efficacy and safety were comparable to those who remained on Remicade. Plus, remission rates in Crohn’s disease and ulcerative colitis were similar with CT-P13 and Remicade.

In addition, the time to study drug discontinuation was almost identical between the two groups.

“The data show that safety and efficacy are maintained post-switch and should give confidence to physicians looking to move their patients onto biosimilar infliximab for non-medical reasons such as cost. I am hopeful that switching will lead to financial savings that can in turn enable more patients to receive this life-changing medicine,” said Jørgen Jahnsen, Professor of gastroenterology at the University of Oslo, Norway, and co-author of the NOR-SWITCH study.¹⁴

Therefore, despite the studies illustrating that the infliximab biosimilars (Inflectra and Renflexis) are equally effective as the infliximab biologic (Remicade), biosimilars in the U.S. have not reached their expected market share. This unexpectedly low use of biosimilar products is understandable in light of the disincentives inherent in the “buy-and-bill” process, fail-first policies, and the barriers created by regulatory uncertainty from the FDA.

Estimating the Potential Biosimilar Savings – An Infliximab Case Study

If the costs of these barriers were low, then policy reforms to eliminate them would not be a pressing issue. However, the evidence to date indicates that the costs in terms of lost health care savings are high. This section documents the size of these lost potential savings by comparing the different per-patient and total market costs of the infliximab biologic to the per-patient and total market costs of infliximab biosimilars. These costs are estimated for employer-based plans and the Medicare program.

The biologic version of infliximab, known as Remicade, was originally licensed in 1998.¹⁵ There are currently two biosimilars that directly compete against the reference product Remicade: Inflectra, which was approved by the FDA in April 2016; and Renflexis, which was approved by the FDA in April 2017. Infliximab treats immune disorders including:

- Moderately to severely active rheumatoid arthritis;
- Moderately to severely active Crohn’s disease;
- Moderately to severely active ulcerative colitis;
- Chronic severe plaque psoriasis; and,
- Active psoriatic arthritis.

These immune disorders afflict large numbers of Americans and impose a heavy burden on patients living with these disorders. Table 1 summarizes the patient population, economic costs, and medications typically prescribed to treat these conditions. For these immune suppressant conditions, immune suppressant

biologics including infliximab are typically prescribed to treat patients when other therapies have not been effective (although some evidence shows that biologics may have value as a first line treatment for rheumatoid arthritis).¹⁶

TABLE 1
BACKGROUND INFORMATION ON THE COMMON IMMUNE DISORDERS TREATED BY INFLIXIMAB

CONDITION	EST. PATIENT POPULATION	TYPICAL CONDITION ONSET	ECONOMIC BURDEN	MEDICATIONS
Rheumatoid arthritis ¹⁷	1.3 million (2017) Nearly three times as many women as men have the disease.	In women, RA commonly begins between ages 30 and 60. In men, it often occurs later in life.	RA directly costs the U.S. economy \$19.3 billion a year (in 2005 dollars). ¹⁸ Costs by stakeholder Employers: 33% Patients: 28% Government: 20% Caregivers: 19%	Methotrexate is the first line drug for patients with RA; however, the majority of patients with RA fail on this drug due to inefficacy or adverse events. ¹⁹ Biologics are used when Methotrexate has failed.
Crohn's disease ²⁰	780,000 Equally common between males and females	Late adolescence early adulthood (between the ages of 15 and 30). Children are twice as likely to be diagnosed with Crohn's as ulcerative colitis.	Annual economic costs of \$3.6 billion. Medical expenses per patient is \$8,265, (31.4% hospital costs, 33.3% medications).	Sulfasalazine Corticosteroids Immunosuppressants (e.g. methotrexate) Biologics
Ulcerative colitis ²¹	907,000 Equally common between males and females.	Late adolescence early adulthood (between the ages of 15 and 35).	Annual economic cost is estimated to be about \$2.7 billion. Medical expenses per patient are \$7,948 (40% hospital costs, 28% medicines, 35% outpatient care).	Aminosalicylates (Mild to Moderate) Corticosteroids (Moderate to Severe, not intended for long-term use) Immune modifiers (Moderate to Severe, suppress the body's immune response so that it cannot cause ongoing inflammation) Biologic therapies (Moderate to Severe, suppresses the immune system to reduce inflammation, typically prescribed when have not responded to conventional therapy).
Chronic severe plaque psoriasis	7.5 million	Late adolescence early adulthood (between the ages of 15 and 35).	Annual economic costs of \$135 billion including: medical expenses; work productivity; intangible costs; impact on quality of life; and medical expenses related to psoriasis comorbidities. ²²	Management typically starts with topical treatments such as corticosteroids. If not effective, progress to phototherapy, systemic therapy, and biologics.
Psoriatic arthritis	2.25 million (Approx. 30% of patients with psoriasis) Equally common between males and females.	Onset typically occurs between the ages of 30 and 55 in people who have psoriasis.	Annual economic costs ranging between \$4.0 billion and \$6.8 billion (including direct and indirect costs).	Treatments include: NSAIDs, Corticosteroids (directly injected into the joint), DMARDs, and biologics.

The savings potential of biosimilars is based on their lower prices relative to biologics. For this analysis, the prices used for comparison is the ASP because, as noted above, it reflects the impacts from all discounts and rebates. However, providers (e.g. a hospital) do not just receive the ASP as reimbursement from a payer (e.g. insurance company or Medicare). The ASP represents the costs to acquire the drug but does not include the costs the provider incurred to administer it. Generally, as discussed above, these provider costs are reimbursed as a percentage of the ASP. The actual percentage mark-up applied varies across commercial providers and Medicare, which, statutorily, pays a 6 percent mark-up on ASP.

As noted by Simmons-Stern et al. (2018) while “ASP source information is not directly available to the public, CMS [Centers for Medicare & Medicaid Services] uses manufacturer-provided data to publish a value called the Medicare Payment Limit for each eligible product on a quarterly basis. This payment limit accounts for blended average discounts to commercial (non-government) customers and is, therefore, a good proxy for net price once we remove the statutory 6 percent mark-up”.²³

Consequently, this analysis bases the annualized alternative cost estimates on the Medicare Payment Limit data effective April 1, 2018 through June 30, 2018 minus Medicare’s statutory 6 percent mark-up. Table 2 summarizes the estimated ASP for Remicade, Inflectra, and Renflexis. Table 2 presents these data without the 6 percent mark-up, as well as alternative mark-up scenarios that are common in the commercial payer market.

TABLE 2
ALTERNATIVE ASP MARK-UP SCENARIOS
COMMERCIAL MARKET
PRICES EFFECTIVE APRIL 1, 2018 THROUGH JUNE 30, 2018

	ASP PER 100 MG (EXCL. PROVIDER MARK-UP)	0%	6%	10%	15%	20%
Inflectra	\$649.98	\$649.98	\$688.97	\$714.97	\$747.47	\$779.97
Renflexis	\$656.64	\$656.64	\$696.04	\$722.30	\$755.14	\$787.97
Remicade	\$785.73	\$785.73	\$832.87	\$864.30	\$903.59	\$942.87

Source: CMS Payment Allowance Limits for Medicare Part B Drugs and Author calculations

As discussed above, Medicare attempts to diminish the provider incentive to prescribe biologics rather than biosimilars by basing biosimilars’ mark-up on the ASP of the reference biologic. Consequently, the gap between biosimilars ASP and biologics ASP after the mark-up will differ between Medicare and the commercial market. This gap will also differ because of the budget sequester. Due to the sequester, Medicare Part B reimburses biosimilars and biologics at ASP plus 4.3 percent rather than the statutory 6.0 percent. The ASP prices summarized in Table 3 reflect the prices for infliximab accounting for these issues.

TABLE 3
SEQUESTER CONSTRAINED ASP MARK-UP
MEDICARE

	ASP PER 100 MG (EXCL. PROVIDER MARK-UP)	ASP INCLUDING 4.3% MARK-UP
Inflectra	\$649.98	\$683.76
Renflexis	\$656.64	\$690.43
Remicade	\$785.73	\$819.51

Source: CMS Payment Allowance Limits for Medicare Part B Drugs and Author calculations

Leveraging these prices, both the per-patient and total market cost savings potential of the biosimilar version of infliximab can be calculated.

Starting with the per-patient savings, the average patient will exhibit different characteristics across these conditions (e.g. women are two to three times more likely to get rheumatoid arthritis than men) and require different dosages. Therefore, the estimated per-patient savings will vary depending upon the specific condition being treated.

Table 4 summarizes the dosage and estimated average weight considerations for patients with the five largest immune suppressant conditions that are treated with infliximab. Additionally, the initial use of infliximab differs slightly from the use on a maintenance schedule, which is once every eight weeks for all five conditions – or 6 ½ times a year. For simplicity, this analysis estimates the savings for patients on a maintenance schedule.

TABLE 4
DOSAGE AND WEIGHT CONSIDERATIONS FOR PATIENTS TREATED WITH INFLIXIMAB ON MAINTENANCE
SCHEDULE PER PATIENT

	RHEUMATOID ARTHRITIS	CROHN'S DISEASE	ULCERATIVE COLITIS	PSORIATIC ARTHRITIS	PLAQUE PSORIASIS
Dose (mg / kg)	3.00	5.00	5.00	5.00	5.00
Average Weight (kg)	79.51	82.50	82.50	84.56	84.56
Total Dose (mg)	238.54	412.50	412.50	422.82	422.82
Maintenance Sched. (annual)	6.5	6.5	6.5	6.5	6.5

Source: Author Calculations based on various sources.²⁴

Based on the prices in Table 2 and the total doses in Table 4, the costs per dose using alternative mark-up scenarios (0 percent, 6 percent, 10 percent, 15 percent, and 20 percent) can be estimated, which are reported in Table 5.

TABLE 5
INFLIXIMAB PER PATIENT COST PER DOSE
INFLECTRA, RENFLEXIS, AND REMICADE
COMMERCIAL MARKET

	RHEUMATOID ARTHRITIS	CROHN'S DISEASE	ULCERATIVE COLITIS	PSORIATIC ARTHRITIS	PLAQUE PSORIASIS
	0% Mark-up				
Inflectra	\$1,550	\$2,681	\$2,681	\$2,748	\$2,748
Renflexis	\$1,566	\$2,709	\$2,709	\$2,776	\$2,776
Remicade	\$1,874	\$3,241	\$3,241	\$3,322	\$3,322
	6% Mark-up				
Inflectra	\$1,644	\$2,842	\$2,842	\$2,913	\$2,913
Renflexis	\$1,660	\$2,871	\$2,871	\$2,943	\$2,943
Remicade	\$1,987	\$3,436	\$3,436	\$3,522	\$3,522
	10% Mark-up				
Inflectra	\$1,706	\$2,949	\$2,949	\$3,023	\$3,023
Renflexis	\$1,723	\$2,980	\$2,980	\$3,054	\$3,054
Remicade	\$2,062	\$3,565	\$3,565	\$3,654	\$3,654
	15% Mark-up				
Inflectra	\$1,783	\$3,083	\$3,083	\$3,160	\$3,160
Renflexis	\$1,801	\$3,115	\$3,115	\$3,193	\$3,193
Remicade	\$2,155	\$3,727	\$3,727	\$3,820	\$3,820
	20% Mark-up				
Inflectra	\$1,861	\$3,217	\$3,217	\$3,298	\$3,298
Renflexis	\$1,880	\$3,250	\$3,250	\$3,332	\$3,332
Remicade	\$2,249	\$3,889	\$3,889	\$3,987	\$3,987

Source: CMS Payment Allowance Limits for Medicare Part B Drugs and Author calculations

These per patient cost estimates assume that all vials of the medicines are completely used (e.g. there is no wastage), and that patients are 100 percent compliant with their prescribed regiment. Further, the ASP used for the analysis is based on the prices that prevailed April 1, 2018 through June 30, 2018, which may not have provided sufficient time for the competitive pressures from the biosimilars (particularly Renflexis, which was introduced in April 2017) to take effect. Consequently, it is probable that the price gap, and resulting per patient savings, between the biosimilars and Remicade will widen further in the future.

The annual costs per patient are simply the total costs per dose multiplied by the average number of doses per year, or 6.5. These results are presented in Table 6.

TABLE 6
ANNUAL PER PATIENT INFLIXIMAB COSTS
INFLECTRA, RENFLEXIS, AND REMICADE
COMMERCIAL MARKET

	RHEUMATOID ARTHRITIS	CROHN'S DISEASE	ULCERATIVE COLITIS	PSORIATIC ARTHRITIS	PLAQUE PSORIASIS
0% Mark-up					
Inflectra	\$10,078	\$17,428	\$17,428	\$17,863	\$17,863
Renflexis	\$10,181	\$17,606	\$17,606	\$18,046	\$18,046
Remicade	\$12,183	\$21,067	\$21,067	\$21,594	\$21,594
6% Mark-up					
Inflectra	\$10,683	\$18,473	\$18,473	\$18,935	\$18,935
Renflexis	\$10,792	\$18,663	\$18,663	\$19,129	\$19,129
Remicade	\$12,914	\$22,331	\$22,331	\$22,890	\$22,890
10% Mark-up					
Inflectra	\$11,086	\$19,170	\$19,170	\$19,650	\$19,650
Renflexis	\$11,200	\$19,367	\$19,367	\$19,851	\$19,851
Remicade	\$13,401	\$23,174	\$23,174	\$23,754	\$23,754
15% Mark-up					
Inflectra	\$11,590	\$20,042	\$20,042	\$20,543	\$20,543
Renflexis	\$11,709	\$20,247	\$20,247	\$20,753	\$20,753
Remicade	\$14,010	\$24,228	\$24,228	\$24,833	\$24,833
20% Mark-up					
Inflectra	\$12,094	\$20,913	\$20,913	\$21,436	\$21,436
Renflexis	\$12,218	\$21,128	\$21,128	\$21,656	\$21,656
Remicade	\$14,620	\$25,281	\$25,281	\$25,913	\$25,913

Source: CMS Payment Allowance Limits for Medicare Part B Drugs and Author calculations

The annual per patient savings are simply the difference between the average costs for the biosimilar versions of infliximab (Inflectra and Renflexis) and the costs for Remicade. These cost differences for the different percentage mark-up scenarios are presented in Table 7. Table 7 illustrates that, on a per patient basis, the infliximab biosimilars can create between \$2,100 of savings and \$4,400 of savings relative to the biologic version depending upon the condition and average percentage mark-up.

TABLE 7
ANNUAL PER PATIENT INFlixIMAB BIOSIMILAR SAVINGS
INFLECTRA AND RENFLEXIS RELATIVE TO REMICADE
COMMERCIAL MARKET

	RHEUMATOID ARTHRITIS	CROHN'S DISEASE	ULCERATIVE COLITIS	PSORIATIC ARTHRITIS	PLAQUE PSORIASIS
0% Mark-up	\$2,053	\$3,550	\$3,550	\$3,639	\$3,639
6% Mark-up	\$2,176	\$3,764	\$3,764	\$3,858	\$3,858
10% Mark-up	\$2,259	\$3,906	\$3,906	\$4,003	\$4,003
15% Mark-up	\$2,361	\$4,083	\$4,083	\$4,185	\$4,185
20% Mark-up	\$2,464	\$4,261	\$4,261	\$4,367	\$4,367

Source: CMS Payment Allowance Limits for Medicare Part B Drugs and Author calculations

Table 8 reproduces the calculations of Table 5 through 7 for the Medicare market as opposed to the commercial market. As Table 8 illustrates, on a per patient basis, the infliximab biosimilars create per patient savings between \$2,100 and \$3,600 on average.

TABLE 8
PER PATIENT COST PER DOSE, ANNUAL COSTS, AND ANNUAL BIOSIMILAR SAVINGS
INFLECTRA AND RENFLEXIS RELATIVE TO REMICADE
MEDICARE

	RHEUMATOID ARTHRITIS	CROHN'S DISEASE	ULCERATIVE COLITIS	PSORIATIC ARTHRITIS	PLAQUE PSORIASIS
	Cost per dose				
Inflectra	\$1,631	\$2,821	\$2,821	\$2,891	\$2,891
Renflexis	\$1,647	\$2,848	\$2,848	\$2,919	\$2,919
Remicade	\$1,955	\$3,381	\$3,381	\$3,465	\$3,465
	Annual Cost				
Inflectra	\$10,602	\$18,334	\$18,334	\$18,792	\$18,792
Renflexis	\$10,705	\$18,512	\$18,512	\$18,975	\$18,975
Remicade	\$12,707	\$21,973	\$21,973	\$22,523	\$22,523
	Annual Biosimilar Savings				
Inflectra	\$2,105	\$3,640	\$3,640	\$3,731	\$3,731
Renflexis	\$2,002	\$3,461	\$3,461	\$3,548	\$3,548
Biosimilar Average Discount	\$2,053	\$3,550	\$3,550	\$3,639	\$3,639

Source: CMS Payment Allowance Limits for Medicare Part B Drugs and Author calculations

Tables 5 through 8 demonstrate that the infliximab biosimilars offer significant per patient savings to both commercial payers and the Medicare program relative to the costs of prescribing the infliximab biologic.

While data limitations make it difficult to directly extrapolate the per patient savings to the entire infliximab market, the total potential savings for employer-plans and Medicare enrollees can be estimated based on total market data provided by IMS Health data (IQVIA).²⁵ Based on these data, the total market sales of infliximab, excluding sales to VA hospitals, in 2017 were 7.5 million 100 mg vials (units), up 1.8 percent from 2016 (see Table 9).

TABLE 9
TOTAL INFLIXIMAB SALES (VIALS 100 MG)
2015 - 2017

	2015	2016	2017
Total Market (Excl. Closed Insurance Systems)	7,046,337	7,215,881	7,466,435
Remicade Sales	7,046,337	7,215,259	7,347,614
Biosimilar Sales	-	622	118,821
+ Closed Insurance Systems Sales	354,000	200,000	200,000
= Total Adjusted Market (Excluding VA Sales)	7,400,337	7,415,259	7,547,614

Source: IQVIA Data and Author calculations

According to the IMS Health data, approximately 60 percent of these sales were to the commercial market, 30 percent to Medicare, and 10 percent to Medicaid. Applying these shares to the total adjusted market sales of infliximab, 4.5 million units are sales to patients covered in the commercial market, and 2.3 million units are sales to patients covered by Medicare (see Table 10).

TABLE 10
TOTAL INFLIXIMAB SALES (VIALS 100 MG)
CATEGORIZED BY COMMERCIAL MARKET, MEDICARE, AND MEDICAID
2015 - 2017

	MARKET VOLUME BREAKDOWN		
	2015	2016	2017
Commercial	4,440,202	4,449,155	4,528,568
Medicare	2,220,101	2,224,578	2,264,284
Medicaid	740,034	741,526	754,761

Source: IQVIA Data and Author calculations

The commercial market is comprised of people covered by employer-sponsored plans (49 percent of the total U.S. population), and people sponsored by non-group or individual plans (7 percent of the total U.S. population).²⁶ These figures indicate that 87.5 percent of the people covered in the commercial market are covered by employer-sponsored plans. Applying these shares to the 4.5 million units in the commercial market, 4.0 million units are covered by employer plans, see Table 11.

TABLE 11
TOTAL INFliximab SALES (VIALS 100 MG) COVERED BY EMPLOYER PLANS
2015 - 2017

COMMERCIAL MARKET BREAKDOWN			
	2015	2016	2017
Employer Plans As a Percentage of Commercial Market	87.5%	87.5%	87.5%
Employer Plans (in units)	3,885,177	3,893,011	3,962,497

Source: IQVIA Data and Author calculations

Having estimated the total number of infliximab units that are covered by employer plans (4.0 million) and Medicare (2.3 million units), the annualized infliximab expenditures based on alternative biosimilar share assumptions can be estimated using the same ASP data from above.

Starting with a hypothetical (that all infliximab sales are the biologic Remicade), the total infliximab expenditures on patients covered by employer-sponsored health insurance would range between \$3.1 billion and \$3.7 billion (depending upon the effective ASP mark-up). The biosimilar versions of infliximab sell for a lower ASP, therefore the larger the market share for the biosimilar versions of infliximab, the greater the overall savings to employer-sponsored health plans compared to the full biologic baseline. Since the division of the biosimilar market share between Inflectra and Renflexis is unknown, the analysis assumes the biosimilar market is divided equally between these two biosimilars. Table 12 presents these lower overall expenditure levels and the expenditures associated with the no biosimilar baseline.

TABLE 12
TOTAL INFliximab EXPENDITURES COVERED BY EMPLOYER PLANS
VARIOUS MARK-UP ASSUMPTIONS

		0% ASP MARK-UP	6% ASP MARK-UP	10% ASP MARK-UP	15% ASP MARK-UP	20% ASP MARK-UP
BIOSIMILAR MARKET SHARE	0.0%	\$3,113,438,838	\$3,300,245,168	\$3,424,782,721	\$3,580,454,663	\$3,736,126,605
	10.0%	\$3,060,968,185	\$3,244,626,276	\$3,367,065,003	\$3,520,113,412	\$3,673,161,822
	20.0%	\$3,008,497,532	\$3,189,007,384	\$3,309,347,285	\$3,459,772,162	\$3,610,197,038
	30.0%	\$2,956,026,879	\$3,133,388,492	\$3,251,629,567	\$3,399,430,911	\$3,547,232,255
	40.0%	\$2,903,556,226	\$3,077,769,600	\$3,193,911,849	\$3,339,089,660	\$3,484,267,471
	50.0%	\$2,851,085,573	\$3,022,150,708	\$3,136,194,131	\$3,278,748,409	\$3,421,302,688
	60.0%	\$2,798,614,920	\$2,966,531,816	\$3,078,476,412	\$3,218,407,158	\$3,358,337,904
	70.0%	\$2,746,144,267	\$2,910,912,923	\$3,020,758,694	\$3,158,065,908	\$3,295,373,121
	80.0%	\$2,693,673,615	\$2,855,294,031	\$2,963,040,976	\$3,097,724,657	\$3,232,408,337
	90.0%	\$2,641,202,962	\$2,799,675,139	\$2,905,323,258	\$3,037,383,406	\$3,169,443,554

Source: IQVIA Data and Author calculations

The difference between the total infliximab expenditures under alternative biosimilar market shares, and the total infliximab expenditures under the no biosimilar baseline, is the estimated aggregate savings to employer-sponsored health plans. These differences are provided in Table 13. Table 13 illustrates that, at current ASP differences, greater use of biosimilars offers significant potential savings for employer-sponsored health plans. For example, if biosimilars became one-half of the infliximab market, then expenditures by employer-sponsored health plans would be \$262 million to \$315 million lower compared to the baseline scenario of no sales of the biosimilar versions of infliximab. Like the estimated savings on a per patient basis, as the competition from the biosimilars intensifies, it is likely that these aggregate savings will increase over time.

TABLE 13
TOTAL POTENTIAL INFLIXIMAB SAVINGS CREATED BY BIOSIMILARS FOR EMPLOYER PLANS
VARIOUS MARK-UP ASSUMPTIONS

		2017 COMMERCIAL TOTAL INFLIXIMAB SAVINGS				
		0% ASP MARKUP	6% ASP MARKUP	10% ASP MARKUP	15% ASP MARKUP	20% ASP MARKUP
BIOSIMILAR MARKET SHARE	10.0%	\$52,470,653	\$55,618,892	\$57,717,718	\$60,341,251	\$62,964,783
	20.0%	\$104,941,306	\$111,237,784	\$115,435,436	\$120,682,502	\$125,929,567
	30.0%	\$157,411,959	\$166,856,676	\$173,153,155	\$181,023,752	\$188,894,350
	40.0%	\$209,882,612	\$222,475,568	\$230,870,873	\$241,365,003	\$251,859,134
	50.0%	\$262,353,264	\$278,094,460	\$288,588,591	\$301,706,254	\$314,823,917
	60.0%	\$314,823,917	\$333,713,352	\$346,306,309	\$362,047,505	\$377,788,701
	70.0%	\$367,294,570	\$389,332,244	\$404,024,027	\$422,388,756	\$440,753,484
	80.0%	\$419,765,223	\$444,951,136	\$461,741,745	\$482,730,007	\$503,718,268
	90.0%	\$472,235,876	\$500,570,029	\$519,459,464	\$543,071,257	\$566,683,051

Source: IQVIA Data and Author calculations

Table 14 presents these savings as a percentage of the baseline expenditure levels. Regardless of the assumed mark-up, as a percentage of the baseline expenditure levels, biosimilars can lower total expenditures between 1.7 percent (assuming a 10 percent biosimilar share) and 15.2 percent (assuming a 90 percent biosimilar share).

TABLE 14
PERCENTAGE POTENTIAL INFLIXIMAB SAVINGS CREATED BY BIOSIMILARS FOR EMPLOYER PLANS
VARIOUS MARK-UP ASSUMPTIONS

2017 COMMERCIAL TOTAL INFLIXIMAB SAVINGS		
BIOSIMILAR MARKET SHARE	10.0%	-1.7%
	20.0%	-3.4%
	30.0%	-5.1%
	40.0%	-6.7%
	50.0%	-8.4%
	60.0%	-10.1%
	70.0%	-11.8%
	80.0%	-13.5%
	90.0%	-15.2%

Source: IQVIA Data and Author calculations

Similar calculations can be made for Medicare enrollees, which are summarized in Table 15. Table 15 shows that, depending upon the share of infliximab prescribed to Medicare patients, total Medicare savings could range from \$30 million (10 percent biosimilar share) to \$270 million (90 percent biosimilar share).

TABLE 15
INFLIXIMAB EXPENDITURES AND POTENTIAL BIOSIMILAR SAVINGS
MEDICARE PROGRAM

		2017 MEDICARE TOTAL INFLIXIMAB EXPENDITURES	2017 MEDICARE TOTAL INFLIXIMAB SAVINGS	2017 MEDICARE PERCENTAGE INFLIXIMAB SAVINGS
BIOSIMILAR MARKET SHARE	0.0%	\$1,855,609,547		
	10.0%	\$1,825,626,317	\$29,983,230	-1.6%
	20.0%	\$1,795,643,087	\$59,966,460	-3.2%
	30.0%	\$1,765,659,857	\$89,949,691	-4.8%
	40.0%	\$1,735,676,626	\$119,932,921	-6.5%
	50.0%	\$1,705,693,396	\$149,916,151	-8.1%
	60.0%	\$1,675,710,166	\$179,899,381	-9.7%
	70.0%	\$1,645,726,936	\$209,882,612	-11.3%
	80.0%	\$1,615,743,705	\$239,865,842	-12.9%
	90.0%	\$1,585,760,475	\$269,849,072	-14.5%

Source: IQVIA Data and Author calculations

These calculations, based on the latest ASP prices, confirm the savings expectations of biosimilars. The large potential savings that are not being realized is an indication that the barriers identified in the previous section are, in fact, a costly obstruction. Consequently, reforms to eliminate these obstacles are an important policy focus.

Conclusion

Biosimilars have yet to yield the expected health care savings due to their slower than expected adoption. The current price points for biologic and biosimilar versions of infliximab indicate that there are large potential savings, nevertheless. If biosimilars can reach 50 percent of the infliximab market, for instance, then the estimated annual cost reductions for patients with employer-based coverage could be as high as 8.4 percent, or between \$262 million and \$315 million in annual cost savings, depending upon the actual average mark-up percentage. For Medicare, the potential savings could be as high as 8.1 percent, or nearly \$150 million in savings a year.

Taken together, commercial payers and Medicare could save between \$412 million and \$465 million a year, for just one reference biologic product alone. Applying these savings to the 40 different biosimilar medicines approved for use in Europe, tens of billions of dollars in annual health care savings are attainable if a robust biosimilar market in the U.S. develops.

The large existence of these potential savings is an indication that the slower than expected adoption of biosimilars is due to market and regulatory barriers that inefficiently discourage their use. These barriers include the current “buy-and-bill” system for purchasing biosimilars, the fail-first policies of many health insurance plans, and the excessive regulatory uncertainty. These barriers create dis-incentives that bias the market against biosimilars. Consequently, eliminating these barriers that are inhibiting the adoption of biosimilars should be a top policy priority that would create significant health care savings.

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Addendum

This study's annualized cost savings for biosimilar versions of infliximab were estimated based on the Medicare Payment Limit data that were effective April 1, 2018 through June 30, 2018. After releasing the study, CMS updated its Medicare Payment Limit price data, which are now effective as of July 1, 2018 through September 30, 2018. This Addendum updates the calculated savings estimates to reflect the most recent CMS data.

Table 1 summarizes the updated commercial market pricing data for the biologic and biosimilar versions of infliximab that were effective between July 1, 2018 through September 30, 2018 and compares these data to the prices effective April 1, 2018 through June 30, 2018. As Table 1 illustrates, the prices for both biosimilar versions of infliximab have decreased, while the price for the originator biologic version of infliximab has increased. The same trends are also evident for Medicare prices, see Table 2. These widened price gaps indicate that the potential savings from wider use of the biosimilar versions has increased relative to the savings estimated in the study.

TABLE 1
ALTERNATIVE ASP MARK-UP SCENARIOS, COMMERCIAL MARKET
PRICES EFFECTIVE APRIL 1, 2018 THROUGH JUNE 30, 2018 & JULY 1, 2018 THROUGH SEPTEMBER 30, 2018

		ASP PER 100 MG (EXCL. PROVIDER MARK-UP)	0%	6%	10%	15%	20%
Inflectra	Apr. – Jun.	\$649.98	\$649.98	\$688.97	\$714.97	\$747.47	\$779.97
	Jul. – Sept.	\$602.30	\$602.30	\$638.44	\$662.53	\$692.65	\$722.76
Renflexis	Apr. – Jun.	\$656.64	\$656.64	\$696.04	\$722.30	\$755.14	\$787.97
	Jul. – Sept.	\$644.73	\$644.73	\$683.41	\$709.20	\$741.44	\$773.68
Remicade	Apr. – Jun.	\$785.73	\$785.73	\$832.87	\$864.30	\$903.59	\$942.87
	Jul. – Sept.	\$791.50	\$791.50	\$838.99	\$870.65	\$910.23	\$949.80

Source: CMS Payment Allowance Limits for Medicare Part B Drugs and Author calculations

TABLE 2
SEQUESTER CONSTRAINED ASP MARK-UP MEDICARE

		ASP PER 100 MG (EXCL. PROVIDER MARK-UP)	ASP INCLUDING 4.3% MARK-UP
Inflectra	Apr. – Jun.	\$649.98	\$683.76
	Jul. – Sept.	\$602.30	\$636.33
Renflexis	Apr. – Jun.	\$656.64	\$690.43
	Jul. – Sept.	\$644.73	\$678.76
Remicade	Apr. – Jun.	\$785.73	\$819.51
	Jul. – Sept.	\$791.50	\$825.53

Source: CMS Payment Allowance Limits for Medicare Part B Drugs and Author calculations

Using the same methodology described in the study, the per patient and total market savings potential of the biosimilar version of infliximab are re-estimated in this Addendum to illustrate how much the potential savings have increased. Overall, the annualized estimated savings are 27 percent higher based on the latest pricing data relative to the estimated savings based on the prices that prevailed just one-quarter earlier.

Table 3 illustrates that, on a per patient basis, the savings based on the most recent price data are between \$2,605 and \$5,540 depending upon the mark-up and specific disease treated. The per patient savings for Medicare range, on average, between \$2,605 and \$4,617, see Table 4.

TABLE 3
ANNUAL PER PATIENT INFLIXIMAB BIOSIMILAR SAVINGS
COMMERCIAL MARKET, PRICES EFFECTIVE APRIL 1, 2018 THROUGH JUNE 30, 2018 & JULY 1, 2018
THROUGH SEPTEMBER 30, 2018

		RHEUMATOID ARTHRITIS	CROHN'S DISEASE	ULCERATIVE COLITIS	PSORIATIC ARTHRITIS	PLAQUE PSORIASIS
0% Mark-up	Apr. - Jun.	\$2,053	\$3,550	\$3,550	\$3,639	\$3,639
	Jul. - Sep.	\$2,605	\$4,504	\$4,504	\$4,617	\$4,617
6% Mark-up	Apr. - Jun.	\$2,176	\$3,764	\$3,764	\$3,858	\$3,858
	Jul. - Sep.	\$2,761	\$4,774	\$4,774	\$4,894	\$4,894
10% Mark-up	Apr. - Jun.	\$2,259	\$3,906	\$3,906	\$4,003	\$4,003
	Jul. - Sep.	\$2,865	\$4,955	\$4,955	\$5,078	\$5,078
15% Mark-up	Apr. - Jun.	\$2,361	\$4,083	\$4,083	\$4,185	\$4,185
	Jul. - Sep.	\$2,995	\$5,180	\$5,180	\$5,309	\$5,309
20% Mark-up	Apr. - Jun.	\$2,464	\$4,261	\$4,261	\$4,367	\$4,367
	Jul. - Sep.	\$3,126	\$5,405	\$5,405	\$5,540	\$5,540

Source: CMS Payment Allowance Limits for Medicare Part B Drugs and Author calculations

TABLE 4
PER PATIENT ANNUAL BIOSIMILAR SAVINGS
MEDICARE, PRICES EFFECTIVE APRIL 1, 2018 THROUGH JUNE 30, 2018 & JULY 1, 2018 THROUGH SEPTEMBER 30, 2018

		RHEUMATOID ARTHRITIS	CROHN'S DISEASE	ULCERATIVE COLITIS	PSORIATIC ARTHRITIS	PLAQUE PSORIASIS
Inflectra	Apr. - Jun.	\$2,105	\$3,640	\$3,640	\$3,731	\$3,731
	Jul. - Sep.	\$2,934	\$5,073	\$5,073	\$5,200	\$5,200
Renflexis	Apr. - Jun.	\$2,002	\$3,461	\$3,461	\$3,548	\$3,548
	Jul. - Sep.	\$2,276	\$3,935	\$3,935	\$4,034	\$4,034
Biosimilar Average Discount	Apr. - Jun.	\$2,053	\$3,550	\$3,550	\$3,639	\$3,639
	Jul. - Sep.	\$2,605	\$4,504	\$4,504	\$4,617	\$4,617

Source: CMS Payment Allowance Limits for Medicare Part B Drugs and Author calculations

The total market savings are also larger. Overall, assuming a 50 percent biosimilar market share, the biosimilar versions of infliximab could deliver total market savings to employer-sponsored plans between \$332.8 million and \$399.4 million (see Table 5), and \$190.1 million to Medicare (see Table 6).

TABLE 5
TOTAL POTENTIAL INFLIXIMAB SAVINGS CREATED BY BIOSIMILARS FOR EMPLOYER PLAN
VARIOUS MARK-UP ASSUMPTIONS, PRICES EFFECTIVE
APRIL 1, 2018 THROUGH JUNE 30, 2018 & JULY 1, 2018 THROUGH SEPTEMBER 30, 2018

			2017 COMMERCIAL TOTAL INFLIXIMAB SAVINGS				
			0% ASP MARKUP	6% ASP MARKUP	10% ASP MARKUP	15% ASP MARKUP	20% ASP MARKUP
BIOSIMILAR MARKET SHARE	10%	Apr. - Jun.	\$52,470,653	\$55,618,892	\$57,717,718	\$60,341,251	\$62,964,783
		Jul. - Sep.	\$66,564,012	\$70,557,852	\$73,220,413	\$76,548,613	\$79,876,814
	20%	Apr. - Jun.	\$104,941,306	\$111,237,784	\$115,435,436	\$120,682,502	\$125,929,567
		Jul. - Sep.	\$133,128,023	\$141,115,705	\$146,440,826	\$153,097,227	\$159,753,628
	30%	Apr. - Jun.	\$157,411,959	\$166,856,676	\$173,153,155	\$181,023,752	\$188,894,350
		Jul. - Sep.	\$199,692,035	\$211,673,557	\$219,661,239	\$229,645,840	\$239,630,442
	40%	Apr. - Jun.	\$209,882,612	\$222,475,568	\$230,870,873	\$241,365,003	\$251,859,134
		Jul. - Sep.	\$266,256,047	\$282,231,410	\$292,881,652	\$306,194,454	\$319,507,256
	50%	Apr. - Jun.	\$262,353,264	\$278,094,460	\$288,588,591	\$301,706,254	\$314,823,917
		Jul. - Sep.	\$332,820,059	\$352,789,262	\$366,102,065	\$382,743,067	\$399,384,070
	60%	Apr. - Jun.	\$314,823,917	\$333,713,352	\$346,306,309	\$362,047,505	\$377,788,701
		Jul. - Sep.	\$399,384,070	\$423,347,115	\$439,322,477	\$459,291,681	\$479,260,884
	70%	Apr. - Jun.	\$367,294,570	\$389,332,244	\$404,024,027	\$422,388,756	\$440,753,484
		Jul. - Sep.	\$465,948,082	\$493,904,967	\$512,542,890	\$535,840,294	\$559,137,699
	80%	Apr. - Jun.	\$419,765,223	\$444,951,136	\$461,741,745	\$482,730,007	\$503,718,268
		Jul. - Sep.	\$532,512,094	\$564,462,820	\$585,763,303	\$612,388,908	\$639,014,513
	90%	Apr. - Jun.	\$472,235,876	\$500,570,029	\$519,459,464	\$543,071,257	\$566,683,051
		Jul. - Sep.	\$599,076,106	\$635,020,672	\$658,983,716	\$688,937,521	\$718,891,327

Source: IQVIA Data and Author calculations

TABLE 6
INFLIXIMAB POTENTIAL BIOSIMILAR SAVINGS
MEDICARE PROGRAM, PRICES EFFECTIVE
APRIL 1, 2018 THROUGH JUNE 30, 2018 & JULY 1, 2018 THROUGH SEPTEMBER 30, 2018

		BIOSIMILAR SAVINGS BASED ON APRIL - JUNE ASP	BIOSIMILAR SAVINGS BASED ON JULY - SEPTEMBER ASP
BIOSIMILAR MARKET SHARE	10.00%	\$29,983,230	\$38,036,578
	20.00%	\$59,966,460	\$76,073,156
	30.00%	\$89,949,691	\$114,109,734
	40.00%	\$119,932,921	\$152,146,313
	50.00%	\$149,916,151	\$190,182,891
	60.00%	\$179,899,381	\$228,219,469
	70.00%	\$209,882,612	\$266,256,047
	80.00%	\$239,865,842	\$304,292,625
	90.00%	\$269,849,072	\$342,329,203

Source: IQVIA Data and Author calculations

The updated ASP data (effective July 2018 through September 2018), indicate that there are large potential savings to employer sponsored plans and Medicare. For example, if biosimilars were to grow to 50 percent of the market, the total savings could equal between \$523.0 million and \$589.6 million. These savings estimates are larger than the potential savings estimated in the study – between \$412.2 million and \$464.7 million.

These data confirm that large potential savings are not being realized, the estimated savings will likely continue to grow over time, and the barriers identified in the study are a costly obstruction. Consequently, reforms to eliminate these obstacles are an important policy focus.

About the Author



Wayne H. Winegarden, Ph.D. is a Senior Fellow in Business and Economics, Pacific Research Institute, as well as the Principal of Capitol Economic Advisors and a Contributing Editor for *EconoS-TATS*.

Dr. Winegarden has 20 years of business, economic, and policy experience with an expertise in applying quantitative and macro-economic analyses to create greater insights on corporate strategy, public policy, and strategic planning. He advises clients on the economic, business, and investment implications from changes in broader macroeconomic trends and government policies. Clients have included Fortune 500 companies, financial organizations, small businesses, state legislative leaders, political candidates and trade associations.

Dr. Winegarden's columns have been published in the *Wall Street Journal*, *Chicago Tribune*, *Investor's Business Daily*, *Forbes.com*, and *Townhall.com*. He was previously economics faculty at Marymount University, has testified before the U.S. Congress, has been interviewed and quoted in such media as CNN and Bloomberg Radio, and is asked to present his research findings at policy conferences and meetings. Previously, Dr. Winegarden worked as a business economist in Hong Kong and New York City; and a policy economist for policy and trade associations in Washington D.C. Dr. Winegarden received his Ph.D. in Economics from George Mason University.

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