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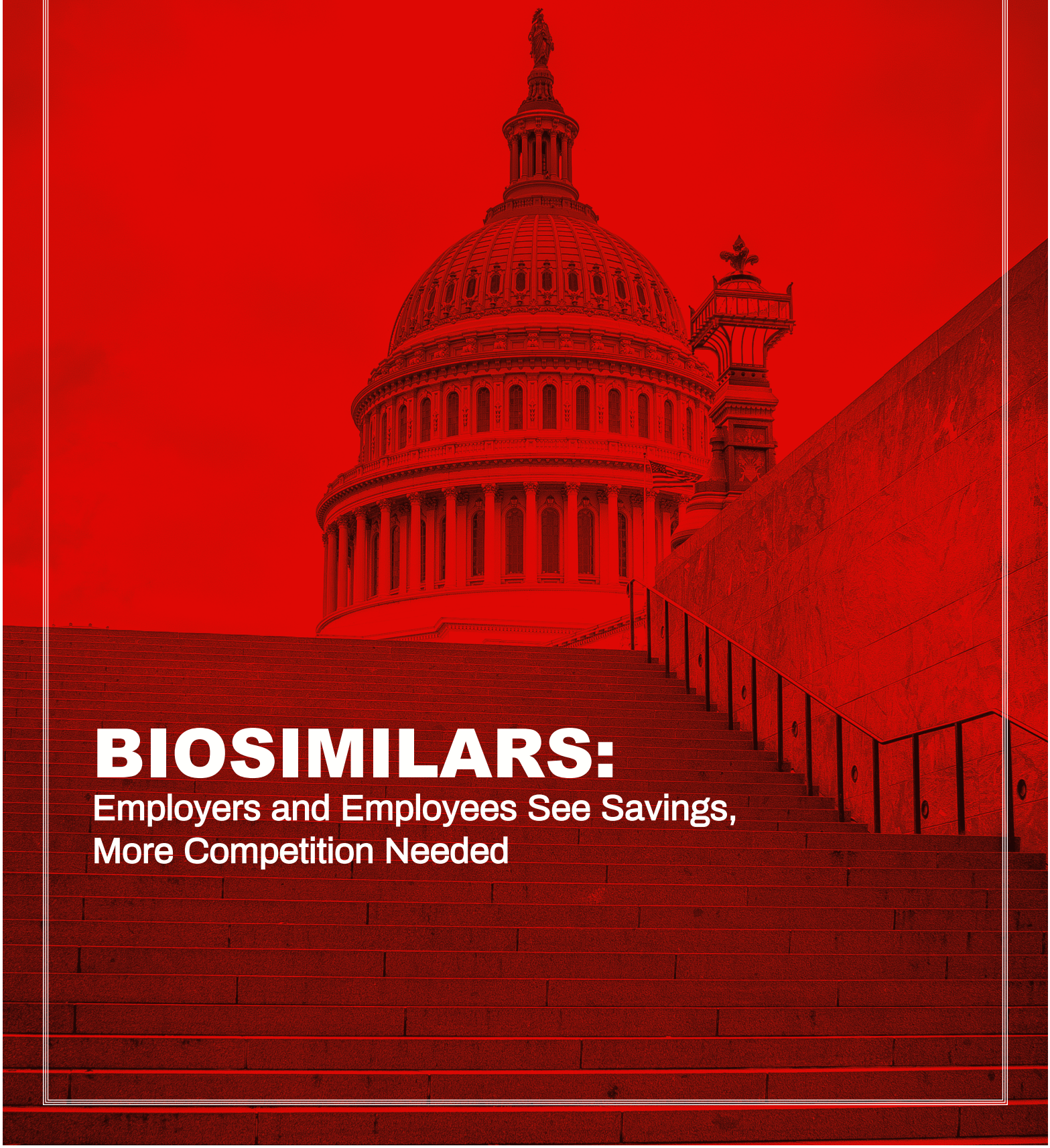

BIOSIMILARS:

Employers and Employees See Savings, More Competition Needed

ERIC
THE ERISA INDUSTRY COMMITTEE
Shaping benefit policies before they shape you.

A Letter from ERIC President and CEO Annette Guarisco Fildes

March 31, 2020

Today, more than 180 million Americans receive health care benefits through their employer. It's a shared burden, with employers paying approximately 80% of premiums. Of all health care costs, spending on specialty drugs—which are primarily biologics—has risen dramatically. Employers are bearing the brunt of the rising cost of these medicines, and the problem is getting worse. According to Express Scripts data, in 2010, these specialty medicines comprised 25% of total drug spend. That increased to nearly half (47.7%) of all spending on prescription drugs in 2018. This expensive trend impacts employees AND employers: as costly specialty drugs continue to rise in price, employees often share the cost in co-pays or coinsurance or higher premiums.

One potential means to address this unsustainable trend is to increase competition and lower costs through the use of biosimilar medicines. Congress established an approval pathway for biosimilars, which are lower-cost equivalent versions of biologic medicines, in the Affordable Care Act (ACA), and accompanying Biologics Price Competition and Innovation Act (BPCIA) in 2010. Since that time, however, only two biologics face meaningful competition from biosimilars, and for those interested in lowering drug prices, uptake of biosimilar medicines has been disappointing. ERIC and our member companies believe that increased availability and adoption of biosimilar medicines represent a promising market-based solution to high biologic costs for employers, employees, and their families**.**

ERIC launched a new initiative to better understand the current landscape of employers and biosimilars and explore how continued use of biosimilars can reduce health care costs. Our three-pronged approach examines how employers, employees, and their families can realize greater benefits from the presence and utilization of biosimilar options. Included you will find:

1) **Biosimilar Medications – Savings Opportunities for Large Employers, Mariana Socal, MD, Ph.D., Gerard Anderson, Ph.D., et al. —** Analyzing health plan data from 13 large employers, a team of researchers at the Johns Hopkins Bloomberg School of Public Health found that employers, employees, and their families achieved significant savings from biosimilars in 2018. At ERIC, we see these results as an indication of the tremendous opportunity for more savings that employers, employees, and their families can realize.

2) **Employer Strategies for Use of Biosimilar Pharmaceuticals** — Recognizing that employers continue to innovate independently, ERIC commissioned Segal, a leading benefits consulting firm, to provide strategic and practical recommendations for employers on opportunities to increase biosimilar uptake.

3) **U.S. Policies Impacting Biosimilar Drugs** — Lastly, ERIC retained Fidelity Investments to compile a detailed accounting of legislative and regulatory approaches that federal and state governments can take to promote a favorable environment for biosimilars to compete with biologics, leading to lower-cost choices for employers and employees.

Everyone has a role to play—including employers and the government—to realize greater benefits from biosimilar options.

ERIC's large employer member companies recognize that there are plan designs and benefits strategies they can employ to help promote access to biosimilars. At the same time, federal and state governments can ensure a robust, competitive marketplace for biosimilar medications by considering and adopting pro-competitive policies.

Working together, we believe that we can increase the use of biosimilar medicines, lower costs, and create a more sustainable environment for employers providing benefits and the employees and families depending on them.

Sincerely,

Annette Guarisco Fildes
President & CEO
The ERISA Industry Committee

About The ERISA Industry Committee

ERIC is a national advocacy organization that exclusively represents large employers that provide health, retirement, paid leave, and other benefits to their nationwide workforces. With member companies that are leaders in every sector of the economy, ERIC advocates on the federal, state, and local levels for policies that promote flexibility and uniformity in the administration of their employee benefit plans. *Learn more at eric.org.*

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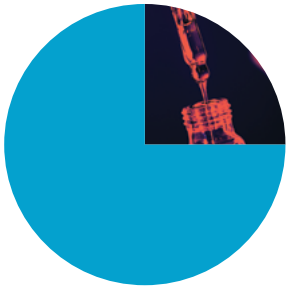
BIOSIMILARS AT 10 YEARS

Employers and Employees See Savings From Biosimilar Medicines, More Competition Needed

180 million Americans receive health care benefits through their employer
("Health Insurance Coverage in the US: 2018" - US Census Bureau)

10 years since Congress established a pathway for newer, lower cost biosimilars to compete with expensive biologics

Spending on specialty drugs has gone up since 2010:



2010, the year the biosimilars pathway was created, was the first year in which spending on specialty drugs comprised

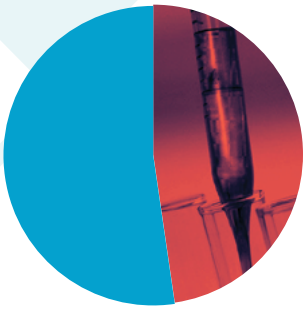
25% of total drug spend

(Express Scripts 2010 Drug Trend report)

The latest data shows

nearly half (47.7%)

of all spending on prescription drugs are for specialty drugs



(Express Scripts 2018 Drug Trend report)

ERIC commissioned first-of-its-kind research that found the increased use of biosimilars can bring significant savings to large employers and their employees and families

Companies would save an average of

$1.53 million

on infliximab if they used the biosimilar alternative*

*Assuming 100% uptake

All U.S. self-insured companies could have saved

$1.4 billion

on just two biologics in 2018 if they utilized biosimilars in their drug spend*

*Using the JHU study savings and usage rates for infliximab and filgrastim

Patients who took the biosimilar paid on average

12% (~$300) & 45% (~$600)

less out-of-pocket than those who took the biologic*

*infliximab and filgrastim, respectively

("*Biosimilar Medications – Savings Opportunities for Large Employers*" - Johns Hopkins Bloomberg School of Public Health, March 2020)

What can the public and private sectors do?

Fidelity found **more than 20** federal legislative and policy options to encourage a competitive biosimilars market

(U.S. Policies and Regulations Impacting Biosimilar Drugs)

Segal identified **four** main strategies for employers to foster greater biosimilar uptake

(*Employer Strategies for Use of Biosimilar Pharmaceuticals*)

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Biosimilar Medications – Savings Opportunities for Large Employers

A report for ERIC – The ERISA Industry Committee

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March 2020

EXECUTIVE SUMMARY

The cost of biologic therapies is a key driver behind rising health plan costs. This study analyzed biologic spending by 13 large US employers to determine the savings opportunities for those large employers and their health plan beneficiaries if biosimilars were used instead of the reference biologics. The study also extrapolated savings to all employers that self-insure health coverage and the Medicare program.

Background

Biosimilars are therapies developed to compete with biologic products if the biologic patents and other market protections have expired. Biosimilars promote competition and add therapeutic options to the marketplace, helping reduce prices. This study aimed to identify the savings that large employers, members of ERIC (The ERISA Industry Committee), and their employees and families covered under the employer's health plan, could realize if the current demand for reference biologics was replaced by biosimilars. Over 150 million Americans have health insurance coverage through their employer, making up the largest proportion of the insured population.

Methods

Based on the market availability of biosimilars, the analysis focused on two drugs: filgrastim and infliximab. These were the first two drugs to have biosimilars introduced in the US market. ERIC member companies (plan sponsors) were invited to participate in this study. Companies that chose to participate were asked to provide data on utilization and spending on biologics and biosimilars from their prescription drug benefit and their medical health plans between January 01, 2018 and December 31, 2018. Potential savings due to plan adoption of biosimilars were calculated by comparing price differences between claims for the biosimilar and the reference biologic in our sample and applying these differences to current plan spending on reference biologics. Data on rebates were not available to the researchers.

Sample

A total of 28 pharmacy benefit managers and health plans providing service to 13 ERIC member companies provided data for this study. Participating companies reported an average of 2 million claims for prescription and medical drugs, spending an average of $ 273.3 million dollars in 2018.

Findings

Spending on the two study drugs represented up to 2.7% of the typical company's annual spending on pharmaceuticals. Overall, biosimilars represented 68.8% of filgrastim claims but only 0.5% of infliximab claims, and there was marked variation in biosimilar utilization across different vendors for the same company. When matched for a series of characteristics to ensure an appropriate comparison, the biosimilar offered a median discount of 32% over the price of the reference biologic for infliximab and a median discount of 26% over the price of the reference biologic for filgrastim. Under these discount rates, the participating companies would have saved an average of $1.53 million (range: 723 thousand – 4.93 million) on infliximab and an average of $17,838 on filgrastim in 2018.

Biosimilar savings for beneficiaries in the 13 companies in terms of lower out-of-pocket costs were statistically significant due to a combination of lower frequency of coinsurance requirements and lower biosimilar list prices compared to beneficiaries taking the biologic. For infliximab, biosimilar users paid on average 12% less (about $300) and filgrastim users paid on average 45% less (about $600) out-of-pocket costs per year.

A comparison with price differentials obtained from external benchmarks - Average Sales Price and Wholesale Acquisition Cost - is presented. Across all the study and the external price metrics, biosimilar prices were lower than the biologic prices. Extrapolated to all employers who self-insure health coverage, potential savings at full biosimilar substitution could have amounted to $407 million according to a market-based methodology and up to $1.4 billion according to a company-size methodology in 2018. Potential savings to the Medicare program were estimated at $279 million in 2018.

Conclusions

This study looked at the early diffusion of the first two drugs to have a biosimilar in the US market (filgrastim and infliximab). At full biosimilar substitution on these two drugs, the companies that participated in this study could have saved, on average, $1.5 million in 2018. Biosimilar use also provided savings to the employees taking these drugs: out-of-pocket costs were significantly lower for beneficiaries taking the biosimilar when compared to beneficiaries taking the reference biologic. When extrapolated to all employers who self-insure health coverage, potential savings at full biosimilar substitution could have amounted to $407 million to up to $1.4 billion in 2018.

Rebates play a major role in biologic and biosimilar reimbursement, and the lack of information on company-specific rebates that might be paid to the pharmacy benefit manager/health plan and the self-insured company may have influenced our savings calculations. Confidential rebates are not available to the general public, but they should be made available to the plan sponsor.

For the biosimilars market to promote price competition and successfully generate savings, it is important that plan sponsors reconsider their options based on the full savings potential offered by each product. Increased transparency and greater access to information are an important first step.

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INTRODUCTION

Small Molecule Drugs – Branded Products

In order to be licensed for sale and marketing in the United States, a drug must be reviewed and approved by the US Food and Drug Administration (FDA). Conventional drugs are often called "small molecule drugs" because they tend to have small molecular size and non-complex chemical structure. When seeking FDA approval, branded "small molecule" drugs must provide evidence to ensure that the drug is safe and effective in its proposed use(s), that the drug's benefits outweigh its risks, that the drug's proposed labeling is appropriate, and that the drug's manufacturing methods are adequate.[1]

Small Molecule Drugs – Generics

A generic drug, as defined by the FDA,[1] is "a copy" of a conventional brand-name drug that has the same "active ingredient, conditions of use, dosage form, strength, route of administration, and (with certain permissible differences) labeling" but is produced by a different manufacturer.[a] In order to be FDA-approved, a generic drug must provide evidence that its chemical composition is the same as the brand-name drug and that it is "bioequivalent," meaning it "gets to the part of the body where the (branded) drug works at the same time and in the same amount".[1] Because generic drugs have lower development and approval costs, they typically offer substantial discounts – at the magnitude of 80% or more - as compared with the price of the branded drugs, even though both have the same therapeutic effects.[2]

Biologics

Biologic therapies depend on biotechnology methods to be produced, which typically involves "living systems" to be produced – such as microorganisms (e.g., bacteria), plant cells, or animal cells – and tend to be more chemically complex than non-biologic drugs.[3] Because of the complexity of biologic drugs' production mechanisms and chemical structure, biosimilars have been regulated at much higher standards than generics [Exhibit 1]

Biosimilars

Biosimilars are therapies developed to compete with biologic products if the biologic market protections have expired. Like generic drugs, biosimilars promote competition and add therapeutic options to the marketplace, helping reduce prices and offering an opportunity to bring down drug spending. Biosimilars are subject to stricter regulations and there are more barriers to the uptake of biosimilars in the US market than generic drugs, such as no automatic interchangeability.

[a] However, according to the FDA, a generic drug "may have certain minor differences from the brand-name product, such as different inactive ingredients."

The pathway for FDA approval of biosimilars in the US was created by the Biologics Price Competition and Innovation Act (or BPCIA) as part of the Affordable Care Act (ACA), enacted in 2010. Different than generic drugs, that are considered to be bioequivalent to the reference branded products, biosimilars are defined as "highly similar" to, and having "no clinically meaningful differences in safety, purity, and potency" from an existing FDA-approved reference biological product.[4] Biologic drugs depend on "living systems" such as microorganisms (e.g., bacteria)or cells, and tend to be more chemically complex than non-biologic drugs. [3] Because of the complexity of biologic drugs' production mechanisms and chemical structure, biosimilars have been regulated at much higher standards than generics [Exhibit 1].

Similarities and Differences between Biosimilars and Generic Drugs

For the approval of a non-biologic, "small molecule" generic, the FDA requires bioequivalence studies demonstrating that the generic has the same chemical composition, purity and quality as the reference product, as well as the same bioavailability in healthy volunteers.[5] Once approved for marketing, a generic becomes substitutable for the branded reference product at the pharmacy without the need for a new medical prescription.

In contrast, for the approval of a biosimilar, the FDA requires a series of studies, such as analytical (in-vitro) studies demonstrating "highly similar" chemical composition to the reference product, purity and quality; toxicity studies on animal models; and comparative clinical studies on patients with the clinical condition, demonstrating that the safety and effectiveness of the biosimilar product, its immunogenicity, and its pharmacokinetics and pharmacodynamics are expected to be the same as the reference biologic.[6]

Differently than generic drugs, biosimilars do not become directly substitutable for the reference product upon approval. While a patient holding a prescription for a branded product may be dispensed the generic, a patient who is prescribed the reference biologic needs a new prescription from their medical provider if they would like to get the biosimilar instead.[b] The direct substitutability for the reference product is only granted to a biosimilar product if the manufacturer of the biosimilar carries out a specific type of clinical trial – often called a "switching study"- where patients with the clinical condition treated by the drug are exposed to the reference product, the biosimilar, and again the reference product in a sequence, and monitored for clinical effectiveness and safety.

In addition to the lack of substitutability for the reference products, there are many other barriers to the use of biosimilars in the US market. Different than conventional branded and generic drugs, biosimilars and biologics do not share the same non-proprietary name (proper name, or "generic" name). [7, c] This difference contributes to generating confusion among prescribers, pharmacists, and patients.[8] Disinformation and uncertainty about biosimilars is often reflected in patients and providers' reluctance to switch products.[9] Lastly, price negotiations that rely heavily on drug rebates and discounts may favor the utilization of the biologic over the biosimilar. [10]

[b] Pharmacists often perform this function via a call to the physician, so the patient may not necessarily need to take action in order to obtain the new prescription.

[c] Until March 2020 all biosimilars had a random 4-letter suffix added to their non-proprietary names. After March 2020 all biologics, including reference products and biosimilars, will have different, random 4-letter suffixes added to their non-proprietary names.

Biosimilars Today

There are 26 biosimilars approved for sale in the US market today [Exhibit 2]. [11] Despite so many approved products, only a few biosimilars are actually available in the market. Many approved biosimilars have not been launched because of patent disputes and other legal challenges between the manufacturer of the reference product and the manufacturer of the biosimilar. To date, only two drugs have had more than one biosimilar launch in the US market: filgrastim and infliximab. These drugs have seen their first biosimilars offer about 15% list price reductions over the reference biologic. [12] However, as is common in the pharmaceutical industry, the list price may have little relation to the actual transaction price. The market entry of the second biosimilar has been associated with more substantial price decreases. [Exhibit 3].

In spite of the multiple barriers, the Congressional Budget Office (CBO) has estimated that the use of biosimilars could generate savings of about $25 billion over 10 years, roughly 0.5 percent of national spending on prescription drugs. [13] Some of the assumptions regarding the biosimilars market come from the European experience. The European Medicines Agency established a pathway for the regulation of biosimilar drugs six years before the FDA. There are over 70 biosimilar drugs currently available in the European market with widespread utilization, generating millions in savings. [14] The RAND corporation estimated that biosimilars could reduce spending in the US market by $54 billion from 2017-2026.[15] Several other studies have followed, demonstrating a potential for cost savings from biosimilars to both patients and plan sponsors in the US. [16-19] Because biologics represent a large source of drug expenditures in the US today, biosimilars represent a significant opportunity to reduce costs. However, it is unclear what are the actual savings from biosimilars in practice in the US.

Opportunities for Employers that Self-Insure Health Coverage

About half of Americans who have health insurance today receive their coverage through their employer.[20] Large employers generally do not purchase health insurance for their employees, but rather offer health coverage through a self-insured health plan.[21] Of US employers offering health insurance, the majority (61%) offers health coverage through a self-insured health plan.[21] All ERIC member companies sponsor self-insured health plans for their employees. Some also purchase health insurance in certain circumstances, such as for small populations of employees in a geographic area. The cost of biologics is equally challenging in the case of purchased health insurance but not addressed in this study.

Employers that self-insure their health coverage bear the risk of losses in their health insurance pool. Therefore, significant increases in their pharmaceutical cost raise the need for an offset elsewhere, often resulting in increased premiums or cost-sharing for employees. Responsible management including measures to control drug costs is important in order to preserve employees' benefits while preventing premium and cost-sharing increases. This is especially important to workers enrolled in high-deductible health plans (HDHPs), who bear the burden of high drug prices even more directly.

Most employers with self-insured health plans contract with a pharmacy benefit manager (PBM) to manage their prescription drug benefit, i.e. manage the coverage of drugs used in an outpatient setting. Most self-insured employers also contract with at least one medical health plan vendor to manage their medical benefit, i.e., the coverage of medical services. The medical benefit includes doctor visits, hospitalizations, and procedures, including drugs administered in a medical setting - for example, drugs that require an intravenous infusion in a physician practice or in a hospital outpatient department. It is common for a self-insured employer to contract with multiple health insurance carriers in order to offer a choice of multiple health insurance plans for their employees.[d]

In both the prescription and the medical benefit, drug coverage is typically determined by a drug formulary. Usually, the PBM sets the drug formulary for the prescription benefit, determining the drugs to be covered for outpatient use and the medical health plan vendor sets the drug formulary for the medical benefit determining the drugs that will be covered in the medical setting. While designing the formulary, the PBM or the medical carrier simultaneously negotiates the prices of the drugs that will be covered. Usually, the pharmaceutical manufacturers will provide price concessions (discounts and rebates) for the opportunity of placing their drug in the formulary.[22]

The drug formulary lists the drugs that will be covered and specifies the requirements that are in place in order to access the drug. For example, whether a drug requires the doctor to submit clinical information in order to obtain a special authorization from the plan ("prior authorization"). In addition, the drug formulary specifies how much cost-share the beneficiary is required to pay in order to access the drug. There are two main types of cost-share: a "copayment," in which the patient is required to pay a fixed-dollar amount for each prescription, or a "coinsurance," in which the patient is required to pay a percentage of the drug cost of each prescription.

When patients are required to pay a coinsurance, the amount is calculated over the list price of the drug. This means that, even if the PBM or the medical plan vendor was able to negotiate a lower drug price for the plan sponsor, the beneficiary may not benefit from that price negotiation. The drug's list price is typically the highest price of a drug, and because of price negotiations, no plan sponsor ever actually pays the list price. However, beneficiaries may face the drug's full list price when they are required to pay a coinsurance, when the level is often based on the list price, or when they are in the deductible phase, when they are required to pay the list price in full for their drugs. This is a problem especially for beneficiaries enrolled in HDHPs, where they are required to pay full list price until their high deductible is met. As of 2018, this represented 29% of workers with private health insurance. [21]

Study Aims

The goal of this study was to assess the savings that large employers, members of ERIC (The ERISA Industry Committee), and their employees and families covered under the employers' plans, could obtain if the current usage of the reference biologics was replaced by biosimilars. First, we sought to identify the extent to which the company's beneficiaries were being treated with reference biologics or

[d] In certain cases, the medical health plan vendor may also manage the outpatient prescription drug benefit, in which case the self-insured employer will not directly contract with a PBM ("carve-in" model).

with biosimilars in practice. Next, we estimated the potential savings that could be obtained if the beneficiaries that were treated with a reference biologic had been treated with a biosimilar instead.

METHODS

Data Sources

ERIC member companies (plan sponsors) were invited to participate in this study. Companies that chose to participate were asked to provide data on utilization and spending on biologics and biosimilar drugs from their prescription drug benefit and their medical health plan benefit. Because each self-insured plan sponsor could contract with multiple vendors (PBMs and/or medical insurance carriers) to manage their health insurance plans and drug benefit ("data donors"), each participating company could provide more than one source of data.

Time Frame

All information reflected the plan sponsors' spending and utilization between January 1, 2018 and December 31, 2018.

Study Drugs

Based on the market availability of biosimilars, the analysis focused on two drugs: filgrastim and infliximab. These were the first two drugs to have biosimilars introduced in the US market. Because each of these drugs had two biosimilars available in the market at the onset of this study, the analysis included a total of six different products [Exhibit 4]. It is important to mention that the savings are likely to be greater when there are two or more biosimilars on the market.[23]

For infliximab, the analysis included the reference biologic Remicade® and the biosimilars Inflectra® and Renflexis®. The reference biologic was launched in the US market in 1998 and has eight FDA-approved indications. The biosimilars were launched in the US market in 2016 and 2017 respectively and are FDA-approved for the same indications as the reference product. Infliximab is mainly used as an immunosuppressant to treat patients with auto-immune conditions, such as rheumatoid arthritis, Crohn's disease, ulcerative colitis, and others.

For filgrastim, the analysis included the reference biologic Neupogen®, the biosimilar Zarxio®, and the alternative biologic Granix®. The reference biologic was launched in the US market in 1991, and the biosimilar was launched in 2015. A second biosimilar (Nivestym®) was launched in 2018, but there was no utilization for these products recorded by the participating companies, and therefore it was not part of the study. The alternative biologic was approved before the biosimilars pathway was fully implemented, and therefore it was never designated as a biosimilar. Filgrastim is an adjunctive treatment for patients undergoing chemotherapy. Filgrastim works by stimulating the production of

blood cells, and therefore, is also used in other conditions where blood cell counts are too low. The reference product has six FDA-approved indications, and the biosimilar is approved to treat five of them (the indication that is not approved for the biosimilar is a very rare condition where patients have symptoms after being exposed to acute radiation). The alternative biologic is only approved to treat one of the six reference product indications. Yet, it is widely used in clinical practice as a competitor to the reference product, [24] and therefore in this study we treated it as a biosimilar.

Data Collection

Data collection was performed using a standardized data collection template that aggregated information at the drug level. The goal was to perform an apples-to-apples comparison. For each drug, the following information was collected: total number of users, total number of claims, total spend, average age of the users, percentage of users who were female, type and level of cost-share required from the beneficiaries to access the drug, average out-of-pocket costs to beneficiaries, and the clinical conditions for which each drug was prescribed. Because the data was collected in aggregated form per drug, no patient information was collected. In addition to the drug-specific information, participating companies were requested to report their overall number of beneficiaries and pharmaceutical benefit spend.

Data Analysis

The data analysis was implemented through a series of descriptive statistics, regression models, and graphics using Stata statistical package version 15 (StataCorp, College Station, TX). Most descriptive statistics were aggregated at the level of company (plan sponsor) or vendor (data donor). When applicable, data was weighted by number of claims or number of users of each product.

Savings Calculations

Potential savings due to plan adoption of biosimilars were calculated by comparing price differences between the biosimilar and the reference biologic and applying these differences to current plan spending on reference biologics. We estimated savings to plan sponsors under two scenarios: 100% adoption of biosimilars (if all beneficiaries who took the reference biologic in 2018 had taken a biosimilar instead), and 50% adoption of biosimilars (if half of the beneficiaries who took the reference biologic in 2018 had taken the biosimilar instead).

The price comparison between biologic and biosimilar was implemented by comparing the negotiated prices for each drug from the claims data in our sample. The goal was to allow for an apples-to-apples comparison. The comparison matched the price per claim paid for the biosimilar and biologic with the same active ingredient, dosage form and strength, within the same plan sponsor (ERIC member company) and data donor (medical or prescription benefit vendor). The matching technique was needed because negotiated prices for drugs vary according to the drug's market share, and there was a very large variation in market share for biologics and biosimilars between data donors from the same company and across participating companies. In addition, the price comparisons included only drugs

where claims for the biologic and biosimilar contained a similar number of units and where the vendor had reimbursed at least one claim for the reference biologic and all corresponding biosimilars over the course of the year. This strict comparison approach was intended to capture prices that could actually be compared. Namely, the strategy aimed to exclude vendors where the reference product placed a "rebate wall", i.e., where the payor was contractually required to purchase exclusively the biologic in exchange for deep price concessions.[10] Contractual terms and price concessions are not observable, which may have limited the inferences from our analysis. Rebates play a major role in biologic and biosimilar reimbursement, and due to the lack of information on company-specific rebates that might be paid to the PBM/medical vendor and the self-insured company, our potential savings estimates should be viewed as minimum levels of rebates to achieve cost parity between biosimilars and biologics.

Lastly, the out-of-pocket differences observed between employees taking the biosimilar and the biologic in our sample were also used to estimate how much employees would have saved if the beneficiaries who took the biologic had switched to the biosimilar instead.

Sensitivity Analysis: Accounting for Drug Rebates

The negotiated prices of drugs in our sample reflect negotiated discounts but do not account for rebates provided by drug manufacturers. Drug rebates are typically realized months after each claim is finalized and are not necessarily traceable back to each claim. For example, drug rebates may be negotiated as a "bundle" and depend on the market share of other drugs in the manufacturer's portfolio, not only the drugs of interest in this study. Rebates are negotiated at the contractual level with each benefit vendor and plan sponsor and are, therefore, confidential information. Companies in the study may know this information for their company.

To assess the robustness of our results, a sensitivity analysis was implemented in two steps. First, we compared the price differentials obtained by our original matching criteria (strict criteria) to the price differential obtained across all biologic and biosimilar pairs within the same company (plan sponsor) and benefit vendor, as long as the drugs were matched by active ingredient, dosage form, and strength.

Next, we compared the study results to two external price benchmarks: Wholesale Acquisition Cost (WAC), a measure of drug prices that does not account for any discounts or rebates [25] and Average Sales Price (ASP), a calculated price defined in regulation by the Medicare program that reflects the "weighted average of all manufacturer sales prices" and includes all rebates and discounts that are privately negotiated between medical and prescription benefit vendors and drug manufacturers.[e] The ASP methodology is presumed to mirror the reimbursement for physician-administered drugs in the commercial market and it is calculated by CMS.[26] All price comparisons were implemented for biosimilar and reference biologic drugs matched by the same active ingredient, dosage form, and strength.

Extrapolating Savings

An extrapolation of savings to other employers that self-insure health coverage was implemented in two ways. First, the savings were extrapolated by multiplying the savings found in our sample of 13

[e] Medicaid and certain federal discounts and rebates are exempted from the ASP calculation.

companies by the inverse of the proportional ratio of the self-sponsored employer health insurance market represented by the participating companies. Second, we used publicly available 2018 sales data for each of the biologics under study (Remicade® and Neupogen®).[27,28] We assumed that employers represented 50% of the market for these drugs, and that self-insured employers represented 61% of the employer-sponsored health insurance market. We then applied the biosimilar discount ratios found in this study to the estimated self-insured employers' spending on each of the biologics.

An extrapolation of savings to the Medicare program was implemented by applying the discount ratio between the biosimilar and the biologic using ASP prices to Medicare's total spending on the biologic in 2018. Because the Medicare Part B program accounts for over 95% of infliximab utilization and over 80% of filgrastim utilization, the Medicare savings were calculated for the Part B program only. ASP prices were obtained from the July 2018 CMS Payment limit[29] and Medicare utilization and spending rates were obtained from the 2018 CMS Medicare Drug Spending Dashboard & Data.[30]

Confidentiality and Data Protection

The identity of the participating companies and their vendors was kept confidential. When required, non-disclosure agreements were established for data transfer. The study was exempt from review by internal review boards because it did not constitute human subjects research.

RESULTS

Overview of data sources and participating companies

A total of 13 companies participated in this study, representing a diverse set of industries, ranging from the food and beverage to the technology industry [Exhibit 5]. Most companies were in the technology sector, followed by the financial sector.

Reflecting the multiple different benefit packages provided by the participating companies, a total of 28 different data sources were included in the study ("data donors"). Some were health insurance plans providing medical benefits while others were PBMs providing prescription drug benefits. All companies that participated provided PBM data. Out of the thirteen companies that participated, two companies provided PBM data only; seven companies provided data from their PBM plus one medical health insurance vendor; and four companies provided data from their PBM plus two medical health insurance vendors.

Data donors (i.e., the different vendors of prescription and medical benefits who provided data for this study) included the three largest PBMs (which together comprehend more than 80% of the US prescription drug benefit market), [23] as well as a variety of major medical insurance carriers.

Participating companies reported an average of 174.8 thousand beneficiaries in 2018 (minimum of 21 thousand and maximum of 484 thousand beneficiaries). These companies reported an average of 2 million claims for prescription and medical drugs, spending an average of $273.3 million dollars (minimum $290 million and maximum $569 million) in 2018 [Exhibit 6].

Study Drugs: Utilization and Spending Overview

These are expensive drugs, but these drugs are not used by many patients in the employed population. The study drugs (infliximab and filgrastim) were used by an average of 186 users in each company in 2018 (minimum 18 and maximum 683 users). These drugs generated an average of 1,176 claims and average spending of $4.7 million (range: $288 thousand to $16.6 million) [Exhibit 7].

Patients using the study drugs varied in age between 9.7 years and 74 years old. On average, a patient using the study drugs was 48.7 years old. About 55% of users were women (minimum 26% - maximum 81%). Although the users represented a small minority of the overall beneficiaries in these companies (on average, only 0.06%), the spending on these two drugs represented up to 2.7% of the typical company's total spending on pharmaceuticals during the year 2018.

Most of the utilization and most of the spending occurred through the medical benefit – on average, 83% of all claims and 86% of the spending was channeled through the medical health plan vendors, and only 17% of claims and 14% of spending through the prescription benefit vendors. This is because the drugs are typically physician administered drugs and are paid under the medical benefit.

Comparison: Infliximab vs. Filgrastim

Infliximab had greater utilization and spending than filgrastim. Overall, companies spent an average of $4.8 million on infliximab in 2018 (range: $226,417 to $15.6 million) and an average of $254,486 on filgrastim (range: $8,776 to $983,607) [Exhibit 8a].

Infliximab was used by more beneficiaries and cost more per claim than filgrastim. On average, infliximab was used by 172 beneficiaries per company (range: 10 - 534 beneficiaries), while filgrastim was used by 59 beneficiaries per company (range: 1 - 198 beneficiaries). Each claim for infliximab costed the plan sponsor an average of $4,762, while each claim for filgrastim cost, on average $903. In total, each beneficiary using infliximab cost the plan sponsor an average of $28,111.83, while each beneficiary using filgrastim cost the plan sponsor an average of $4,550.65 [Exhibit 8b-d].

Comparison between Biologics and Biosimilars: Overall Utilization and Spending

The utilization of biosimilars varied considerably by drug. Overall, 68.8% of filgrastim claims went to buy the biosimilar[f] but only 0.5% of infliximab claims went to the buy the biosimilar [Exhibit 9].

For the same drug, the share of biosimilar utilization varied across the different data donors [Exhibit 10a-b]. Most of the vendors for infliximab had less than 1% of utilization for the biosimilar (16 out of 26 data donors had 0% biosimilar utilization), but for one vendor the biosimilar represented a total of 5.15% of infliximab claims. Although for filgrastim the biosimilar had much greater utilization, there were still three vendors for which the biosimilar represented 0% of all filgrastim claims. All other

[f] We treated the alternative biologic tbo-filgrastim (Granix®) as a biosimilar for the purposes of this analysis. A sensitivity analysis excluding this drug did not significantly change the results.

vendors for filgrastim had at least 30% of claims for the biosimilar, with 3 vendors reporting 100% of the filgrastim claims for the biosimilar.

Because plan sponsors contracted with multiple vendors, there was significant variation in the percentage utilization of biosimilars across different vendors for the same plan sponsor [Exhibit 11a-c] For the same drug and same company, the differences between vendors could be as striking as having one vendor at 0% biosimilar utilization and the other vendor at 100% biosimilar utilization, which occurred in the case of filgrastim. This is important because utilization determines the price concessions that manufacturers will provide on their drugs. Therefore, such striking differences in utilization mean that vendors may be offering strikingly different prices on the same drugs for their plan sponsors.

Comparison between Biologics and Biosimilars: Patient Characteristics

Overall, patients using the biosimilar tended to be older than patients using the biologic for both study drugs [Exhibit 12a-b]. A greater percentage of women tended to take the biosimilar rather than the biologic infliximab, but a lower percentage of women tended to take the biosimilar rather than the biologic filgrastim. While these differences are statistically significant, their meaning is unclear. It is likely that, to some extent, these differences reflect the conditions that the different products were being used to treat.

When analyzing the conditions that the drugs were prescribed for, we found that the biologic and the biosimilar were similarly likely to have been prescribed to treat an off-label condition (about 10% for all drugs) [Exhibit 13a-b]. The exception was the alternative biologic tbo-filgrastim (Granix®), which was used to treat an off-label condition in over 50% of cases. This suggests that the alternative biologic Granix® may be prescribed for more indications than the one indication that it is approved to treat, likely behaving in clinical practice as a competitor for the reference biologic in more cases than its one approved indication would indicate.

It is also possible that the differences in patient characteristics may reflect different uptake patterns by prescribers treating certain conditions, or different acceptability patterns of patients who have certain conditions. Rheumatoid arthritis for example, one of the main indications of infliximab, is a condition that predominates among women. If rheumatologists were more amenable to prescribing the biosimilar, or if rheumatoid arthritis patients were more likely to accept the biosimilar, this pattern would be consistent with the results that we obtained. Our data, however, does not allow us to investigate such relationships. We are also not able to examine whether the venue where patients are treated might have influenced the product utilization.

Most likely it is payment and billing practices that differ across hospitals and physician practices, favoring one or the other product. Rebates to physicians and hospitals may be greater for the biologic or biosimilar depending on the negotiation. Or, a certain type of facility may be under different contractual terms with the benefit vendor allowing it to charge more or less for the biologic or the biosimilar. If one patient population were treated more frequently in a certain type of venue, this could also influence the demographic differences that we observed.

How are Patients Paying for their Biologics and Biosimilars? A comparison of out-of-pocket spending

Overall, the majority of patients are required to pay a coinsurance in order to obtain both of the drugs in our study. Patients utilizing biosimilars tended to be required coinsurance less frequently than patients utilizing the reference biologic for both drugs, infliximab (76.7% for biosimilar vs. 85.4% for biologic on average) and filgrastim (90.8% for biosimilar vs. 95.2% for biologic, on average), but this difference was only statistically significant in the case of filgrastim [Exhibit 14a-b]. When required a coinsurance, the percentage of the cost of the drug did not vary between biologics and biosimilars, being on average about 20% for infliximab products and 22% for filgrastim products.

Overall, patients taking the biosimilar had lower out-of-pocket payments than patients taking the biologic, over the course of the year 2018. Infliximab biologic users paid on average $2,890.27 in out-of-pocket costs and biosimilar users paid on average $2,533.20 over the course of the year (p=0.056). This means that biosimilar users paid about $330 less out-of-pocket than biologic users over the course of the year, on average, a difference of about 12%.

Filgrastim biologic users paid an average $1,319.87 out-of-pocket, while biosimilar users paid on average $721.01 over the course of the year 2018, a difference that was statistically significant (p<0.0001). This means that biosimilar users paid almost half out-of-pocket cost than biologic users, a difference of about $600.

A combination of lower frequency of coinsurance requirements and lower biosimilar list prices is likely to have explained the differences that we found. While most plan sponsors tend to have out-of-pocket maximums in place, the information on out-of-pocket costs collected in this study reflects true payments incurred by the beneficiaries and therefore suggests that these expenditures were lower than the maximum.

It is important to mention that our data does not contain information on whether the patients received coupons or used patient assistance programs to help pay for their drugs. Coupons and patient assistance programs are designed to help patients afford prescription drugs by reducing their out-of-pocket costs.[31] If patient assistance programs or coupons were available to some, but not all products or patients examined in our study, they might have differentially influenced our findings.

Price Comparison between Biologics and Biosimilars

The price comparison was implemented comparing the median price differential across drugs within the same data donor and plan sponsor, matching biosimilar and reference biologics with the same active ingredient, dosage form and strength, where the claims for the biosimilar and the reference biologic had a similar number of units and where the data donor had at least one claim for the biologic and for the corresponding biosimilars during the year 2018. This matched price comparison included a total of two drug pairs for infliximab and seven drug pairs for filgrastim. **The comparison found that, when matched for all characteristics, the biosimilar price represented 68% of the price of the biologic for infliximab and 74% of the price of the biologic for filgrastim. [Exhibit 15].** This means that the biosimilar offered a

median discount of 32% over the price of the reference biologic for infliximab and a median discount of 26% over the price of the reference biologic for filgrastim.

Savings calculations: How much could plan sponsors save by increasing biosimilar utilization?

Under the estimated discounted rates described above, the participating companies would have saved an average of $1.53 million (range: 723 thousand – 4.93 million) on infliximab and an average of $17,838.01 (range: $2,281.76 – $ 87,801.74) on filgrastim during the year 2018 [Exhibit 16 a-b].

Company-specific savings depended mostly on two dimensions: the number of beneficiaries utilizing each drug, and the percentage of biosimilar use currently achieved by the company. Companies with low drug utilization had the lowest savings and companies with large utilization and low biosimilar market share had the highest estimated savings [Exhibit 17a-b].

Sensitivity Analysis

Relaxing the matching criteria that we utilized to estimate the price differentials in our study, we compared the median price differential across all drug pairs from the same data donor and plan sponsor, as long as the biosimilar and the reference biologic had the same active ingredient, dosage form and strength. This approach yielded a total of eight drug pairs for infliximab and 29 drug pairs for filgrastim. **In this approach, the biosimilar price represented 75% of the price of the biologic for infliximab and 84% of the price of the biologic for filgrastim. [Exhibit 18 a-b].** This means that the biosimilar offered a median discount of 25% over the price of the reference biologic for infliximab and a median discount of 16% over the price of the reference biologic for filgrastim.

The comparison with external price benchmarks found that, for infliximab, the biosimilar price was, on average, 23% lower than the biologic according to the ASP, and 19% lower than the biologic according to the WAC. For filgrastim, the biosimilar price was, on average, 36% lower than the biologic according to the ASP, and 17% lower than the biologic according to the WAC [Exhibit 19 a-b].

Across all internal and external metrics, biosimilar prices were lower than the biologic prices. Although our study results did not account for rebates, they have the same direction suggested by the ASP calculation. Given the wide variation in utilization and market share of products that we identified in our sample, it is likely that companies may be obtaining a wide range of price differentials. The level of rebates may not be disclosed to the general public, but they should be made available to the plan sponsor.

Savings Extrapolation to All Employers that Self-Insure Health Coverage

The 13 companies that participated in this study represented 1.5% of the US employer-sponsored health insurance market.[21,22] Assuming that all employers that self-insure health coverage had the same utilization pattern than the companies that participated in this study, and that all employers that self-insure health coverage were to achieve 100% biosimilar substitution, the savings to all on the two study drugs obtained through our first extrapolation approach would amount to a total of $1.4 billion in 2018.

It is important to note that this study found a large variation in the savings per each participating company; therefore, this estimate may not accurate reflect the potential savings.

Through our second, market-based savings extrapolation approach, we estimated the US employer-sponsored insurance market to be approximately half of the US market of Remicade® and Neupogen®. We then estimated that self-insured employers represented 61% of the US employer-sponsored insurance market. Applying the biosimilar discount rates found in our study to the estimated market size of these two drugs, the potential savings to all employers that self-insure health coverage would amount to a total of $407 million in 2018.

Savings Extrapolation to the Medicare Program

In 2018, the Medicare Part B program had 65.2% biosimilar utilization for filgrastim and 10.7% biosimilar utilization for infliximab. At 100% biosimilar utilization, and assuming discount rates of 23% for infliximab and 36% for filgrastim as estimated based on ASP prices, the Medicare Part B program could have saved a total of $279 million in 2018 ($264.4 million on infliximab and $14.5 million on filgrastim).

DISCUSSION

This analysis included 13 of America's largest employers offering self-insured health coverage to their nationwide workforce and the many prescription drug and medical health insurance plan vendors with whom these companies contract in order to manage the benefits that they offer to their employees and families.

The study examined two specific drugs – filgrastim and infliximab – that were the first drugs to have biosimilars in the US market. We found that these drugs were used by a very small percentage of the companies' beneficiaries but accounted for up to 3% of the companies' overall drug spending. One drug in particular – infliximab – had the most utilization and spending. This drug is also where the lowest biosimilar utilization occurred – in most companies, less than 1% of all infliximab claims were dispensed with a biosimilar product - and therefore presented the largest opportunity for savings.

The savings to plan sponsors were estimated at an average of $1.53 million dollars per year (range: $723 thousand to $4.93 million) on infliximab alone, if all the current biologic utilization had been replaced by the biosimilar. At 50% substitution rate, plan sponsors could save close to a million dollars a year on this one single drug. Savings on the second study drug (filgrastim) were much more modest, due to much lower utilization, lower price, and higher current biosimilar market share (average of 68% of biosimilar utilization across all participating companies).

When the biosimilar discount rates estimated in this study were extrapolated to all employers that self-insure health coverage, the potential savings amounted to $407 million according to a market-based methodology, and up to $1.4 billion according to a company-size methodology. The Medicare Part B program had greater biosimilar utilization in 2018 and different estimated discount rates based on ASP prices; when extrapolated to the Medicare Part B program, savings from full biosimilar substitution for the two drugs in this study would have amounted to a total of $279 million in 2018.

While the price comparisons and savings estimates reflected prices negotiated on behalf of plan sponsors by their prescription drug benefit managers and medical health insurance plan vendors, these analyses did not account for confidential drug rebates that are passed on to the plan sponsor according to the market share and formulary placement of each drug. Yet, our estimates provide an assessment of the minimum levels of rebates that should be offered by reference biologic manufacturers to achieve cost parity between biosimilars and biologics.

In addition, the comparisons between our estimates and other price benchmarks – drug list prices before rebates and discounts, and CMS-calculated average sales prices that account for both rebates and discounts – suggest that our estimates may reflect true price relationships and realistic potential savings under the different substitution rates scenarios.

Of note, none of the discounts or rebates that get negotiated on behalf of plan sponsors are available to beneficiaries. Up to 95% of beneficiaries taking the study drugs were requested to pay a percentage of the drug's price in order to obtain the drugs they needed. Our analysis showed that beneficiaries taking the biosimilar have statistically significantly lower out-of-pocket spending than beneficiaries taking the reference biologic. Because out-of-pocket payments are calculated over the drug's list price, before rebates and discounts, our findings suggest that beneficiaries will be better-off by utilizing a biosimilar. In the case of filgrastim, the out-of-pocket spending of beneficiaries taking the biosimilar was, on average, 45% lower than the out-of-pocket spending of beneficiaries taking the biologic.

Although our study did not obtain patient-specific information, the aggregated characteristics of the beneficiaries taking each product suggested that beneficiaries taking the biosimilar tend to be older than those taking the biologic, in both study drugs. Biosimilar utilizers tended to be more frequently female in the case of infliximab and more frequently male in the case of filgrastim as compared to the biologic utilizers. Although these differences are statistically significant, their meaning could not be further explored given the nature of the data collected in this study. It is likely that these characteristics may reflect health conditions, patient preferences, physician prescribing practices, or the characteristics of the locations where patients receive care and may be more conducive to the use of one over the other product. It is important that such factors be explored by further studies focusing on patient and provider behavior, and on facility purchasing and reimbursement practices.

There was no significant difference in terms of off-label utilization between biologics and biosimilars except for the biologic alternative Granix® (tbo-filgrastim). This drug is approved for only one out of the reference biologic's six indications, and yet it seems to behave as a competitor to the reference biologic in more clinical situations than the FDA-label would allow. Different than the other products, whose off-label use represented about 10% of cases, Granix® was used for an off-label indication in more than half of patients. This behavior is one of the reasons why Granix® was treated in our study as a biosimilar when implementing the statistical analyses.

Drug price negotiations in the US depend heavily on drug rebates and discounts that are negotiated confidentially between the plan sponsor (represented by the PBM or insurance carrier) and drug manufacturers.[32] Information on rebates and discounts is not public, therefore it is possible that the true difference in price between the reference biologic and their biosimilar(s) may be higher or lower than the estimates found in our study. Confidential rebates are defined in contractual provisions between each plan vendor (PBM or health insurance carrier) and drug manufacturers. These contractual

arrangements are not available to the general public, but they should be made available to the plan sponsor.

Coupons and patient assistance programs are also available to patients with employer-sponsored health insurance. These programs are designed to help patients afford prescription drugs by reducing their out-of-pocket costs. However, these programs are more likely to cover expensive specialty drugs and branded drugs than the corresponding generics or less expensive therapeutic alternatives.[31] It is possible that the availability of coupons or patient assistance programs also may influence patients' or providers' choice of product, for example, if these programs were more likely to cover the biologic over the biosimilar. This question, however, is beyond the scope of our study.

Our study found that there was a large discrepancy of biosimilar market share between different vendors for the same company. This means that the likelihood of a beneficiary receiving a "better deal" in their drug benefit does not depend on the company that they work for, but rather, on their choice of health plan or drug benefit carrier. In addition, a large variation in biosimilar market share for the same company is inefficient. Most drug savings depend on the size of the market share. Companies whose market share is fragmented across multiple products may not be benefitting from all the savings that they could, as our empirical price comparisons have showed. However, they may benefit from the volume of their PBM or medical plan vendor.

The striking differences in number of users, drug prices, plan spending and biosimilar market share across the two drugs in our study (filgrastim and infliximab) are reflective of the multiple factors that determine drug utilization and biosimilar market penetration. While there are important clinical differences between these two drugs – filgrastim being for used in recurrent occasions and having clear biomarkers to monitor its effect, for example, while infliximab is a drug for chronic use without good biomarkers to monitor its benefits – it is likely that non-clinical factors also play an important role in determining biosimilar uptake. For example, payment systems that rely on high rebates may favor the more expensive biologic rather than the cheaper biosimilars.[33] At their extreme, such reimbursement incentives may generate "rebate traps" where the plan sponsor will be better-off by purchasing the reference biologic exclusively,[10] a choice that penalizes beneficiaries with higher out-of-pocket costs as our study has shown.

It is also possible that the difference between the two drugs reflects different levels of maturity in the biosimilars market. While filgrastim was the first drug to have a biosimilar introduced in the US market and has had two biosimilar competitors in the market for the last five years, infliximab biosimilars had been available for little over a year at the beginning of our study period. It is possible that, as the infliximab market matures, the market uptake of the biosimilar may increase.

The entry of competitors in markets where the reference products have lost patent protection is intended to bring costs down and offer greater therapeutic choices. For the biosimilars market to promote price competition and successfully generate savings, it is important that plan sponsors reconsider their options based on the full savings potential offered by each product. Having access to this information requires that plan sponsors be allowed to know and be able to audit all the contractual arrangements between their PBM and health insurance benefit vendors and drug manufacturers. Plan sponsors may increase the efficiency of their price negotiations and achieve substantial savings for their organizations as well as their beneficiaries. Increased transparency and greater access to information are important first steps.

CONCLUSIONS

This study looked at the early diffusion of the first two drugs to have a biosimilar in the US market (filgrastim and infliximab). The bottom line is that when matched for all characteristics, the biosimilar price represented 68% of the price of the biologic for infliximab and 74% of the price of the biologic for filgrastim, and patients who took the biosimilar paid on average 12% and 45% less out-of-pocket than those who took the biologic, respectively.

At full biosimilar substitution on these two drugs, the companies that participated in this study could have saved, on average, $1.5 million in 2018. When extrapolated to all employers who self-insure health coverage, potential savings at full biosimilar substitution could have amounted to $407 million to up to $1.4 billion in 2018.

Rebates play a major role in biologic and biosimilar reimbursement, and the lack of information on company-specific rebates that might be paid to the pharmacy benefit manager/health plan and the self-insured company may have influenced our savings calculations. Confidential rebates are not available to the general public, but they should be made available to the plan sponsor.

For the biosimilars market to promote price competition and successfully generate savings, it is important that plan sponsors reconsider their options based on the full savings potential offered by each product. Increased transparency and greater access to information are an important first step.

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Exhibit 1. Comparison between the regulatory requirements for approval of biosimilars and generic drugs in the United States

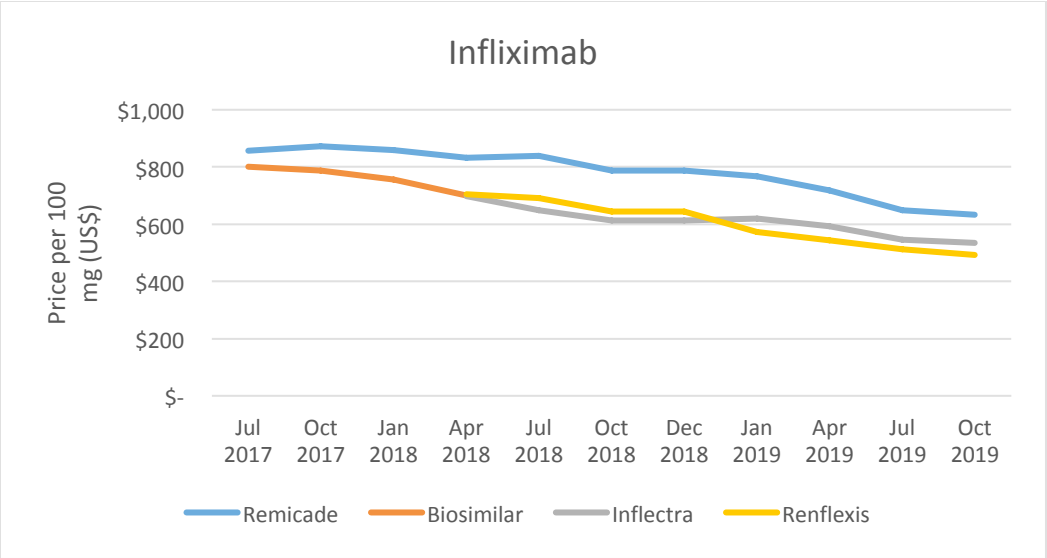
Drug	Biosimilars	Generic Drugs ("Small Molecule")
Approval Pathway Regulation	Biologics Price Competition and Innovation Act (2010)	Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act) (1984)
Approval Requirements[1]	• Analytical (in-vitro) studies: demonstrate "highly similar" chemical composition to the reference product, purity & quality • Toxicity studies on animal model • Comparative clinical study on patients with the clinical condition: demonstrate safety & effectiveness, assess immunogenicity, pharmacokinetics & pharmacodynamics	• Bioequivalence studies: demonstrate same chemical composition, purity and quality as the reference product, & same bioavailability in healthy volunteers
Criteria for allowing for the drug to be substitutable for the reference product by the pharmacist without the intervention of the prescriber[2]	• Fulfillment of all criteria for biosimilarity; plus: • Clinical "switching" studies: demonstrate same clinical result in any given patient; demonstrate that risk from switching is not greater than using reference product alone	• Automatically granted upon fulfillment of bioequivalence criteria described above
Non-proprietary naming of product[3]	United States Adopted Names Council (USAN)-designated proper name of the biologic *plus* a four-letter suffix devoid of meaning	Same USAN-designated proper name as the reference drug

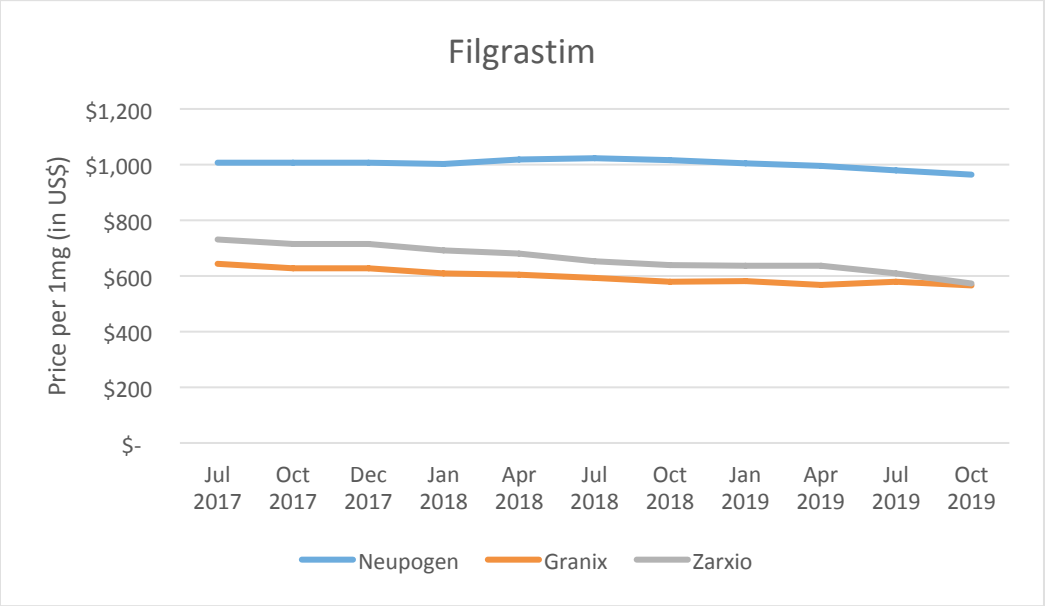
Notes: [1]. The specific studies required for biosimilar approval may vary on a case-by-case basis; [2]. This property is called "interchangeability" in the case of biosimilars. As of March 2020, these rules will not apply to biosimilar insulins. [3]. The non-proprietary names of all reference biologics approved by the FDA on or after March, 2020 will *also* contain a four-letter suffix devoid of meaning, which will be different than the suffix of their biosimilars. Exhibit adapted from Socal, Garrett, Tayler, Bai & Anderson "Naming Convention, Interchangeability, And Patient Interest in Biosimilars" - article forthcoming on *Diabetes Spectrum*, 2020. Source: Food and Drug Administration. https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda; https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products#biosimilar.

Exhibit 2. Overview of FDA-Approved Biosimilars as of December, 2019

Brand Name	Non-Proprietary Name	Product Type	FDA Approval Date	US Market Launch Date
Neupogen	**Filgrastim**	**Reference**	**1991**	**1991**
Zarxio	filgrastim-sndz	biosimilar	2015	2015
Nivestym	filgrastim-aafi	biosimilar	2018	2018
Remicade	**Infliximab**	**Reference**	**1998**	**1998**
Inflectra	infliximab-dyyb	biosimilar	2016	2016
Renflexis	infliximab-abda	biosimilar	2017	2017
Ixifi	infliximab-qbtx	biosimilar	2017	n/a
Neulasta	**Pegfilgrastim**	**Reference**	**2002**	**2003**
Fulphila	pegfilgrastim-jmdb	biosimilar	2018	2018
Udenyca	pegfilgrastim-cbqv	biosimilar	2018	2019
Epogen, Procrit	**Epoetin alfa**	**Reference**	**1989**	**1989**
Retacrit	epoetin alfa-epbx	biosimilar	2018	2018
Rituxan	**Rituximab**	**Reference**	**1997**	**1997**
Truxima	rituximab-abbs	biosimilar	2018	2019
Avastin	**Bevacizumab**	**Reference**	**2004**	**2004**
Mvasi	bevacizumab-awwb	biosimilar	2017	2019
Zirabev	bevacizumab-bvzr	biosimilar	2019	2019
Herceptin	**Trastuzumab**	**Refernce**	**1998**	**1998**
Ogivri	trastuzumab-dkst	biosimilar	2017	2019
Kanjinti	trastuzumab-anns	biosimilar	2019	2019
Ontruzant	trastuzumab-dttb	biosimilar	2019	n/a
Herzuma	trastuzumab-pkrb	biosimilar	2018	n/a
Trazimera	trastuzumab-qyyp	biosimilar	2019	n/a
Enbrel	**Etanercept**	**Reference**	**1988**	**1998**
Erelzi	etanercept-szzs	biosimilar	2016	n/a
Eticovo	etanercept-ykro	biosimilar	2019	n/a
Humira	**Adalimumab**	**Reference**	**2002**	**2003**
Hyrimoz	adalimumab-adaz	biosimilar	2018	Expected 2023
Cyltezo	adalimumab-adbm	biosimilar	2017	Expected 2023
Amjevita	adalimumab-atto	biosimilar	2016	Expected 2023

Exhibit 3. ASP Price Trajectories of Filgrastim and Infliximab Biosimilars and Biologics, 2017-2019





Source: Medicare Part B Drug Average Sales Price. Retrieved from: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice. Manufacturer's ASP must be calculated by the manufacturer and submitted to CMS every calendar quarter. ASP is a market-based price that reflects the weighted average of all manufacturer sales prices and includes all rebates and discounts that are privately negotiated between manufacturers and purchasers (with the exception of Medicaid and certain federal discounts and rebates). This methodology mirrors reimbursement for physician-administered drugs in the commercial market. (source: https://catalyst.phrma.org/medicare-monday-what-is-asp)

Exhibit 4. Study drugs: Reference Biologics and Corresponding Biosimilars

4a) INFLIXIMAB

Main Uses: Immunosuppressant treatment for patients with auto-immune conditions

Therapeutic Category: [1] Anti-rheumatic, disease modifying; gastrointestinal agent, miscellaneous; immunosuppressant agent; monoclonal antibody; tumor necrosis factor (TNF) blocking agent

Products	**Commercially Available Preparations[1]** (Route of Administration, Dosage Form, & Strength)	**FDA- Approved Indications[2]**
REMICADE (infliximab) **Reference Biologic** US market launch: 1998	Intravenous use. Reconstituted solution [preservative-free]: 100mg	1. Crohn's disease 2. Pediatric Crohn's disease 3. Ulcerative colitis 4. Pediatric ulcerative colitis 5. Rheumatoid Arthritis (in combination with methotrexate) 6. Ankylosing spondylitis 7. Psoriatic arthritis 8. Plaque psoriasis
INFLECTRA (infliximab-dyyb) **Biosimilar** US launch: 2016	Intravenous use. Reconstituted solution 100mg	Same as Remicade, all indications
RENFLEXIS (infliximab-adba) **Biosimilar** US launch: 2017	Intravenous use. Reconstituted solution [preservative-free]: 100mg	Same as Remicade, all indications

Sources: [1]Wolters-Kluwer Lexicomp® online drug database. https://online.lexi.com/lco/action/home;
[2]FDA Online Label Repository https://labels.fda.gov/

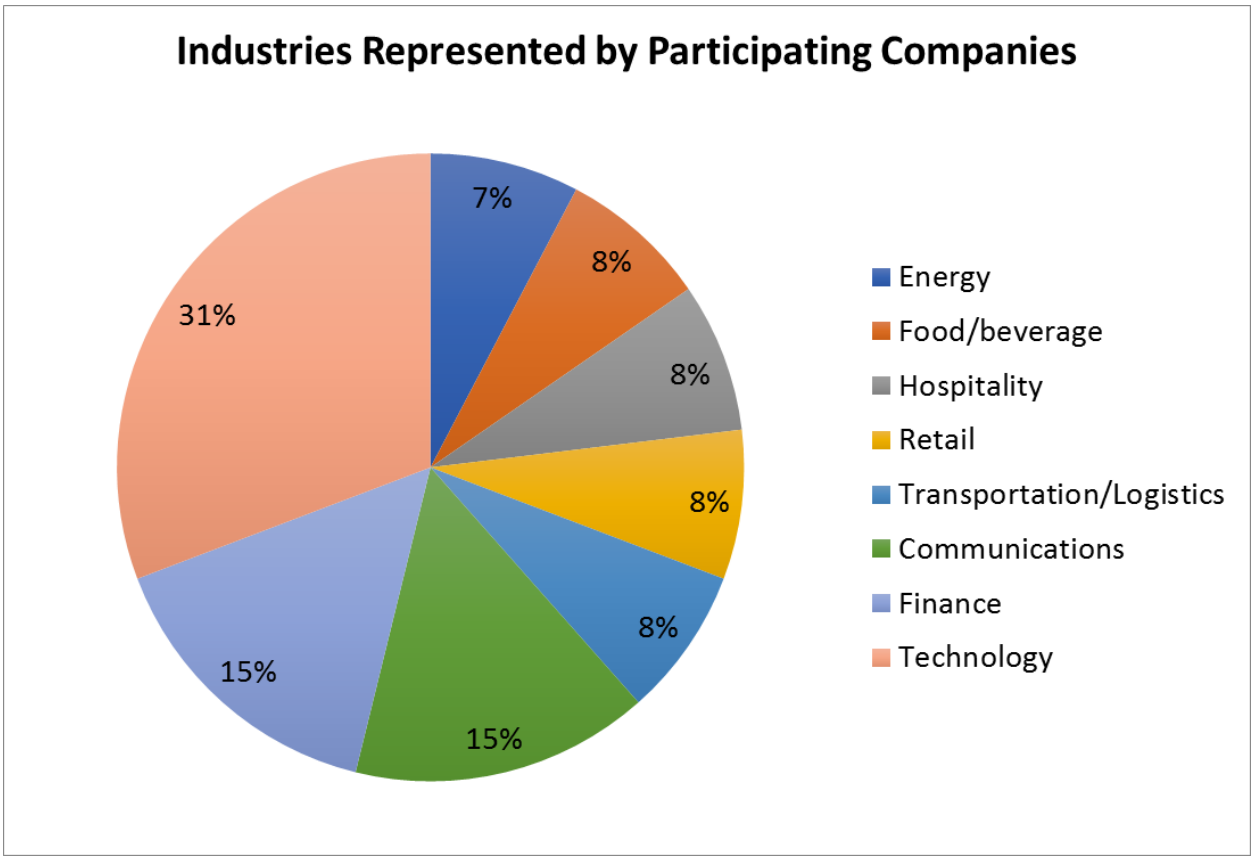
4b) FILGRASTIM

Main Use: adjunctive treatment for patients undergoing chemotherapy
Therapeutic Category: [1] Colony Stimulating Factor; Hematopoietic Agent

Products	**Commercially Available Preparations[1]** (Route of Administration, Dosage Form, & Strength)	**FDA- Approved Indications[2]**
NEUPOGEN (filgrastim) **Reference Biologic** US market launch: 1991	Intravenous or subcutaneous Solution: 300 mcg/mL (1 mL); 480 mcg/1.6 mL (1.6 mL) Solution Prefilled Syringe: 300 mcg/0.5 mL (0.5 mL); 480 mcg/0.8 mL (0.8 mL)	1. Patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs with a significant incidence of severe neutropenia with fever 2. Patients with acute myeloid leukemia 3. Patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation 4. Blood for collection by leukapheresis 5. Congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia 6. Patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome)
ZARXIO (filgrastim-sndz) **Biosimilar** US launch: 2015	Intravenous or subcutaneous Solution Prefilled Syringe [preservative free]: 300 mcg/0.5 mL (0.5 mL); 480 mcg/0.8 mL (0.8mL)	Same as Neupogen except #6
GRANIX (tbo-filgrastim **Alternative Biologic** US launch: 2013	Subcutaneous Solution, [preservative free]: 300 mcg/mL (1 mL); 480 mcg/1.6 mL (1.6 mL) Solution Prefilled Syringe, [preservative free]: 300 mcg/0.5 mL (0.5 mL) 480 mcg/0.8 mL (0.8 mL)	Only approved for Neupogen's #1 indication (Patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs with a significant incidence of severe neutropenia with fever)

Sources: [1]Wolters-Kluwer Lexicomp® online drug database. https://online.lexi.com/lco/action/home;
[2]FDA Online Label Repository https://labels.fda.gov/
Note: Our study also requested data on the biosimilar Nivestym (launched 2018), but there was no utilization reported by any participating companies in the year 2018.

Exhibit 5. Overview of Industries Represented by the Participating Companies



Source: N=13 ERIC member companies that donated data for this study.

Exhibit 6. Characteristics of Participating Companies

Overall Benefit	Avg (sd)	Min - Max
Number of Users (in thousands)	174.8 (143.7)	21 – 484
Number of Claims/year (in thousands)	2051.9 (1503.7)	154 – 4,469
Drug Spending (in $ millions)	$ 273.3 (198.8)	$ 29 - $ 569

Notes: The table reflects 11 ERIC member companies with information, and the benefit types for which the companies provided information (medical or prescription). Two companies did not provide full information and are therefore not included in this description.

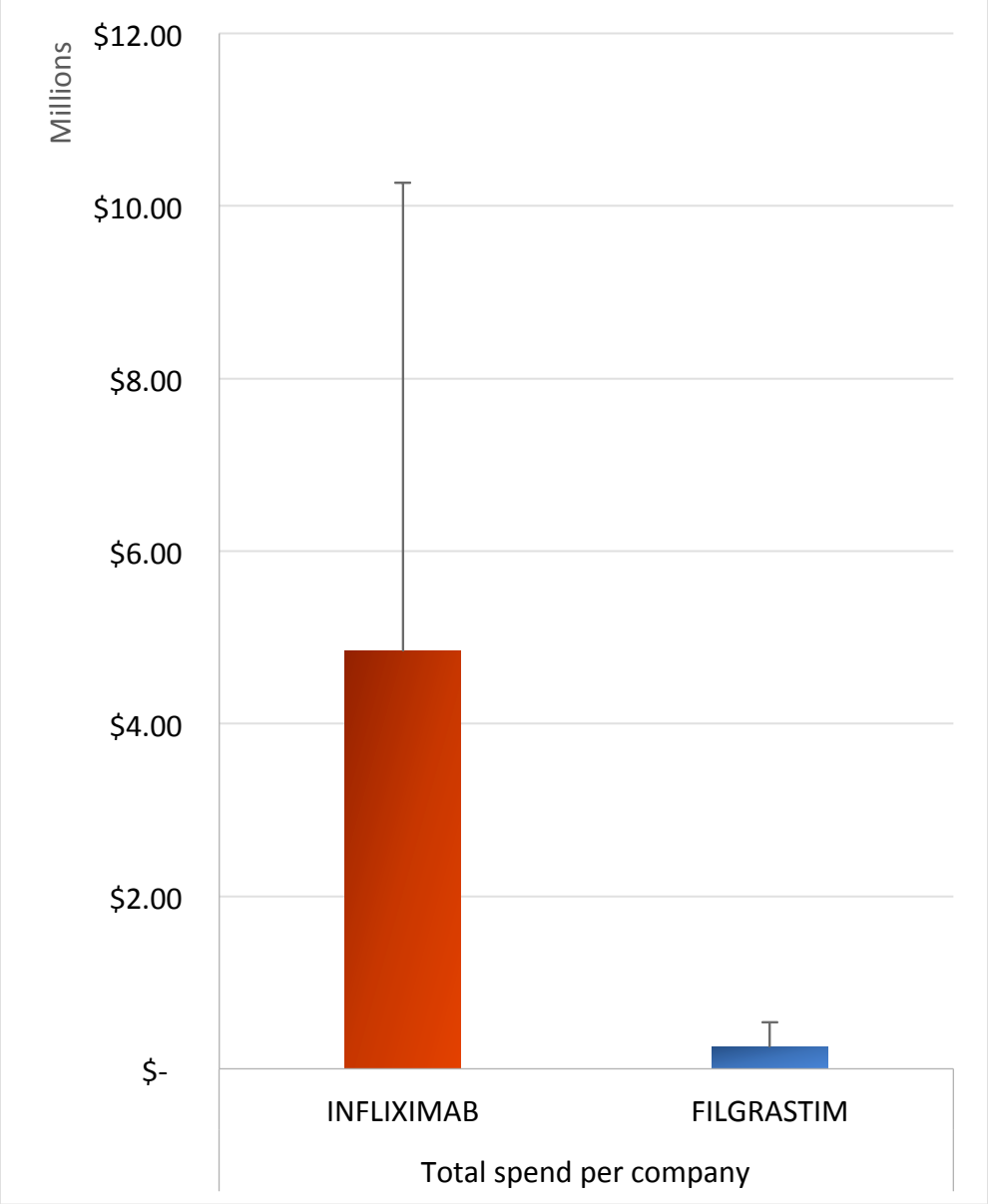
Exhibit 7. Overview of Study Drugs: Utilization and Spending

Drugs of Interest	Avg (sd)	Min - Max
Users[1]		
Number of Users	186 (209)	18 - 683
Average Age	48.7 (10.7)	9.7 - 74
% Female	55% (14%)	26% - 81%
Claims[1]		
Number of Claims	1,176 (1,146)	72 – 3,507
Spending[1]		
Drug Spending (in millions)	$4.7 ($5.6)	$288 thousand - $16.6 million
% of Company's Overall Benefit[2]		
% of Company's total number of users	0.06% (0.04%)	0.02% - 0.12%
% of Company's total drug claims	0.03% (0.03%)	0.01% - 0.11%
% of Company's overall drug spending	1% (0.9%)	0.18 - 2.7%
Distribution Channel: Medical vs. Prescription[2]		
% Claims through medical benefit	83.2% (22%)	37.9% - 99.5%
% Spend through medical benefit	86% (24%)	14.6% - 100%

Notes: [1] N=13 ERIC member companies. [2]N=11 ERIC member companies with information.

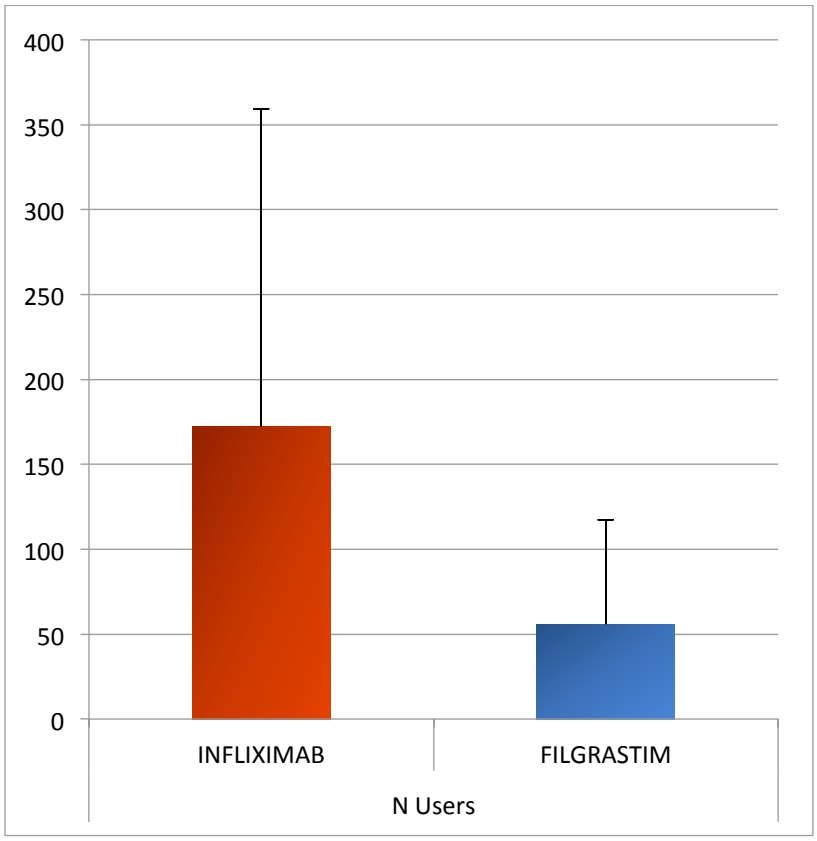
Exhibit 8. A Comparison Between the Two Study Drugs: Infliximab and Filgrastim

8a) Total Spending per Company



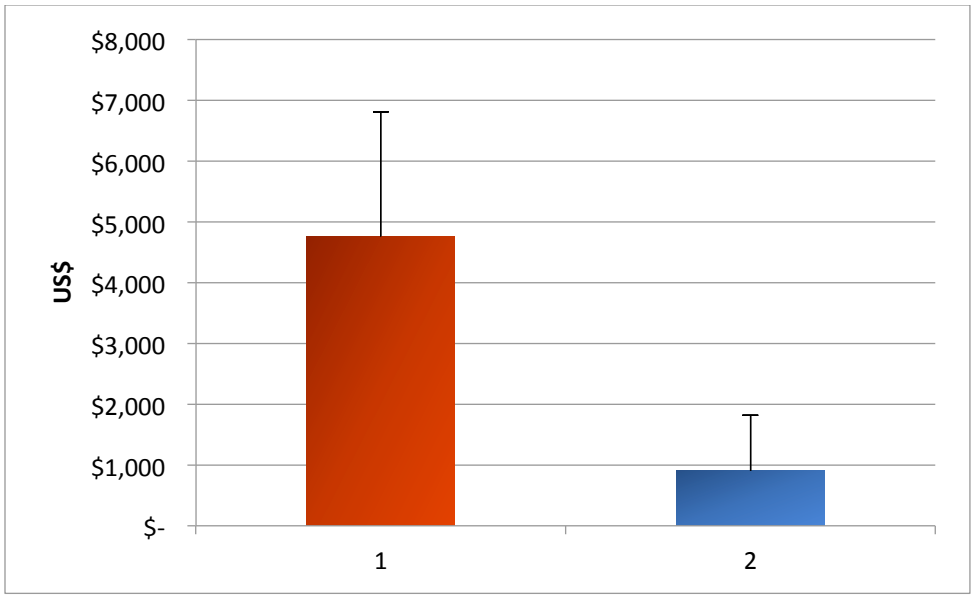
Note: Average and standard deviation for the year 2018. Data aggregated from medical and prescription drug benefit from 13 ERIC member companies.

8b) Number of Users per Company



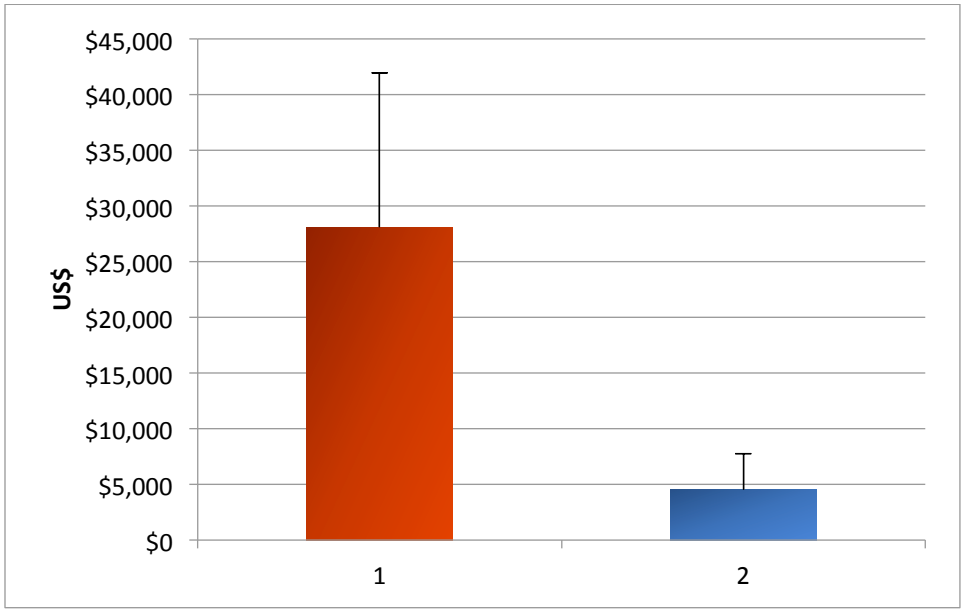
Note: Average and standard deviation for the year 2018. Data aggregated from medical and prescription drug benefit from 13 ERIC member companies.

8c) Plan Sponsor (Company) Spending per Claim



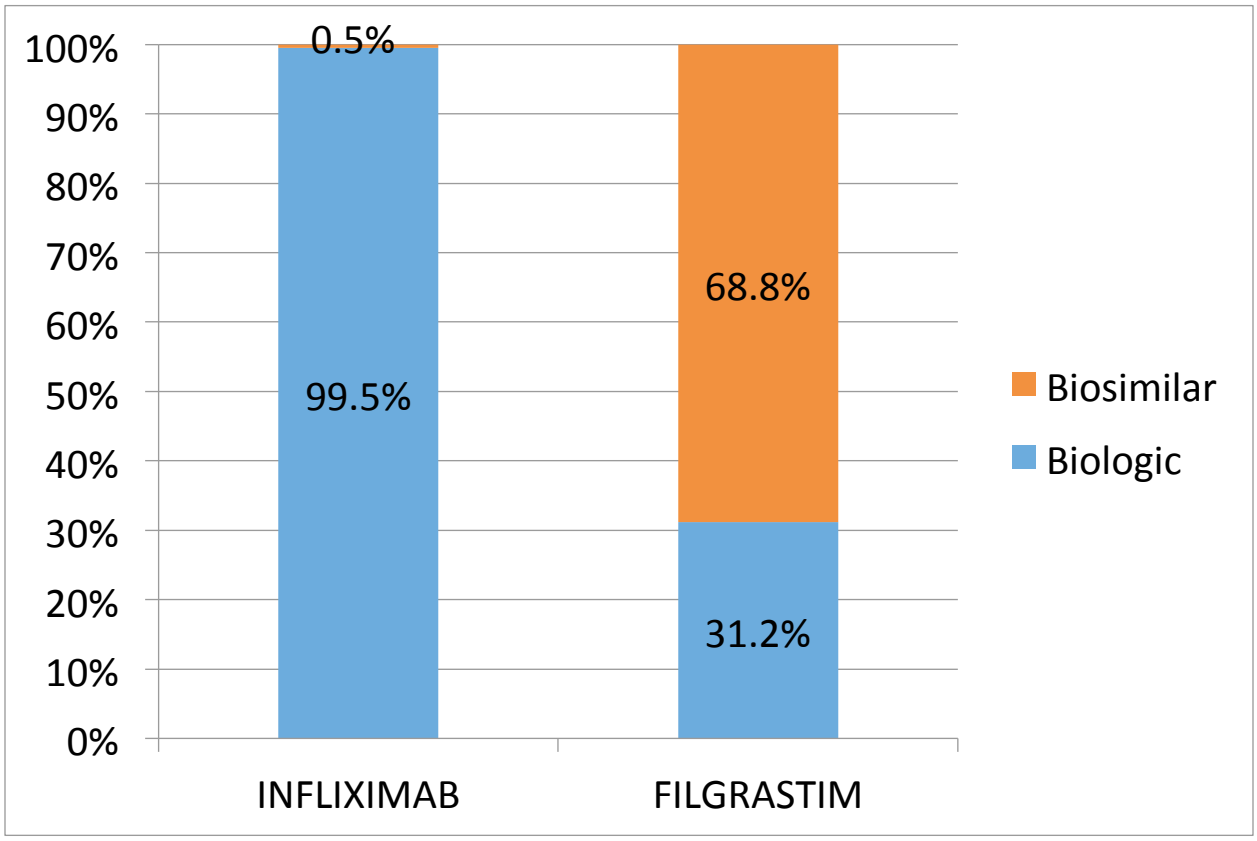
Note: Estimates reflect average and standard deviation, weighted by the number of claims, for the year 2018. Data aggregated from medical and prescription drug benefit from 13 ERIC member companies. Drug 1: Infliximab; Drug 2: filgrastim.

8d) Plan Sponsor (Company) Spending per User



Note: Estimates reflect average and standard deviation, weighted by the number of users, for the yes 2018. Data aggregated from medical and prescription drug benefit from 13 ERIC member companies. Drug 1: Infliximab; Drug 2: filgrastim.

Exhibit 9. Overall Biosimilar Market Share: Comparison between the Study Drugs



Note: Estimates reflect average market share, for the biosimilar vs. the biologic, among all claims for the drug during the year 2018. Data from N=26 (infliximab) and N=28 (filgrastim) medical and prescription drug benefit carriers ("data donors") representing 13 ERIC member companies.

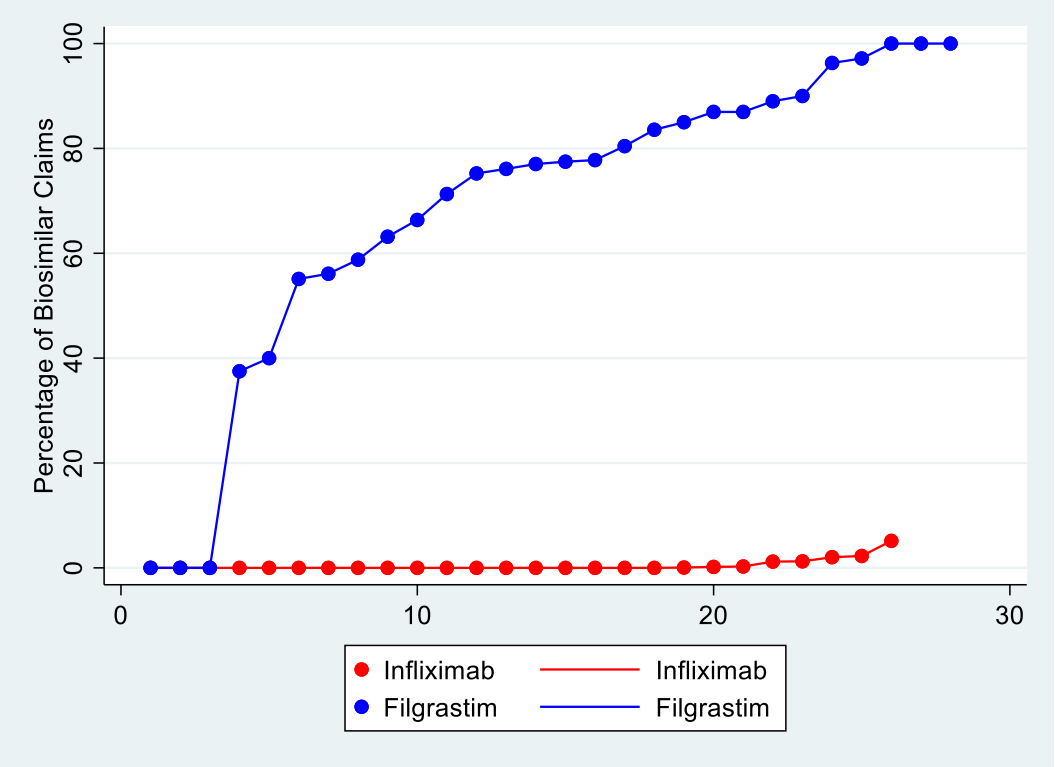
Exhibit 10. Biosimilar Market Share per Study Drug & Data Donor

10a) Overview

Percentage of Biosimilar Claims	Avg (sd)	Minimum %	Maximum %
INFLIXIMAB	0.54% (1.14%)	0%	5.14%
FILGRASTIM	68.8% (29.4%)	0%	100%

N=26 data donors for infliximab, 28 data donors for filgrastim

10b) Comparison by Drug and Data Donor



N=26 data donors for infliximab, 28 data donors for filgrastim

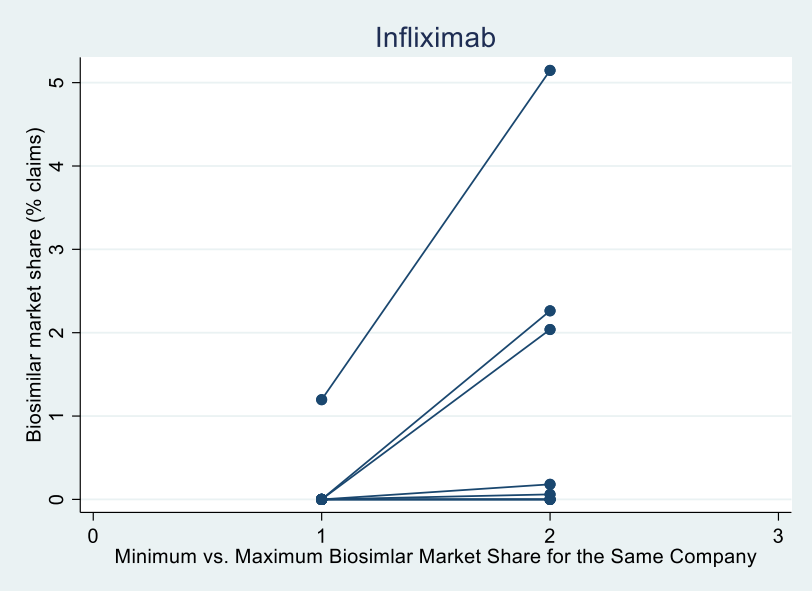
Exhibit 11. Variation in Biosimilar Market Share within Each Participating Company

11a) Overview (companies with 2+ donors)

Difference within company	Avg (sd)	Minimum %	Maximum %
INFLIXIMAB	1% (1.3%)	0%	4%
FILGRASTIM	41% (31%)	6.1%	100%

N=11 companies with two or more data donors

11b) INFLIXIMAB



11c) FILGRASTIM

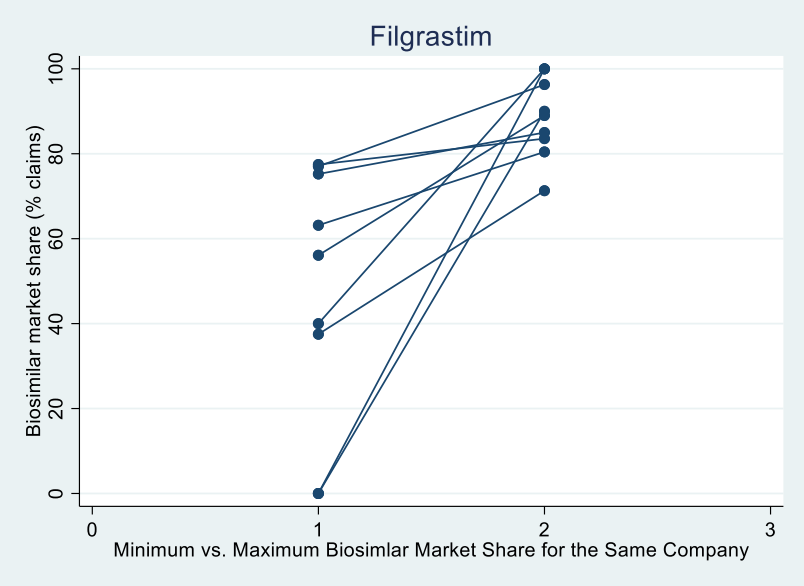


Exhibit 12. Characterization of Patients Using Reference Biologic and Biosimilar Products

12a) INFLIXIMAB

	Biologic	Biosimilar	p-value
Average Age (95% CI)[1]	40.6 (40.6 – 40.7)	46.5 (46 – 47.9)	<0.001
% Female (95% CI) [1]	45.7% (45.5%-45.8%)	71.4% (69.2% - 73.6%)	<0.001
% Off-label use (95% CI) [2]	11.3% (10.7% - 11.9%)	9.7% (8.0% - 11.4%)	NS

Notes: [1]N = 12,621 claims with information; estimates obtained by linear regression weighted by the number of claims for each drug. [2]N=1,106 beneficiaries with information; estimates obtained by independent samples t-tests with equal variances. NS: p-value > 0.05.

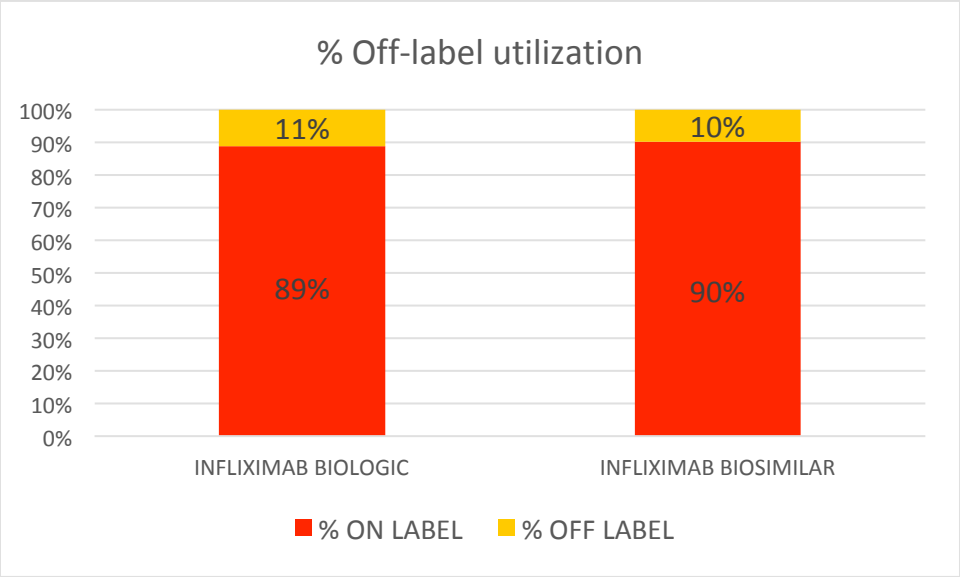
12b) FILGRASTIM

	Biologic	Biosimilar	p-value
Average Age (95% CI) [1]	50.4 (50.1-50.8)	53.3 (53.0-53.5)	<0.0001
% Female (95% CI) [1]	61.8% (60.6% - 62.8%)	60% (59.2% - 60.8%)	0.014
% Off-label use (95% CI) [2]	8.8% (7.2% - 10.4%)	9.5% (8.0% - 11.0%)	NS

Notes: [1]N = 3,455 claims with information; estimates obtained by linear regression weighted by the number of claims for each drug. [2]N=228 beneficiaries with information; estimates obtained by independent samples t-tests with equal variances. NS: p-value > 0.05.

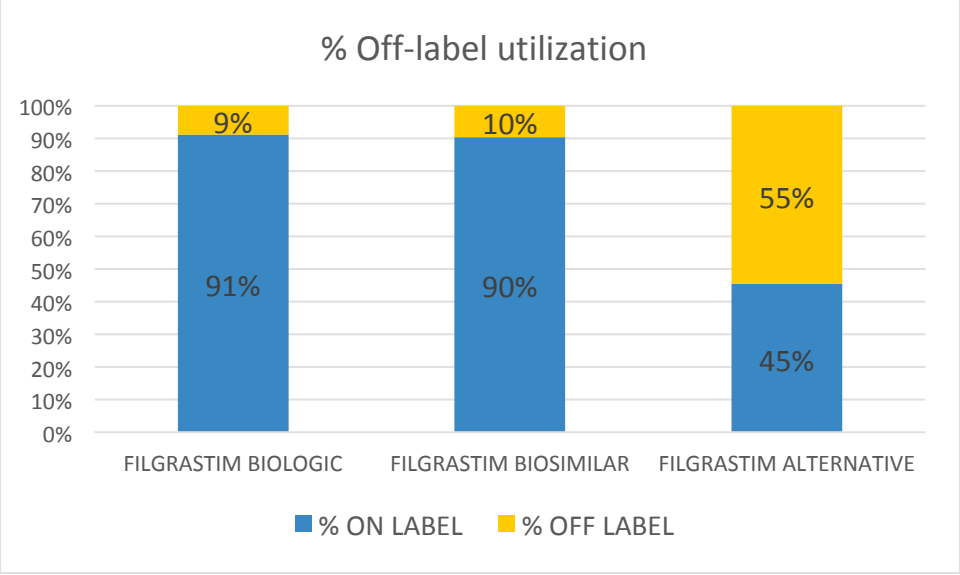
Exhibit 13. Clinical Conditions for which Study Drugs Were Prescribed: Biologics vs. Biosimilars

13a) INFLIXIMAB



Notes: N= 10 ERIC member companies with information.

13b) FILGRASTIM



Notes: N= 10 ERIC member companies with information.

Exhibit 14. How are patients paying for their drug? A Comparison between biologic and biosimilars

14a) INFLIXIMAB

INFLIXIMAB	Biologic	Biosimilar	p-value
% Requires Coinsurance (95% CI)[1,a]	85.4% (84.6%-86.2%)	76.7% (64%-89.3%)	NS
Average Coinsurance Level (95% CI) [1,b]	20.5% (20.4%-20.6%)	20% (17.8%-20.7%)	NS
Average Out-of-Pocket Spending (95% CI) [2,c]	$ 2,890.27 (2,851.55 - 2,929.00)	$ 2,553.20 (2,207.72 – 2,898.68)	0.056
Difference between biosimilar and biologic out-of-pocket costs[2,c] Average (%)		$ -337.07 (12%)	

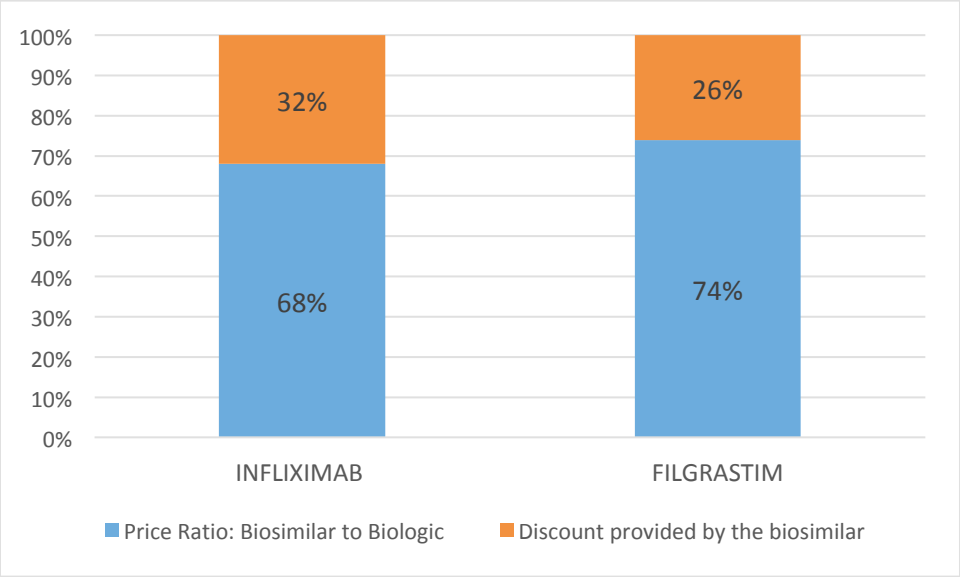
Notes: [1]N = 4,117 claims with information. [2]N= 6,446 claims with information. [a]Frequency in which members are required to pay a coinsurance (i.e., a percentage of the drug's cost) in order to obtain the drug they need, as opposed to a paying a fixed-dollar copay. [b]Average percentage of the drug cost that patients are required to pay, among those for whom coinsurance is required. [C]Average cost paid by the patient for the drug over the course of the year, regardless of their type of cost-share (copay or coinsurance). Estimates obtained by linear regression weighted by the number of claims for each drug. CI: confidence interval. NS: not statistically significant (p-value greater than 0.05).

14b) FILGRASTIM

FILGRASTIM	Biologic	Biosimilar	p-value
% Requires Coinsurance (95% CI) [1,a]	95.2% (92.7%-97.7%)	90.8% (89.4%-92.2%)	0.003
Average Coinsurance Level (95% CI) [1,b]	22.4% (21.6%-23.2%)	22.1% (21.7%-22.5%)	NS
Average Out-of-Pocket Spending (95% CI) [2,c]	$ 1,319.87 (1,244.17 – 1,395.57)	$ 721.01 (675.07 - 766.96)	<0.0001
Difference between biosimilar and biologic out-of-pocket costs[2,c] Average (%)		$ -598.86 (45%)	

Notes: [1]N = 1,338 claims with information. [2]N=2,827 claims with information [a]Frequency in which members are required to pay a coinsurance (i.e., a percentage of the drug's cost) in order to obtain the drug they need, as opposed to a paying a fixed-dollar copay. [b]Average percentage of the drug cost that patients are required to pay, among those for whom coinsurance is required. [C]Average cost paid by the patient for the drug over the course of the year, regardless of their type of cost-share (copay or coinsurance). Estimates obtained by linear regression weighted by the number of claims for each drug. CI: confidence interval. NS: not statistically significant (p-value greater than 0.05).

Exhibit 15. How are Plan Sponsors paying for the drugs? Price differential between the biosimilar and reference biologic



Note: data reflects median ratios of the price of the biosimilar to the biologic, and corresponding discounts offered by the biosimilar over the price of the biologic, for the two drugs under study. In the case of infliximab, biologic prices reflect average cost per claim of Remicade® and biosimilar prices reflect average cost per claim of Inflectra®. In the case of filgrastim, biologic prices reflect average cost per claim of Neupogen® and biosimilar prices reflect average cost per claim of Zarxio®. Price comparisons are based on the analysis of drug claims in the study sample, matching biosimilar and reference biologic by the same active ingredient, dosage form and strength, within the same plan sponsor (ERIC member company) and data donor (medical or prescription benefit vendor). Price comparisons included only drugs where claims for the biologic and biosimilar contained a similar number of units and where the vendor had reimbursed at least one claim for the reference biologic and all corresponding biosimilars over the course of the year. N=2 comparison groups for infliximab; 7 comparison groups for filgrastim.

Exhibit 16. How much could companies save under increased biosimilar utilization? An Overview

16a) INFLIXIMAB

Savings	Average (sd)	Min	Max
100% biosimilar substitution (in US$ million)	$ 1.53 ($ 1.72)	$ 723 thousand	$ 4.93
50% biosimilar substitution	$ 739,987 ($ 828,149)	$ 32,787	$ 2.32 million

Note: data reflects estimated savings at different levels of biosimilar substitution, utilizing the ratio between biosimilar and biologic prices identified in the matched analysis of drug claims from the study sample. N=13 participating ERIC member companies, totaling 26 different data donors.

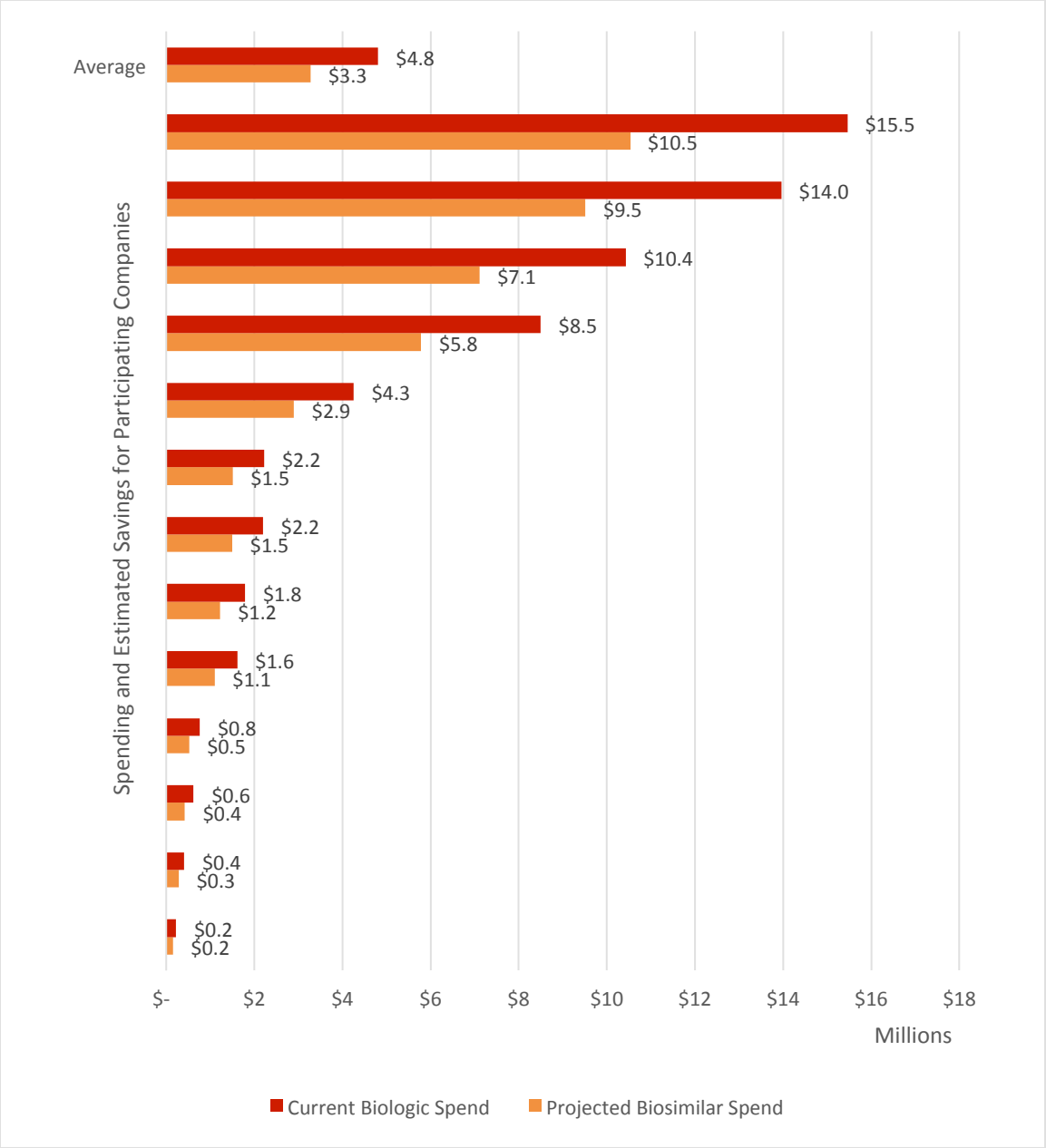
16b) FILGRASTIM

Savings (in US$)	Average (sd)	Min	Max
100% biosimilar substitution	$ 17,838.01 ($ 24,112.91)	$2,281.76	$87,801.74

Note: data reflects estimated savings at full biosimilar substitution, utilizing the ratio between biosimilar and biologic prices identified in the matched analysis of drug claims from the study sample. The analysis of 50% biosimilar substitution was not performed because most companies are already over 50% biosimilar filgrastim utilization. N=13 participating ERIC member companies, totaling 28 different data donors.

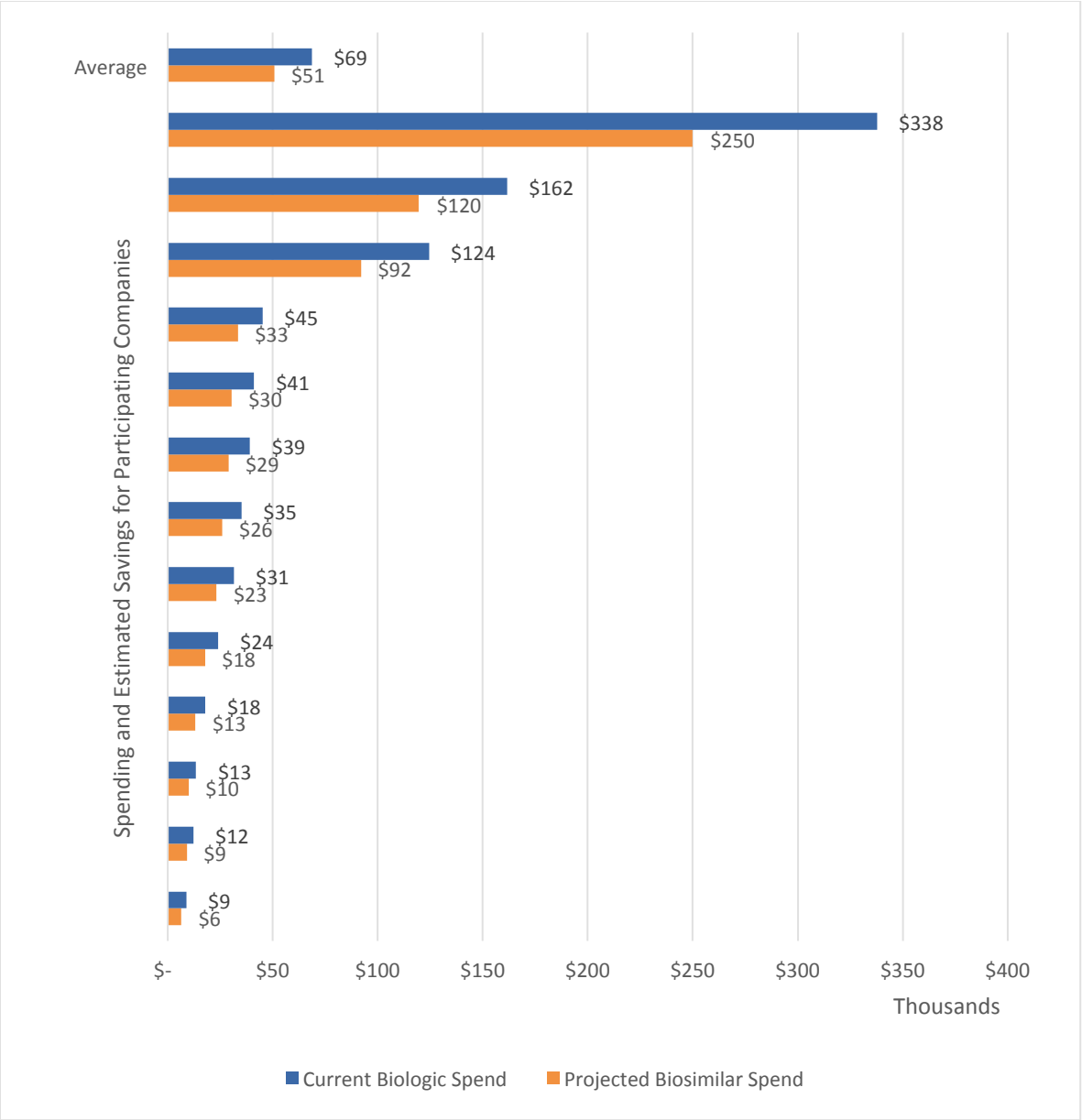
Exhibit 17. Estimated Savings per Plan Sponsor: A Comparison with Current Spending Levels

17a) INFLIXIMAB



Source: Data reflects N=13 participating ERIC member companies, totaling 26 different data donors (prescription drug and medical benefit vendors).

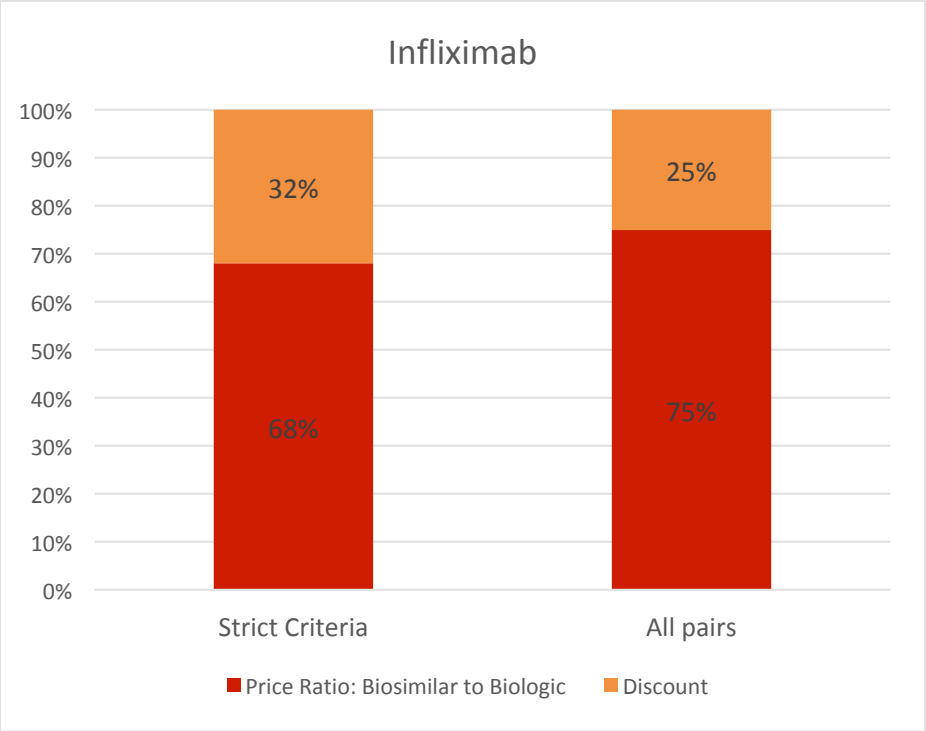
17b) FILGRASTIM



Source: Data reflects N=13 participating ERIC member companies, totaling 28 different data donors (prescription drug and medical benefit vendors).

Exhibit 18. Sensitivity Analysis (Part 1): A comparison of price differentials in this study

18a) INFLIXIMAB

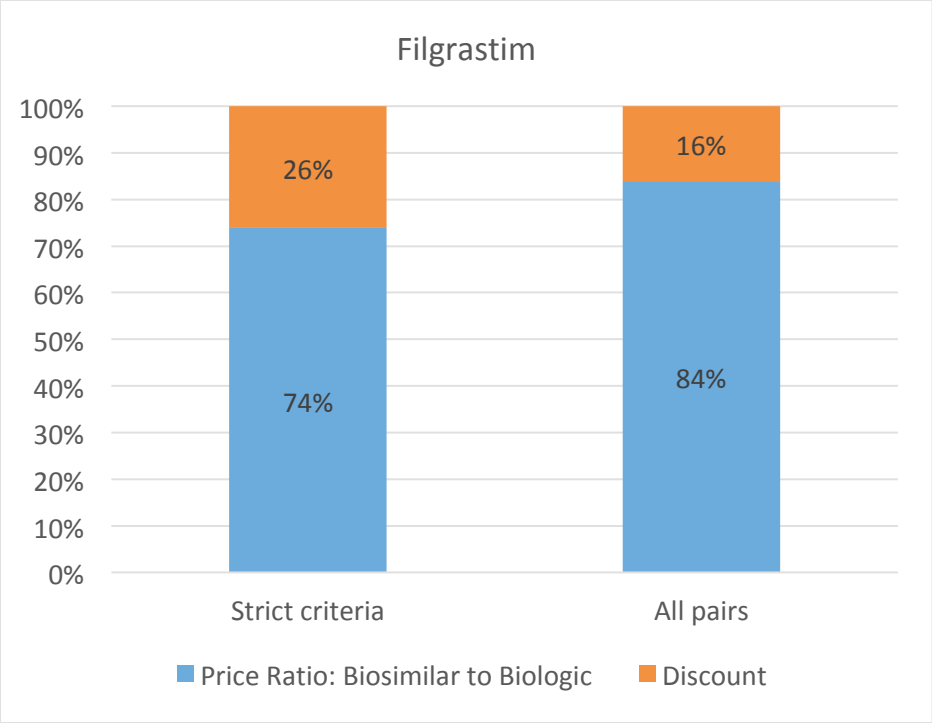


Note: data reflects median ratios of the price of the biosimilar to the biologic, and corresponding discounts offered by the biosimilar over the price of the biologic, for the drugs under study. Infliximab prices reflect average cost per claim of reference biologic Remicade® and biosimilar Inflectra®.

"Strict criteria" reflect price comparisons obtained by matching biosimilar and reference biologic by the same active ingredient, dosage form and strength, within the same plan sponsor (ERIC member company) and data donor (medical or prescription benefit vendor). Price comparisons included only drugs where claims for the biologic and biosimilar contained a similar number of units and where the vendor had reimbursed at least one claim for the reference biologic and all corresponding biosimilars over the course of the year. N=2 comparison groups.

"All pairs" reflect price comparisons obtained by matching biosimilar and reference biologic by the same active ingredient, dosage form and strength, within the same plan sponsor (ERIC member company) and data donor (medical or prescription benefit vendor). N=8 comparison groups.

18b) FILGRASTIM



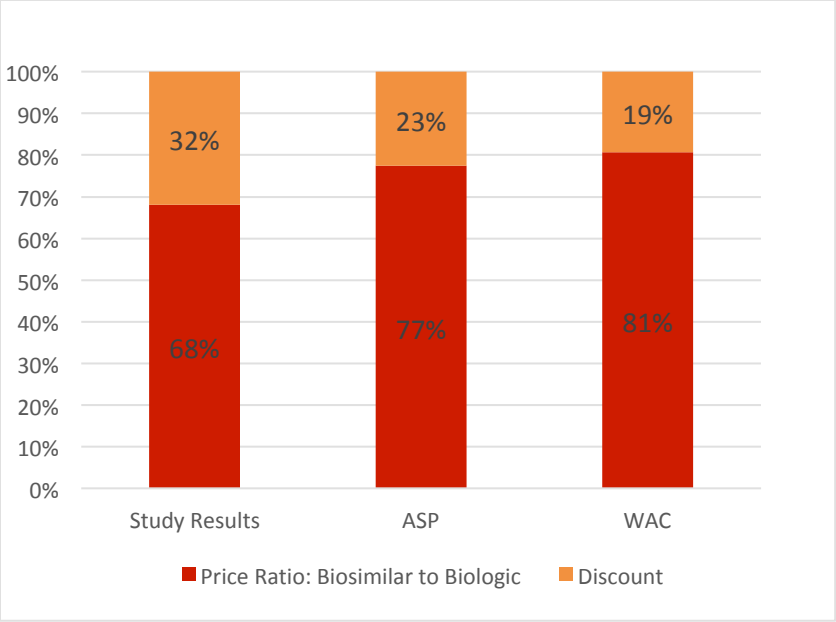
Note: data reflects median ratios of the price of the biosimilar to the biologic, and corresponding discounts offered by the biosimilar over the price of the biologic, for the drugs under study. Filgrastim prices reflect average cost per claim of reference biologic Neupogen® and biosimilar Zarxio®.

"Strict criteria" reflect price comparisons obtained by matching biosimilar and reference biologic by the same active ingredient, dosage form and strength, within the same plan sponsor (ERIC member company) and data donor (medical or prescription benefit vendor). Price comparisons included only drugs where claims for the biologic and biosimilar contained a similar number of units and where the vendor had reimbursed at least one claim for the reference biologic and all corresponding biosimilars over the course of the year. N=7 comparison groups.

"All pairs" reflect price comparisons obtained by matching biosimilar and reference biologic by the same active ingredient, dosage form and strength, within the same plan sponsor (ERIC member company) and data donor (medical or prescription benefit vendor). N=29 comparison groups.

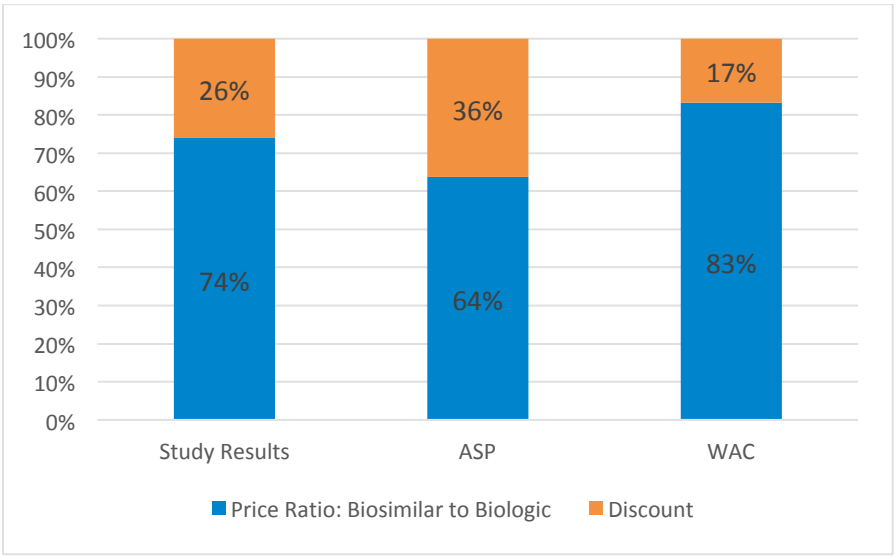
Exhibit 19. Sensitivity Analysis (Part 2): A comparison with external price benchmarks

19A) INFLIXIMAB



Source: Study estimates reflect median discount across company claims matched by strict criteria. ASP: average sales price obtained from July 2018 CMS Payment limit. Price differential adjusted for 6% provider fee. WAC: wholesale acquisition cost. Differentials presented for infliximab 100mg/10ml Remicade® and Inflectra®.

19B) FILGRASTIM



Source: Study estimates reflect median discount across company claims matched by strict criteria. ASP: average sales price obtained from July 2018 CMS Payment limit. Price differential adjusted for 6% provider fee. WAC: wholesale acquisition cost. Differentials presented for filgrastim 300mcg/0.5mL Neupogen® and Zarxio®.

Employer Strategies for Use of Biosimilar Pharmaceuticals

Segal

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This paper was prepared in March 2020 for The ERISA Industry Committee (ERIC) by Segal, an objective and industry-leading strategic global human resources and employee benefits consulting firm. For media inquiries, please contact Amira Rubin at 212.251.5322.

Introduction

Employers want to provide their employees with access to safe, effective and affordable prescription drugs as a part of their employee benefit health coverage. However, the continuing rise in prescription drug costs, especially specialty drugs, has made this goal ever more challenging to meet, despite the various strategies employers use to control costs while maintaining high-quality prescription drug benefits.

Employers have a relatively new instrument in their drug-management toolkit: biosimilars. Mirroring the use of generic drugs for brand-name non-biologic drugs, biosimilars have the promise of being less expensive alternatives to their biologic brand-name counterparts. This is good news for employers, since biologics make up the majority of specialty drug costs and are a leading driver of overall rising prescription drug cost trends for most employers.

This paper introduces biosimilars, the market challenges facing them and the strategies employers can follow to increase their use and/or help manage ongoing utilization.

Background

Brand-name drugs come in two forms: non-biologic and biologic. Most non-biologic drugs are chemically synthesized.[1] Biologics are more complex than non-biologics. Biological products, which are regulated by the U.S. Food and Drug Administration (FDA), are a diverse category of products and are generally large, complex molecules.[2] They are isolated from a variety of sources (human, animal or microorganism) and may be produced by biotechnology methods and other cutting-edge technologies.[3] They also include a wide range of products, such as vaccines, gene therapy and recombinant therapeutic proteins.[4] Biologics are usually administered through injection rather than other methods, such as pills or oral liquid form.

Once brand-name non-biologic drugs are free from their original patents, other pharmaceutical manufacturers may produce generic versions. Non-biologic generic drugs have the identical chemical composition and perform in the same manner as their brand-name counterparts. Moreover, generics do not require as many levels of clinical trials as the original brand-name drug before receiving FDA approval, resulting in lower generic drug development costs.

Brand-name biologics are more complex to develop and manufacture. A biosimilar is a biologic that is "similar" to another brand-name biologic medicine (commonly known as the reference product). While not identical to their biologic counterparts, biosimilars have the same clinical effect, and regulators have created guidelines to support their development, making them less expensive than their reference product. Since biosimilars cannot be perfectly substituted with their originator biologics (as seen with most non-biologic generic and originator brand-name drugs), they have more modest price discounts when compared to that of generics.[5]

In 2010, Congress passed the Biologics Price Competition and Innovation Act (BPCIA), which established an abbreviated regulatory process for biosimilars and paved the way for their approval.[6]

[1] U.S. Food and Drug Administration. "What Are 'Biologics' Questions and Answers." [website], www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers. February 6, 2018.

[2] U.S. Food and Drug Administration, "Biosimilar and Interchangeable Products." [website], https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products#biological. October 23, 2017.

[3] U.S. Food and Drug Administration. Resources for You (Biologics)." [website], https://www.fda.gov/vaccines-blood-biologics/resources-you-biologics. March 28, 2019.

[4] Refer to the FDA webpage cited in footnote 3.

[5] ER Kabir, SS Moreino and Siam Sharif. "The Breakthrough of Biosimilars: A Twist in the Narrative of Biological Therapy." *Biomolecules*. (August 24, 2019.)

[6] The BPCIA was signed into law as part of the Patient Protection and Affordable Care Act. (See Section 7001.)

The first biosimilar approved by the FDA came out in the U.S. market nearly five years ago to great excitement: Zarxio®, used to treat neutropenia[7] associated with chemotherapy. It competes with the popular drug Neupogen®. Since the launch of Zarxio®, uptake has been slow but steady. As of December 2019, the FDA has approved 26 biosimilar products used to treat anemia, autoimmune diseases and cancer. The biosimilars approved most recently by the FDA are Avsola™ and Abrilada™. However, of the approved FDA drugs, only 15 have launched in the U.S.[8] Factors contributing to the delay in bringing biosimilars to market include legal and patent disputes, manufacturing issues, and prescriber and patient awareness. The hope is that the biosimilar market will continue to expand with increased awareness and support from the medical community and policymakers.[9]

Biosimilar drugs are generally 15 to 20 percent less expensive than their biologic counterparts, and some may be as much as 30 percent less. For example, a comparison of the list price for the biologic Neupogen® and the biosimilar Zarxio® shows that Zarxio® costs roughly 17 percent less than Neupogen® Plan sponsors may see a discount of greater than 17 percent after accounting for negotiated discounts through their medical or pharmacy provider. The following chart illustrates an average discounted price per prescription for a sampling of large employer clients.[10]

Label Name	Average Price Per Unit
Zarxio® INJ 300/0.5	$498
Neupogen® INJ 300/0.5	$643

Source: Segal (2018)

"Availability of biosimilar and interchangeable products that meet the FDA's robust approval standards will improve access to biological products through lower treatment costs and enable greater economies of scale in biosimilar manufacturing."

— FDA's Biosimilars Action Plan

[7] Neutropenia is a low count of neutrophils, a type of white blood cell.

[8] For details, refer to the table on page 11.

[9] The FDA published its Biosimilars Action Plan in July 2018, outlining how it will promote innovation and competition in biologics and biosimilars.

[10] Price comparisons are based on a sample of discounted network prices before rebates and copays are considered.

The Employer's Role in Promoting Biosimilars

Employers can play a significant role in promoting biosimilars as an alternative to more expensive biologic drugs, where medically appropriate. This paper describes four strategies employers may consider to promote and/or manage their use.

1. Increase understanding of biosimilars by health plan participants and health care providers through education and incentives.
2. Adopt clinical management programs.
3. Design the payment features of prescription drug benefits to account for biosimilars.
4. Address biosimilar drugs when negotiating pharmacy benefit manager (PBM) contracts.

Implementing these strategies effectively could increase biosimilar awareness and use, and help employers maximize their cost savings on specialty drugs.

Increase Understanding of Biosimilars by Health Plan Participants and Health Care Providers

Biosimilar drug production is growing and the availability of these biosimilars is relatively new. So too, is the understanding of the benefits of these drugs. While some providers and patients are new to the issue, others may have misconceptions that need to be overcome. Effective biosimilar education can result in plan participant and health provider awareness and use. The FDA has produced a variety of educational materials in its role as the steward of safe and effective biosimilar products. Provider education coupled with medically appropriate incentives may also increase biosimilar awareness and use, since most patients rely on their health care providers for guidance on the appropriate medications for their health-related needs.

FDA educational resources

The FDA offers a variety of patient and provider educational materials, including graphics, drop-in content and social media messages, to help promote understanding of biosimilars.[11] Additionally, the FDA has produced a stakeholder toolkit, to "help you promote [the] FDA as a resource for information on biosimilars…and encourage prescribers and patients to talk to each other about these medications."[12]

Plan participant education

Employers use various methods to communicate with plan participants about their health care benefit options. Biosimilar information can be included in print, email and online communications to highlight their use and potential cost savings. Additionally, real-time benefit lookup tools and cost calculators offered by many benefit plan vendors should include biosimilars as available options. While the impact of direct-to-participant communications may be limited given the few biosimilar drugs currently available, this should increase as more biosimilar products become available in the market.

Provider incentives

Provider incentives may be used to encourage prescribing biosimilar drugs when medically appropriate. These incentives can be offered through direct contracting arrangements or by working with the employer's insurance carrier or third-party administrator to ensure that the contracted health care providers are aware of and considering biosimilars as a treatment option.

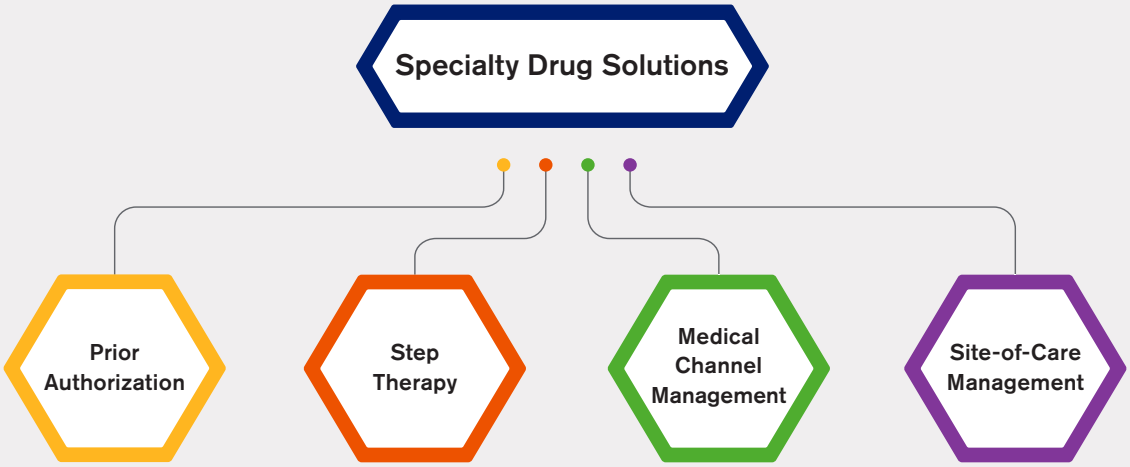
[11] U.S. Food and Drug Administration. "Health Care Provider Materials." [website] https://www.fda.gov/drugs/biosimilars/health-care-provider-materials. September 23, 2019. U.S. Food and Drug Administration. "Prescribing Biosimilar and Interchangeable Products." [website] https://www.fda.gov/drugs/biosimilars/prescribing-biosimilar-and-interchangeable-products. October 23, 2017.

[12] Refer to the Stakeholder Toolkit in the first webpage referenced in footnote 11.

Adopt Clinical Management Programs

Employers commonly use a variety of clinical management techniques to improve health care quality while lowering costs. Employers can take advantage of these same techniques with their prescription drug benefits and apply specific utilization management (UM) strategies, such as prior authorization, step therapy, medical channel management and confirming the most appropriate and cost-effective location for administering biosimilars.

Strategies for specialty drug utilization management



Prior authorization

Prior authorization is one of the most common UM strategies used by employers. When a PBM flags a drug for prior authorization, the prescription is not filled at the point of sale. Instead, the PBM will conduct a coverage review that consists of contacting the prescribing physician to review the reason for and dose of the drug in light of the patient's clinical situation, and then discuss other options available to treat the condition.

This UM technique helps ensure appropriate use of selected drugs and guides the selection of drugs that are most effective for a particular health condition. Biosimilars should be included in this authorization process as an alternative to more expensive biologic drugs. That said, while biosimilars are generally less expensive than their biologic counterpart, managing their proper use to make sure they are the most appropriate treatment for a medical condition will still be important for clinical quality.

Step therapy

Step therapy is another PBM formulary management tool used to drive savings. It promotes taking lower-cost, therapeutically equivalent medication to treat certain conditions before "stepping up" to more expensive drugs. For instance, generic drugs, which are typically less costly than brand-name drugs, are commonly prescribed as the first step.

Similar to prior authorization, the PBM flags more expensive drugs for step-therapy review. This means a pharmacist will be restricted from filling the drug until the PBM staff contacts the prescribing health care provider and reviews the reason for prescribing an advanced step drug rather than starting with a drug in a lower step.[13]

Other traditional cost-management strategies encouraging generic drug usage may also apply in the biosimilar market. However, unlike conventional generic drugs, a pharmacist cannot substitute a biosimilar for a biologic without a health care provider's prescription specifically indicating the biosimilar.

Medical channel management

Effective health care strategy should include a determination of which employer-sponsored benefit program is best suited to cover specialty drugs. The goal of this approach is to see across both medical and pharmacy benefits to ensure specialty drugs — including biosimilars — are being managed effectively. Medical channel management changes the way certain specialty drugs are paid for by excluding them from coverage under the employer's medical benefit and, instead, covering them under the pharmacy benefit. This strategy can be effective when applied to select self- and clinician-administered biologic drugs.

One reason employers may wish to consider this option is to address the concerns of drugs purchased by health care providers and administered in their offices, which can often be more expensive. Another benefit of this approach is the lack of specificity associated with some medical plan billing practices. For instance, J code billing — which is a common billing practice used by medical plans — allows one code to be used for many drugs (and non-drugs). On the other hand, pharmacy benefit billing uses a National Drug Code, a unique 11-digit code for each drug, assigned upon FDA approval.

However, employers should also be aware that it is not always beneficial to administer specialty drugs through their pharmacy benefit. For example, drugs requiring specialized medical care or expertise — such as intravenous chemotherapy drugs — may be best covered under the medical benefit. Similarly, employers should understand that a PBM's cost-savings estimate for specialty drugs may not always be as high as expected (or quoted). In some cases, medical carriers are better able to leverage provider discounts and allow those providers to dispense medications, resulting in deeper savings for the plan. In other cases, carriers contract with select pharmacies to deliver specialty drugs directly to health care providers who administer the drugs to the patients. These specialty drugs are also typically covered under the patient's medical benefit. Finally, some carriers may offer a fee schedule that applies a fixed unit price per drug based on industry standards, while other carriers contract with network physicians to administer select specialty medications. The costs of these specialty medications may be lower than the combined discounts and rebates offered by PBMs under a pharmacy benefit.

Data analytics can help employers understand whether coverage of a biologic or a biosimilar under a medical or pharmacy benefit will provide the best pricing for specialty drugs. In some cases, it may make sense to carve out specialty drugs from the medical benefit, but in other cases, the potential savings associated with carving out a specialty drug will not outweigh the risk of participant and/or physician disruption. Ultimately, employers must weigh both the savings opportunity and the non-financial considerations to determine appropriate specialty drug carve-outs.

[13] Segal's Fall 2017 *Data*, "Managing the High and Rising Cost of Prescription Drug Coverage; Segal's Research Finds Wide Variance in PBM's Prior Authorization Denial Rates for Specialty Drugs."

Site-of-care management

Injectables can be either self-administered or non-self administered. Specialty infusion and non-self administered injectable drugs often require administration by a trained clinician. Scrutinizing where drugs are administered has increased with the realization that that there is a substantial cost difference among facilities that dispense the same drug. This is especially important for biologics and biosimilars, which are often administered through non-self-administered injections or infusions.[14] A site-of-care analysis can be part of the clinical management process and, depending on plan design, the benefits of an alternative site-of-care can be reviewed with the patient and provider.[15] Plan participants should be armed with resources that provide the most cost-effective and highest-quality facilities available to administer these drugs. For instance, an infusion administered in a hospital outpatient setting may be more costly than if administered at a physician's office or through home-infusion services, where appropriate. Employers interested in encouraging plan participants to obtain care at the most appropriate sites where value and quality are consistent should work with their carriers and benefit advisors.

Case Study: Injectables. In 2019, a large self-funded health plan conducted a drug review of high-cost injectable claims for specialty drugs including Herceptin® and Neulasta®, to help ensure patients start and continue therapy at a clinically appropriate and cost-effective health care provider. The table below summarizes the allowed unit cost range for four relatively high-volume, high-cost drugs in two settings. The amounts were calculated by dividing the total allowed amount by the approved units per claim for each provider. Typically, outpatient facilities, most notably those owned and operated by a hospital system, have substantially higher charges than physicians for treatment delivered in the office or by specialty pharmacies. These disparities could lead to potential savings to employers through site-of-care analysis, plan design and contracting strategies that avoid high-cost settings.

Specialty drug cost variations for active and non-medicare retirees*

	Herceptin®		Neulasta®		Avastin®		Perjeta®	
	Physician	Outpatient Hospital	Physician	Outpatient Hospital	Physician	Outpatient Hospital	Physician	Outpatient Hospital
Minimum	$99	$150	$4,682	$4,314	$75	$71	$12	$17
Median	$107	$207	$4,688	$9,442	$81	$161	$12	$24
Maximum	$116	$396	$7,477	$18,004	$91	$301	$13	$46

* Prices shown are allowed amounts

Source: Segal (2019)

[14] Infusions or infusion therapy means a drug is administered intravenously.
[15] Medical Benefit Management (CVS Health webpage).

Design the Payment Features of Prescription Drug Benefits

Employers interested in expanding the use of biosimilars by their plan participants (where appropriate) should confirm that biosimilars are included in the payment provisions of their prescription drug benefits. This can generally be accomplished through plan design and formulary strategy.

Plan design

Plan design is a powerful tool to help mitigate growing prescription drug costs. A successful plan design should balance quality and cost savings. Tiering, a common pharmacy benefit plan design, places equally effective drugs in different tiers to incentivize the use of the least costly tiers. Typically, it rewards a patient with a lower copay for using a lower-cost generic or preferred brand-name drug.

In a traditional three-tier design, generics typically fall in tier 1. However, employers are now implementing four, six or even eight-tier benefit designs. These tiering strategies are designed to further drive consumerism around the price of the medication. As the number of biosimilars in the market grows, we may see increased use of multi-tier plan designs especially for specialty drugs.

Example of a six-tier strategy

Tier 1 Generics
Tier 2 Preferred Brands
Tier 3 Non-Preferred Brands
Tier 4 Specialty Generic or Biosimilar
Tier 5 Preferred Specialty
Tier 6 Non-Preferred Specialty

Example of an eight-tier strategy

Tier 1 Generics (lower cost)
Tier 2 Generics (higher cost)
Tier 3 Preferred Brands
Tier 4 Non-Preferred Brands
Tier 5 Specialty Generic or Biosimilar (lower cost)
Tier 6 Specialty Generic or Biosimilar (higher cost)
Tier 7 Preferred Specialty
Tier 8 Non-Preferred Specialty

Formulary strategy

Some PBMs are including biosimilars in their formularies. Strategies vary by PBM and may prefer biosimilars based on the specific formulary and the overall cost strategy. Anecdotal experience indicates that there is limited patient disruption associated with preferring biosimilars versus brand-name biologic drugs.

Formulary strategy can include two different techniques: (1) exclusion, where a drug is left off the drug formulary, or (2) changing the drug to preferred/non-preferred status. In the past few years, exclusionary formularies have been a more common practice for many of the PBMs. There are a number of drug classes with viable therapeutic alternatives, which allow employers to leverage the targeted drug exclusion strategy. Formulary-based drug strategies have also expanded to include specialty drugs. There are now enough drug options to treat conditions such as anemia, multiple sclerosis and rheumatoid arthritis to create a specialty preferred drug list. This strategy can play a role in price negotiations with the PBM and pharmaceutical manufacturers because it promotes more competitive pricing within a drug class.

Address Biosimilar Drugs when Negotiating PBM Contracts

As noted earlier in this paper, biosimilars are generally 15 to 20 percent less expensive than their biologic counterparts, although some biosimilars may be as much as 30 percent less. While these savings may not be as high as those of generic drugs, they still provide meaningful cost reductions for the expensive biologics. Employers should review their PBM contract provisions with their benefit advisors and legal counsel and pay particular attention to the provisions related to value-based pricing, inflation-protection caps and manufacturer rebates.

Value-based pricing

There is a movement for some PBMs to offer outcomes-based or value-based pricing. This approach supports setting different drug prices for certain medical conditions. For example, while some oncology medications are approved to treat multiple types of cancer, the cost of each drug may not be justified given the low success rate for specific cancers. Therefore, linking a portion of the drug reimbursement to clinical results or outcomes may help avoid the use of less-effective drugs. A positive value-based result on biosimilar drugs compared to their reference product will likely help physicians feel more comfortable prescribing them.

Inflation-protection caps

Specialty drugs have about 10 to 20 percent yearly inflation rates. Due to this high rate of increase, some PBMs offer inflation-protection caps, which are intended to shield plans from the full impact of these year-over-year price increases. High inflation rates will likely be an issue with biosimilars, as well. Employers should understand how their plan's inflation cap is calculated by the PBM and confirm the PBM delivers these protections to all specialty drugs, including biosimilars.

Manufacturer rebates

PBMs negotiate rebates from drug manufacturers for formulary placement. Higher rebates are paid by the manufacturer to have their drug receive a more preferred formulary position. Based on the selected PBM formulary, a biosimilar drug may be preferred over a reference brand-name product. Plan sponsors should ensure that biosimilars are included in rebate payment calculations.

The Biosimilar Pipeline

Due to increased spending on specialty drugs year over year, employers should be familiar with the biosimilar drug pipeline. This pipeline continues to evolve with many manufacturers seeking FDA approval for biosimilar versions of many biologic drugs. The table below shows FDA-approved biosimilar drugs and whether they have been launched into the U.S. market.

Biosimilar Drug Name (chemical name*)	FDA Approval Date	Innovator Drug Name	Biosimilar Launch
Avsola™ (infliximab-axxq)	December 2019	Remicade®	No
Abrilada™ (adalimumab-afzb)	November 2019	Humira®	No
Ziextenzo® (pegfilgrastim-bmez)	November 2019	Neulasta®	Yes
Hadlima™ (adalimumab-bwwd)	July 2019	Humira®	No
Ruxience™ (rituximab-pvvr)	July 2019	Rituxan®	Yes
Zirabev™ (bevacizumab-bvzr)	June 2019	Avastin®	Yes
Kanjinti™ (trastuzumab-anns)	June 2019	Herceptin®	Yes
Eticovo™ (etanercept-ykro)	April 2019	Enbrel®	No
Trazimera™ (trastuzumab-qyyp)	March 2019	Herceptin®	Yes
Ontruzant® (trastuzumab-dttb)	January 2019	Herceptin®	No
Herzuma® (trastuzumab-pkrb)	December 2018	Herceptin®	No
Truxima® (rituximab-abbs)	November 2018	Rituxan®	Yes
Udenyca® (pegfilgrastim-cbqv)	November 2018	Neulasta®	Yes
Hyrimoz™ (adalimumab-adaz)	October 2018	Humira®	No
Nivestym™ (filgrastim-aafi)	July 2018	Neupogen®	Yes
Fulphila™ (pegfilgrastim-jmdb)	June 2018	Neulasta®	Yes
Retacrit™ (epoetin alfa-epbx)	May 2018	Epogen®/Procrit	Yes
Ixifi™ (infliximab-qbtx)	December 2017	Remicade®	No
Ogivri™ (trastuzumab-dkst)	December 2017	Herceptin®	Yes
Mvasi™ (bevacizumab-awwb)	September 2017	Avastin®	Yes
Cyltezo® (adalimumab-adbm)	August 2017	Humira®	No
Renflexis® (infliximab-abda)	May 2017	Remicade®	Yes
Amjevita™ (adalimumab-atto)	September 2016	Humira®	No
Erelzi® (etanercept-szzs)	August 2016	Enbrel®	No
Inflectra® (infliximab-dyyb)	April 2016	Remicade®	Yes
Zarxio® (filgrastim-sndz)	March 2015	Neupogen®	Yes

* The chemical names for drugs are determined by the International Union of Pure and Applied Chemistry (IUPAC).

Source: Biosimilar Product Information (FDA website, January 9, 2020)

Overall, almost half of biosimilars approved by the FDA have been released to market with many of them not publicly announcing a release date due to ongoing patent litigation or previously announced settlements delaying release. Biosimilar release dates between January 2023 and September 2023 have been announced for the top-selling prescription drug in the world: Humira®. While it is exciting that the FDA is approving an increasing number of biosimilar drugs, we continue to question the various legal tactics and negotiations between brand-name and biosimilar manufacturers to delay the release of less expensive alternatives to higher-cost medications.

Outside of the U.S., biosimilars are widely available for many biologic drugs and the number of biosimilars in development is extensive. However, with so many biosimilars in the market and more on the way, there is concern that market saturation will lead many manufacturers to reevaluate their efforts in categories with too small a market to allow for effective competition or sufficient profitability.[16] What this means in the U.S. is unknown at this time due to the limited number of available biosimilars. Many of these drugs have small populations of patients and newer drugs are being developed on a continuous basis, which may lead a manufacturer to reassess the market and its investment in creating biosimilars with potentially limited payoff.

The following table is a representative sample of biologic drugs, their respective manufacturers and the biosimilars in development worldwide. The great majority of these biosimilars are in preclinical development and not yet available for use.

Active Agent	Reference Product (Drug Manufacturer)	Number of Biosimilars in Development
Tumor necrosis factor mAb	Humira® (AbbVie)	25
Tumor necrosis factor mAb	Remicade® (Janssen/J&J)	14
Erythropoietin; epoetin alpha	Epogen® (Amgen)/Procrit® (J&J)	86
Granulocyte colony stimulating factor; filgrastim	Neupogen® (Amgen)	57
Granulocyte colony stimulating factor; pegylated; pegfilgrastim	Neulasta® (Amgen)	20
Tumor necrosis factor, mAb-like fusion protein	Enbrel® (Amgen)	28
CD20 mAb	Rituxan® (Genentech/Roche)	48
Her2 receptor mAb; trastuzumab	Herceptin® (Genentech/Roche)	37
Insulin glargine	Lantus® (Sanofi)	7
Vascular endothelial growth factor mAb; bevacizumab	Avastin® (Genentech/Roche)	22
Insulins	Multiple insulin products	50
Interferon alpha	Multiple interferon alpha products	69
Interferon beta	Multiple interferon beta products	26
Human growth hormone; somatropin	Nutropin® (Genentech)	34

Source: Cheng Liu and K. John Morrow, Jr., *Biosimilars of Monoclonal Antibodies: A Practical Guide to Manufacturing, Preclinical and Clinical Development* (John Wiley & Sons, Inc., December 2016) page 387. (Reprinted with permission.)

[16] Cheng Liu and K. John Morrow, Jr., *Biosimilars of Monoclonal Antibodies: A Practical Guide to Manufacturing, Preclinical and Clinical Development* (John Wiley & Sons, Inc., December 2016) page 387.

Putting the Biosimilar Pieces Together

While utilization of the handful of available biosimilars is currently low, there is positive movement towards the growth of these drugs. Although biosimilars are still an emerging drug option, they offer another way for employers to offer high-quality, affordable drug options to their health plan participants. Employers interested in fully exploring the benefits of offering these drugs to medical and pharmacy plan participants should work with their partners and benefit advisors, develop a go-forward prescription drug strategy including biosimilars and make efforts towards creating awareness of these drug options.

Work with partners. Employers should work with their PBMs, health plan carriers, pharmacy benefit consultants and legal counsel to understand the ongoing evolution of the biosimilar market and monitor the pipeline of new biosimilar drugs. It is also important for employers to identify which PBMs are promoting greater use of biosimilar drugs and include biosimilar provisions and competitive payment features in their PBM contracts. For example, as modifications are made to how biosimilars are administered or where they are administered, there may be savings opportunities for employers.

Develop a strategy. Employers interested in exploring the cost-savings potential of biosimilars should include them in their pharmacy benefit strategy. There are numerous clinical management strategies employers can take to improve the quality of care offered to plan participants while also lowering costs.

Create awareness. It is not too early to increase awareness of biosimilars through communication campaigns aimed at plan participants and health care providers. Additionally, it may be helpful to consider how PBMs and health plan carriers will handle newly launched biosimilars. Some PBMs are already making strides by promoting select biosimilars on their formularies.

This paper was prepared in March 2020 for The ERISA Industry Committee (ERIC) by Segal, an objective and industry-leading strategic global human resources and employee benefits consulting firm. For media inquiries, please contact Amira Rubin at 212.251.5322.

Segal

UPDATED: MARCH 2020

U.S. Public Policies Impacting Biosimilar Drugs

This overview offers insights on known legislation as of March 19, 2020. Given that the policy landscape is dynamic and changes often, this overview is a limited snapshot in time.

Fidelity INVESTMENTS

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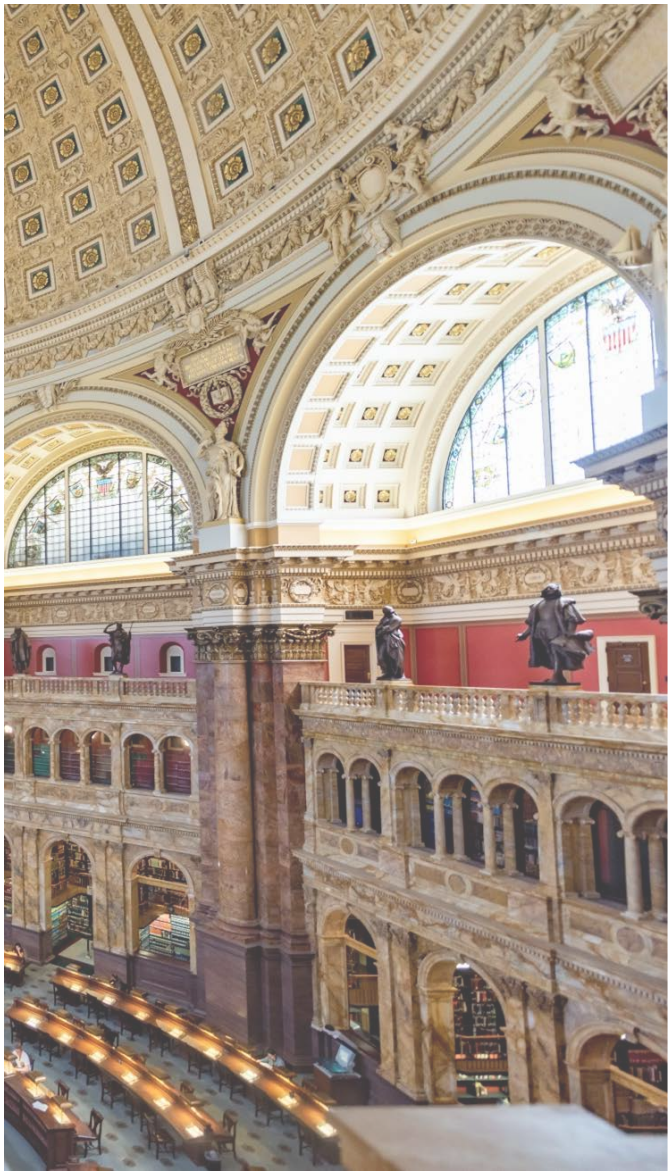
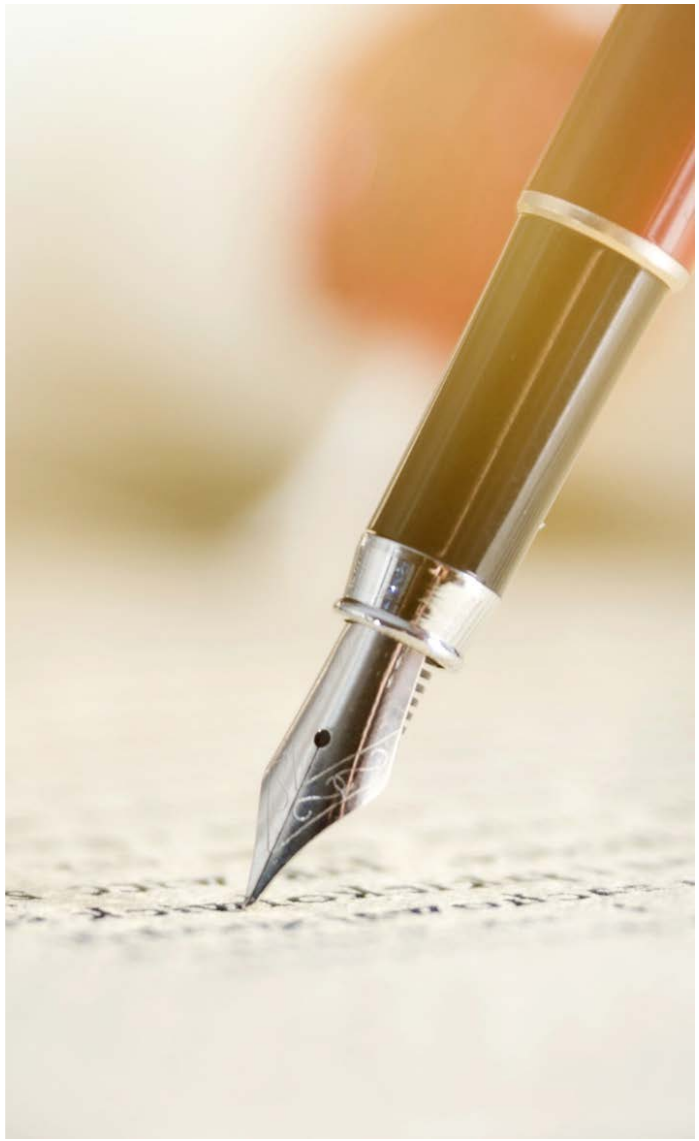
INTRODUCTION

One of the key drivers of the health care policy debate is the rising costs of prescription drugs – and principally products that are known as "biologics." Biologics have been available for many years; however, our scientific knowledge of cells, tissues, blood, and other complex substances has led to discoveries in the treatment of cancers, rare diseases, and complex health care problems. Congress has already recognized the need for competitive products in the marketplace to obtain more options for patients and reduce pricing. The Affordable Care Act created a pathway for biosimilars so that similar products can be approved by the U.S. Food and Drug Administration (FDA) and made available to patients. There are many other policy changes that Congress and state policymakers are evaluating that would make biosimilars more available and accessible, lowering the cost of care for everyone and improving health for the larger population.



Many of these proposed ideas are identified in this summary with a focus on key areas to ensure patients can access affordable products; that physicians can have full information on the availability of biosimilar products that are similar to other products; that FDA will move toward implementing a final process for interchangeable products (i.e., generic products); that biologics, biosimilars, and interchangeable biologic products can be available and administered in the lowest cost setting; and that employers can have transparent information on the availability and appropriate uses of these products in evaluating coverage and payment.

Policymakers must align their interests to ensure patients have access to affordable prescription medications. The federal regulatory process for introducing biosimilars and interchangeable products can be improved to provide prescription drug companies with assurances of the requirements. State lawmakers should also evaluate their rules and



policies to ensure that physicians are notified when alternative and more affordable products are available for their patients, and to provide physicians with the discretion needed to determine the most appropriate course of treatment for patients. Aligning access to affordable biologics and promoting improved patient outcomes should be priorities.

This compilation was prepared for The ERISA Industry Committee (ERIC), which is a Washington, DC-based trade association that advocates exclusively for federal, state, and local public policies that support the ability of large employers to provide health, retirement, and compensation benefits to their nationwide workforces. Regarding prescription drug costs, ERIC advocates on the federal level for a competitive marketplace with full transparency of cost and quality information. On the state level, ERIC has drafted model legislation that could help streamline state regulation and improve the flow of biosimilar drugs into the market and patients' hands.

THE REGULATORY OUTLOOK? SLOW MOVING.

The Biologics Price Competition and Innovation Act (BPCI Act) of 2009 (passed as part of the Affordable Care Act) created an expedited FDA licensure pathway for biological products. Since 2015, the FDA has approved 19 biosimilars in the U.S., but only seven are currently on the market, and none have been deemed "interchangeable."[1] An interchangeable product is a biosimilar product that meets additional requirements outlined by the BPCI Act (see below).

In 2019, the FDA released a set of guidelines intended to spur the market for biosimilars. The new guidelines set testing standards for a biosimilar to be declared interchangeable, allowing pharmacists to replace a branded drug with a generic biologic in the same way they currently do for small-molecule drugs, without having to talk with a doctor first.[2]

The FDA plans to use insulin as a test case for the new guidance. "Anything the FDA can do to encourage competition in this space is very useful to the consumer," says Michael Carrier, a professor at Rutgers Law School who specializes in pharmaceutical patent law." As helpful as it is, though, there are still many hurdles to biosimilar competition," he warns.[2]

Physicians and patients need to be aware of their state regulations since this may affect their treatment choices. At the state level, automatic substitution laws and requirements for notifying physicians can vary.

WHAT CAN CONGRESS AND THE ADMINISTRATION DO NOW?

Federal policymakers have proposed laws to strengthen the spirit of patent exclusivity, reform FDA processes, expand negotiation and financial incentives for payers, institute pricing and cost caps, and broaden consumer education. Some of these bills are described below.

Patent Related Proposals

Bill #	Bill Name	Co-Sponsors	Summary	Status
S. 659	**The Biologic Patent Transparency Act**	Sens. Collins (R-ME), Kaine (D-VA)	Requires the manufacturers of approved products to disclose and list patents covering their products with the FDA. By requiring patent information to be published in FDA's "Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations," commonly referred	Referred to Senate HELP Committee

Bill #	Bill Name	Co-Sponsors	Summary	Status
			to as the "Purple Book," the bill imposes transparency requirements that are similar to what are required for small molecule drugs under the Hatch-Waxman framework, which has proven successful in promoting the development and use of generic drugs. The bill also targets competition-stymieing patent thickets that delay competition without providing meaningful product improvements by restricting enforcement of patents that are issued after a biosimilar application has been submitted to the FDA. It will encourage manufacturers to apply for patents sooner, allowing prospective biosimilar manufacturers to challenge weak or invalid patents earlier in the product development process. The bill will also standardize publication of the "Purple Book" and require that the FDA make enhancements to it that will promote competition.[3]	
S. 64	**The Preserve Access to Affordable Generics and Biosimilars Act**	Sens. Grassley (R-IA), Klobuchar (D-MN)	Aims to strengthen the Federal Trade Commission's (FTC) ability to challenge settlement agreements ("pay for delay" deals) between large brand drug companies and generic drug companies in court, which will help lower prescription drug prices for Americans.[4]	Referred to Senate Judiciary Committee
H.R. 2375		Reps. Nadler (D-NY), Collins (R-GA)		

Bill #	Bill Name	Co-Sponsors	Summary	Status
H.R. 1499	**The Protecting Consumer Access to Generic Drugs Act**	Democratic proposal sponsored by Rep. Rush (D-IL)	Prohibits the practice of "pay-for-delay," in which brand name drug companies compensate generics for delaying the entry of generic drugs into the market. This practice leads to decreased competition and increased drug prices for Americans.[5]	Referred to House Energy & Commerce Committee, House Judiciary Subcommittee on Antitrust, Commercial, and Administrative Law
S. 1895	**The Lower Healthcare Costs Act**	Sens. Alexander (R-TN), Murray (D-WA)	Aims in a broad bipartisan Senate bill to reduce the prices of prescription drugs, prominently featuring biosimilars' role in doing so.[6] "The legislation would require updates to the FDA's Purple Book, which provides stakeholders with information on biologics. It would codify the Purple Book as a single, searchable list of information that would include, among other information, materials related to patents on biologics. It also proposes updates to the Orange Book, which addresses small-molecule drugs. The FDA would be required to remove patent information if a patent is found to be invalid."[7]	Introduced by Senate HELP Committee Chair & Ranking Member
S. 1140 H.R. 2011	**The Protecting Access to Biosimilars Act**	Sens. Cassidy (R-LA), Smith (D-MN) Reps. DeGette (D-CA), Reed (R-NY)	Amends federal law regarding licensing for biological products (targets Insulin, specifically).[8]	Referred to Senate HELP Committee Referred to House Energy & Commerce Committee

Bill #	Bill Name	Co-Sponsors	Summary	Status
S. 1209	**The Reforming Evergreening and Manipulation that Extends Drug Years ("REMEDY") Act**	Sens. Cassidy (R-LA), Durbin (D-IL)	Amends the FDA statute to remove incentives for drug manufacturers to file excessive patents, and would lift onerous legal barriers that delay generic market entry. Under this policy, once the substance patent and all exclusivities expire, generic manufacturers would be allowed to enter the market more easily. The REMEDY Act also increases transparency and removes hurdles for generic drug companies by ensuring that when a patent is invalidated by a ruling at the U.S. Patent and Trademark Office and upheld on appeal, the FDA's listing of relevant drug patents would be updated. The bill would lower prescription drug prices and promote competition by removing barriers to FDA approval for lower-cost generic drugs. Many high-cost, brand-name drugs are shielded from competition because of the ability to manipulate the system by "evergreening" or filing numerous additional patents to their product in an attempt to forestall generic competition. The REMEDY Act would crack down on pharmaceutical monopolies and lower patient costs.[9]	Referred to Senate HELP Committee
H.R. 3812		Reps. McKinley (R-WV), Welch (D-VT)		Referred to Energy & Commerce Committee

Reforming FDA Processes

Bill #	Bill Name	Co-Sponsors	Summary	Status
S. 1169	**The Ensuring Timely Access to Generics Act**	Sens. Cassidy (R-LA), Shaheen (D-NH)	Provides direction to the FDA on how to curb the number of unnecessary citizens petitions, a tactic brand drug manufacturers can use to delay generic medications from accessing the market. Under the bill, the FDA would gain the authority to deny citizens petitions if they deem their primary purpose is a way to delay the approval of a drug's transition to the generic marketplace. The legislation aims to reduce the costs of prescription drugs by making generic medicine more quickly accessible to consumers.[10]	Referred to Senate HELP Committee
H.R. 2455		Reps. Joyce (R-PA), Brindisi (D-NY)		Referred to House Energy & Commerce Committee
	American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs	President Trump's May 2018 proposal to lower drug prices.	Accelerates FDA approval of generic drugs. Studies show that greater generic competition is associated with lower prices. FDA is publishing the names of drugs that have no competitors to spur new entrants and bring prices down. Over 1,000 generic drugs were approved in 2017, which is the most in FDA's history in a calendar year by over 200 drugs. These generic approvals saved American consumers and taxpayers nearly $9 billion in 2017. Also, in 2017, President Trump's FDA established a Drug Competition Action Plan to enable patients to access more	Certain proposals included in this package can be achieved via regulation, though other proposals would require Congressional action.

Bill #	Bill Name	Co-Sponsors	Summary	Status
			affordable medications by focusing the agency's efforts in three key areas: (1) improving the efficiency of the generic drug development, review, and approval process; (2)maximizing scientific and regulatory clarity for complex generic drugs; and (3)closing loopholes that allow brand-name drug companies to "game" FDA rules in ways that forestall the generic competition Congress intended. The agency also has taken steps to prioritize its review of generic drug applications; issued guidance to improve efficiencies in the development, review, and approval processes for generic drugs, including complex generic drugs; and issued guidance to streamline the submission and review process for shared system Risk Evaluation and Mitigation Strategies (REMS), and to allow collective submissions to streamline the review of shared REMS. Also, speeds access to more affordable generics by spurring competition. Today, a generic manufacturer that has been awarded 180-day exclusivity for being the first generic to file can "park" its application with FDA, preventing additional generic manufacturers from entering the market. The President's FY2019 Budget proposes to prevent companies from using their 180day exclusivity to indefinitely delay real competition and savings for consumers by seeking a legislative change to start a company's 180-day exclusivity clock in certain instances when another generic application is ready for approval but is blocked solely by such a first applicant's 180-day exclusivity.	

Bill #	Bill Name	Co-Sponsors	Summary	Status
			Finalizes a policy in which each biosimilar for a given biologic gets a billing and payment code under Medicare Part B to incentivize the development of additional lower-cost biosimilars. Prior approaches to biosimilar coding and payment would have created a race to the bottom of biosimilar pricing, while leaving the branded product untouched, making it an unviable market that few would want to enter.[11]	
N/A	**Office of the White House, "A BUDGET FOR A Better America PROMISES KEPT. TAXPAYERS FIRST.** Budget for Fiscal Year 2020.[12]	Included in President Trump's proposed Department of Health & Human Services (HHS) Budget for FY 2020	Gives the FDA more authority to address abuses of citizen petitions. The budget proposes to give FDA the authority to summarily deny citizen petitions and eliminate the 150-day response timeframe for addressing such petitions. Citizen petitions have come under fire as methods used to delay generic or biosimilar competition.[13]	The President releases an annual proposed budget for the federal government. It rarely advances in Congress, but rather is viewed as a roadmap for where the administration recommends focusing resources.
N/A	**Office of the White House, "A BUDGET FOR A Better America PROMISES KEPT. TAXPAYERS**	Included in President Trump's proposed Department of Health & Human	Amends the Public Health Service Act to state that biologics do not have to meet the same United States Pharmacopeia standards as non-biologic drugs. According to the budget, this revision will make it easier for biosimilars to enter the market.	The President releases an annual proposed budget for the federal government. It rarely advances in

Bill #	Bill Name	Co-Sponsors	Summary	Status
	FIRST. Budget for Fiscal Year 2020.[14]	Services (HHS) Budget for FY 2020		Congress, but rather is viewed as a roadmap for where the administration recommends focusing resources.
S. 340	**The Creating and Restoring Equal Access to Equivalent Samples ("CREATES") Act**	Sens. Leahy (D-VT), Grassley (R-IA)	"Allows a biosimilar or generic developer to bring a civil action against an innovator drug company if the latter refuses to make available enough samples of a product for testing. It would also explicitly empower the FDA to approve alternative REMS, programs if a generic or biosimilar developer and the innovator company are unable to arrive at a single shared system. Both objectives are intended to allow biosimilar and generic competition to enter the market sooner, thereby driving down drug prices for US patients."[15]	Enacted into law in December 2019 as part of a broader government spending bill (H.R. 1865).
H.R. 965		Reps. Cicilline (D-RI)		
H.R. 2374	**Stop STALLING Act**	Reps. Jeffries (D-NY), Sensenbrenner (R-WI)	Enables the Federal Trade Commission to deter the filing of sham citizen petitions to cover an attempt to interfere with the approval of a competing generic drug or biosimilar, to foster competition and facilitate the efficient review of petitions filed in good faith to raise legitimate public health concerns.[16]	Marked up by House Judiciary Committee

Bill #	Bill Name	Co-Sponsors	Summary	Status
S. 1224		Sens. Klobuchar (D-MN), Grassley (R-IA)		Reported out of Senate Judiciary Committee
Budget for Fiscal Year 2017 (p. 66)	**Office of the White House, "Meeting Our Greatest Challenges: Opportunity for All,"** Budget for Fiscal Year 2017	President Barack Obama	Proposes to reduce biologic exclusivity to seven years in the Obama Administration budget for fiscal year 2017. Biologics approved by the FDA are granted 12 years of exclusivity —substantially longer than the five years typically granted to traditional, small-molecule pharmaceuticals. Other high-income countries grant biologics fewer years of exclusivity than the U.S., and many provide small-molecule drugs and biologics the same period of exclusivity. This proposal also included a prohibition on "additional periods of exclusivity for brand biologics due to minor changes in product formulations." According to the Office of Management and Budget, these proposals together would have generated federal savings of $6.96 billion over 10 years.	The President releases an annual proposed budget for the federal government. It rarely advances in Congress, but rather is viewed as a roadmap for where the administration recommends focusing resources.
H.R. 3379	**Price Relief, Innovation, and Competition for Essential Drugs Act**	Democratic proposal sponsored by Schakowsky (D-IL) and 22 others.	Amends the Public Health Service Act to shorten the exclusivity period for brand name biological products from 12 to 5 years.[17]	Referred to the House Committee on Energy & Commerce Committee.

Expanding Negotiation/Financial Incentives for Payers

Bill #	Bill Name	Co-Sponsors	Summary	Status
H.R. 3	**The Lower Drug Costs Now Act**	Democratic proposal sponsored by Rep. Pallone (D-NJ)	Provides the Department of Health and Human Services (HHS) the authority to "directly negotiate prices on the top 250 drugs with the greatest total cost to Medicare and the entire US health system without competition from at least two generic, biosimilar or interchangeable biologics on the market."[18] Each year, the most expensive 250 drugs would be subject to review. Not only that, but the price would be available to all payers—not just Medicare.[19]	Referred to House Energy & Commerce Committee, House Ways & Means Committee, House Education & Labor Committee
H.R. 4455	**BIOSIM Act**	Reps. Schrader (D-OR), Gianforte (R-MT)	Provides for a temporary payment increase under the Medicare program for certain biosimilar biological products to encourage the development and use of such products.[20]	Referred to House Energy & Commerce Committee, House Ways & Means Committee
H.R. 4629	**Star Rating for Biosimilars Act**	Reps. Tonko (D-NY), Gibbs (R-OH)	Requires HHS to add a new set of measures to the 5-star rating system under the Medicare Advantage program to encourage increased access to biosimilar biological products.[21]	Referred to House Energy & Commerce Committee, House Judiciary Committee
S. ___		Sens. Cassidy (R-LA), Menendez (D-NJ)		Unknown

Bill #	Bill Name	Co-Sponsors	Summary	Status
H.R. 4597	**The Acting to Cancel Copays and Ensure Substantial Savings ("ACCESS") for Biosimilars Act**	Reps. King (R-NY), Peters (D-CA)	Eliminates cost-sharing for biosimilar biological products furnished under Part B of the Medicare program.[22]	House Energy & Commerce Committee, House Ways & Means Committee
	"FAILURE TO LAUNCH": Barriers to Biosimilar Market Adoption (Part 2)	Proposal from the Biosimilars Council	Reduces rebate and discounting schemes when a new biosimilar enters the market, especially if exclusionary contracting to obstruct price competition is involved.[23]	Published September 2019

Instituting Pricing Caps/Mandated Cost Caps

Bill #	Bill Name	Co-Sponsors	Summary	Status
S. 102	**The Prescription Drug Price Relief Act**	Democratic proposal sponsored by Sen. Sanders (D-VT)	Establishes a series of oversight and disclosure requirements relating to the prices of brand-name drugs. Specifically, the bill requires HHS to review at least annually all brand-name drugs for excessive pricing; HHS must also review prices upon petition. If any such drugs are found to be excessively priced, HHS must (1) void any government-granted exclusivity; (2) issue open, nonexclusive licenses for the drugs; and (3) expedite the review of corresponding applications for generic drugs and biosimilar biological products. HHS must also create a public database with its determinations for each drug.[24]	Referred to Senate HELP Committee
H.R. 465		Democratic proposal sponsored by Rep. Khanna (D-CA)		Referred to House Energy & Commerce Subcommittee on Health, House Judiciary Subcommittee on Antitrust, Commercial, and Administrative Law

Broadening Consumer's Education

Bill #	Bill Name	Co-Sponsors	Summary	Status
S. 1681	**The Advancing Education on Biosimilars Act**	Senators Enzi (R-WY) and Hassan (D-NH)	Requires HHS to establish, maintain, and operate an internet website consisting of educational materials regarding the meaning and use of biosimilar biological products and interchangeable biological products.[25]	Referred to the Senate HELP Committee
H.R. 4400		Reps. Bucshon (R-IN) and Engel (D-NY)		Referred to the House Energy & Commerce Committee, House Ways & Means Committee

This overview offers insights on known legislation as of March 19, 2020. Given that the policy landscape is dynamic and changes often, this overview is a limited snapshot in time.

HOW ARE STATES GETTING INVOLVED?

While there are solutions that can be implemented at the federal level, many states have taken it upon themselves to pass certain policies to diminish the burden on consumers and increase access to effective treatments. For several decades, every state has regulated the use of brand-name and generic prescription drugs through statutes and agency or board rules with varying rules across the country. In the past five years at least 45 states have considered legislation establishing state standards for substitution of a "biosimilar" prescription product to replace an original biologic product.[12]

Many states have taken it upon themselves to pass certain policies…

Recent state legislation also includes efforts to promote provider discretion in determining the best course of treatment for patients. On April 1, 2019, Arkansas enacted HB 1269, permitting prescribers to limit biosimilar substitution, so it can be within the provider's discretion to decide what treatment is in a patient's best interest. Maine enacted similar legislation in the same month and included language that lends a reasonable time period (five business days) for a pharmacist to notify the prescriber of a biosimilar substitution.

Several active state bills would impact access to biosimilars. In D.C., policymakers are considering legislation (B30-0430) that would authorize licensed pharmacists to dispense interchangeable biological products and to require reasonable notifications to physicians when such interchangeable biological products are dispensed. Maryland has also recently introduced HB 664, requiring pharmacists to inform consumers when there is a less costly therapeutically equivalent drug or device, or interchangeable biologic.

CONCLUSION: WHAT SHOULD POLICYMAKERS DO?

It's vitally important to increase competition and streamline the approval framework for getting biosimilars to market as these important and more affordable drugs will expand access for patients and lower costs for all. Policymakers must recognize that private-sector employers pay, on average, 80 percent of health coverage for their workers and families, including for the cost of drugs, and that biologic spending is the fastest-growing part of their health care costs. Making biosimilars more available and accessible to patients will lower health care costs for all and improve health and wellbeing. Employers can use their health plan design to accelerate the use of biosimilars in their plans, but the federal and state governments hold the keys to making these life-saving medications more accessible and available to employees and families across the country.

LEARN MORE

For more information about this topic, please contact ERIC at www.eric.org or call 1.202.789.1400.

About ERIC

ERIC is the only national association that advocates exclusively for large employer plan sponsors on health, retirement, compensation, and paid leave public policies at the federal, state, and local levels. With member companies that are leaders in every sector of the economy, ERIC promotes uniformity and flexibility for nationwide benefit plans.

About Fidelity Workplace Consulting

Fidelity Workplace Consulting is a dedicated business unit that focuses on solving workplace challenges for clients. From analysis to change management and measurement, Fidelity consultants help employers assess and improve the effectiveness of their benefit programs, engage employees, and design and implement successful workforce planning strategies.

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