

# The Economic Viability of a U.S. Biosimilars Industry

BY ALEX BRILL

February 2015

## EXECUTIVE SUMMARY

Drug manufacturers have recently begun submitting biosimilar applications to the Food and Drug Administration (FDA), leading many to believe that a robust U.S. biosimilar industry and substantial health savings are right around the corner. In this paper, I present an empirical assessment of the viability of biosimilars in the U.S. market and caution against such optimism given biosimilars' considerable development costs, moderate expected market share, and diminished profit margins relative to a typical biologic.

To date, the biosimilars policy debate in the United States has been driven by a focus on preserving the incentive to innovate new biologics—a focus that led lawmakers to allot 12 years of exclusivity for biologics when a U.S. biosimilar pathway was established in 2010. Adequate incentives to encourage innovation are vital given the clinical benefit of many biologics. But this should not obscure the reality that there will not be a robust biosimilars industry if the regulatory framework and economic conditions are not conducive to manufacturers' bringing biosimilars to market. Key policy decisions regarding biosimilars are outstanding, and these decisions are likely to affect the economic viability of biosimilars.

### Potential impediments to biosimilar market uptake include:

- **Regulatory Burdens.** As the FDA continues to elaborate the biosimilars pathway, two decisions in particular will affect the economic viability of biosimilars: the naming conventions the agency establishes and the clinical testing the agency may require biosimilars to repeat.
- **Statutory Burdens.** State laws intended to restrict biosimilar substitution could have the effect of hindering market uptake of biosimilars.

- **Market Risks.** Payors' coverage decisions will impact utilization, but it is unclear how insurance companies and government health care programs will handle coverage of and reimbursement for biosimilars. In addition, the perception of biosimilars among doctors and the general public will play a substantial role in determining biosimilar utilization.

Even without these impediments, biosimilars will be costly and time-consuming to develop, requiring an estimated 8–10 years and \$100 million–\$200 million. Just as is the case with a biosimilar's reference product, a manufacturer's decision to bring a biosimilar to market will depend on whether the future sales of that product will allow the manufacturer to recoup development costs.

In this paper, I present the results of a break-even analysis in which I test the economic viability of biosimilars in the United States. This analysis shows that a biosimilar manufacturer would not find it worthwhile to enter the U.S. market for most average (by sales) biologics even under favorable market conditions. Under potential regulatory and market constraints that limit biosimilar market share, only the largest biologics would attract biosimilar competition.

## Summary of Results:

- **Base-Case Scenario.** In the base-case scenario of the analysis, which includes many favorable assumptions about the market for biosimilars and assumes an average development cost, a biosimilar is viable only for biologics with average annual sales exceeding \$897.6 million.
- **Alternative Scenario 1: Diminished Market Share.** In an alternative scenario that considers the market share impact of potential regulatory, statutory, and market impediments, average annual biologic sales need to be \$1.3 billion for a biosimilar to break even.
- **Alternative Scenario 2: Lower R&D Costs.** In a final scenario that models lower biosimilar R&D costs without the impediments considered in alternative scenario 1, a biosimilar would break even if average annual biologic sales exceed \$626.9 million.

In short, the decision of a biosimilars manufacturer to enter the U.S. market is more tenuous than commonly perceived. The analysis presented here shows that a robust U.S. biosimilars market for a broad spectrum of biologic products is unlikely but that biosimilar entry for blockbuster biologic products is viable. Adverse decisions by policymakers and effective dissuasion by biologics manufacturers not only may impede biosimilar market share, but may stifle market entry altogether for many products.

## INTRODUCTION

Nearly five years after the creation of a U.S. biosimilars pathway, it remains to be seen whether the United States will develop a robust biosimilars market. To date, key policy decisions are outstanding, and not a single biosimilar has entered the market, though four biosimilar applications have been submitted to the Food and Drug Administration (FDA). Because biosimilar market entry will be limited without the proper regulatory implementation and economic environment, it is essential that policymakers, payors, and prescribers understand what is necessary to make biosimilars economically viable in the United States.

The U.S. debate over biosimilars has long been driven by a focus on preserving biologics manufacturers' incentive to innovate. That objective is valid given the clinical benefit of many biologics. But it should not obscure the reality that there will not be a robust biosimilars industry if the regulatory framework and economic conditions are not conducive to manufacturers' bringing biosimilars to market. Policy decisions often perceived to be matters of transparency or clinical safety and efficacy are also powerful tools to discourage biosimilar development. As federal policymakers, state lawmakers, and brand biologic manufacturers articulate their positions on remaining policy matters and impress upon patients, physicians, and pharmacists key issues regarding the safety, efficacy, and sameness of biosimilars, they have the ability to influence the market uptake of biosimilars and thereby affect the willingness of manufacturers to bring biosimilars to market.

While some experts have begun to highlight various impediments to a biosimilars market, most

policymakers and industry analysts assume that the United States will have a thriving biosimilars industry once certain regulatory hurdles are resolved. In this paper, I caution against the popular notion that a robust U.S. biosimilars market is a foregone conclusion. I present an empirical model that tests a manufacturer's ability to recoup the substantial cost of bringing a biosimilar to market with proceeds from future sales. According to the model's results, a biosimilar manufacturer would not find it worthwhile to enter the market for most average (by sales) biologics even under favorable market conditions. Under potential regulatory and market constraints that limit biosimilar market share, the model shows that only the largest biologics would attract biosimilar competition. In short, the decision of a biosimilars manufacturer to enter the U.S. market is more tenuous than commonly perceived. Adverse decisions by policymakers and effective dissuasion by biologics manufacturers not only may impede biosimilar market share, but may stifle market entry altogether for many products.

## BACKGROUND

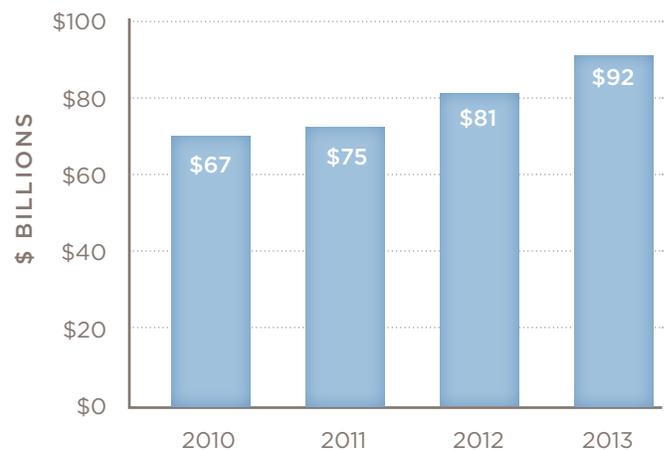
Biologic medicines—which differ from traditional small-molecule pharmaceutical products in that they are created using a biological process or made from living cells—are among the most expensive drugs available and represent a large and growing share of drug spending in the United States. In 2013, biologics comprised 28 percent (roughly \$92 billion) of U.S. drug spending, an increase of nearly 10 percent since 2012 (*IMS 2014*). And spending on biologics and other specialty drugs is projected to increase dramatically in the coming years (*Prime Therapeutics 2014*).

There has long been generic competition for small-molecule drugs, thanks to the Hatch-Waxman Act of 1984. But until 2010 there was no framework in the United States for generic competition (and the savings typically associated with such competition) for biologics. Generic versions of biologics—known as follow-on biologics or biosimilars because they are not chemically identical to their reference products, as small-molecule generics are—have been available in Europe since 2006 and cost 10–35 percent less than their reference products (*Scott Morton, Stern, and Stern 2014*). Drawn to the potential savings such a price discount would generate, many U.S. policymakers and patient advocates pushed for the creation of a regulatory pathway for biosimilars to enter the U.S. market. The Biologics Price Competition and Innovation Act (BPCIA), which was part of the Affordable Care Act of 2010, established such a pathway and left to the FDA the task of regulatory implementation.

In the ensuing years, the FDA has issued six draft guidance documents for biosimilar manufacturers: three in 2012, one in 2013, and two in 2014.

But the agency has yet to elaborate or finalize some key elements of the pathway, including the clinical testing a biosimilar must undergo. In addition, though not mandated by statute, the FDA has opted to consider biosimilar naming conventions. After more than four years of waiting for regulatory clarity, four drug companies (Novartis’s generic drug division, Sandoz; South Korean firm Celltrion; Canadian firm Apotex; and U.S. firm Hospira) filed biosimilar applications with the FDA for filgrastim (brand name Neupogen®), infliximab (brand name Remicade®), pegfilgrastim (brand name Neulasta®), and epoetin alfa (brand name Epogen® and Procrit®), respectively. According to the FDA Deputy Commissioner for Policy, Planning, and Legislation, fourteen biosimilars currently are under development (*Howard 2014*). But the outcome of the four applications is uncertain, as is the number of biosimilar applications that will follow.

### U.S. BIOLOGIC SPENDING HAS STEADILY INCREASED IN RECENT YEARS



Source: IMS Health.

## Expectations for Biosimilars in the United States

Before the BPCIA was enacted, there were great expectations about the savings that biosimilars would achieve. According to the Congressional Budget Office (*CBO 2008*), the BPCIA would generate estimated savings of \$25 billion nationally from 2009 to 2018 (\$5.9 billion for the federal government). Other estimates ranged up to \$108 billion in national savings over ten years (*Shapiro et al. 2008*). Despite continued uncertainty about the biosimilar pathway in the years following its creation, optimism about biosimilar savings is still widespread. Some health economists have attempted to temper expectations for biosimilar savings, warning, “It took more than a decade after the passage of the Hatch-Waxman Act for generic products to produce substantial cost savings, and that is also a likely scenario for biosimilars” (*Grabowski, Guha, and Salgado 2014*). But other health policy analysts remain hopeful. For example, a November 2014 analysis from the RAND Corporation estimates \$44.2 billion in national biosimilar savings from 2014 to 2024 (*Mulcahy, Predmore, and Matthe 2014*).

In all cases, researchers make seemingly optimistic assumptions about the willingness of manufacturers to submit biosimilar applications and differ primarily on the presumed market share biosimilars will capture and the price discount they will offer the health care sector. Missing thus far is an empirical assessment of the necessary conditions for biosimilar manufacturers to decide to enter the market and the degree of competition that will arise given the particular regulatory environment and market perception of biosimilars in the United States.

Given the realities of the economics of drug development, estimates that assume competition across a broad spectrum of biologic products will likely prove overly optimistic. The decision to

submit a biosimilars application to the FDA is not exogenous to the regulatory and marketplace environment. State substitution laws, federal decisions regarding biosimilar naming, and the perception of biosimilars in the marketplace not only carry the risk of diminishing biosimilar market share, but hold the potential to prevent biosimilar entry altogether for products of a certain size.

## Biosimilars and the Economics of Drug Development

Understanding the economics of biosimilar drug development is key to assessing whether a robust market (and accompanying savings) will materialize in the United States. In the pharmaceutical industry—and the biologics industry in particular—bringing a product to market involves years of costly R&D and, by necessity, substantial trial and error. Innovative drug firms rely on the sales of successful products to cover R&D expenses for both successes and failures. In simple terms, it is important to temporarily shield innovator drugs from competition to give these firms time to recoup expenses so that they can continue to innovate and bring vital new medicines to market. In the pharmaceutical industry, patents protect innovator drugs from competition for a certain period of time, and additional protection is available in the form of market exclusivity. Because of the desire to promote biologics innovation, and because innovative drug companies have powerful voices, the pre-BPCIA economic debate over biosimilars was dominated by concerns about the appropriate period of exclusivity for biologics.

Missing thus far is an empirical assessment of the necessary conditions for biosimilar manufacturers to decide to enter the market.

During the lead up to the BPCIA, a widely cited study (*Grabowski 2008*) concluded that 12.9–16.2 years of exclusivity are required to allow biologics manufacturers to break even—that is, to reach the point at which the sales of a product make up the cost of bringing the product to market. Subsequent research I authored challenged the appropriateness of two of the assumptions in that study’s model (the discount rate and contribution margin<sup>1</sup>) and the assumption that the brand biologic manufacturer must recoup all costs prior to biosimilar entry (*Brill 2008*). I argued that adjusting those assumptions showed that seven years of exclusivity is adequate to ensure that a portfolio-style biologics investment breaks even. Additional research by the Federal Trade Commission (*FTC 2009*) concluded that, given both expected patents and the existence of market-based pricing, no exclusivity was necessary to protect biologic innovation. Nevertheless, the BPCIA allotted biologics 12 years of exclusivity.

At no point during this economic debate did policymakers or analysts rigorously investigate the conditions under which biosimilars would actually attempt to enter the market. At that time and in the intervening years, the development of a robust biosimilar industry seemed certain, and four recent biosimilar application submissions to the FDA likely reinforce that impression. But there is reason to question the inevitability of a competitive U.S. biosimilars industry for all but the largest biologic products.

**There is reason to question the inevitability of a competitive U.S. biosimilars industry for all but the largest biologic products.**

<sup>1</sup> The discount rate refers to the cost of capital for a biopharmaceutical manufacturer and is the interest rate used in calculating the net present value of cash flows. The contribution margin represents revenues net of variable costs (but not fixed costs).

## Potential Impediments to U.S. Biosimilar Market Entry

The risks and impediments that may hamper the development of a robust U.S. biosimilars market can be grouped into three categories: those arising from regulatory decisions; those pertaining to statute, particularly at the state level; and those that have to do with market dynamics broadly.

### Regulatory Burdens

As noted above, the FDA continues to work on elaborating the regulatory pathway for biosimilars. Two decisions in particular that will affect the economic viability of biosimilars are the naming conventions the FDA establishes and the clinical testing the agency may require biosimilars to repeat.

1. The most prominent U.S. advocates of unique international nonproprietary names (INNs) for biosimilars include PhRMA and BIO, the trade associations for the brand pharmaceutical industry and biotech industry, respectively. They argue that unique INNs will enhance patient safety by making it easier to track which product a patient receives (*BIO et al. 2006*). Those in favor of a European-style approach in the United States, whereby a biosimilar and its reference product share an INN, are led by the Generic Pharmaceutical Association (GPhA), which contends, “A different naming policy would run counter to the policy adopted internationally for generic pharmaceuticals. Currently, products are successfully traced using national drug codes (NDCs), batch and lot numbers” (*GPhA 2013*). In terms of biosimilar market entry and competition, requiring biosimilars to have names distinct from their reference products would have the effect of curbing biosimilar utilization by impeding substitution of a biosimilar for its reference product.

2. The FDA's guidance thus far as it relates to biosimilar clinical trials leaves much to the judgment of the manufacturer preparing an application, as the agency rejects a "one-size-fits-all" approach (*Bourgoin and Nuskey 2013*). This uncertainty about what clinical trials may be required creates burdens of its own that will adversely affect biosimilar entry. On top of this, if the FDA requires more extensive clinical testing for biosimilars than expected (or necessary), the added expense would make it more difficult for a biosimilar manufacturer to break even because it would raise costs without being offset by an increase in sales.

Regulatory burdens are not limited to biosimilar-specific policies. An example is the misuse of Risk Evaluation and Mitigation Strategies (REMS), which are required by the FDA for certain pharmaceuticals to ensure patient safety. As I described in a recent paper, brand drug companies have been using REMS programs to block generic manufacturers' access to drug samples (*Brill 2014*). This practice can be expected to extend to biosimilars. Specifically, the risk of a biosimilar manufacturer not acquiring a necessary sample of a reference product for testing poses the possibility of a delay in market entry and further diminution of the economic viability of the product.

**An important but somewhat amorphous challenge confronting biosimilar uptake is how biosimilars will be perceived among doctors and the general public.**

### **Statutory Burdens**

In anticipation of biosimilars in the United States, many states legislatures have passed or are considering laws limiting substitution of biosimilars for their reference products if the biosimilar is deemed interchangeable with the reference product. These laws could have the effect of hindering market uptake of biosimilars by serving as an advocacy venue for detractors of biosimilar competition generally. As Emory University School of Law Professor Joanna Shepherd has argued, "These laws are straightforward in their approach: they seek to impose dubious patient consent, recordkeeping, and physician notification requirements to discourage healthcare professionals and consumers from dispensing or consuming biosimilars" (*Shepherd 2014*).

### **Market Risks**

It remains unclear how insurance companies and government health care programs will determine biosimilar coverage, reimbursement, and drug rebates. This uncertainty represents an additional risk to biosimilar manufacturers, as payors' coverage decisions will impact utilization. An important but somewhat amorphous challenge confronting biosimilar uptake is how biosimilars will be perceived among doctors and the general public. If some doctors and patients are hesitant to prescribe or use biosimilars, the market will be diminished and industry hindered.

## MODELING BIOSIMILAR VIABILITY

To test the viability of biosimilar market entry, I constructed an empirical model based on the 2008 model mentioned above. For a full description of the original model, as well as the economic debate over the proper period of exclusivity for biologics, see Grabowski 2008 and Brill 2008.

In brief, the 2008 model examined the average product (by peak annual sales) in a stylized portfolio of biologics and attempted to find the point at which the net present value of free cash flows from sales equals or exceeds the net present value of development and other fixed costs for the manufacturer. This is referred to as a break-even analysis. The new model I constructed to assess biosimilar viability, which for the sake of clarity I will call the Brill 2015 model, uses a biologic with a Grabowski 2008 sales profile as the reference product for a hypothetical biosimilar to test the break-even point for a biosimilar manufacturer.

### Methodology and Assumptions

The Brill 2015 model assumes that a biosimilar has a 15-year product life and enters the market following the reference product's 12 years of exclusivity. In addition to R&D costs specific to biosimilars, the Brill 2015 model assumes launch, production, and post-entry R&D costs commensurate with these types of costs for the biologic in the 2008 model. The Brill 2015 model also assumes a relatively low cost of goods sold for the biosimilar, consistent with the 60 percent contribution margin determined in Brill 2008. The Brill 2015 model assumes the same discount rate as Brill 2008 (10 percent).

These assumptions are more favorable to a robust biosimilar market than the market assumptions

in Grabowski 2008. The Brill 2015 model also incorporates the following three assumptions that favor biosimilar entry but could reasonably be altered. For this reason, the Brill 2015 model should be considered a conservative assessment of biosimilar viability.

1. The model assumes manufacturers have excess production capacity and would incur only \$25 million for plant retrofitting expenses. The cost of building a new manufacturing plant (as opposed to retrofitting an existing plant) is estimated to be \$250 million–\$1 billion (*FTC 2009*).
2. The model assumes the earliest possible point of biosimilar market entry (12 years after biologic market entry), but there is reason to anticipate later entry due to the potential for litigation and regulatory delays.
3. The model assumes that only one biosimilar manufacturer would compete with a biologic and thus would not have to share the market (and revenue) with other biosimilars. But if one biosimilar manufacturer finds the market conducive to entry, it is likely that others will also want to enter.

Using these assumptions, I model three scenarios below. The first, the base-case scenario, does not incorporate any of the regulatory, statutory, and market impediments described in the previous section and assumes biosimilar R&D costs of \$150 million, the midpoint of the \$100 million–\$200 million cost estimate for developing a biosimilar (*FTC 2009*), though another estimate puts R&D costs at \$300 million (*Usdin 2015*). I then test an alternative scenario that takes into account potential impediments to biosimilar uptake.

Finally, I test an additional alternative scenario that assumes a more favorable environment for biosimilars. This scenario does not include potential regulatory, statutory, or market impediments and assumes the low end of the estimate of biosimilar R&D expenses (\$100 million).

The model should be considered a conservative assessment of biosimilar viability.

### Base-Case Scenario

Table 1 presents the assumptions in the base-case scenario of the break-even analysis for the representative biosimilar. For estimates of biosimilar market penetration and price discounts, I rely on the assumptions in CBO's cost estimate for the BPCIA (*CBO 2008*). There are other estimates of biosimilar market penetration and price discounts (for example, Avalere Health, Express Scripts, and Grabowski), but I consider CBO the most authoritative source.

TABLE 1. ASSUMPTIONS IN BASE-CASE BIOSIMILAR BREAK-EVEN ANALYSIS

Category	Assumption	Source
Pre-approval biosimilar R&D costs	\$150 million over 8 years pre-biosimilar entry	FTC 2009
Biosimilar market entry	12 years after biologic market entry	BPCIA
Biosimilar market penetration	10% in year 1, increasing to 35% by year 4	CBO 2008
Biosimilar price discount (relative to biologic)	20% in year 1, increasing to 40% by year 4	CBO 2008
Contribution margin, year 1	-63% of biosimilar sales	Adapted from Grabowski 2008
Contribution margin, year 2	-7% of biosimilar sales	Adapted from Grabowski 2008
Contribution margin, year 3	41% of biosimilar sales	Adapted from Brill 2008
Contribution margin, year 4 onward	33% of biosimilar sales	Adapted from Brill 2008
Sales decline for obsolescence	3.5% starting in biologic year 10	Grabowski 2008
Post-approval R&D costs	35% of pre-approval R&D costs over 8 years post-entry	Grabowski 2008
Plant retrofitting costs	\$25 million over 2 years pre-entry	Grabowski 2008
Launch costs 2 years pre-entry	10% of biosimilar sales in year 1	Adapted from Grabowski 2008
Launch costs 1 year pre-entry	20% of biosimilar sales in year 1	Adapted from Grabowski 2008
Discount rate	10%	Brill 2008

In the base-case scenario, I first model a biosimilar for a biologic with average annual sales of \$250 million. I begin here because the FTC in 2009 predicted that biosimilars would enter biologic markets that exceeded \$250 million in annual sales. Under the cost and cash-flow assumptions outlined in **Table 1**, a biosimilar for a biologic with this sales profile would not come close to breaking even 15 years after the biosimilar entered the market. Indeed, at the 15-year mark, the difference between the present value of the fixed costs and the present value of expected net revenues is over \$200 million (see **Table 2**).

I next use as a reference product the biologic on which the Grabowski 2008 analysis is based: the mean product in a stylized biologics portfolio (a biologic with peak annual sales of \$713 million and average annual sales of \$513.9 million). A biosimilar for this product also would not break even after 15 years on the market. In fact, in the base-case scenario, a biosimilar is viable only for biologics with average annual sales exceeding \$897.6 million.

### Alternative Scenario 1: Diminished Market Share

The regulatory, statutory, and market impediments discussed in the previous section would have the effect of reducing biosimilar market penetration. In the alternative scenario of the model, I consider the potential impact of these various barriers by modeling a reduction in biosimilar market penetration of 10 percentage points, to 25 percent. Under this scenario, average annual biologic sales would need to exceed \$1.3 billion for a biosimilar to expect to break even after 15 years on the market, a threshold 47 percent higher than under the base-case scenario.

In theory, the effects of each impediment could be modeled separately, but there are not yet vetted assumptions about the impact of individual barriers to biosimilar market entry. This scenario is intended only to illustrate the impact of a combination of potential impediments to biosimilar adoption.

**TABLE 2. SUMMARY OF RESULTS (\$ MILLIONS)**

Components of Break-Even Analysis	Base-Case Scenario			Alternative Scenario 1: Diminished Market Share		Alternative Scenario 2: Lower R&D Costs	
	FTC Prediction	Average Biologic	Break-Even Point	Average Biologic	Break-Even Point	Average Biologic	Break-Even Point
Reference Product							
<b>Avg. Annual Sales of Reference Product</b>	\$250.0	\$513.9	\$897.6	\$513.9	\$1,323.2	\$513.9	\$626.9
<b>PV of Biosimilar R&amp;D and Fixed Costs</b>	-\$297.2	-\$305.8	-\$318.2	-\$305.8	-\$332.0	-\$218.6	-\$222.3
<b>PV of Biosimilar Free Cash Flow</b>	\$88.6	\$182.2	\$318.2	\$129.0	\$332.0	\$182.2	\$222.3
<b>NPV of Biosimilar at 15 Years</b>	<b>-\$208.6</b>	<b>-\$123.6</b>	<b>\$0.0</b>	<b>-\$176.8</b>	<b>\$0.0</b>	<b>-\$36.4</b>	<b>\$0.0</b>

## Alternative Scenario 2: Lower R&D Costs

In the second alternative scenario, I return to the market penetration assumptions of the base-case scenario and examine biosimilar viability if R&D costs are at the lower end of the \$100 million–\$200 million estimate. If a biosimilar manufacturer spends \$100 million on R&D, a biosimilar for an average biologic comes close to breaking even after 15 years. But average annual biologic sales would need to exceed \$626.9 million (rather than \$513.9 million) for a biosimilar to break even in this scenario.

While beyond the scope of this paper, the model developed here could be utilized to test the impact of different biosimilar price assumptions, higher or lower development costs, and delayed biosimilar market entry, among others.

## Model Limitations

Several limitations to the model should be noted. First, the model is illustrative of biosimilars' market potential broadly and is not intended for specific individual products. There may be market reasons that a manufacturer would choose to make a biosimilar that would not break even according to the model and scientific reasons that a manufacturer could not manufacture a product that the model suggests would break even.

Second, as mentioned above, the model only assesses the break-even point for one biosimilar manufacturer for a given reference product. If more than one biosimilar manufacturer were to enter a given market, revenues would be divided, making it more difficult for an individual manufacturer to break even. The risk of this additional competition would act as a disincentive for biosimilar entry altogether. Therefore, the results presented here may be optimistic.

Third, the model does not account for the globalization of biosimilars and the potential for extrapolation of data from other countries, which could benefit U.S. biosimilar manufacturers by reducing the fixed cost for U.S. product launches. For example, for those biosimilars already approved in other markets, the incremental cost of launching a biosimilar in the United States would be considerably lower than assumed in the model. Therefore, the existence of biosimilars in Europe and elsewhere could lead to more biosimilars in the United States.

Finally, the model does not account for the impact on demand that the FTC (2009) estimates would result from biosimilar price competition. This effect has the potential to increase the total market for a given therapeutic product and thereby encourage biosimilar entry for those products near the break-even point.

## Conclusion

The analysis I present above shows that a robust U.S. biosimilars market for a broad spectrum of biologic products is unlikely but that biosimilar entry for blockbuster biologic products is viable. Several issues, including naming, substitution, and the perception of biosimilars, have yet to be determined and could still affect biosimilar competition.

Biosimilars and the savings they can generate will become all the more important as biologic spending in the United States rises. Biologics already comprise more than a quarter of U.S. drug spending, and this share is projected to increase dramatically in the coming years (*IMS 2014 and Prime Therapeutics 2014*).

It is essential for policymakers to understand the consequences of certain policy decisions on the development of a U.S. biosimilars market and to help create the market dynamics necessary for a biosimilars industry to thrive. This will require a paradigmatic shift in the conventional thinking on biosimilars, as policymakers—even those interested in encouraging a biosimilars industry in the United States—have to date focused on preserving innovators' incentives. The model presented here demonstrates that without this kind of shift, biosimilar competition may be limited and the desired health care savings reduced.

## SOURCES

BIO, EBE, EFPIA, EuropaBio, IFPMA, and PhRMA. 2006. "Policy Position on Naming of Biotechnology-Derived Therapeutic Proteins." October 31.

Bourgoin, Andrew Fischer and Beth Nuskey. 2013. "An Outlook on US Biosimilar Competition." Thomson Reuters White Paper. April.

Brill, Alex. 2008. "Proper Duration of Data Exclusivity for Generic Biologics: A Critique." Matrix Global Advisors White Paper. November.

Brill, Alex. 2014. "Lost Prescription Drug Savings from Use of REMS Programs to Delay Generic Market Entry." Matrix Global Advisors White Paper. July.

Congressional Budget Office (CBO). 2008. Cost Estimate for S. 1695 Biologics Price Competition and Innovation Act of 2007. June 25.

Federal Trade Commission (FTC). 2009. "Emerging Health Care Issues: Follow-on Biologic Drug Competition." June.

Generic Pharmaceutical Association (GPhA). 2013. "GPhA Citizen Petition on Naming of Biosimilar Products." September 19.

Grabowski, Henry G. 2008. "Follow-on Biologics: Data Exclusivity and the Balance between Innovation and Competition," *Nature Reviews Drug Discovery* 7 (June): 479–88.

Grabowski, Henry G., Rahul Guha, and Maria Salgado. 2014. "Regulatory and Cost Barriers Are Likely to Limit Biosimilar

Development and Expected Savings in the Near Future," *Health Affairs* 33, no. 6 (June): 1048–57.

Howard, Sally. 2014. Comments at Express Scripts event "Rx Innovation: A Discussion on Biosimilars, Patient Access and Affordability." December 4.

IMS Institute for Healthcare Informatics. 2014. "Medicine Use and Shifting Costs of Healthcare: A Review of the Use of Medicines in the United States in 2013." April.

Mulcahy, Andrew W., Zachary Predmore, and Soeren Mattke. 2014. "The Cost Savings Potential of Biosimilar Drugs in the United States." RAND Corporation. November.

Prime Therapeutics. 2014. "Report on Prescription Drug Costs."

Scott Morton, Fiona M., Ariel Dora Stern, and Scott Stern. 2014. "Biosimilars: Theory, Empirics, and Policy Implications." Working Paper. May 15.

Shapiro, Robert J. et al. 2008. "The Potential American Market for Generic Biological Treatments and the Associated Cost Savings." February.

Shepherd, Joanna. 2014. "Biologic Drugs, Biosimilars, and Barriers to Entry." Emory Legal Studies Research Paper no. 14-284. February 1.

Udsin, Steve. 2015. "Zarxio Lessons," *BioCentury*. January 26.

Special thanks to Prime Therapeutics for providing financial support for this research. The author is solely responsible for the content. Any views expressed here represent only the views of the author.



## ABOUT THE AUTHOR

Alex Brill is the CEO of Matrix Global Advisors, an economic policy consulting firm. He is also a research fellow at the American Enterprise Institute and in 2010 served as an advisor to the Simpson-Bowles Commission. Previously, he was chief economist and policy director to the House Ways and Means Committee. Prior to his time on the Hill, he served on the staff of the President's Council of Economic Advisers.

