

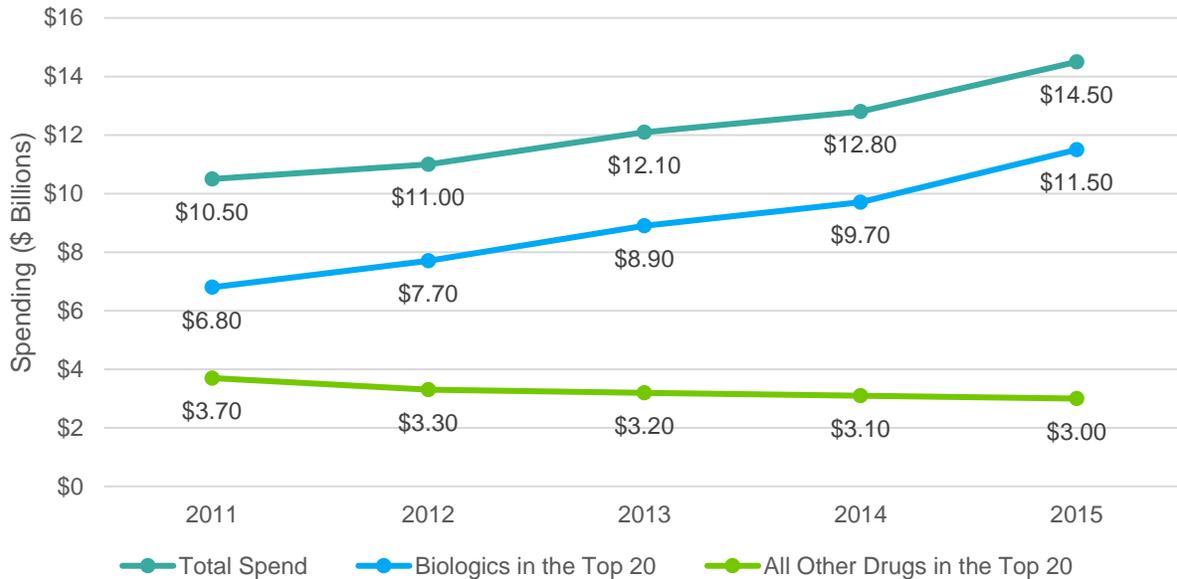
FIVE OBSTACLES TO COMPETITION IN THE UNITED STATES BIOLOGICS MARKET

Biosimilars have the opportunity to foster competition, but there are policy and market barriers that limit the growth of a functioning market

While attention on drug prices continues, discussions regarding competition often focus on generic drugs, which have long played a role in spurring competition and cost reduction within the pharmaceutical industry. However, biologics have become an increasingly important part of care delivery in the United States.

In 2010, a biosimilar approval pathway was created with an expectation that a multi-source competitive market could offer potential savings for the U.S. health system.¹ As of February 2017, the pipeline of biosimilars in development includes 64 biosimilars, referencing 23 different originator products, enrolled in the Biosimilar Product Development Program at the U.S. Food and Drug Administration (FDA). *Biologics have grown to represent 79% (\$11.5B) of Medicare Part B and 21% (\$8.7 B) of Medicare Part D spending for the top 20 drugs in each program.*² The timing of available biosimilars is notable for the healthcare system. Six of the 12 biologics covered by Medicare Part B no longer have outstanding exclusivity as of 2017, representing a total of \$5.28 billion in Medicare Part B spending in 2015.

Top 20 Part B Trends



¹ The biosimilar pathway was created by the Biologics Price Competition and Innovation Act (BPCIA) as Title VII of the Patient Protection and Affordable Care Act in 2010. Available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/UCM216146.pdf> Last accessed 24 May 2017

² Avalere Analysis of 2011-2015 Medicare Part B and Part D Drug Spending Data, available at CMS website (<https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/2015MedicareData.html>)



To promote a sustainable environment for both innovator and biosimilar manufacturers, five key policy and market issues must be carefully considered and addressed.

Obstacle 1: Complexity of Development

While the biosimilars market often draws comparisons to the generics market, the underlying fundamentals of the market are different. The development costs and timelines for biosimilars more closely resemble those of branded products than generics. While generics typically experience a three- to five-year development timeline and a cost of \$1 to 5 million dollars, biosimilar development requires 8 to 10 years and potentially costs \$200 million or more due to the complexity of the molecules involved.^{3, 4} Because of this more complex research and development model, it is unlikely that biosimilars pricing will ever match the level of savings seen in the generic pharmaceutical market.

Obstacle 2: Prescribing Patterns

The biosimilar market is further complicated by patient and provider reticence to switch from a reference biologic to a biosimilar. However, this manifests itself differently in different therapeutic areas. For example, when chronic conditions are well managed with a biologic, providers and patients are often hesitant to switch.⁵ In contrast, for acute patients, providers and patients may consider the option of starting a new patient on a biosimilar or a reference product. Nonetheless, because the biosimilar manufacturer may be competing for smaller subsets of their reference product's market, this level of uncertainty in provider prescribing patterns and patient choices can further complicate biosimilar market viability.

Obstacle 3: Interchangeability

The FDA recently published a draft guidance on demonstrating interchangeability, a designation that would allow an interchangeable biologic to be automatically substituted at a pharmacy (subject to state law).⁶ As of yet, however, the draft guidance is not finalized and no products have been approved as interchangeable. Although interchangeability is unlikely to impact a biologic or biosimilar covered under Medicare Part B (physician-administered products would not be subject to pharmacy-level substitution), the designation could be very impactful for Part D, where reference products have a total market of \$3.1 billion.⁷ Also, the existence of a potential interchangeability designation may create a perception of inferiority for biosimilars that have not been approved as interchangeable.

Obstacle 4: Physician Reimbursement Model

In the Calendar Year (CY) 2016 Physician Fee Schedule final rule, the Centers for Medicare & Medicaid Services (CMS) finalized biosimilar HCPCS (Healthcare Common Procedure Coding System) product coding and payment. The policy states that the first biosimilar to an originator will be issued a unique HCPCS code and will be paid by the average sales price (ASP)

³ DiMasi, Joseph A., Henry G. Grabowski, and Ronald W. Hansen. "Innovation in the pharmaceutical industry: new estimates of R&D costs." *Journal of health economics* 47 (2016): 20-33.

⁴ Federal Trade Commission. Emerging health care issues: follow-on biologic drug competition. June 2009 Report. Available at: <http://www.ftc.gov/os/2009/06/P083901biologicsreport.pdf>. Accessed May 2, 2017.

⁵ Danese, Silvio, et al. "ECCO position statement on the use of biosimilars for inflammatory bowel disease—an update." *Journal of Crohn's and Colitis* 11.1 (2017): 26-34.

⁶ FDA. "Considerations in Demonstrating Interchangeability With a Reference Product." 2017. <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm537135.pdf>. Last accessed 2 May 2017.

⁷ Avalere Analysis



methodology. However, once a second biosimilar to the same originator is available, coding and payment changes. Specifically, after the second biosimilar is approved, biosimilars to the same innovator product will share a HCPCS code. Payment for the biosimilar will be calculated as a blended ASP of all biosimilars in the shared HCPCS code. In either case, one or multiple biosimilar the same originator, the plus 6 percent add-on amount based on the innovator product's ASP. The originator will continue to remain separate from this process, with a unique HCPCS product code and non-blended ASP payment. This policy creates an environment where biosimilar manufacturers may compete on price, but does not provide an incentive for providers to prescribe the biosimilar over the originator product.

Obstacle 5: Payer Coverage and Consumer Out-of-Pocket Costs

Reimbursement for biosimilars is further complicated by benefit designs and coverage decisions in the Medicare Part D and commercial markets. Under Medicare Part D, in the coverage gap between initial coverage and catastrophic coverage – otherwise known as the “donut hole” – biosimilars are disadvantaged relative to originator products. For purposes of the “donut hole,” biosimilars are treated as generics and only patient spending counts towards the true out-of-pocket limit (TrOOP), the point at which the patient moves into the catastrophic coverage benefit of Medicare Part D. In contrast, originator products are treated as branded products. For branded products, both the patient cost sharing and the coverage gap discount program (CGDP) discounts from the manufacturer count towards the patient's TrOOP. As a result, a patient taking an originator product will move through the coverage gap faster, paying less out-of-pocket. Conversely, the patient taking the biosimilar will spend longer in the coverage gap and have to pay more out-of-pocket to reach the catastrophic coverage threshold. As such, patients are incented to use the originator product, rather than the biosimilar, due to the lower out-of-pocket spending in the coverage gap.⁸

In the commercial market, payers face a different choice. For example, the first two biosimilars launched in the United States (Zarxio®[filgrastim-sndz] and Inflectra®[infliximab-dyyb]) both launched with a 15% discount to the originators' pricing.^{9, 10} To compete against a biosimilar, originator manufacturers can deploy many tools. While this competition will generate short-term savings to payers, it also could hamper a biosimilar's ability to build market share, which may limit future investment in the space.

The Future of Biosimilar Market:

While the potential for biosimilars exists, both as a new market and a way to spur competition, the market-at-large continues to evolve. As such, development of the market may come slowly— for example, generics growth changed over time from 19% of drugs dispensed in 1984¹¹ to over 80% of all prescription filled in retail settings in 2016.¹²

⁸ Avalere Health. “Patient Out-of-Pocket Costs for Biosimilars in Medicare Part D”. Avalere Health, April 2016. Web. 19 May 2017. Available at: http://go.avalere.com/acton/attachment/12909/f-02c0/1/-/-/-/20160412_Patient%20OOP%20for%20Biosimilars%20in%20Part%20D.pdf.

⁹ Hirschler, Ben, and Michael Shields. "Novartis Launches First U.S. 'biosimilar' Drug at 15 Percent Discount." Reuters. Thomson Reuters, 03 Sept. 2015. Web. 02 May 2017. Available at: <http://www.reuters.com/article/us-novartis-drug-idUSKCNOR30C220150903>

¹⁰ "Pfizer Announces The U.S. Availability Of Biosimilar INFLECTRA® (infliximab-dyyb)." Pfizer News. Pfizer, 17 Oct. 2016. Web. 02 May 2017. Available at: http://www.pfizer.com/news/press-release/press-release-detail/pfizer_announces_the_u_s_availability_of_biosimilar_inflectra_infliximab_dyyb

¹¹ Dicken, J. E. "Drug Pricing: Research on Savings from Generic Drug Use". United States Government Accountability Office. 2012, Jan.

¹² Association for Accessible Medicines. “2016 Annual Report”. Web. 24 May 2017. Available at: <http://accessiblemeds.org/wp-content/uploads/2017/02/AAM-Annual-Report-2017.pdf>.



Lack of competition in the biologics market affects all manufacturers, payers, patients, and providers. Without sustainable competition, the healthcare system will continue to seek new ways to manage the costs of biologics. As the generics market has shown, competition can be increased while still encouraging investment in groundbreaking new therapies. Biosimilar competition could help spur the next generation of innovative biologics. A multi-source environment that leaves room for innovation and competition should be seen as a sign that the biotechnology market is maturing, much like the pharmaceutical market.

Methodology

Avalere used 2011-2015 Medicare Part B and Part D Drug Spending Data, available at CMS website (<https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/2015MedicareData.html>) for this analysis. The Drug Spending Data contains the summary information on the Part B drugs administered and billed directly by providers as well as on the Part D drugs available from Part D Prescription Drug Event (PDE) data. The top 20 Part B and Part D drugs were identified by the amount of total spending reported in the Drug Spending Data, which represents the sum of the Medicare payment and beneficiary liability. Analyses of Part B drugs are limited to all Part B fee-for-service Medicare beneficiaries, but exclude any beneficiaries in the Medicare Advantage program. For Part D drugs, spending is based on the gross drug cost, which represents the total spending for the prescription claim, including Medicare, plan, and beneficiary payments.

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