

Payor Strategies to Promote Biosimilar Utilization

By Alex Brill

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1350 Connecticut Ave. NW | Suite 610 | Washington, DC 20036
www.matrixglobaladvisors.com

EXECUTIVE SUMMARY

Biologics are among the most expensive drugs available and represent a large and increasing share of U.S. drug spending. Biosimilars, less expensive copies of these highly complex pharmaceuticals, are just beginning to enter the U.S. market, but a robust biosimilars industry that yields maximum benefit for patients is far from certain. Because biosimilar utilization can be significantly facilitated by physicians, the full potential of biosimilars in the United States will be realized more quickly if doctors embrace their use. In light of this, a carefully constructed physician incentive from public and private payors could boost biosimilar utilization significantly, benefitting patients and the health care system as a whole.

Public and private health care payors have long employed coverage and reimbursement strategies geared toward patients and providers in pursuit of containing costs and improving health care outcomes. In some areas of health care that are less patient-driven, beneficiary cost may be disconnected from treatment decisions because patients' financial concerns are not foremost in physicians' minds when discussing treatment options with patients. Biosimilar utilization will likely fall into this category. To overcome this disconnect, policymakers and payors should encourage better alignment between patients' financial concerns and physicians' approach to presenting treatment options. This would be in keeping with recent payment reforms that reward providers who meet outcome metrics that improve quality and save money.

When a U.S. pathway for biosimilars was established in the Affordable Care Act in 2010, biosimilars were expected to bring substantial savings to the U.S. health care system. These products have been available for nearly a decade in Europe, where biosimilar prices average 10–35 percent lower than reference product prices. However, as time has passed, uncertainty about the robustness of the U.S. biosimilars market has grown. Some experts still predict large biosimilar savings, but others are tempering expectations. Existing policies that have been successful in encouraging generic drug utilization likely will not apply to biosimilars. And previous research I conducted found that moderate competition for blockbuster biologics is feasible, but a large number of biologics (and thus a significant share of spending) may escape the positive competitive pressures brought by biosimilars.

Therefore, it is all the more important to implement policies to encourage biosimilar utilization. Policymakers and payors could, in a manner similar to how some payors promote increased generic utilization, encourage physicians to use biosimilars, by rewarding them for doing so. It would, of course, be necessary to construct biosimilar utilization incentives to ensure that they serve their intended purpose. In addition, the legal and ethical implications of incentives would need to be carefully considered. But, considering the cost savings that biosimilars could offer to patients and taxpayers, it is well worth the effort to create well-crafted incentives.

INTRODUCTION

Public and private health care payors have long employed coverage and reimbursement strategies in pursuit of the dual purpose of containing cost growth and improving health care outcomes. On the provider side, this includes transitioning from fee-for-service to pay-for-performance reimbursement as well as episodic bundles. On the patient side, payors use tiered copays, deductibles, and other strategies to help patients understand the cost of health care and encourage them to seek efficient treatment. In some areas of health care that are less patient-driven, consideration of beneficiary cost may be disconnected from treatment decisions. This is largely because the financial concerns of patients are not foremost in physicians' minds when discussing treatment options with patients. To overcome this disconnect, policymakers and payors should look for ways to encourage better alignment between patients' financial concerns and physicians' approach to presenting treatment options.

This type of disconnect is likely to arise with the introduction in the United States of biosimilars, copies of highly complex pharmaceutical products known as biologics, which are made from living cells and treat diseases like cancer and autoimmune disorders. Biologics are among the most expensive drugs available and represent a large and increasing share of U.S. drug spending. Biosimilars, which have been available in Europe for nearly a decade and are just now entering the U.S. market, offer the same clinical benefit as their reference products but cost considerably less.

The first U.S. biosimilar—Zarxio, which reduces the risk of infection in cancer patients receiving chemotherapy—was launched in September 2015 by Novartis's generic drug division, Sandoz. Zarxio is a copy of Amgen's Neupogen, a biologic with 2014 U.S. sales of \$839 million.¹ On April 5, 2016, the Food and Drug Administration (FDA) approved the second U.S. biosimilar: Celltrion's Inflectra, a biosimilar of Janssen Biotech's Remicade, which treats autoimmune diseases.² More biosimilars

are expected to follow, but a robust U.S. biosimilars industry that yields maximum benefit for patients is far from certain.

Many biologics are physician-administered, which could limit the effectiveness of patient-oriented incentives like those in place for small-molecule generic drugs. For example, automatic substitution policies that have facilitated widespread generic drug utilization will not apply to biosimilars when a biosimilar is not deemed interchangeable with its reference biologic. An interchangeable designation for biosimilars is not expected in the near term, as the FDA has not yet offered guidance on receiving this designation.

Put simply, the full potential of biosimilars in the United States will be more quickly realized if doctors embrace their use. Much as payors have developed effective strategies to encourage efficiencies elsewhere in medicine—including offering physician incentives for increased generic prescribing—a carefully constructed physician incentive from government health care plans, private

insurance companies, and other payors could boost biosimilar utilization significantly, benefitting patients and the health care system as a whole. Because biosimilars are just becoming available in the United States, putting incentives for their utilization in place now would maximize these benefits in a manner consistent with broader trends in health care payment reform.

In this paper, I first discuss recent health care payment reforms as they relate to promoting health care quality and cost-effectiveness among physicians and patients. I then describe the biosimilars landscape in the United States and the promise that biosimilars hold but that may not be realized. Finally, I present a new proposal for payors to incentivize biosimilar utilization, thereby unlocking financial benefits for patients and taxpayers.

I. HEALTH CARE PAYMENT REFORM

Dramatic payment reforms have been implemented across a wide spectrum of payors and services within the U.S. health care system. In recent years, as there has been increasing emphasis on health care quality, payment reforms have shifted toward incentives for providing high-quality health care in a cost-effective manner. In general, these incentives are geared toward providers and patients separately.

Provider Incentives

Paying providers fairly for health care services in a manner that encourages quality and efficiency has been a goal of U.S. policymakers and health care experts

for decades. In the standard fee-for-service model in the U.S. health care system, providers have a financial incentive to treat as many patients as possible, which can lead to potentially harmful overtreatment and unnecessary costs. This payment model is aptly described as “volume-driven.”³ Over the years, and with varying degrees of success, public and private payors have embraced strategies geared toward reducing the incentive for providers to pursue volume, thereby improving health care quality and promoting cost savings.

In the 1990s, health care payment reform was marked by a shift toward “managed care” strategies such as capitation, or per-person rather than per-service payments.⁴ In the ensuing years, however, concerns arose that this model ignored quality⁵ and that capitation created the financial incentive for providers to take on relatively healthy patients and avoid the sickest population.⁶ More recent payment reforms, under the umbrella of “value-based purchasing,” attempt to encourage quality while not incentivizing providers to shirk their responsibility to patients. These reforms include “bundled payments”—that is, a fixed payment per episode of care rather than per patient or per service—and pay-for-performance programs. Pay-for-performance programs assess certain metrics, such as hospital readmissions, lab tests for specific diseases, and surgical and hospital-acquired infections, in order to reward positive results, or penalize poor results. In addition to improvements in quality of care, cost savings are an

important goal of value-based programs. To effectively implement these programs, vast quantities of clinical and outcome data are required, but through the use of electronic medical records and health information technology broadly, these mechanisms are now in place for hospital systems and other large providers.

Private insurance companies and government health care programs have increasingly shifted toward value-based purchasing. For example, value-based programs comprise 30 percent of Aetna's medical spending and 20 percent of Blue Cross and Blue Shield companies' spending in 2015.⁷ On the federal level, the Affordable Care Act (ACA) included a variety of payment reforms geared toward rewarding outcome improvement and cost containment. Most notable among these initiatives are accountable care organizations (ACOs). ACOs comprise doctors, hospitals, and other health care providers who coordinate care for Medicare patients, sharing in savings that result from "delivering high-quality care and spending health care dollars more wisely."⁸ The Centers for Medicare and Medicaid Services (CMS) announced in January 2015 its goal to link 50 percent of Medicare payments to alternative payment models like ACOs by 2018.⁹

The ACA also established the Center for Medicare and Medicaid Innovation within CMS, and a host of demonstration projects related to performance and quality are currently underway. In addition, CMS gives

bonus payments to Medicare Advantage plans based on quality ("star") ratings. The specific design traits of this program are controversial, but the intent is to reward insurers who achieve high marks on quality metrics across a range of criteria.

While assessments of the effectiveness of value-based purchasing have shown mixed results,¹⁰ there is general consensus about the worthiness of encouraging providers to pursue improved outcomes and cost savings. These goals also drive incentives for patient behavior.

Patient Incentives

Private and public payors have long employed various strategies such as deductibles, tiered copays, and provider networks to encourage patients to use the most cost-effective health care services, particularly in outpatient care. For example, for a patient choosing an in-network service in 2015, the average copay for a visit to the emergency room is \$123;¹¹ an urgent care center, \$33;¹² and a primary care physician, \$24.¹³ These cost differentials serve as an incentive for someone not experiencing a dire emergency to obtain health care services in a more cost-effective manner than by going to the emergency room.

Another example is the average copay for generic drugs, which payors set much lower than the copay for brand drugs. While health plans employ automatic generic substitution, receiving a brand drug is still an option for patients, but a more expensive option, reflecting the underlying cost of the brand drug. In 2015, for health

plans with three or more drug tiers (that is, 81 percent of covered workers' plans¹⁴), the average copay for a generic (first-tier) drug is \$11, while copays for drugs in the second, third, and fourth tiers average \$31, \$54, and \$93, respectively.¹⁵ Among the top ten Medicare Part D plans, copays in 2015 ranged from \$0 to \$8 for preferred generics; \$2 to \$9 for non-preferred generics; \$20 to \$45 for preferred brands (though three plans had a copay of 20 percent of the cost of a preferred brand); 35 percent to 50 percent of the cost of a non-preferred brand (though three plans had set copays of \$40, \$85, and \$89, respectively, for non-preferred brands); and 25 percent to 33 percent of the cost of a specialty drug.¹⁶

Broadly speaking, many of the innovative health insurance copay, coinsurance, and deductible design innovations are captured by value-based insurance design (VBID) strategies that seek to optimize patient out-of-pocket costs to reflect the patients' willingness to pay and the value inherent in a given health care product or service. For example, insurers utilizing these strategies may lower (or eliminate) the copay on a medicine shown to be highly effective in preventing a costly hospital admission if patients are shown to increase their adherence to the drug when their out-of-pocket costs decrease.

While VBID and other strategies show promise, there is a limit to the usefulness of such incentives because patients understandably tend to delegate significant decision-making to

their physicians. One reason for this ceding of authority is the "informational disadvantage" of patients relative to doctors—a disadvantage that some health economists argue can be addressed through patient incentives.¹⁷ But, the inclination to delegate authority is more easily—and appropriately—overcome with patient incentives in some health care arenas than others. In the context of highly complex care, it would be neither simple nor appropriate to incentivize patients to take decision-making in their own hands because the "informational disadvantage" in these cases arises from the extensive education and training physicians receive. But, when patients rely on doctors' choices for them, a natural gap can exist between doctors' priorities and patients' interests—particularly patients' financial interests. This gap can be addressed with physician incentives geared toward promoting patients' interests.

Aligning Physician Decisions with Patient Interests

In keeping with the movement in health care payment reform toward rewarding providers who meet outcome metrics that improve quality and save money, payors should also consider incentives that encourage physicians to help patients pursue treatments that require lower out-of-pocket expenses. Survey research has found that while physicians *believe* it is important to control out-of-pocket expenses for patients, they seldom or never consider themselves familiar with patients' drug formularies or likely copays.¹⁸ Carefully constructed physician incentives could result

in better alignment between a patient's financial concerns and the physician's approach to reviewing treatment options.

A key example of the utility of this type of incentive lies in the nascent U.S. biosimilars market. Biosimilars have the potential to offer significant cost savings. But, even though the benefits will accrue to patients through lower coinsurance costs and lower premiums, physicians can have a significant impact on biosimilar utilization, for reasons explained above. This is the exact type of situation in which a well-crafted prescriber-focused incentive could help inform and align physicians' behaviors with patients' financial interests and the societal objective of achieving efficiencies in the health care industry.

II. THE PROMISE OF BIOSIMILARS

Biosimilars in the United States

Biologics comprise 28 percent (roughly \$92 billion) of U.S. drug spending,¹⁹ and spending on these highly complex products is projected to increase dramatically in the coming years.²⁰ Because biosimilars are expected to be priced lower than their reference biologics, the savings opportunity from biosimilars is huge. Indeed, when a U.S. pathway for biosimilars was established in the ACA in 2010, biosimilars were expected to bring substantial savings to the U.S. health care system.²¹ These products have been available for nearly a decade in Europe, where biosimilar prices average 10–35 percent lower than reference product prices.²² However, as time has passed, uncertainty about the

robustness of the U.S. biosimilars market has grown. Some experts still predict large biosimilar savings,²³ but others are tempering expectations.²⁴

Because competition drives lower prices, the more competition there is in the biosimilars market, the greater the savings will be. To predict how much biosimilar competition to expect, in February 2015, I modeled the viability of the U.S. biosimilars industry.²⁵ My results showed that moderate competition for blockbuster biologics is likely, but a large number of biologics (and thus a significant share of biologic spending) may escape biosimilars' positive competitive pressures.

Indeed, biosimilars of the largest biologics are currently on their way to market, with the FDA working with 51 biosimilar development programs.²⁶ Once available, these biosimilars will bring substantial savings to patients, taxpayers, and the U.S. health care system. But action is needed if we want a robust industry similar to the small-molecule generic drug industry, with broad competition and savings.

Impediments to Biosimilars

Unlike small-molecule generic drugs, biosimilars are costly and time-consuming to develop, requiring an estimated 8–10 years and \$100 million–\$200 million in research and development (R&D) costs.²⁷ In addition, there are regulatory, statutory, and market impediments with which biosimilar manufacturers have to contend.

On October 30, 2015, CMS issued a Final Rule that groups all biosimilars for a given reference product in one Medicare Part B

reimbursement code, thereby setting reimbursement at a blended average of the biosimilars' prices. Stakeholders argued that this would discourage biosimilar manufacturers from entering the market, due to the limitations this policy would impose on a manufacturer's ability to affect reimbursement.²⁸ But CMS finalized the policy as originally proposed.

In August 2015, the FDA released its long-awaited proposal on biosimilar naming, announcing its intention to give each biosimilar a random four-letter suffix to differentiate it from the reference biologic and from other biosimilars—a naming convention that does not prioritize biosimilar utilization and that breaks with the European practice of using the same international nonproprietary name for a reference biologic and its follow-on products.

Ultimately, a biosimilar manufacturer must weigh the costs, time, and manifold uncertainties involved in bringing a biosimilar to market and decide whether to proceed. This decision will depend on whether the future sales of that product will allow the manufacturer to “break even”—that is, recoup development costs. My February 2015 study presented the results of a break-even analysis that tested the economic viability of biosimilars in the United States in a base-case scenario and two alternative scenarios: 1) a scenario in which potential regulatory and market constraints limit biosimilar market share, and 2) a scenario with favorable market conditions in the form of lower R&D costs.

Even in the scenario with better market conditions, I found that only the largest biologics would attract biosimilar competition. While there will be substantial benefit from these biosimilars, the potential savings from a broader array of biosimilars will be limited without encouragement.

In light of this, payors—public and private alike—need more tools and strategies to encourage biosimilar utilization and maximize the savings and benefits for patients and taxpayers. In addition to formulary strategies and other tools that payors can employ, payors could look physicians to help drive biosimilar utilization and unlock these benefits.

III. PHYSICIAN INCENTIVES FOR BIOSIMILAR UTILIZATION

One way that policymakers and payors could encourage physicians to use biosimilars, in addition to promoting physician education around biosimilars, is by rewarding them for doing so. Private payors already use these types of payments to reward physicians' generic drug prescribing. For example, Excellus BlueCross BlueShield in New York offered higher office-visit payments for physician groups that increased generic prescribing by at least 5 percent, an incentive that reportedly resulted in a 10–12 percent reduction in patients' out-of-pocket expenses.²⁹

It would, of course, be necessary to construct biosimilar utilization incentives to ensure that they serve their intended purpose—to encourage better alignment between patients' financial concerns and

physicians' approach to presenting treatment options. In addition, the legal implications of incentives would need to be carefully considered. The federal anti-kickback statute prohibits any entity from providing an inducement in return for federal health care program business, with the exception of specific "safe harbor" regulations. But, as a March 2015 *PLOS Medicine* article explained, these restrictions do not apply in all circumstances:

The [federal] anti-kickback statute clearly precludes Medicare Part D insurance providers and Medicaid managed care organizations [MCO] from offering physicians financial incentives to prescribe . . . follow-on biologics. Its reach beyond these programs, though, is limited in two respects. First, the anti-kickback statute exempts "any amount paid by an employer to an employee" so hospitals and managed care organizations that employ physicians can safely incorporate generic drug and follow-on biologic prescribing as a measure in their pay-for-performance schemes. Second, the anti-kickback statute does not prohibit physicians from accepting prescribing bonuses from private health plans.³⁰

In order for Medicare Part D and Medicaid MCO patients to benefit from a physician incentive, policymakers may need to create a safe harbor for these payors. In Medicare Part B, where the majority of biologics in Medicare are used, federal reimbursement

for biosimilars would need to be amended. The ACA already includes a provision to guard against a financial incentive in Part B for physicians to choose reference biologics over biosimilars. This provision could be modified to offer a small financial incentive for physicians to choose biosimilars.

Part B reimbursement for doctors is set at the average sales price (ASP) of a product plus 6 percent of the ASP to compensate for acquisition and handling. The ACA set biosimilar reimbursement at the biosimilar's own ASP plus 6 percent of the reference product's ASP. Since a reference biologic's ASP would likely be higher than a biosimilar's ASP, this provision removes any incentive for a physician to earn more by using a reference biologic and receiving 6 percent of a higher amount. If a biosimilar were instead reimbursed at its ASP plus 8 percent of the reference product's ASP, it would create a financial incentive for physicians to use biosimilars.

Even with legal concerns addressed, there are ethical considerations that would need to be carefully considered in constructing physician incentives. As the authors of the recent *PLOS Medicine* article note, payments "for initiating treatment-naïve patients . . . could prompt unnecessary treatment or preclude clinically preferable treatment."³¹ The appropriateness of a physician incentive may need to be assessed on a product-by-product basis. But, considering the savings that biosimilars could offer to patients, it is well worth the effort to create well-crafted incentives for biosimilar utilization.

CONCLUSION

With health care spending again on the rise, it is all the more important to pursue incentives aimed at increasing value within the health care sector. While many reforms have been implemented across the sector, cost-saving biosimilar utilization may not be fully realized unless physician and patient incentives are better aligned. Payors, seeking to improve the value of care through the use of appropriate

incentives, are well situated to facilitate the growth of biosimilars. Because higher utilization of biosimilars will drive competition in the market, incentivizing their utilization will have the downstream effect of increasing the robustness of the biosimilars market overall, further benefiting U.S. patients and the health care system.

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.

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NOTES

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