Understanding Stakeholder Perception of Biosimilars

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Introduction

Congress created a biosimilar approval pathway in 2010, but since then only 29 biosimilars have been approved in the United States. The uptake of biosimilars in the United States has been relatively slow due to a combination of market factors and policies that have both delayed and discouraged utilization. Some payers fear that slow uptake could lead biosimilar manufacturers to exit the market if they do not see enough potential for return on their investment. Eleven years after the biosimilar market began, this research seeks to understand physician, patient, and payer perspectives on biosimilars—including clinical confidence in and barriers to adoption—and how to encourage broader take-up.

Background

Biologic drugs are large, complex molecules that are typically grown or synthesized from living organisms using complex manufacturing processes.[1] Biologics are regulated and approved by the Food and Drug Administration (FDA) for quality and consistency.[2] In 2010, Congress passed the Biologics Price Competition and Innovation Act (BPCIA), which created an abbreviated pathway for the FDA to approve biosimilar products that are highly similar and have no clinically meaningful differences from their existing FDA-approved reference biologic product (also called brand or innovator biologics).

As of December 2020, the FDA has approved 29 biosimilars, although only a portion of these have actually launched (see Table 1). While there has been a significant increase in the number of biosimilars approved by the FDA in the past five years, the United States is just beginning to catch up to other countries around the world, namely European markets, where biosimilars are more widely approved and used.[3] Nine biosimilars recently approved by the FDA are not currently being marketed due to patent settlements or other business decisions, and no approved biosimilars have been approved as interchangeable—a designation that allows biosimilars to be substituted for reference drugs at the pharmacy without physician consent.[4]

Uptake of available biosimilars remains relatively slow, with the collective market share of all biosimilars currently exceeding 50 percent for only one of the seven brand, reference products with which they compete.[5] That lag is driven by a combination of factors, including patent litigation, drug coverage and payment policies, formulary placements for these products, and competition from brand biologics. Currently, biosimilars' average sales price (ASP) at launch is typically 3 percent to 24 percent below the

[1] U.S Food and Drug Administration. (2020, March 23). Biosimilar and Interchangeable Biologics: More Treatment Choices. Retrieved March 9, 2021, from https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices.

[2] U.S. Food and Drug Administration. (2017, October 23). Biosimilar and Interchangeable Products. Retrieved March 9, 2021, from https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products#biological.

[3] Feldman, M., & Reilly, M. S. (2020). A White Paper: US biosimilars market on pace with Europe. *Generics and Biosimilars Initiative Journal, 9*(4), 150-154. doi:10.5639/gabij.2020.0904.025.

[4] Vizient. (2021, January). Winter 2021 Pharmacy Market Outlook. Retrieved March 10, 2021, from https://www.vizientinc.com/-/media/documents/sitecorepublishingdocuments/public/PMO121_PharmacyMarketOutlook_Public.pdf.

[5] Amgen Biosimilars. (2020, September). *2020 BIOSIMILAR TRENDS REPORT* (Rep.). Retrieved March 10, 2021, from Amgen Biosimilars website: https://www.amgenbiosimilars.com/-/media/Themes/Amgen/amgenbiosimilars-com/Amgenbiosimilars-com/pdf/USA-CBU-80723-2020-Amgen-Biosimilar-Trends-Report.pdf.

brand biologics' ASP.[6] As a comparison, the FDA estimates that nonbiologic generics are sold at a price of 80-85 percent below brand-name medication.[7] While the biosimilars' ASP is typically lower than brand biologics, brand manufacturers can compete by increasing their rebates to encourage payers to maintain preference for the brand biologic on their formulary.[8] A study in 2019 found that U.S. health plans covered biosimilars as preferred in only 14 percent of coverage decisions.[9]

Table 1. Biosimilars Launched in the United States

Launched Biosimilars (Winter 2020)	Reference Biologic
Mvasi (bevacizumab-awwb)	Avastin
Zirabev (bevacizumab-bvzr)	Avastin
Retacrit (epoetin alfa-epbx)	Epogen/Procrit
Ogivri (trastuzumab-dkst)	Herceptin
Herzuma (trastuzumab-pkrb)	Herceptin
Trazimera (trastuzumab-qyyp)	Herceptin
Kanjinti (trastuzumab-anns)	Herceptin
Ontruzant (trastuzumab-dttb)	Herceptin
Udenyca (pegfilgrastim-cbqv)	Neulasta
Ziextenzo (pegfilgrastim-bmez)	Neulasta
Fulphila (pegfilgrastim-jmdb)	Neulasta
Zarxio (Filgrastim-sndz)	Neupogen
Nivestym (filgrastim-aafi)	Neupogen
Inflectra (Infliximab-dyyb)	Remicade
Renflexis (infliximab-abda)	Remicade
Truxima (rituximab-abbs)	Rituxan
Ruxience (rituximab-pvvr)	Rituxan

Most biologic and biosimilar drugs are currently covered under the medical benefit and reimbursed via the "buy-and-bill" method, in which providers purchase the physician-administered drug and are reimbursed at a percent-of-charge or ASP plus a markup.[10] Some health plans have begun to shift distribution for these products to specialty pharmacies and thus have begun to cover them through the pharmacy benefit.[11] This reduces provider payment incentives to use one product over another and increases plans' ability to control product selection via their formulary. Future biosimilars are expected to increasingly be self-administered and covered via the pharmacy benefit.[12]

Beyond these structural limitations, some stakeholders continue to question physicians' willingness to use biosimilars and patients' willingness to take these products. Researchers have tried to examine the patient, physician, and practice characteristics associated with biosimilar use. One study found that the practice setting and hospital ownership status had the largest association with biosimilar usage, with patient characteristics weakly associated with biosimilar uptake. [13] Another study finds that biosimilar use is most likely to grow when its relative reimbursement ratio is higher than the brand biologic across settings of care.[14]

Numerous surveys of providers were conducted prior to 2018, before many biosimilars had launched in the United States. Many of these surveys were based in Europe and had very small sample sizes. A systematic review of factors that affect health care provider knowledge and acceptance of biosimilar medicines found that "an overall lack of biosimilar familiarity in U.S. and European health care settings accompanies concerns about biosimilar safety, efficacy, extrapolation and interchangeability."[15]

In this rapidly shifting market, new and more comprehensive survey data and qualitative research can yield insights about the knowledge of, demand for, and willingness to use biosimilars.

[6] Amgen Biosimilars. (2020, September). *2020 BIOSIMILAR TRENDS REPORT* (Rep.).
[7] U.S. Food and Drug Administration. (2018, June 1). Generic drugs: Questions & Answers. Retrieved March 10, 2021, from https://www.fda.gov/drugs/questions-answers/generic-drugs-questions-answers#2
[8] Carioto, J., & Mirchandani, H. (2018). Barriers and potential paths for biosimilars in the United States.
[9] Chambers, J. D., Lai, R. C., Margaretos, N. M., Panzer, A. D., Cohen, J. T., & Neumann, P. J. (2020). Coverage for biosimilars vs. reference products among US commercial health plans. *JAMA*, *323*(19), 1972-1973.
[10] Carioto, J., & Mirchandani, H. (2018). Barriers and potential paths for biosimilars in the United States.
[11] Niyogi, S., Adolph, N., Pashchinskiy, A. (2021). Biosimilars in the U.S.: Reimbursement and Impacts to Uptake. IQVIA. https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/biosimilars-in-the-us-reimbursement-and-impacts-to-uptake.pdf?&_=1617122442873.
[12] U.S. Food and Drug Administration. (2020, December 17). *Biosimilar product information*. U.S. Food and Drug Administration. https://www.fda.gov/drugs/biosimilars/biosimilar-product-information.
[13] Dean, E. B., Johnson, P., & Bond, A. M. (2021). Physician, practice, and patient characteristics associated with biosimilar use in Medicare recipients. *JAMA Network Open*, *4*(1), e2034776-e2034776.
[14] Niyogi, S., Adolph, N., Pashchinskiy, A. (2021). Biosimilars in the U.S.: Reimbursement and Impacts to Uptake. IQVIA. https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/biosimilars-in-the-us-reimbursement-and-impacts-to-uptake.pdf?&_=1617122442873.
[15] Leonard, E., Wascovich, M., Oskouei, S., Gurz, P., & Carpenter, D. (2019). Factors affecting health care provider knowledge and acceptance of biosimilar medicines: a systematic review. Journal of managed care & specialty pharmacy, 25(1), 102-112.

Research Methodology

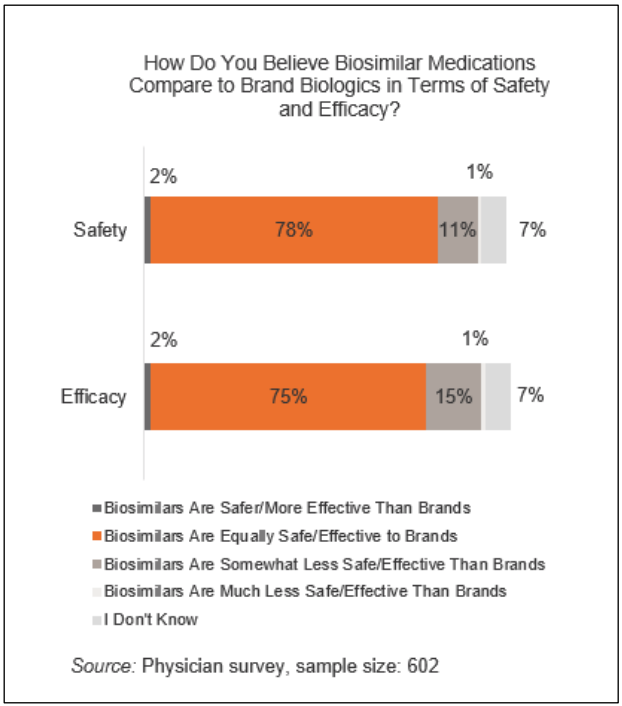
The purpose of this research was to further understand stakeholder perceptions of biosimilars. NORC at the University of Chicago (NORC) conducted quantitative and qualitative research of provider, patient, and payer perceptions of biosimilars to understand how stakeholders' actions may affect uptake of biosimilars in the future. NORC conducted two surveys, two focus groups, and 20 interviews, including:

- A **patient survey** of 618 patient respondents who had been prescribed a biologic medication in the previous 12 months to treat a diagnosed condition
- A **physician survey** of 602 specialists who regularly prescribe biologic medications to their patients, including hematology/oncology, rheumatology, gastroenterology, dermatology, and ophthalmology
- Two 90-minute **patient focus groups** with a total of 16 patients taking biologic medications
- Thirteen **stakeholder interviews** with **payers and group purchasing organizations (GPOs)**
- Seven **stakeholder interviews** with **providers**—both physicians who prescribe biologics and individuals responsible for purchasing

Perception of Biosimilars

PHYSICIANS BELIEVE BIOSIMILARS ARE EQUALLY SAFE AND EFFECTIVE AS THE BRAND BIOLOGICS, AND THEY ARE COMFORTABLE PRESCRIBING THEM. More than three out of four physicians surveyed indicated that biosimilars are equally safe and effective as brand biologics, with only a small number believing they are somewhat less safe and effective (see Figure 1).

Figure 1. Most physicians consider biosimilars equally safe and effective compared to brands



Source: Physician survey, sample size: 602

> "FDA approval paradigms are highly similar. They may not be interchangeable yet, and they're certainly not exact replicas. But in terms of the efficacy and safety, they're so highly similar that it would be difficult to make a case that they're less safe or less efficacious than the original branded molecules."
> —Gastroenterologist

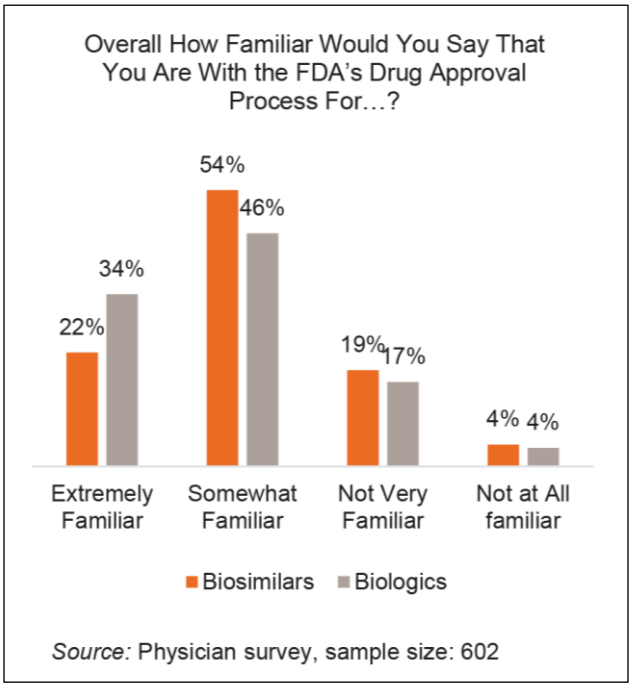
In discussions, prescribing physicians consistently said they are not deterred from prescribing biosimilars based on their safety and efficacy relative to the brand. GPO leaders also indicated high levels of confidence in the safety and efficacy of biosimilars, with one saying they view them to be "almost identical" to brands.

Almost all (94 percent) of physicians report being comfortable (55 percent very comfortable; 39 percent somewhat comfortable) with prescribing biosimilars that have been approved by the FDA. Eight out of 10 physicians report having prescribed a biosimilar to their patients in the last 12 months. Further, 77 percent of physicians expect to prescribe biosimilars more often in the next 12 months. When asked about their familiarity with the FDA's drug approval process for biosimilars and biologics, more than three in four physicians report being familiar with the process, with physicians reporting they are only slightly less familiar with the process for biosimilars (see Figure 2).

Payers and GPOs indicated that their pharmacy and therapeutics (P&T) committees, which are responsible for

making coverage and formulary placement decisions for prescription drugs, deem biosimilars to be clinically comparable to branded biologics. One GPO leader interviewed expressed their comfort with the FDA approval process and shared that they also looked at markets in other countries for additional context.

Figure 2. Three out of four physicians reported being extremely or somewhat familiar with the FDA's approval process.



> "By definition, they are a highly similar type of product. So we consider those products clinically comparable to the innovator products."
> — Payer

> "Europe is ahead of us. So we watch that and pay attention to that as well. So by the time the biosimilars are being approved over here, there's a little bit of background or a little bit of history there that we can rely on and look at."
> — GPO

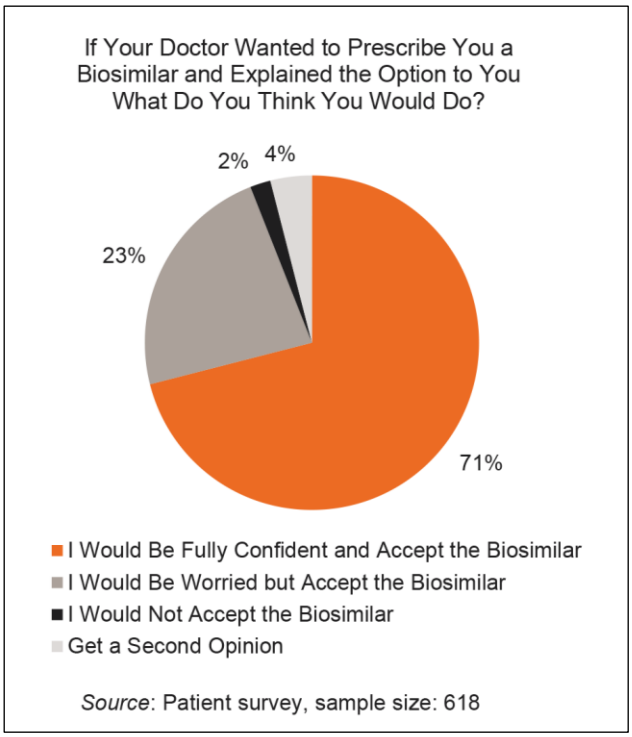
Policy Implication: Though prior research has underscored the need for education and data to address physicians' doubts about the safety and efficacy of biosimilars, our findings suggest high levels of clinical confidence among physicians who are regularly prescribing biologics. While physicians would welcome more data on biosimilars, they largely perceive them to be on par with brand biologics.

PATIENTS TRUST THEIR DOCTORS' TREATMENT RECOMMENDATIONS AND EXPRESS CONFIDENCE IN BIOSIMILARS.

Among patients taking biologics, 99 percent report trusting their doctors somewhat (17 percent) or a great deal (82 percent) to make the right decisions for them when prescribing medicines. Further, 77 percent of patients say they always accept their doctors' prescription recommendations. Focus group participants supported this finding, unequivocally stating that specialists are their most trusted source of information, and to some extent, pharmacists.

Among patients surveyed, 71 percent said they would be fully confident and accept a biosimilar if their physician prescribed it. Another 23 percent of patients said they would be worried but accept the biosimilar (see Figure 3).

Figure 3. Seven out of ten patients would be fully confident and accept a biosimilar if prescribed by their physician.



Similar to physicians, patients report high levels of confidence in the safety and efficacy of biosimilars. Seventy-seven percent of patients believe that biosimilars are equal or better than branded biologics in terms of efficacy, and 79 percent of patients believe them to be equal or better in terms of safety. The vast majority of patients (95 percent) say that they are extremely or somewhat confident that the FDA approval process is sufficient to ensure that prescription drugs are safe and effective. One focus group respondent described their reasoning as follows:

> "[To me,] FDA approval means it's gone through a lot of testing and it seems like it's going to be okay. It hasn't killed anybody. And then they list the side effects. Even if only one person out of 10,000 who tested it gets that side effect, they list it. So I feel like if it is FDA approved, I can go and read about the medication and come to my own conclusion."
> — Biologics Patient

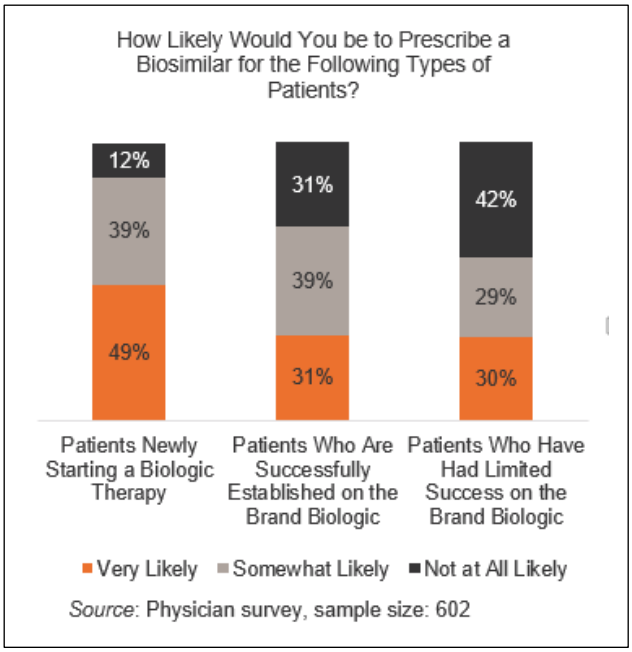
Physicians report low levels of biosimilar awareness among their patients, with 61 percent of doctors reporting that few or none of them are aware biosimilars exist. Forty percent of doctors say they rarely or never talk with their patients about the risks and benefits of biosimilars compared to biologics. However, 84 percent of patients who had been prescribed a biosimilar in the past 12 months reported having a discussion with their doctors about the difference between a biosimilar and a brand biologic before receiving the biosimilar.

Policy Implication: Our research clearly finds that physicians' recommendations and confidence are the most important factors driving patients' willingness to take a biosimilar. Continuing to focus resources on encouraging physician prescribing will be more important than broad-scale patient education.

PHYSICIANS ARE MORE LIKELY TO PRESCRIBE A BIOSIMILAR TO A PATIENT WHO IS NEWLY STARTING THERAPY THAN TO PATIENTS WHO ARE ALREADY SUCCESSFULLY ESTABLISHED ON A BRANDED BIOLOGIC TREATMENT.

Forty-nine percent of physicians reported that they were very likely to prescribe biosimilars for patients newly starting on a biologic therapy, compared to 31 percent who were very likely to prescribe biosimilars for patients who are successfully established on a brand biologic (see Figure 4).

Figure 4. Physicians most likely to prescribe a biosimilar for patients newly starting a biologic therapy



When asked to elaborate, one physician explained that while they are very open to starting new patients on biosimilars, they hesitate to switch patients who are doing well on their current regimen.

> "I'd much prefer to start a new bio-need patient on a biosimilar agent. I have a lot of reservations trying to switch over a patient that is doing well and stable on a name-brand biologic. That is where I sort of put up a stop sign and try and avoid if at all possible."
> — Dermatologist

The physician suggested that patients may also hesitate to switch, but that patient willingness to change may be driven by their history of treating their disease.

> "A patient that has moderate to severe psoriasis but hasn't been down the path of being on various disease modifying drugs such as methotrexate, cyclosporine, and later on was introduced to biologic and is doing well is going to have a totally different approach than a patient that really chose the biologic agent as a first line of therapy and they're doing very well on it. They're going to be quicker to flip the switch and be willing to change over to a biosimilar than that psoriasis patient that has had several sustained medications and finally found one that works."
> — Dermatologist

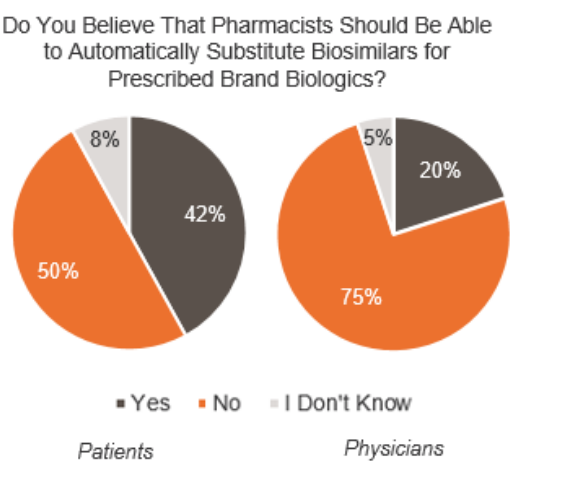
Policy Implication: Despite physicians' general acceptance of biosimilars, doctors are much less willing to switch a stabilized patient onto a biosimilar. There may be more new-starts on biosimilars the longer biologics are on the market, but rapid shifts from brands to biosimilars for

established patients are unlikely. Additional data on side effects, real-world evidence about patient switches, or interchangeability designations could increase physicians' comfort with moving established patients to biosimilars.

PHYSICIANS ARE LARGELY OPPOSED TO AUTOMATIC SUBSTITUTION BY PHARMACISTS, WHILE THE REACTION FROM PATIENTS IS MIXED.

Automatic substitution is the ability to allow pharmacists to automatically switch a patient's biologic prescription to a biosimilar without requiring explicit approval from a doctor. Currently, pharmacists have the legal ability to substitute branded drugs with products classified as therapeutically equivalent, which are often generic drugs. In the case of existing biosimilars, however, pharmacists do not currently have the ability to switch a prescription from a brand biologic to a biosimilar. Only 20 percent of physicians said that pharmacists should be authorized to substitute biosimilars for prescribed brand biologics (see Figure 5). When asked about this in an interview, one physician explained they were hesitant because they want to be aware of decisions made around their patient's course of treatment.

Figure 5. Physicians more likely than patients to say that pharmacists shouldn't be able to automatically substitute biosimilars for prescribed brand biologics.



Sources: Patient survey, sample size: 618; Physician survey, sample size: 602

> "If the patient is no longer doing as well [on a drug], is that due to the natural progression of the disease? Is it due to the fact that the medicine was changed? And is not really as effective even though it's supposed to be? So I'm against interchangeability and automatic substitution anywhere after the patient leaves the office."
> — Rheumatologist

Patients were somewhat more accepting of automatic substitution, with 42 percent indicating that pharmacists should be able to substitute biosimilars. Focus group participants, however, had strong negative reactions to the idea of a pharmacist automatically substituting their biologic for a biosimilar, citing fears that their doctors would not be consulted, concerns about comparability of the drugs, and worries about side effects. Some patients even said that they would refuse the drug until they consulted with their physician.

> "For me, it's not as much that I don't trust them, as I don't see it as just being a straight generic. I won't want to see it just substituted for the brand name. I'd want to have a discussion about prescribing this particular medication."
> — Biologics Patient

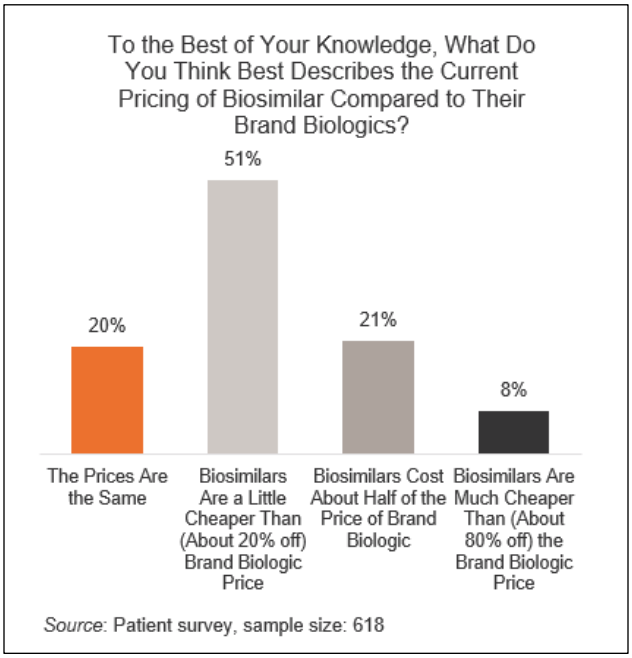
Policy Implication: This research uncovered a high level of physician opposition to automatic substitution, but we did not fully examine the source of the opposition. Providers may be more opposed to substitution for biologics, given the product complexity and side effect profiles. Additional FDA guidance and education on interchangeability standards for biosimilars may be helpful. However, efforts to expand interchangeability at the state or federal level may be met with physician resistance if not paired with better information about clinical outcomes from switching.

Cost Savings from Biosimilars

BOTH PATIENTS AND PHYSICIANS BELIEVE THAT BIOSIMILAR OUT-OF-POCKET COSTS ARE LOWER THAN BRANDED BIOLOGICS, BUT DRUG DISCOUNT PROGRAMS MAY MITIGATE DIFFERENCES IN PATIENT COSTS.

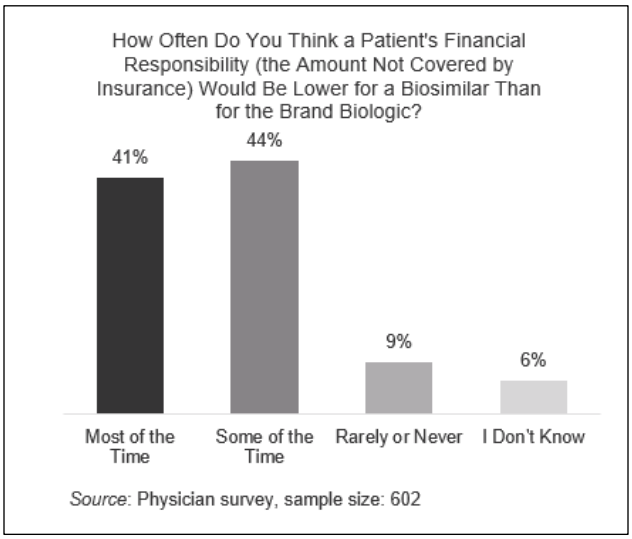
Five out of ten patients believe that biosimilars are a little cheaper than branded biologics, while 20 percent believe the prices are the same (see Figure 6). Meanwhile, 85 percent of physicians think a patient's financial responsibility would be lower for a biosimilar than for the brand biologic some or most of the time. Some focus group participants expressed concerns that cheaper products may be lower quality (see Figure 7).

Figure 6. More than half of patients surveyed reported thinking that biosimilars are cheaper than branded biologics



> "My doctor looking to prescribe the lowest cost medication makes me really uncomfortable that somebody is going to cheapen what my health needs. It just makes me think that if it's cheaper, I'm probably going to get less benefit out of it because it's just a lower class of medication. I'm at a point now where I need the strong stuff and that usually comes at a cost."
> — Biologics Patient

Figure 7. Most physicians reported thinking a patient's financial responsibility would be lower for a biosimilar than for the brand biologic



Cost is an important factor for patients, with 8 in 10 reporting that they consider their out-of-pocket costs when filling a prescription most (44 percent) or some (37 percent) of the time. Most patients said they would be somewhat or very likely to use a biosimilar if it were cheaper than the branded biologic, though doctor recommendations are far more important than cost. Doctors are also concerned about patient costs, and 66 percent say that they would be more likely to prescribe biosimilars if they knew that they would reduce patient out-of-pocket costs.

According to our survey, a majority of patients have received support from a prescription drug discount program for biologic medications. Some stakeholders described how manufacturers of originator biologics often provide patients with vouchers or coupons to help pay for their out-of-pocket expenses, which may mitigate differences in out-of-pocket costs between brand biologics and biosimilars.

> "The other side of the coin is with the out-of-pocket savings that name brand manufacturers are providing to the patients, namely vouchers or coupons, particularly every month off of their copays, it makes it very competitive with the biosimilar for out-of-pocket expenses to the patient. You tell patients they're going to save money, but it really boils down to most of these companies have a savings plan to cut the out-of-pocket expense to the same or less than the biosimilar agent."
> — Dermatologist

Policy Implication: Providers would benefit from more detailed information about the impact of prescribing biosimilars on patients' out-of-pocket costs. Drug discount and coupon programs play an important role in reducing patient financial liability for biologics today, but they also reduce a patient's incentive to accept the lowest-cost product.

DESPITE THE FACT THAT THE EXISTENCE OF BIOSIMILARS DRIVES DOWN NET PRICES, BRAND BIOLOGICS OFTEN MAINTAIN PREFERRED COVERAGE.

Plans report that the presence of a biosimilar—and particularly multiple biosimilars for the same reference product—produce significant savings during manufacturer negotiations. However, such savings do not always result in preferred coverage and utilization of the biosimilar. Often, manufacturers of the brand biologic begin offering deep discounts and rebates for their products when biosimilars come to market. These rebates, in combination with legacy contracting arrangements, may limit preferred coverage for biosimilars by health plans.

> "Having the ability to buy a biosimilar does change the contracting and the negotiation strategy. And that's one thing that you could argue. Anytime that there's a biosimilar that comes on the market, it gives us that opportunity to have the conversation because there's no longer just one option… I feel it puts pressure on the branded company to adjust their price points a little bit."
> — GPO

> "Over the next two or three years, I think you're going to see biosimilars across the board preferred on every benefit design. It may take three years… because the manufacturers look to mitigate the price [difference] by contracting for the originator to lower the price."
> — Payer

> "So if there's a biosimilar, we absolutely can try to…get the biosimilar on contract. And then it just depends on how the previous contract was written to inhibit us from actually being able to put [the biosimilar] on contract right away, depending on what the branded contract reads. We may have to wait until that contract expires in order to do that."
> — GPO

Physicians also expressed concerns related to these rebate arrangements, which do not always flow through to patient coinsurance and provider acquisition costs.

> "A lot of times we've seen [pharmaceutical manufacturers] who have gone to a payer, and offered a huge rebate to make their brand product preferred on the formulary. And what that does, is it provides a better discount for the payer. And that keeps the branded product locked in as a preferred agent. But it impacts the provider and the patient, the two most important people in the process. So the patient, sometimes even though this is a preferred product, on the formulary it leaves them with $1,000 vial and they might have a 10 percent, 20 percent copay as part of that, versus a $500 one with a 10 percent or 20 percent copay. So it can be substantial."
> — Payer

Policy Implication: Current pricing and contracting approaches can prevent payers from encouraging the use of biosimilars, which inhibits growth of the market. Policies that reduce back-end rebates or require those price concessions flow through to patients may support biosimilar market growth. Plans could also address patient cost-sharing by including a dedicated formulary tier or preferred tier placement with lower cost-sharing for biosimilars.

PAYERS AND PHYSICIANS SEEK ADDITIONAL TRANSPARENCY ABOUT PRICES FOR BRAND BIOLOGICS AND BIOSIMILARS, WHICH COULD ENCOURAGE GREATER PRESCRIBING.

Physicians expressed a need for additional information on net product prices and how they are being reimbursed for biologics and biosimilars. If they received this information, physicians say they would prescribe biosimilars more often.

> "I mean that these things not only are not exactly transparent, so you don't really know if you're saving money or not. It's kind of a guessing game…So I imagine that if we can get some real data and we really know what's going on, we would make our decisions maybe a little bit more rationally."
> — Gastroenterologist

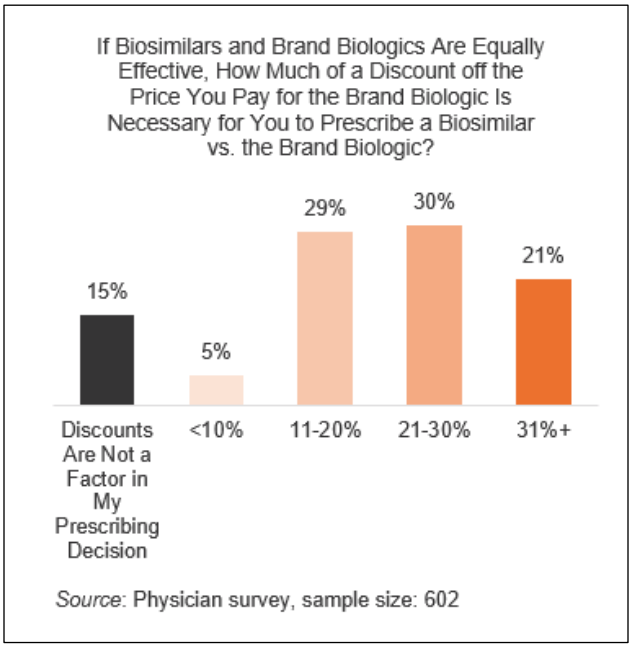
> "So [if I'm] the biosimilar manufacturer and the originator just offered a contract to cut that price in half, they're beating me at my price. I'm going to lower my price if I want to get any of the market share. So you still have that competition, which is good, the problem is it is not transparent."
> — Payer

Physicians report that even relatively small price differences would encourage greater prescribing. One-third of physicians report that they would increase biosimilar prescribing if they knew biosimilars' prices were even 20 percent lower than those of brand biologics.

Policy Implication: Physicians want more information about the true net cost of the product, and want rebates to flow through to patient cost sharing and acquisition costs. Policy changes that would increase price transparency to both physicians and patients could encourage broader adoption.

> "It's extremely expensive to enter that market and to come up with the biosimilar. And so if drug manufacturers are not seeing the usage and they're not getting their money back from that, I would see there [would] be some hesitation or difficulty for other companies to enter that market or decide to continue to develop those biosimilars."
> — GPO

Figure 8. Physicians reported that discounts over 11% were most likely to affect prescribing decisions



Policy Solutions

Current data show the U.S. biosimilar landscape is now advancing at its fastest rate since the BPCIA was signed into law.[16] However, due to current market forces and the COVID-19 pandemic, 2020 saw the lowest number of biosimilar approvals since 2016. Data have shown that the biosimilar market uptake continues to trend upward, suggesting that there is more room for expansion of the biosimilar market in the United States if the market remains viable.[17] Our research provides data to focus biosimilar policy action around key barriers to broader uptake.

RECOMMENDATIONS:

- Issue additional FDA guidance and real-world data on product outcomes and interchangeability for biosimilars.
- Limit incentives that encourage high list prices and promote more innovative contracting arrangements to benefit both patients and the system at large.
- Increase transparency requirements to both physicians and patients regarding the actual price of the drugs.

ISSUE ADDITIONAL FDA GUIDANCE AND REAL-WORLD DATA ON PRODUCT OUTCOMES AND BIOSIMILAR INTERCHANGEABILITY.

Providing physicians with additional guidance and data would give them greater ability to make decisions around safety and efficacy of biosimilars as treatment mechanisms. While physicians who have experience with biosimilars view biologics and biosimilars to be equally safe and efficacious, giving more data to physicians who are not yet convinced would help address concerns. It is clear that patients rely heavily on their physicians' recommendations for treatment, so additional data could lead to stronger physician confidence.

Today, physicians remain skeptical about the idea of automatic substitution of biosimilars, which may yield resistance if any biosimilars are deemed interchangeable. The FDA released draft guidance and Q&As for the biosimilar industry around interchangeability in November 2020.[18] This guidance makes it clear that the FDA is open to pathways that would support interchangeability for biosimilar products. Additional data, including real-world evidence, about the efficacy and side effects of biosimilars—particularly for established patients who switch treatments—could help build prescriber confidence.

[16] Amgen Biosimilars. (2020, September). *2020 BIOSIMILAR TRENDS REPORT* (Rep.). Retrieved March 10, 2021, from https://www.amgenbiosimilars.com/-/media/Themes/Amgen/amgenbiosimilars-com/Amgenbiosimilars-com/pdf/USA-CBU-80723-2020-Amgen-Biosimilar-Trends-Report.pdf.

[17] Chen, P., McGlynn, K., & Shmuel, J. (2021, February 5). *Biosimilars 2020 Year in Review*. JD Supra. https://www.jdsupra.com/legalnews/biosimilars-2020-year-in-review-4933102/.

[18] U.S Food and Drug Administration. (2020, November). *Biosimilarity and Interchangeability: Additional Draft Q&As on Biosimilar Development and the BPCI Act*. U.S. Food and Drug Administration. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/biosimilarity-and-interchangeability-additional-draft-qas-biosimilar-development-and-bpci-act.

LIMIT INCENTIVES THAT ENCOURAGE HIGH LIST PRICES AND PROMOTE MORE INNOVATIVE CONTRACTING ARRANGEMENTS TO BENEFIT BOTH PATIENTS AND THE SYSTEM AT LARGE.

It is clear from conversations with patients and physicians that cost is not the driving factor in choosing a treatment plan. Patients on biologic medications are particularly interested in the most efficacious and safe drugs, and often trust the advice of their physician. While biosimilars have enabled many payers to negotiate rebates that lower the effective price of biologics, these mechanisms neither support adoption of biosimilars nor reduce out-of-pocket costs to patients. Proposed reforms to drug rebates could reduce price distortions in the market and ensure that patients and payers directly benefit from price concessions. Further, creative benefit designs could encourage broader prescribing of biosimilars and lower costs to patients.

INCREASE TRANSPARENCY REQUIREMENTS TO BOTH PHYSICIANS AND PATIENTS REGARDING THE ACTUAL PRICE OF THE DRUGS.

Payers, physicians, and patients alike expressed interest in more transparency related to biologic and biosimilar costs and pricing. New price transparency rules will require physicians to show certain patients their drug formulary. When comparing the biologic and biosimilar, patients who view safety and efficacy as equal may look to price to make a decision. Providing them with more granular information empowers patients to make the lower-cost decision.

> "I just think the transparency, the visibility education to the end user and the patient so they can understand the efficacy and know that the risks are very limited as opposed to branded. I think that will help improve the adoption and help increase the amount of companies that are going to want to invest into biosimilars. So anything that helps with that type of communication or allowing the overall market to understand that, just education is very key."
> — GPO

Acknowledgements

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ABOUT NORC

NORC at the University of Chicago is an independent research organization headquartered in downtown Chicago with additional offices on the University of Chicago's campus, the DC Metro area, Atlanta, Boston, and San Francisco. NORC also supports a nationwide field staff as well as international research operations. With clients throughout the world, NORC collaborates with government agencies, foundations, educational institutions, nonprofit organizations, and businesses to provide data and analysis that support informed decision-making in key areas, including health care, education, economics, crime, justice, and energy. NORC's decades of leadership and experience in data collection, analysis, and dissemination—coupled with deep subject matter expertise—provide the foundation for effective solutions.

Appendix: Patient and Provider Survey Results

Patient Survey Demographics

Sample: The survey sample consisted of 618 respondents that had been prescribed a biologic medication (excluding vaccines) in the previous 12-months, to treat a diagnosed condition.

GEOGRAPHIC REGION

Region	Percent of Sample
South	33%
North	29%
West	22%
Midwest	17%

INSURANCE STATUS

Type of Insurance	Percent of Sample
ESI	57%
Medicare	27%
Medicaid	8%
None	4%
Other	3%

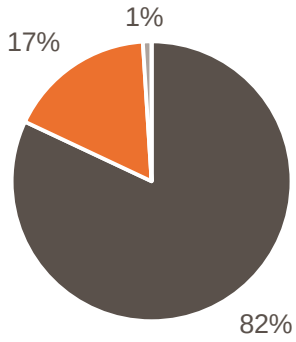
2019 HOUSEHOLD INCOME

Household Income	Percent of Sample
Less than $15,000	4%
$15,000-24,999	5%
$25,000-49,999	13%
$50,000-74,999	18%
$75,000-99,999	17%
$100,000-$149,999	25%
$150,000 or more	18%

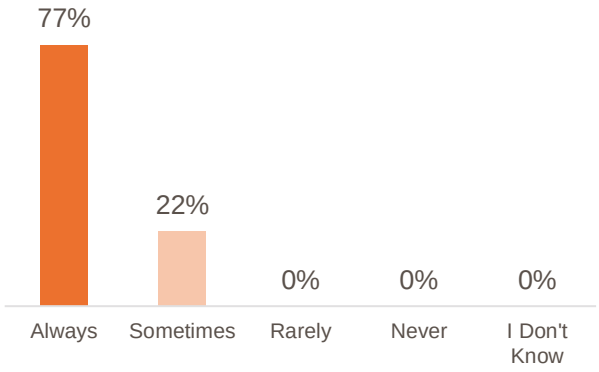
Patient Survey Results

*All results are shown for the full sample (618), unless otherwise noted.

How Much Do You Trust Your Doctor to Make the Correct Decisions For You When Prescribing Medicine?

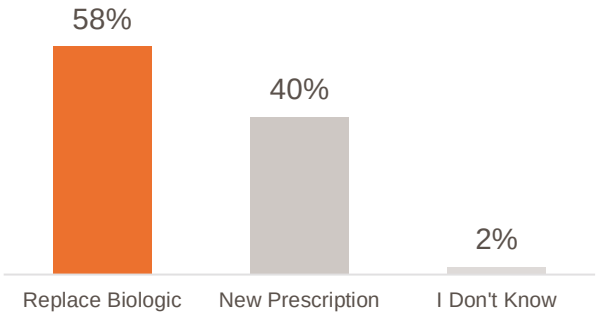


When Your Doctor Prescribes a Medication for You, How Often Do You Accept Your Doctor's Recommendation?



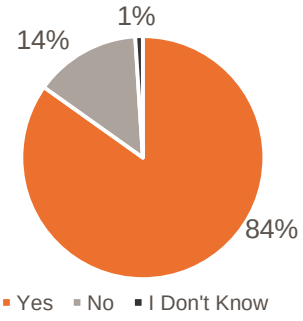
Was the Biosimilar Prescribed to Replace a Brand Biologic You Were Taking Previously or Was the Biosimilar a New Prescription?

Base: 355 Respondents Who Selected "Have Been Prescribed Biosimilar(s)"

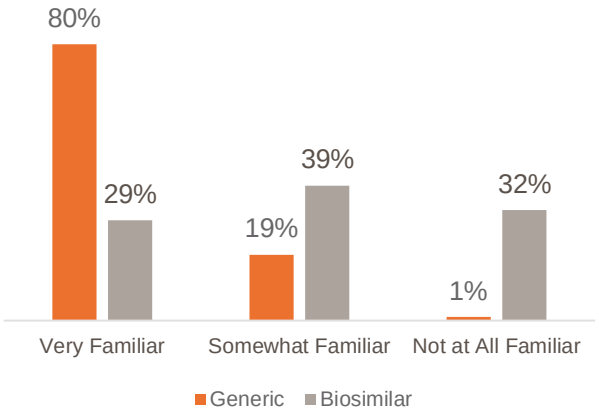


Did You and Your Doctor Have a Discussion About the Differences Between a Biosimilar and a Brand Biologic Before You Received the Biosimilar Prescription?

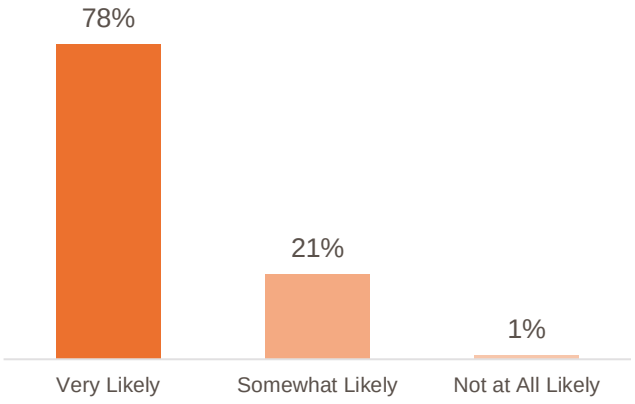
Base: 355 Respondents Who Selected "Have Been Prescribed Biosimilar(s)"



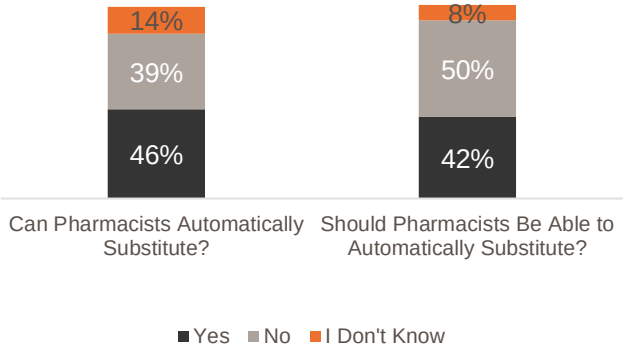
How Familiar Are You With the Following Terms (as They Relate to Prescription Drugs)?



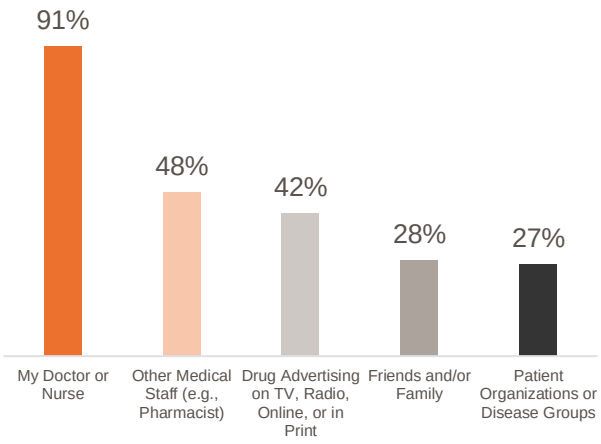
How Likely Are You to Start Treatment on a Biosimilar Instead of a Brand Biologic Drug if Your Doctor Recommends It?



Do You Believe That Pharmacists Can or Should Be Able to Automatically Substitute Biosimilars for Prescribed Brand Biologics Without Doctor Approval?

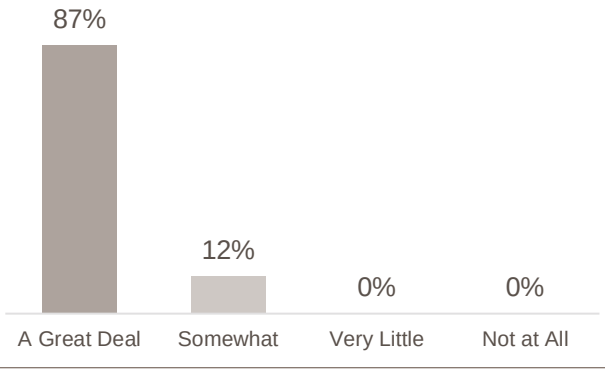


Which Information Sources Do You Use to Learn About Prescription Drugs?

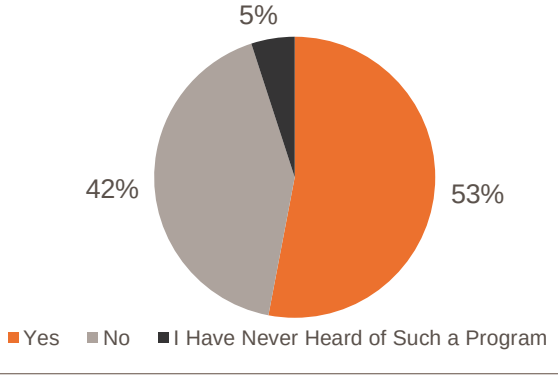


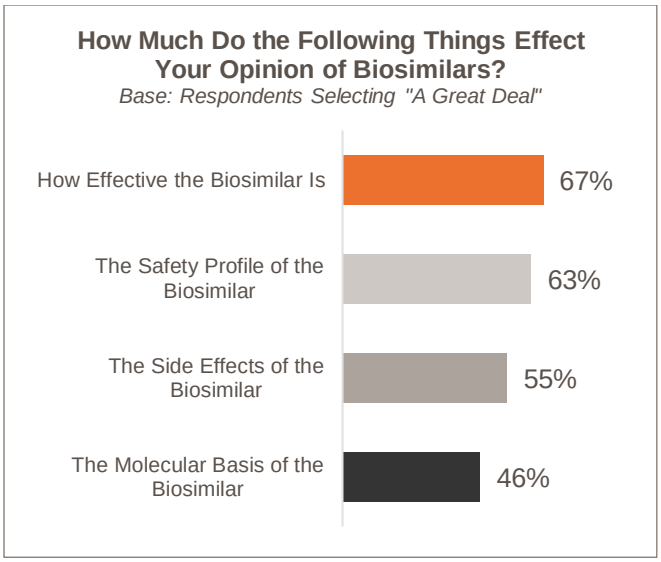
How Much Would You Say You Trust the Doctor or Nurse That You Use to Learn About Prescription Drugs?

Base: 564 Respondents Selecting "Use My Doctor or Nurse to Learn About Prescription Drugs"



To Your Knowledge, Have You Ever Gotten Support From Prescription Drug Discount Programs Such as GoodRx, or Copay Coupons From a Drug Company for Your Biologic Medications?




How Much Do the Following Things Effect Your Opinion of Biosimilars?
Base: Respondents Selecting "A Great Deal"
How Effective the Biosimilar Is
67%
The Safety Profile of the Biosimilar
63%
The Side Effects of the Biosimilar
55%
The Molecular Basis of the Biosimilar
46%

Provider Survey Demographics

Sample: The survey sample consisted of 602 providers across five specialty areas with biosimilars available who regularly prescribe biologic medications.

GEOGRAPHIC REGION

Region	Percent of Sample
South	31%
Northeast	26%
West	21%
Midwest	22%

CLINICAL SPECIALTY

Clinical Specialty	Percent of Sample
Ophthalmology	17%
Dermatology	18%
Rheumatology	20%
Hematology/Oncology	23%
Gastroenterology	21%

PRACTICE SIZE

Practice Size	Percent of Sample
1-20	68%
21-50	15%
51-100	7%
101-200	3%
201+	7%

SITE OF CARE

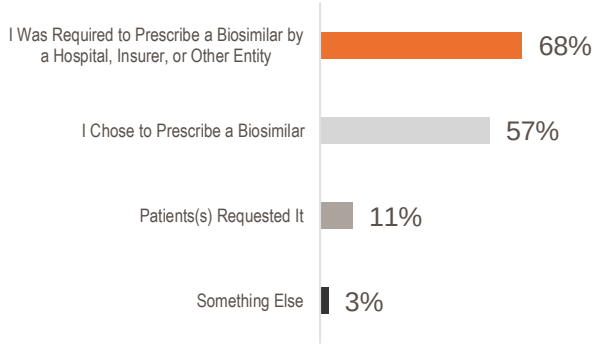
Site of Care	Percent of Sample
Private Practice	67%
Academic Medical Center	21%
Community Hospital	9%
Urban Hospital	2%
Rural Hospital	1%

Provider Survey Results

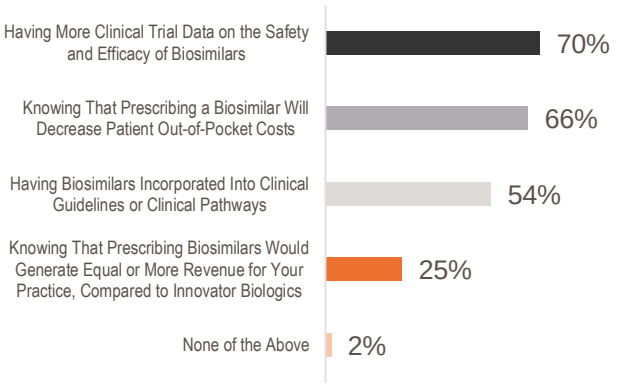
*All results are shown for the full sample (602), unless otherwise noted.

Over the Past 12 Months, Why Did You Prescribe a Biosimilar Medication?

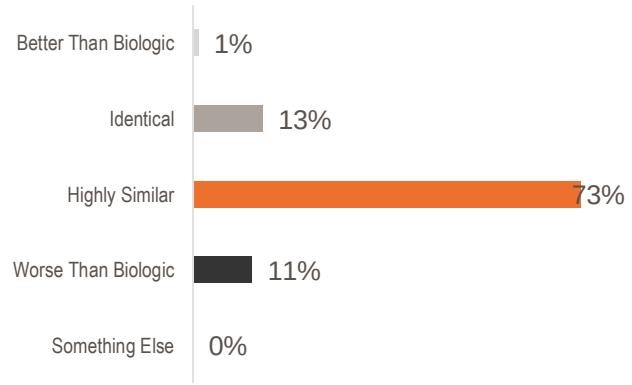
Base: 486 Respondents Who Selected "Personally Prescribed a Biosimilar Medication to Patient(s) in Past 12 Months"



What Factors Would Make You More Likely to Prescribe Biosimilar Medications in the Future?

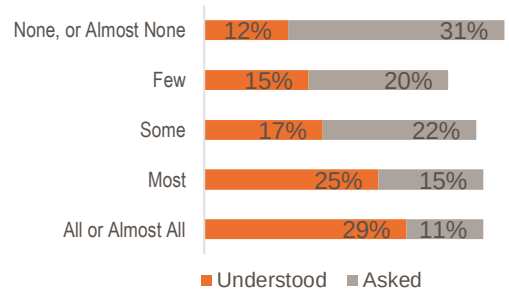


In Your Professional Opinion, Which of the Following Most Accurately Describes a Biosimilar?

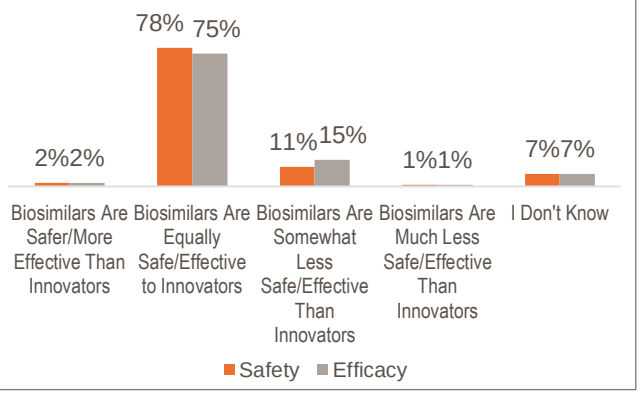


In the Past 12 Months, How Many Patients That You Prescribed a Biosimiar(s) to Understood They Were Being Prescribed a Biosimilar or Asked What a Biosimilar Was?

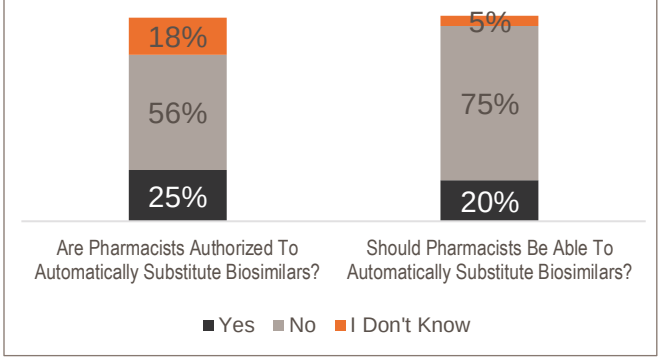
Base: 486 Respondents Who Selected "Personally Prescribed a Biosimilar Medication to Patient)



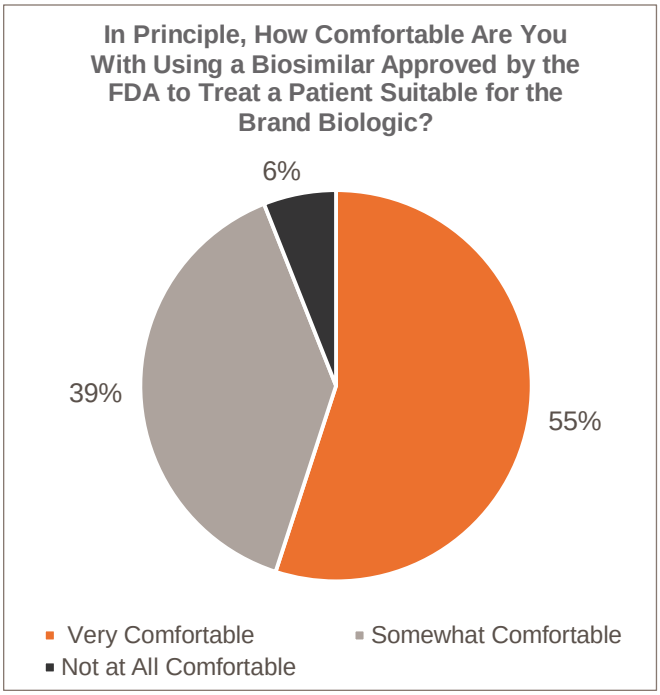
How Do You Believe Biosimilar Medications Compare to Brand Biologics in Terms of Safety and Efficacy?



Do You Believe That Pharmacists Are Authorized to or Should Be Able to Automatically Substitute Biosimilars for Prescribed Brand Biologics?




What Additional Resources About Biosimilars Would You Want?
Additional Head-to-Head Clinical Trial Data
65%
Information About Patient Out-of-Pocket Costs for Biosimilars
60%
Information About Insurance Coverage for Biosimilars
57%
Inclusion of Biosimilars in Clinical Guidelines or Pathways From Specialty Societies
50%
Information About the FDA Approval Process for Biosimilars
41%
Information About Provider Reimbursement for Biosimilars
37%
Additional Pharmacokinetic or Pharmacodymaic Data
27%
Guidance on Biosimilars Prescribing From the Hospital or Group Practice Where You Work
23%
None of the Above
4%
Other
1%


In Principle, How Comfortable Are You With Using a Biosimilar Approved by the FDA to Treat a Patient Suitable for the Brand Biologic?
6%
39%
55%
Very Comfortable
Somewhat Comfortable
Not at All Comfortable