

The Economic Implications of Biosimilars

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Introduction and Regulatory Framework

Biologic drugs, defined as large molecule compounds designed to treat rare or complex diseases, are now the primary driver of cost increases in drug spending in the United States.^{1,2} Annual costs of many biologics approach or exceed \$100,000, with some up to 22 times more expensive than small-molecule drugs.¹

Between 2013 and 2014, CVS/Caremark saw an increase of 32.4% on spending on specialty drugs, including biologics, while spending on small-molecule drugs increased just 6.8%.² This trend is expected to continue, with an anticipated increase of 16% annually between 2015 and 2018.² By 2016, 8 of the 10 top-selling drugs are expected to be biologics; a decade ago, just 1 biologic was in that category.¹

Public payers are also experiencing a significant rise in spending in this category. From 2009 to 2012, as a result of a 32% increase in prescription volume and a 45% increase in prices, spending on biologic drugs under Medicare Part D grew. Gross spending on biologics by high-cost enrollees went from \$1.9 billion to \$3.5 billion, nearly doubling during that same period.³

Thus, payers are eagerly awaiting the arrival of biosimilars, which are biologic products deemed to be highly similar, but not identical, to their branded reference products.⁴ These types of products have been available in Europe since 2006, in Japan since 2009, and in South Korea since 2010. Due to the lack of regulations governing their path to market, biosimilar availability has lagged in the United States.⁵

That changed in 2010 with the approval of the Affordable Care Act (ACA), which implemented the Biologics Price Competition and Innovation (BPCI) Act.¹

Abstract

Between 2013 and 2014, spending on specialty drugs, including biologics, increased 32.4%, while spending on small-molecule drugs increased just 6.8%. By 2016, 8 of the 10 top-selling drugs are expected to be biologics. While many biologics will be going off patent, there will likely be multiple prospective manufacturers of biosimilars, and a growing emphasis on regulatory guidelines to ensure their efficacy and safety, in the very near future. A strong factor and assumption surrounding biosimilar development and use is the potential for health-care cost savings; the introduction of biosimilars is expected to reduce drug costs, although to a lesser degree than seen with small-molecule generic drugs. Managed care clinicians and providers must carefully consider the economic implications and potential cost-effectiveness of uptake of biosimilars for therapy in clinical practice.

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Biosimilars Defined

The Biologics Price Competition and Innovation (BPCI) Act of 2009 established an abbreviated licensure pathway for biological products that are demonstrated to be biosimilar to, or interchangeable with, an FDA-licensed biological product. The BPCI Act requires that such products be “highly similar” to the reference product while acknowledging that, unlike small-molecule generics, they will not be identical. Nonetheless, there should be no clinically meaningful differences between the biosimilar and reference drug in terms of safety, purity, and potency.⁴

Unlike a generic, a biosimilar will require analytical studies demonstrating that it is “highly similar” and has undergone “animal studies, including the assessment of toxicity; and at least 1 clinical study assessment of immunogenicity and pharmacokinetics demonstrating safety, purity, and potency in 1 or more conditions for which approval is sought.”⁶

The BPCI Act established 2 pathways for biosimilars to reach the market: biosimilars and interchangeable biosimilars (as of this writing, the FDA has not issued guidance on the interchangeable biosimilar pathway). In 2015, the FDA finalized regulations for the biosimilar pathway and approved the first biosimilar under the new pathway: filgrastim-sndz (Zarxio), which is based on filgrastim (Neupogen).⁷ In Europe, it has more than a third of the market for its indication, and recently, it surpassed the reference product to become the most prescribed granulocyte-colony stimulating factor (G-CSF).⁸

Under the standard Biologic License Application pathway, even before finalizing guidance on the first biosimilar approval pathway, the FDA had approved the “biosimilar-like” product tbo-filgrastim (Granix) in 2012. It gained more than a 34% share of the short-acting G-CSF hospital market in the first 17 months after its US launch, and it is covered by more than 95% of payers. One reason for the rapid uptake may be due to the existing clinical experience with the product; it has been available in Europe since 2008 and is sold in 49 countries overall.⁹

In 2013, more than 70% of the spending on biologics was attributed to products with patents that have expired or will soon expire; 12 additional biologic product patents are scheduled to expire in the United States by 2020. Therefore, there is good reason to expect that several biosimilars will enter the US market over the next 5 years.¹⁰⁻¹²

Some of the major biologic products with biosimilars in development include commonly prescribed products, such as Humira (adalimumab), Remicade (infliximab), Enbrel (etanercept), Rituxan (rituximab), and Herceptin (trastuzumab), each with 2014 US sales in excess of \$6 billion.¹³

Economic Predictions for Biosimilars

The 2015 Global & USA Biosimilar Market Analysis estimates that the United States will be the biggest market globally, and that biosimilars will account for 4% to 10% of the global biologics market total by 2020, depending on how many biosimilars launch in the United States. Globally, revenues from biosimilars have risen from \$1.1 million in 2007 to \$86.9 million in 2014. There are already 21 approved biosimilars in Europe, and many of the 150 biosimilars in development will also be introduced into the European market.^{11,14}

Estimates for the cost savings of biosimilars for the US market vary widely depending on the analysis. In 2008, the Congressional Budget Office estimated that enacting the BPCI Act would reduce total expenditures on biologics by \$25 billion between 2009 and 2018, with savings of \$5.9 billion for the federal government alone. Savings would equate to around 0.5% of national spending on prescription medications, valued at wholesale prices over that same 10-year period.¹⁵

A 2014 analysis from the Rand Corporation estimated that biosimilars would result in a \$44.2 billion reduction in biologic spending between 2014 and 2024, or approximately 4% of total biologic spending over the period.¹⁶

More recently, the consulting firm Milliman assessed 3 scenarios for biosimilars to estimate potential employer savings¹²:

1. Aggressive market penetration (30%) with complete patient/physician acceptance, a 30% discount, and a \$50 copay differential
2. 15% market penetration, half of patients and physicians accepting their use, 20% biosimilar price discount, and \$50 copay differential
3. Market penetration between 15% and 25% and price discount of 20% to 30%, with both gradually increasing during the 5 years after approval

Based on these scenarios, assuming 10,000 commercial members are involved, employer-projected savings from biosimilars would grow to a range of \$217,283 to \$635,925 in 2019. For Medicare-eligible retiree members aged 65 years or over, projected savings would grow to a range of

■ **Table 1.** Biosimilar Projected Economic Impact by Beneficiary^{16,22}

Economic Beneficiary	Self-administered/Pharmacy Benefit	Clinician-administered/Medical Benefit
Plan Sponsors	<ul style="list-style-type: none"> • High impact, significant savings potential • Expected to be lead candidates for utilizing formulary design and utilization management 	<ul style="list-style-type: none"> • Limited impact and savings potential • May expand if/when the formulary concept thoroughly expands into medical benefit
Patients	<ul style="list-style-type: none"> • Impact dependent on plan design • In most existing specialty formulary design the copay would be the same for the biosimilar vs. reference brand product • If multi-tier specialty plan design becomes more common, a decreased patient cost share for biosimilars is anticipated 	<ul style="list-style-type: none"> • Limited impact and savings potential • Specialty drugs covered under the medical benefit are often subject to a percent coinsurance approach to patient responsibility, so likely to result in small, proportional decrease in out-of-pocket costs

Adapted from Mulcahy AW, Predmore Z, Mattke S. The cost savings potential of biosimilar drugs in the United States. The Rand Corporation website. 2014. <http://www.rand.org/pubs/perspectives/PE127.html>. Accessed October 12, 2015.

\$234,109 to \$695,029 in 2019. Savings would range from 2.6% to 7.6% of 2019 total drug spending and 0.3% to 0.8% of 2019 total healthcare spending for a commercial population; for a retiree population, savings would range from 2.5% to 7.4% of 2019 total drug spending and 0.4% to 1.1% of total healthcare spending.¹²

One thing is certain: no one expects biosimilars to provide the 70% to 80% cost savings seen with generics. In Europe and elsewhere, biosimilars have been priced 20% to 30% lower than the reference drug. Sandoz priced its Zarxio 15% below the reference drug in the United States, and Granix is priced similarly to its reference product.¹⁷⁻¹⁹ As the characteristics of the US biosimilar market have become more clear, payers have become increasingly realistic in their expectations for cost savings; surveys show they expect between 10% and 35% cost reductions.^{20,21}

Table 1^{16,22} provides projections of the economic impact to plan sponsors and patients.^{16,22}

Considerations for Market Entry

Numerous factors will influence the number of entrants into the biosimilar market. We have chosen some of the key influencers here for further discussion.

Cost of Clinical Development and Manufacturing

Compared with generics, biosimilar manufacturers will need to conduct more extensive clinical trials to demonstrate that when it is compared with the reference product, the biosimilar has a high similarity in efficacy and safety end points. The average cost of clinical development for a biosimilar ranges from \$40 million to \$300 million, and development takes up to 5 years; comparatively, development costs \$2 to \$5 million for a generic drug and takes 2 to 3 years.^{10,23}

Because they are produced in living organisms and require several stages of purification, production, and validation, biosimilars are considerably more expensive to manufacture than generics. Even small changes in the manufacturing process require FDA review and approval.^{21,24} Thus, analysts expect the companies that already have experience in manufacturing biologics will have an advantage; they are expected to dominate the biosimilar market.²⁴ Currently, an estimated 150 biosimilars are under development, many by large pharmaceutical companies such as Amgen, Boehringer Ingelheim, Merck, Novartis, and Pfizer, all of which also manufacture branded biologics. Merck and partner Samsung Bioepis Co Ltd, for instance, received approval in September 2015 in South Korea for their first biosimilar, etanercept (Brenzys). Merck has 4 other biosimilars in phase 3 development.^{14,25} Pfizer is gearing up for the biosimilar market with its purchase of biosimilar manufacturer Hospira, while Amgen has at least 9 biosimilars under development and is expecting to launch its first in 2017.¹⁴

Competition

Because the brand and generic drugs contain the identical chemical entity, coupled with the sheer magnitude of the price differential, generics compete with brand name incumbents mainly on cost and rarely compete directly on other characteristics. In addition, several generics of a given brand drug usually enter the market around the same time (following an initial 180-day period of exclusivity granted to the first generic entrant). This is not so with biosimilars. First, since they are not exact copies of the reference drug, the biosimilar and incumbent biologic will be compared on clinical characteristics, such as safety, efficacy, and toxicity, to demonstrate they are

“highly similar.” In addition, the price differential is likely to be relatively small, resulting in competition between biosimilar(s) and the incumbent biologic that approximates the competition in a multi-brand category of drugs. As a consequence of this competition, unlike generics, biosimilar manufacturers will need to provide significant marketing and education around their new products to sway providers and patients from the reference brands and ensure appropriate placement on inpatient and outpatient formularies.²³

Another consideration is that most biosimilars are based on first-generation reference biologics. A relevant observation from the European experience with biosimilars is that as manufacturers bring second- or next-generation products to market, these newer products maintain greater market share against biosimilars.^{23,26}

Biobetters

Biobetters, or biosuperiors, offer an alternative to biosimilars for manufacturers. Rather than just mimicking the reference biologic, biobetters are designed to improve outcomes and/or safety through chemical, formulation, or delivery changes. Such advantages could eliminate the benefit of a price differential between a biosimilar and its reference product.²⁷ This, in turn, could discourage manufacturers from bringing biosimilars to the market by encouraging them to move forward with a biobetter instead.²³

Drivers of Cost Savings

Physician/Patient Uptake

Physicians and patients in the United States have years of experience with existing reference products; therefore, the shift to biosimilars may be challenging. However, the European experience with biosimilars has demonstrated that the products are equally as safe and efficacious as their predecessors, providing a basis for adoption in the United States.

Surveys have found, though, that what US clinicians desire most, in regard to biosimilars, is more education programs and more studies regarding the safety and efficacy of the products. In a 2011 survey from the National Comprehensive Cancer Network Work Group on Biosimilars, which was made up of 277 physicians, nurses, and pharmacists, the results showed that a third had no or low interest in prescribing, dispensing, or administering

biosimilars in the practice setting or needed more information.²⁸ At that time, the most important information they said they needed were studies directly comparing safety and efficacy between the reference product and the biosimilar.

A 2013 survey of 405 US healthcare professionals, including rheumatologists, oncologists, and primary care physicians, found poor understanding of the differences between biosimilars and generics, and between biosimilars and reference products. Ninety-seven percent of respondents requested continuing education on biosimilars.²⁹

Another early survey (2014) indicated that clinicians may be more likely to initially prescribe biosimilars to a treatment-naïve patient than to switch an existing patient, even assuming similar efficacy and safety.²¹ This may be a result of ongoing concerns about differential immunogenicity or a reaction to the enhanced patient communication that may be required. Regardless, these concerns are likely to evolve as experience with biosimilars accumulates.

The entry of biosimilars into the market has the potential to increase access to life-saving treatments by making them more affordable for patients. Price will be important to driving uptake, given the high out-of-pocket costs for biologics (which may differ based on plan design). However, a number of other dynamics will play into the adoption of biosimilars by patients. As with clinician acceptance, patient acceptance depends on the assurance that biosimilars are as safe and effective as the reference product.²⁸ Patients loyal to the reference brand may not have the same level of confidence in the biosimilar manufacturer and may question the manufacturer's experience or knowledge. Patients may also lack the ability to understand developing concepts, such as interchangeable biosimilars.⁷ In addition, because biosimilars are not able to be substituted in the way that generics are, a patient's perception may be that the biosimilars are in some way inferior to the reference product. Patients will likely be inclined to look to their physician for guidance on biosimilars and follow their physician's lead.

Table 2¹² lists the potential drivers of cost savings from biosimilars.¹²

Plan Design

In a survey of 40 payers, including national and regional managed care organizations, pharmacy benefit managers, integrated delivery networks, the Veterans Administration, accountable care organizations, and benefit consultants, it was found that nearly all view biosimilars as a compelling business opportunity for their

■ **Table 2. Drivers of Biosimilar Cost Savings**¹²

- Currently approved biologic drugs
- The FDA approval process
- Physician acceptance and prescribing patterns
- Patient acceptance
- Price differential at entrance into the market and into the future
- Manufacturing costs
- Future trends in biologic utilization and cost per prescription
- Benefit coverage (pharmacy vs medical)
- Safety and efficacy profile of biosimilar compared with reference biologic
- Employer benefit changes to incentivize the use of biosimilars
- Therapeutic interchange
- Manufacturer rebates and discounts
- Approved indications for biosimilar

Adapted from Milliman. Understanding biosimilars and projecting the cost savings to employers – update. 2015. <http://us.milliman.com/uploadedFiles/insight/2015/understanding-biosimilars.pdf>. Accessed October 12, 2015.

entity. To prepare for the coming wave of biosimilars, payers are exploring new payment models and formulary tiers based on the tools available under the benefit where the drug is typically covered. One option for drugs typically covered under the pharmacy benefit is to exclude the reference drug from the formulary or place it on a higher tier with a higher copayment, as is often done with branded drugs that have generic counterparts.²¹

Another survey, this one of 36 payers representing 8 of the top 25 in numbers of covered lives, found that most payers planned to include biosimilars on their formularies, recommend them to patients, and steer members and physicians toward their use via copayment/coinsurance tiering. They also said they would recommend the use of a biosimilar for an off-label indication if the reference biologic had that indication. The longer the biosimilar had been in use, the more likely they were to support off-label use. Eventually, all respondents predicted automatic therapeutic switching of biosimilars for biologics at some point.²¹ In another survey, however, payers said that biosimilars would need to be priced more than 40% lower than the reference product before they would require existing patients to switch to the lower-cost drug.²⁰

Although generics rarely receive pharmacy and therapeutics committee review before being covered,

this is not expected to be the case with biosimilars. Committees will need to consider the most appropriate patient population for the compound, as well as review issues regarding substitutions.²⁸

Additional factors under consideration by plan sponsors are the impact of formulary management and the incremental reduction in costs that may be generated from the resulting competition. Reference biologic manufacturers as well as biosimilar manufacturers may offer larger rebates as an incentive to the plan sponsor to cover or prefer their products, thereby lowering the net cost. Sizeable rebates from reference biologics will become even more likely when “interchangeable” biosimilars enter the market.¹²

FDA Guidance

Over the past 3 years, the FDA has issued 3 final guidance documents and 5 draft guidance documents relative to the implementation of the BPCI Act of 2009. These documents explain the FDA’s current thinking on key scientific factors and regulatory issues involved in submitting applications for biosimilar products to the FDA for evaluation. According to the FDA Center for Drug Evaluation and Research guidance agenda, the agency is expected to issue 3 additional draft guidances on biosimilars in 2015. **Table 3**³⁰ lists the FDA guidance documents.³⁰

The FDA’s guidance, similar to the European Union biosimilar regulations, is expected to facilitate competition, thereby lowering prices for payers and patients. The final FDA regulations will have a large impact on the degree to which prices may be lowered.¹⁶

Interchangeability

Most generics are considered interchangeable once approved, and pharmacists are allowed to switch branded drugs for generics at the point of purchase, subject to state laws. Not surprisingly, analysts expect interchangeability to be one of the most important drivers in determining relative market uptake and sales of biosimilars. Advantages of achieving the interchangeability designation include greater patient and clinician confidence in the product, as well as 1 year of exclusivity before another biosimilar to the reference drug is approved.²²

However, to receive the interchangeability designation for a biosimilar, manufacturers must demonstrate that the drug can “be expected to produce the same clinical result as the reference product in any given patient and, if the biological product is administered more than once to an individual, the risk in terms of safety or

■ **Table 3.** FDA Biosimilar Guidance Documents³⁰

Type	Title	Issue Date
Final	Scientific Considerations in Demonstrating Biosimilarity to a Reference Product	4/28/15
	Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product	4/28/15
	Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009	4/28/15
Draft	Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants	3/29/13
	Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product	5/13/14
	Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the Public Health Service Act	8/4/14
	Biosimilars: Additional Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009	5/12/15
	Nonproprietary Naming for Biological Products	8/27/15
Planned	Considerations in Demonstrating Interchangeability to a Reference Product	Q4 2015
	Labeling for Biosimilar Biological Product	Q4 2015
	Statistical Approaches to Evaluation of Analytical Similarity Data to Support a Demonstration of Biosimilarity	Q4 2015

Adapted from Guidances (drugs): biosimilars. FDA website. <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm290967.htm>. Accessed November 6, 2015.

diminished efficacy of alternating or switching between the use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.”⁶ Studies to demonstrate this cost more than \$50,000 per patient; rather than make this considerable incremental investment in pursuit of the “interchangeable” designation, manufacturers may choose to stop at the “biosimilar” designation.²² Although this approach would accelerate the speed to market, it could also decrease the size of the addressable population because of the potentially lower patient and clinician confidence in the biosimilar (and non “interchangeable”) product.

States are already preparing for the possibility of interchangeability, with the majority having considered legislation that would establish standards for the substitution of a “biosimilar” prescription product to replace an original biologic product. To date, many states and Puerto Rico have signed such legislation into law (Figure³¹). State legislation for substitution varies but often contains similar components. These laws typically require that:

- to be considered for substitution, the biosimilar must first be approved by the FDA with the “interchangeable” designation
- prescribers are allowed to prevent substitution by writing “dispense as written” or “brand medically necessary”

- the dispensing pharmacy must notify the prescriber and the patient of any allowable substitution made (with some states requiring patient consent before making a switch)
- records are retained by the pharmacy and prescriber
- the state must maintain an accessible list of allowed “interchangeable” products
- pharmacists who make a substitution in compliance with the biologics state law are provided immunity
- the pharmacist must explain the cost or price of the reference biologic and the interchangeable biosimilar to the patient (subset of states only)²²

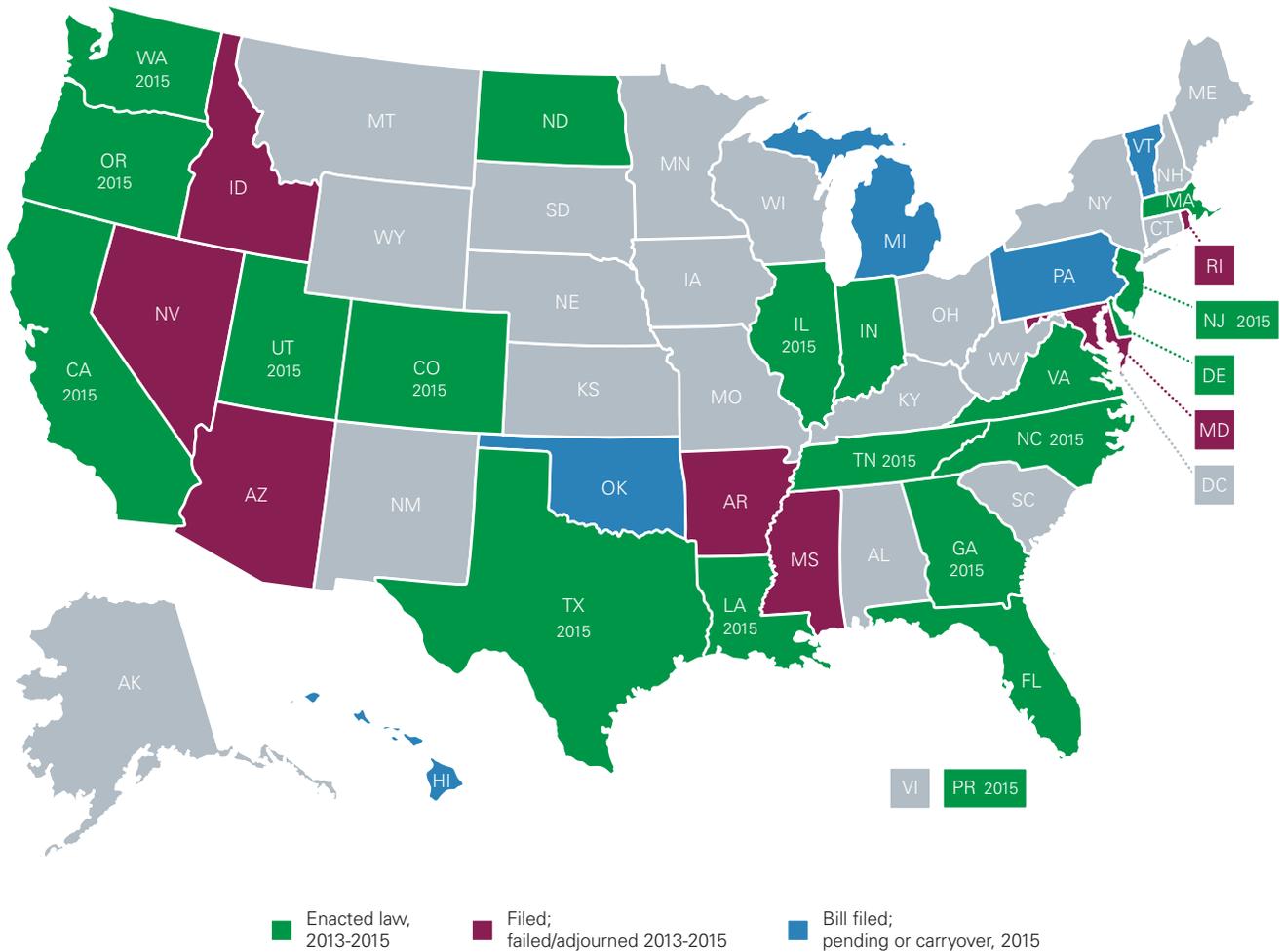
Although some of these requirements are similar to generic substitution laws (such as the use of “brand medically necessary” and notification that substitution occurred), others are unique to “interchangeable” biosimilars.

The FDA is expected to issue their guidance on interchangeability by the end of 2015.³²

Reimbursement

Reimbursement level and provider profitability will contribute to provider uptake of biosimilars. Currently, most biologics are administered in an outpatient setting under the medical benefit and the buy-and-bill model, with provider reimbursement based on the average sales price of the drug. In the current model, if a drug costs less, providers have less economic incentive to prescribe and administer it. However, the ACA requires that Medicare Part B reim-

■ **Figure.** Legislation on Biologics and Biosimilar Substitution, 2013-2015³¹



Reprinted with permission from National Conference of State Legislatures. State laws and legislation related to biologic medications and substitution of biosimilars. 2015. <http://www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx>. Accessed November 23, 2015.

bursement for biosimilars be based on the sum of the drug’s average selling price plus a fixed percentage (currently 6%) of the average selling price of the reference product, thus eliminating the economic incentive to preferentially prescribe the reference product, at least under Medicare.^{12,22}

Conversely, since reimbursement will be the same, there is also no financial incentive to prescribe the biosimilar. In order to encourage uptake of biosimilars, commercial payers may offer a higher margin for biosimilars than they do for the reference product.²²

The CMS also handed reference drugs an advantage in April 2015 when it ruled that biosimilars are exempt

from the mandatory 50% discount in the Medicare Part D coverage gap. This may reduce the cost gap between biologics and biosimilars while patients are in the so-called donut hole.³³

The adoption of alternative reimbursement models and value-based purchasing, such as bundled payments and risk-sharing agreements with accountable care organizations, may also influence the uptake of biosimilars in the outpatient setting.⁷ Based on the amount of economic risk they are managing, as well as the resulting greater tolerance for investing the time with patients necessary to discuss and address any concerns they may have with

■ **Table 4.** Biosimilar Stakeholders Key Considerations ^{7,16,21-24,28,31}

Stakeholder Group	Considerations
Manufacturers	Complex manufacturing process Evolving approval pathway and forthcoming “interchangeable” guidance Competition from reference product and “biobetters” Compliance with state regulations
Prescribers	Safety and efficacy concerns European Union experience and learning(s) Use in treatment naïve vs experienced patients Notification requirements for substitution
Patients	Safety and efficacy concerns Use in treatment naïve vs experienced patients Increase in access and coverage Opportunity for decrease in cost share
Payers	“Interchangeable” guidance Variability in state regulations Adaptation of plan designs/formularies Potential for alternate reimbursement models

biosimilars, providers in these arrangements may be willing to accelerate adoption of biosimilars.

One controversial reimbursement issue revolves around a CMS proposed rule for coding biosimilars. The rule, initially released in July 2015 and finalized October 30, 2015, assigns all biosimilars of a single reference product one Healthcare Common Procedure Coding System (HCPCS) code and bases payment amounts for a biosimilar on the average sales prices of all National Drug Codes assigned to the various biosimilar biological products included within that same billing and payment code.³⁴

The advocacy group Biosimilars Forum, which represents most companies with active biosimilars development portfolios, argued that the rule “inappropriately treats biosimilar products as if they were multisource or generic drugs” and warns that it is likely to dramatically reduce investment in, and the subsequent availability of, biosimilar products.³⁵ Other advocacy organizations, including the Biotechnology Industry Organization and the National Association of Chain Drug Stores, also expressed opposition to the rule.³⁶

Conclusion

As the first biosimilars for today’s revolutionary and expensive biologic drugs enter the market, payers and manufacturers are poised for what could be a great paradigm shift in the pharmacy world. However, given the significant chemical, medical, regulatory, and ensuing market differences between biosimilars and generic drugs, the ultimate economic impact of biosimilars remains unclear.

Table 4^{7,16,21-24,28,31} lists the key considerations for biosimilar stakeholders.

Biosimilar manufacturers are entering a promising market that most of them know well from their biologic drug manufacturing experience. For biosimilars, though, manufacturers face a nascent and evolving approval pathway, a complex manufacturing process, a skeptical customer base (both physicians and patients), a lack of guidance on attaining interchangeability, uncertainty at the state policy level, and strong competition from reference biologics—all of which could limit the market reach of their new products.

Importantly, the level of initial support and uptake from US physicians remains uncertain, although nearly a decade of experience with biosimilars in Europe, Asia, and other countries may provide some with a sense of security. However, there is also often reluctance on the part of many US physicians to accept non-US clinical experience as relevant to their practice and their patients. This reluctance may play a role in defining the slope of the uptake curve for biosimilars as a portion of the specialty prescriber base awaits a greater amount of domestic longitudinal experience to accumulate with these products before routinely prescribing them. Some physician groups have already expressed a particular desire to have the immunogenicity of each product (or lack thereof) better defined before general use commences.

For patients, safety is paramount, but out-of-pocket costs are also of great concern. The greater out-of-pocket costs patients face today, with high-deductible health plans and

other mechanisms for increasing patient cost share, may provide sufficient incentive for members of those plans to switch from branded agents to biosimilars, or to begin treatment with a biosimilar from their initial prescription.

With respect to payers, biosimilars are another persuasive reason to reconsider and refine their plan design and formulary structure. Given the high cost of biologics on the market today, even a 15% to 30% price discount is significant and provides more economic incentive to push the consideration of alternative reimbursement models and approaches to setting fee schedules.

With this complex interplay between economic and human factors in a rapidly growing, and highly regulated environment, predicting the precise shape of the eventual market is tricky business. Nonetheless, biosimilars have the potential to lead to much-needed cost savings, while still providing patients with the safe and efficacious treatment they need—a goal that all the stakeholders can agree on.

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