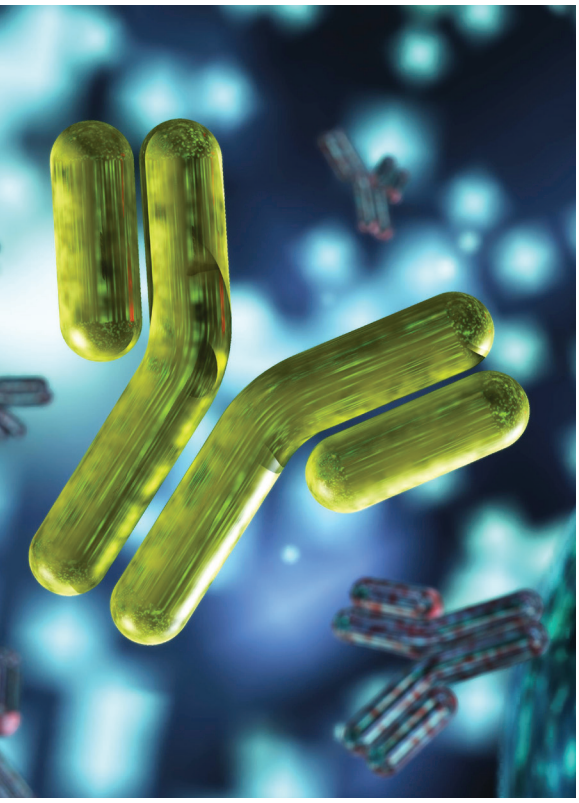

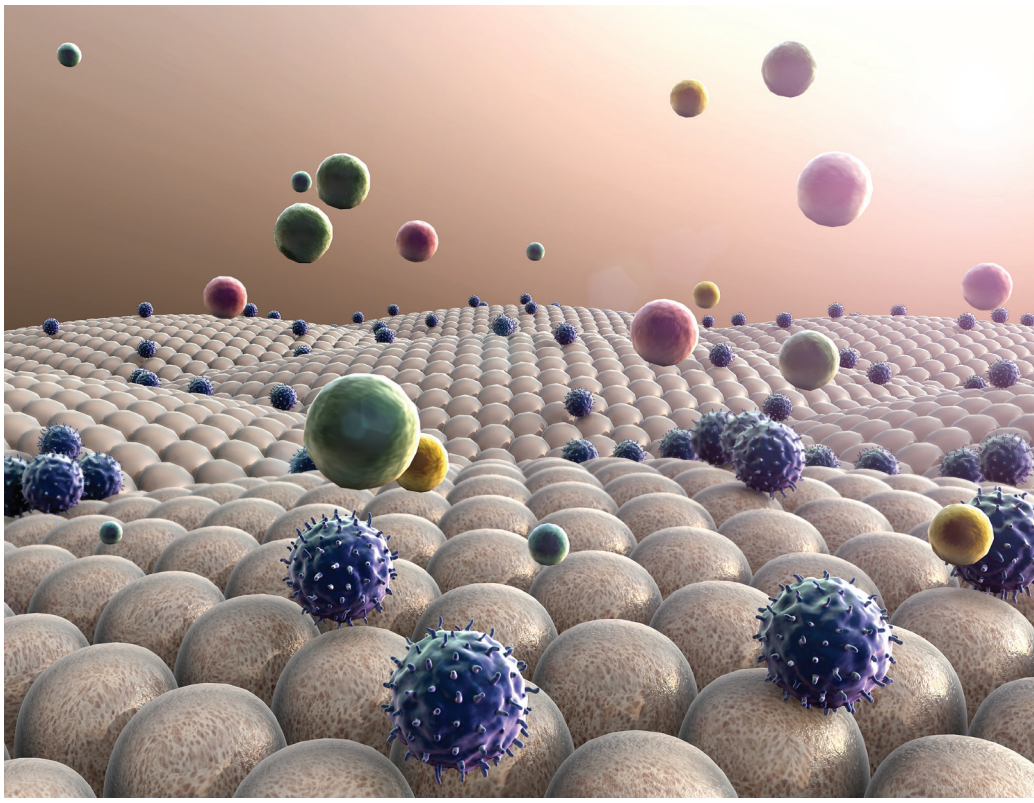

Steps to Reducing Barriers to Biosimilars in the United States

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EXECUTIVE SUMMARY

When the U.S. regulatory pathway for biosimilars was established, many experts assumed that biosimilar competition in the U.S. would be rigorous and that the resulting savings to the health care system would be meaningful. But this has not proven true. In the last eight years, relatively few biosimilars have come to market. While 12 biosimilars have been approved by the FDA, 5 of these approvals were just last year, and only 4 biosimilars have entered the U.S. market. This white paper investigates the barriers — delineated by category in the table below — contributing to the slow entry of biosimilars.

Despite these barriers, there is reason for hope. Recent changes in federal policy are a recognition of the importance of encouraging biosimilars. But additional steps will be required. As detailed in the table, more physician and patient education and competitive biosimilar pricing are necessary. Employer-sponsored health plans should urge benefit managers to encourage biosimilar utilization. Private payors should ensure that physician reimbursement for biosimilars does not create a disincentive to use these products. And the FDA must continue to pursue an open, transparent, and responsive regulatory review process.

BIOSIMILAR BARRIERS AND STRATEGIES, BY CATEGORY

REFERENCE PRODUCT MANUFACTURERS

Brand biologics manufacturers use contracting practices and lifecycle management strategies to protect market share, including penalties for customers who move patients to a biosimilar and additional patents late in a reference product's life.

STRATEGIES

Payors: Adopt longer-term perspective in contracts and formularies

Employers: Identify cost-saving opportunities

Policymakers: Ensure fair market access for biosimilars

BIOSIMILAR MANUFACTURERS

Developing a biosimilar involves substantial expense, and the market for biosimilars is fraught with uncertainty. In addition, biosimilars thus far have entered the market without a steep enough price discount to capture market share.

STRATEGIES

Payors: Institute policies to drive biosimilar utilization

Biosimilar manufacturers: Offer competitive contracting terms

Employers: Require biosimilar coverage in contracts

POLICY

Patent litigation and the threat thereof can be a deterrent for biosimilar development. Biosimilars also are not yet able to obtain a designation of interchangeability, and when they are, they will face barriers to substitution.

STRATEGIES

Congress: Limit frivolous late-stage patents

FDA: Continue to support and clarify interchangeability

STAKEHOLDER EDUCATION AND AWARENESS

Physicians, patients, and employers lack awareness about the safety of and savings opportunity from biosimilars.

STRATEGIES

Biosimilar manufacturers: Provide patient and physician education

Payors: Incentivize stakeholders to gain experience

Employers: Share biosimilar savings with employees

Policymakers: Promote biosimilars as safe and effective

As we approach the 10-year anniversary of the establishment of the U.S. regulatory pathway for biosimilars, it is an appropriate time to examine the state of the biosimilar market in the United States. A decade ago, many experts assumed that biosimilar competition in the U.S. would be rigorous and that the resulting savings from competition would be meaningful to the health care system. But this has not proven true. This white paper investigates the barriers contributing to slow entry of biosimilars in the U.S. and identifies factors that would improve the marketplace for biosimilars.

Biosimilars Landscape

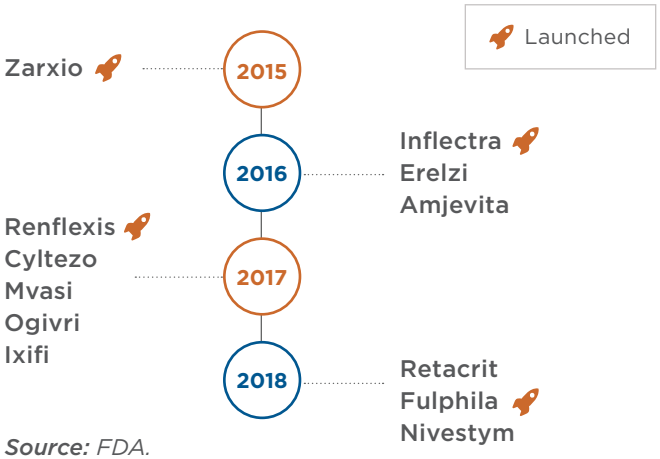
Biosimilars are copies of complex pharmaceutical products known as biologics, which are made from biological substances like proteins or human or animal cells. In this way, biosimilars differ from traditional small-molecule generic drugs, which are chemical copies of their reference products. Biosimilars are "similar" to a biologic, even potentially to the point of being considered interchangeable, but the nature of a biologic means that it cannot be precisely replicated. Unlike small-molecule drugs, biosimilars did not have a pathway for approval by the Food and Drug Administration (FDA) until 2010, with enactment of the Affordable Care Act (ACA), which included the Biologics Price Competition and Innovation Act.

Early on, the commonly held view was that biosimilars would not compete with their reference products to the degree seen in the small-molecule drug market. For one, it is far more time-consuming, costly, and risky to develop a biosimilar than it is a small-molecule generic drug. The Federal Trade Commission estimated that biosimilar development takes 8–10 years and $100 million–$200 million, compared to 3–5 years and $1 million–$5 million for small-molecule generic drugs (*FTC 2009*). And biosimilars, at least at first, would not be eligible for the automatic generic substitution policies that typically govern small-molecule drug dispensing.

Nevertheless, because biologics are so widely used and expensive, biosimilars were still expected to yield substantial health care savings. For example, the Congressional Budget Office (*2008*) estimated that biosimilars would save $25 billion nationally from 2009 to 2018. Economist Robert Shapiro and coauthors (*2008*) predicted $67 billion–$108 billion in U.S. savings over ten years. In 2014, the RAND Corporation estimated that biosimilars would save $44.2 billion from 2014 to 2024 (*Mulcahy, Predmore, and Mattke 2014*).

However, these predictions have not been realized because biosimilars have not entered the market as quickly as hoped. In the eight years since the U.S. biosimilar pathway was established, the number of biosimilars that have come to market has been relatively small. While 12 biosimilars have been approved by the FDA, 5 of these approvals were just last year, and only 4 biosimilars have entered the U.S. market: Zarxio, which is a biosimilar of the anti-infection drug Neupogen; Inflectra and Renflexis, which are both biosimilars of Remicade, used to treat autoimmune diseases; and Fulphila, which is a biosimilar of the anti-infection drug Neulasta (**see Figure 1**).

FIGURE 1. U.S. BIOSIMILARS APPROVED



Source: FDA.

After enactment of the ACA, biosimilars were held back from entering the U.S. market in part due to the FDA taking several years to release guidance for biosimilar manufacturers. As a result, the first biosimilar approval, for Zarxio, did not occur until January 2015. Later that year, Brill (*2015*) developed a novel model of biosimilar development that recognized the high cost and uncertainty facing biosimilar makers. This model illustrated quantitatively why biosimilar manufacturers would find it economically viable to make biosimilars only for biologics with large markets. But considering the number of large biologics on the market, the pace of biosimilar entry has been tepid.

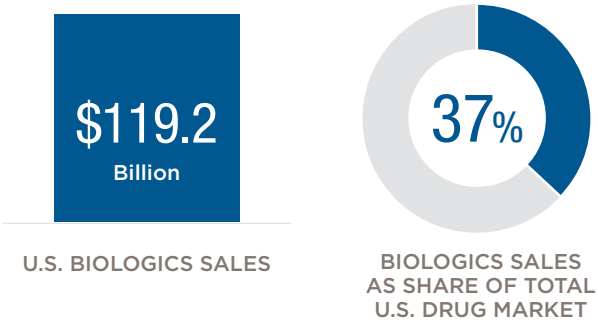
Unrealized Potential of U.S. Biosimilars

Biologics are some of the most expensive drugs on the market, making competition highly desirable for patients and payors, who can benefit from price competition. In 2017, 11 of the top 15 drugs by sales in the United States were biologics (**see Figure 2**). These 11 biologics had revenues of more than $87 billion in 2017 (*PharmaCompass 2018*). The top 3 drugs were all biologics: Humira, an anti-inflammatory used to treat a variety of conditions, including rheumatoid arthritis and Crohn's Disease, had close to $19 billion in revenues, and Enbrel and Eylea, for the treatment of autoimmune diseases and macular degeneration, respectively, each had roughly $8.3 billion in revenues (*PharmaCompass 2018*). Overall, biologics made up 37 percent of total U.S. drug spending in 2017 (**see Figure 3**) (*IQVIA Institute for Human Data Science 2018a*).

FIGURE 2. REFERENCE BIOLOGICS' RANKING IN U.S. DRUG SALES

Source: *PharmaCompass.*

FIGURE 3. TOTAL REFERENCE BIOLOGICS SALES IN THE UNITED STATES

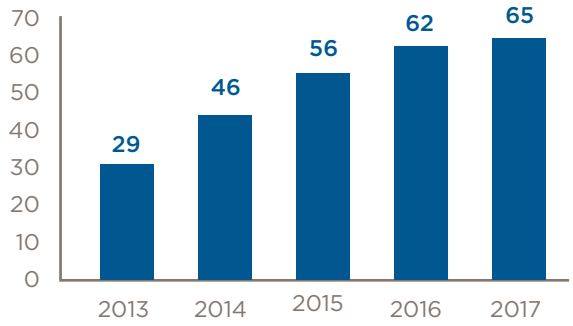


Source: *IQVIA Institute for Human Data Science.*

More than 200 biologics are approved in the United States (*Biosimilars Council 2017*), and many of the top products are or soon will be without patent protection. Health policy researchers have estimated that 15 of the top 20 biologics will be exposed to competition by 2020 (*Kent et al. 2017*). According to the IQVIA Institute for Human Data Science (*2018b*), $37 billion of spending on biologics in the United States will be newly at risk of competition between 2019 and 2022.

However, just because a biologic's patents have expired does not mean that a biosimilar can immediately come to market. As described in greater detail below, a variety of barriers to biosimilar entry exist. One promising sign for the biosimilars market is the number of products in the FDA's Biosimilar Development Program (**see Figure 4**). But this is not the robust market that was hoped for in the United States and exists in Europe.

FIGURE 4. U.S. BIOSIMILARS IN DEVELOPMENT

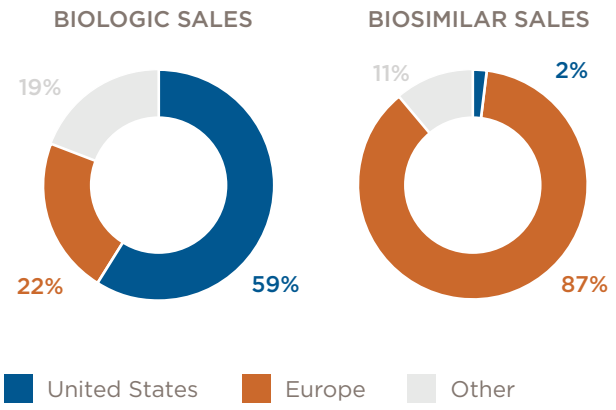


Source: FDA.

Biosimilars in Europe

The U.S. experience with biosimilars is often compared to Europe, which preceded the U.S. in establishing a regulatory pathway for approving biosimilars and has far more of these products on the market. The European Medicines Association (EMA) has approved more than 40 biosimilars (*Aideed 2018*), the first one (Omnitrope, a biosimilar of the growth hormone Genotropin) in 2006. As of June 2018, an additional 13 biosimilar applications were under EMA review (*GaBI 2018*). Around the world, 87 percent of biosimilar sales are in Europe, compared to just 2 percent in the United States, whereas 59 percent of biologic sales are in the United States, and 22 percent in Europe (*IGBA 2018*).

FIGURE 5. SALES OF BIOLOGICS AND BIOSIMILARS IN UNITED STATES VS. EUROPE



Source: IGBA.

Though the U.S. biosimilars pathway was established only six years after the European pathway the biosimilar market in Europe has been far more successful than in the United States. A key difference between the U.S. and European pharmaceutical marketplaces, one that makes comparisons difficult, is the degree of government involvement in price setting and other aspects of the marketplace. In Europe, government price regulation is common for biosimilars, including mandatory discounts and maximum prices. Many countries use reference pricing, where each drug in a specified group is reimbursed at a set amount. Some countries use incentives for physicians to prescribe biosimilars, and a few even have quotas for physician prescribing (*Moorkens et al. 2017*). While the federal government and state governments in the U.S. are payors for health care services and pharmaceuticals, they do not have the control over prices that European governments can exercise.

But some of Europe's success is attributable to strategies that the United States could emulate. For example, European countries have excelled at providing unbiased information about biosimilars and sharing cost savings with stakeholders (*van den Hoven 2018*). However, some barriers that U.S. biosimilars face, as detailed in the next section, are unique to the U.S. health care and legal systems.

Barriers to Biosimilars

The barriers to the development of a vibrant U.S. biosimilars market are many and do not exist in isolation. But for the sake of clarity, this section groups barriers into four categories: those posed by reference product manufacturers, those related to biosimilar manufacturers, those stemming from federal and state policies, and those arising from lack of education.

Barriers Posed by Reference Product Manufacturers

Contracting Practices of Reference Product Manufacturers. One of the biggest barriers to biosimilar entry and uptake arises from the complex,

opaque contracting practices brand biologics manufacturers pursue. As detailed below, a reference product manufacturer can retain market share by using rebates to incentivize payors to hold market share and inhibit market uptake by their competitors. This in turn dissuades biosimilar manufacturers from investing in biosimilar development and entering the market.

A reference product manufacturer can retain market share by using rebates to incentivize payors to hold market share and inhibit market uptake by their competitors.

Most biologics are administered by a physician in a doctor's office, outpatient hospital setting, or inpatient hospital setting and are covered under an insurance provider's medical benefit (Part A or Part B in Medicare) rather than pharmacy benefit (or Medicare Part D). In the outpatient and office settings, physicians receive reimbursement from a patient's insurance company (or Medicare) after administering a biologic to the patient. Private payors (as well as Medicare Part B) also reimburse a small amount on top of the cost of the biologic to compensate providers for handling the drug plus a fee for administering the drug. In the inpatient hospital setting, biologics are usually not reimbursed separately, but rather as part of a diagnosis-related group (DRG), a type of bundled payment.

Manufacturers typically contract with distributors, group purchasing organizations (GPOs), or directly with health systems to supply hospitals and physicians' offices with biologics, frequently offering volume discounts to large customers. For biologics reimbursed under the pharmacy benefit (or Medicare Part D), manufacturers typically contract with pharmacy benefit managers (PBMs), also using rebates to receive preferred placement on health plans' formularies. Rebates become particularly important tools for manufacturers when another biologic (or now biosimilar) can compete for market share. Payors have reportedly identified rebates and discounts as the most significant impediment to biosimilar use (*Edgar et al. 2018*).

A 2017 *JAMA* article explained how brand biologics manufacturers employ aggressive rebate strategies such as taking away all rebates on a biologic if the payor tries to move some patients to a biosimilar (*Hakim and Ross 2017*). Even more traditional contract terms set by brand biologic manufacturers can make heftier rebates conditional on certain levels of usage of a biologic (*Simmons-Stern et al. 2018*). Such a dynamic, different than the typical behavior of brand small-molecule drugs facing generic entry, can limit the pricing advantage of a new biosimilar entering the market.

The effects of contracting and rebates for brand biologics can be seen in the way private payors have pushed the use of brand biologics or simply excluded the biosimilars that have entered the U.S. market so far. According to a recent analysis of biosimilar coverage by private health plans in the United States:

> Across 10 major U.S. health plans, originator products are still preferred over biosimilars. By way of example, Zarxio was covered under the specialty pharmacy benefit by the majority and was only preferred by approximately half of plans. Meanwhile, Inflectra and Renflexis were primarily covered under the medical benefit as a nonpreferred agent — or they were excluded altogether. The formulary status of the Remicade biosimilars highlights how aggressive rebating and contractual terms can impact coverage. (*Edgar et al. 2018*)

In the case of Inflectra, which Pfizer manufacturers, Pfizer has claimed more than just aggressive rebating by Johnson & Johnson (J&J), the manufacturer of the reference product, Remicade. In September 2017, Pfizer filed suit against J&J, asserting that "when Pfizer introduced its competing biologic

Inflectra (infliximab-dyyb) in 2016, J&J deployed improper exclusionary tactics to maintain the dominance of its flagship product," including withholding rebates from insurers who reimburse for Inflectra (*Pfizer 2017*). In August 2018, a district court judge refused to grant J&J's request to have the lawsuit dismissed.

Without weighing in on the merits of Pfizer's claims, FDA Commissioner Scott Gottlieb recently flagged the chilling effect that brand biologics manufacturers' rebate practices have on biosimilar development: "Once biosimilar makers see that the system is rigged against them, what's the incentive for a biosimilar maker to pour money into future investments to develop these lower cost alternatives?" (*Gottlieb 2018*). This is, unfortunately, not the extent of the impediments that face biosimilars in the United States. A brief overview of remaining barriers follows. While these barriers are grouped in general categories, this does not mean that they are siloed. To the contrary, they interact and build on one another.

Other Tactics by Reference Product Manufacturers. In addition to contracting and rebates, reference product manufacturers may use lifecycle management strategies employed in the small-molecule market to retain market share for reference biologics (*Carrier and Minniti 2018*). For example, as discussed in greater detail below, brand biologics manufacturers are beginning to use "patent thickets" — that is, obtaining as many additional patents as possible on the reference product after it is on the market — to deter competitors. There also have been suspicions that brand biologics manufacturers are using a tactic known as counter-detailing, by which they send representatives to physicians to raise doubts about biosimilars (*Cohen et al. 2016*).

Barriers Related to Biosimilar Manufacturers

Development Costs and Uncertainty in a Nascent Market. It is not only expensive to develop a biosimilar – development costs, as noted above, are estimated to be $100 million–$200 million per biosimilar – but there is also considerable uncertainty associated with the development process. These risks and costs, both those related to the necessary R&D and those associated with regulatory approval and market access, serve to discourage all but the most committed and expert biopharmaceutical firms from embarking on a development project. On top of this, the current market for biosimilars is fraught with uncertainty, which itself amounts to a barrier. There will always be some level of uncertainty about the cost to develop and manufacture new biosimilars, but added to this is uncertainty that stems from the lack of maturity in the biosimilars market. This includes uncertainty about how many biosimilar competitors there will be for a given product and what public and physician perception of biosimilars will be. And in many cases, there is uncertainty about when a biosimilar can enter the market, given the practices mentioned above that reference product manufacturers use to extend intellectual property (IP) protection.

The current market for biosimilars is fraught with uncertainty.

Biosimilar Pricing. Biosimilar pricing thus far seems to be a barrier to uptake because brand biologics manufacturers are able to use rebates, as discussed above, to reduce their prices below biosimilar prices. The first two biosimilars to enter the market, Zarxio and Inflectra, launched in 2015 and 2016, respectively, each at only a 15 percent discount relative to the wholesale acquisition cost (WAC) of its reference product. In January 2018, Inflectra had only captured 2.3 percent of the market. Renflexis (a competitor to Inflectra) entered the market in 2017 priced 35 percent below the WAC of the reference product (Remicade). Larger price discounts seem

to translate into higher market share for biosimilars, as evidenced by Zarxio. After launching at a 15 percent discount and not making much headway in gaining market share, Zarxio's price was reduced in 2016 (*Edgar et al. 2018*). RAND researchers reported in 2017 that Zarxio's price discount was 45 percent relative to its reference product (*Mulcahy et al. 2017*). By January 2018, Zarxio had 15 percent of the market (*Edgar et al. 2018*). (It should be noted that Zarxio is unique in that it shares the market with a biosimilar-like product called Granix, which is marketed at a 30 percent discount to the reference product.)

None of the four biosimilars in the U.S. market is reimbursed under commercial health plans' pharmacy benefit (or Medicare Part D). When biosimilars reimbursed under the pharmacy benefit come to market, the negotiations between manufacturers and PBMs will present a new opportunity for competitive pricing.

Policy-Related Barriers

CMS and FDA Policies and Delays. Until the fall of 2017, Centers for Medicare and Medicaid Services (CMS) policies in Medicare Part B and Part D presented significant barriers to biosimilars. These barriers have been resolved recently, as discussed below, but discouraging CMS policies during the critical infancy of the U.S. biosimilars market affected biosimilar manufacturers' decision-making for years. In addition, the FDA, responsible for elaborating the biosimilar pathway, proved to be a barrier by having lengthy delays in issuing various biosimilar guidance. While FDA Commissioner Gottlieb recently assured manufacturers that the FDA would simplify the process for a biosimilar to receive a designation of interchangeability with its reference product (discussed further below), this announcement came after years of relative uncertainty about this aspect of the pathway. The FDA's naming policy for biosimilars, which requires a unique, random four-letter suffix for each biosimilar after the nonproprietary name — also poses a barrier. As the Federal Trade Commission cautioned, differentiating biosimilars in this way could lead prescribers to assume that there are greater differences between biosimilars and their reference product than there truly are (*FTC 2015*).

IP Policy. In addition to the lawsuit discussed above that Pfizer brought against J&J, there are a variety of other existing and potential lawsuits. For example, the biologic Humira, the top-selling drug in the United States, has more than 100 patents, and its manufacturer, AbbVie, has filed suits against Amgen and Boehringer Ingelheim (BI) alleging patent infringements on 61 and 74 patents, respectively (*Sandburg 2018*). AbbVie and Amgen reached a settlement that will allow Amgen's biosimilar to come to market in 2023, but AbbVie's lawsuit against BI continues, with a trial likely not beginning until June 2020 (*Cottler et al. 2017*). In August 2018, AbbVie also brought suit against Sandoz for allegedly infringing Humira patents. Patent litigation will delay biosimilar entry, and the prospect of patent litigation can be a deterrent for biosimilar manufacturers.

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State Laws Limiting Substitution. A biosimilar deemed by the FDA to be interchangeable with its reference product should enjoy additional facility in market adoption. However, barriers to substitution will remain in many states. Thirty-seven states and Puerto Rico have passed laws governing biosimilar substitution, and while these law ostensibly encourage substitution, many actually throw up impediments like requiring that doctors and patients be notified when a substitution occurs, a requirement not necessary for small-molecule drugs.

Barriers Related to Stakeholder Education and Awareness

Lack of Information and Experience among Prescribers. In addition to responding to financial incentives to prescribe brand biologics, many physicians exhibit "prescribing inertia" — they simply write prescriptions for the products they are most accustomed to. Adding to this are relatively low levels of knowledge about biosimilars among many providers. In a recent survey of physicians, less than half (45 percent) believed "that biosimilars would be safe and appropriate for use in both treatment-naive and existing patients," while more than one-third (36 percent) believed "that a biosimilar would be less safe than the reference biologic" (*Crespi-Lofton and Skelton 2017*).

Lack of Education among Patients and Employers. Even more than physicians, patients lack awareness and education about biosimilars. According to a recent survey, 70 percent of U.S. respondents in the general population had never heard of biosimilars, compared to 57 percent who had never heard of biologics (*Jacobs et al. 2015*). Even among patients diagnosed with Crohn's disease; ulcerative colitis; rheumatoid arthritis; psoriasis; breast, lung, or colorectal cancer; or non-Hodgkin's lymphoma, 54 percent had never heard of biosimilars, compared to 33 percent of people diagnosed with these illnesses who had never heard of biologics. Employers who sponsor health plans also have a lack of awareness about biosimilars. And for those who are aware, there is still uncertainty about how to realize the savings biosimilars could offer.

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Reaching a Tipping Point

A natural question that arises after the delineation of so many barriers to biosimilars is whether these products will ever really take off in the United States. Clearly, some are entering the market, but will the U.S. see the biologic drug competition and resulting health care savings that have long been desired? Despite the substantial barriers to biosimilars, there is reason for hope. Already, there have been significant changes in policy and recognition among policymakers and stakeholders about the importance of encouraging biosimilars.

At CMS, two important changes have been made to biosimilar policy, one in Medicare Part B and one in Part D. In Part B, CMS originally planned to group all biosimilars for a given reference product into one code for reimbursement (known as a "J code"), which was widely considered to hinder the willingness of biosimilar manufacturers to enter the market because it would limit each manufacturer's ability to determine their own price. CMS reversed that decision in the fall of 2017 and will instead give each biosimilar its own J code. In Part D, when beneficiaries reach a certain level of drug spending ($3,750 in 2018), they enter what is known as the "coverage gap," where they are responsible for a larger share of their drug costs (until they reach catastrophic coverage). Part D mandates 50 percent discounts from brand drug manufacturers to Medicare beneficiaries in the coverage gap. Because biosimilars were initially excluded from participating in this program, biosimilars could be more expensive than a brand biologic for someone in the coverage gap. With the Bipartisan Budget Act of 2018 enacted in February, Congress fixed this issue and now treats biosimilars like other biologic drugs.

At the FDA, Commissioner Gottlieb has put particular emphasis on biosimilars. In late 2017, the agency launched an education campaign to inform doctors what biosimilars are and how the FDA ensures there are no "clinically meaningful

differences" between a biosimilar and its reference product (*Gottlieb and Christl 2017*). The FDA is also working on simplifying the process for biosimilars manufacturers to prove interchangeability and extrapolate across indications (*InsideHealth Policy 2018*). And in July 2018, the agency released its Biosimilars Action Plan, which outlines 11 key actions it is taking to promote biosimilar development (*FDA 2018*)

On the legal front, the Supreme Court in June 2017 ruled in *Amgen v. Sandoz* that the biosimilar manufacturer could give the reference product manufacturer marketing notice before receiving FDA approval (thereby hastening market entry) and did not have to engage in the so-called patent dance, whereby the biosimilar and reference product manufacturers were to exchange information. This ruling was followed by the Federal Circuit holding that state laws were preempted by federal law, a further win for biosimilar manufacturers.

Despite these positive developments, biosimilars have a long way to go to become a flourishing market. In thinking about success for biosimilars, there are two tipping points to keep in mind. The

TABLE 1. REACHING A TIPPING POINT FOR BIOSIMILARS

CATEGORY	PRIMARY ISSUES	STRATEGIES
Reference Product Manufacturers	1. Rebate practices 2. Lifecycle management (e.g., late-stage patents)	• ***Payors:*** Adopt longer-term perspective in contract negotiations and formulary development • ***Employers:*** Analyze own reference product utilization to identify cost-saving opportunities and implement savings strategies with biosimilars • ***Policymakers:*** Ensure reference product manufacturers do not unduly hinder biosimilar entry
Biosimilar Manufacturers	1. Market uncertainty 2. Limited discounting and low volume	• ***Payors:*** Institute policies — such as tiering, differential coinsurance, and differential physician reimbursement — to drive biosimilar utilization • ***Biosimilar manufacturers:*** Offer competitive and innovative contracting terms, including favorable pricing, to drive volume and payor savings • ***Employers:*** Require biosimilar coverage in contracts
Policy	1. Patent thickets 2. FDA guidance	• ***Congress:*** Limit frivolous late-stage patents and broadly promote biosimilar innovation and utilization • ***FDA:*** Continue to support and clarify interchangeability
Stakeholder Education and Awareness	1. Lack of education and awareness 2. Limited prescribing experience	• ***Biosimilar manufacturers:*** Provide patient and physician education • ***Providers:*** Get real-world experience with biosimilars and educate patients • ***Payors:*** Create incentives for providers, pharmacies, and patients to gain experience • ***Employers:*** Educate employees on the value of biosimilars and share biosimilar savings with employees • ***Policymakers:*** Promote biosimilars as safe and effective, similar to education on generics

first is for biosimilars as a category of products and represents the point at which market, regulatory, legal, perception, and reimbursement issues are reduced such that biosimilars can enter the market with sufficient ease. The second tipping point is for biosimilars within a product class and represents the point at which there are enough competitors to a reference biologic that meaningful savings are achieved.

Reaching the second tipping point should be a natural follow-on to passing the first. What will help reach the first tipping point, as **Table 1** delineates, is physician and patient education, continued FDA leadership, and sufficient biosimilar price discounts. Customers themselves can help promote biosimilar adoption as well. For example, employers sponsoring health plans can urge payors to adopt biosimilars and encourage savings to be distributed to patients. Private payors should ensure that physician reimbursement for biosimilars does not create a disincentive to use these products. And as Brill (*2016*) recommended, carefully constructed incentives from public and private payors could encourage physicians to give fair consideration to biosimilars.

Conclusion

Biosimilars offer incredible health and economic opportunities in the United States, but unless substantial barriers are surmounted, these opportunities will not be fully realized. Even absent reference product manufacturers' efforts to retain market share, significant challenges for biosimilars arise because all parties involved — patients, physicians, payors, and biosimilar manufacturers — need to realize gains from these products for the status quo to change. The last several years have seen the U.S. moving slowly toward a healthy biosimilars market, but there are more hurdles to address before biosimilars realize their full potential.

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MGA is an economic policy consulting firm in Washington, DC. Founded by Alex Brill in 2007, MGA specializes in fiscal, health care, and tax policy matters.

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