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Barriers and potential paths for biosimilars in the United States

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Expensive biologic drugs have driven increasing pharmacy costs and challenged payers to look for ways to control trends. Biosimilars are one option to contain increasing pharmacy costs; however, barriers to biosimilar market entry in the United States are substantial.

Generic drugs often have much lower prices than equivalent or similar brands, because after the brand patent expires, multiple generic manufacturers can compete to supply the market and thus keep production costs low. Payers and consumers may be hoping that after the patent term (can be up to 12 years) for an expensive biologic drug expires, competition will similarly push down price. However, in the U.S., there are many legal, regulatory, and financial obstacles to achieving dramatic cost reductions. Other parts of the world, however, are realizing cost savings from biosimilars.

With many expensive and innovative drugs in the pipeline and pressure from payers, legislators, and the Trump administration, strategies for lowering drug prices are becoming more prominent. Biosimilars can potentially reduce drug costs if barriers in the U.S. are removed or diminished.

Biosimilars are not generics

One industry source estimated $1.7 trillion in savings from generics replacing brands between 2004 and 2016, of which $253 billion was in 2016.[1] The generic to Lipitor, a blockbuster drug, entered the market in November 2011 and, after the 180-day period of exclusivity expired and multiple producers entered the market, now costs 95% less than the brand.[2] There are many pipeline generics coming to the market in 2018 that are expected to help manage costs. However, in the U.S., biosimilars are not generating the same level of cost savings.

Generic drugs are usually fairly simple, inexpensive, quick to produce and have the same active ingredients as the original brand drugs. On the other hand, biosimilars are much larger molecules and more complex than generics, which under current regulatory processes make the approval process more expensive and slower. Biosimilars can be highly similar to the originator (reference) drug, but they may not be exactly the same. This "not exactly the same" presumption has contributed to the slower uptake of biosimilars in the U.S. relative to the rapid acceptance of generic drugs. Additionally, due to the nature of how biologics are produced, there are slight variations between different batches of the same product, even those of reference products. For example, generic drugs are therapeutically equivalent, which means a pharmacist can substitute the prescribed drug for the generic alternative without physician approval (depending on the state). However, no biosimilars currently have been designated to be interchangeable; to date, some reasons the Food and Drug Administration (FDA) has not granted any biosimilar interchangeability status are due to "originator-style" and switching requirements for safety or efficacy data, discussed in more detail below.

U.S. biosimilar experience

Biosimilars have been in the global market since 2006; however, they have been slow to enter the U.S. market. As of July 2018, the U.S. has seen only four biosimilars launched under the regulatory approval pathway for biosimilars established in 2010, even though 12 biosimilars have been FDA approved since that pathway was created.[3] (Figure 1 below)

FIGURE 1: LAUNCHED U.S. BIOSIMILARS AS OF JULY 2018

BIOSIMILAR	REFERENCE DRUG	APPROVAL DATE	LAUNCH DATE
ZARXIO (FILGRASTIM-SNDZ)	NEUPOGEN	MARCH 2015	SEPTEMBER 2015
INFLECTRA (INFLIXIMAB-DYYB)	REMICADE	APRIL 2016	NOVEMBER 2016
RENFLEXIS (INFLIXIMAB-ABDA)	REMICADE	APRIL 2017	JULY 2017
FULPHILA (PEGFILGRASTIM-JMDB)	NEULASTA	JUNE 2018	JULY 2018

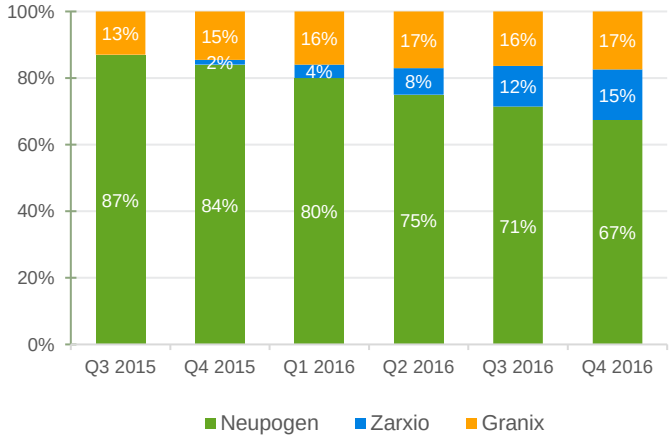
[1] Association for Accessible Medicines. 2017 annual report. www.accessiblemeds.org/resources/reports/2017-aam-annual-report. Updated 2017. Accessed August 2018.

[2] Rosenblatt, M. "The Real Cost of High-Priced Drugs." Harvard Business Review November 2014. https://hbr.org/2014/11/the-real-cost-of-high-priced-drugs. Accessed July 2018.

[3] Harston, A., Storaska, A. "How the U.S. Compares to Europe on Biosimilar Approvals and Products In the Pipeline." August 2, 2018. https://www.biosimilarsip.com/2018/08/02/how-the-u-s-compares-to-europe-on-biosimilar-approvals-and-products-in-the-pipeline-2/. Accessed October 2018.

Zarxio is a short-acting filgrastim that competes with Neupogen (launched in 1991) and Granix (launched in 2013). Figure 2 displays the market share of these three products from Q3 2015 through Q4 2016. By Q4 2016 Neupogen still had the majority of the short-acting filgrastim market share at 67%. One reason suggested for a slow uptake of Zarxio was that its wholesaler average cost (WAC) discount to Neupogen was 15%, but the market expected the discount to be 30%.[4] In addition, patients may have switched from Neupogen to Neulasta, a long-acting filgrastim, which has no competing biosimilar. However, Zarxio together with Granix has grown to about 40% of the filgrastim market through the end of 2017.[5]

FIGURE 2: SHORT-ACTING FILGRASTIM MARKET SHARE (IN UNITS)



An argument for the preservation of brand filgrastim could be that Zarxio was the only biosimilar to filgrastim with no other biosimilar competition along with the introduction of Neulasta. However, Remicade (infliximab) has competition from two launched biosimilars, Inflectra and Renflexis, and in 2018 Remicade continues to hold the majority of market share and preferred formulary position over the biosimilars among the largest insurers (such as Anthem and Humana).[6] Clearly, there are other issues.

Barriers to biosimilars in the U.S.

With about 50 approved biosimilars as of August 2018,[7] biosimilars have much greater market share in the European market than in the U.S. We list important U.S. barriers but we believe that eliminating any single barrier will not expand U.S. use to European levels.

Legal Actions, Patents, and Exclusivity: The Biologics Price Competition and Innovation Act of 2009 (BPCIA), created a 12-year exclusivity period from the date of the reference product approval, and manufacturers must wait at least four years to submit a biosimilar application. After the exclusivity period, patent protection litigations can further extend the market protection of reference products. One litigation example is AbbVie, manufacturer of Humira, who recently reached a settlement agreement that delayed the launch date of Amgen's biosimilar, Amjevita, until 2023 (though the FDA-approved Amjevita in September 2016). Humira has over 100 patents in the U.S., of which only eight were subject to litigation after following the procedures of the BPCIA, also known as the "patent-dance," where the parties agree upon which patents are subject to litigation.[8] Another example of a biosimilar launch delay due to litigation is between Amgen, manufacturer of biologic Enbrel (etanercept), and Sandoz, manufacturer of biosimilar Erelzi (etanercept-szzs). Erelzi was approved in August 2016 with a potential launch in 2028, coinciding with Enbrel's patent extension expiration date.[9] Almost all of the 12 FDA approved U.S. biosimilars went through, or are going through, patent litigations.

Interchangeability: The BPCIA modified the Public Health Service Act (PHS), creating an approval pathway for biosimilars under section 351(k). Similar to generic applications filed under Abbreviated New Drug Applications (ANDA), per the Hatch-Waxman Act of 1984, biosimilars approved under section 351(k) rely on safety and efficacy data from the reference product. Biosimilar manufacturers must provide additional data showing that switching between the reference product and the biosimilar will have no effect on safety or efficacy. A physician may prescribe an approved biosimilar at their own discretion, but the key distinction with interchangeability status is that pharmacists can substitute an interchangeable biosimilar even when the prescription is for the reference product.

The switching studies may be considered an unnecessary obstacle. A recent study from March 2018, comparing global data spanning over 20 years, shows that when patients switch from reference product to biosimilar, there were no meaningful differences in safety or efficacy. Additionally, due to the nature of

[4] Sarshad, M. "Major lessons learned from Zarxio's U.S. launch: the start of a biosimilar revolution." *Generics and Biosimilars Initiative Journal*. 2017, 6-4: pp. 165–173.

[5] Long, D. "Global Generic and Biosimilars Trends and Insights." February 2018. https://accessiblemeds.org/sites/default/files/2018-02/Doug%20Long.pdf. Accessed August 2018.

[6] Back Bay Whitepaper. "U.S. Biosimilars 2018: Opportunities and Challenges." January 2018. https://bblsa.com/documents/Back-Bay-US-Biosimilars-2018.pdf. Accessed July 2018.

[7] Pro Pharma Communications International. "Biosimilars approved in Europe." August 2018. http://www.gabionline.net/Biosimilars/General/Biosimilars-approved-in-Europe. Accessed October 2018.

[8] Royzman, I., Siegel, J. "U.S. Biosimilar Approvals Soar in 2017." December 2017. https://www.biologicsblog.com/new-biosimilar-litigation-reflects-benefits-of-complying-with-bpcia/. Accessed July 2018.

[9] Annis, A. "Expert Insights: Amgen vs. Sandoz Trial on Enbrel Biosimilar Delayed – How Long will Infliximab Biosimilars Dominate the U.S. Anti-TNF Market?" May 2018. https://clinicaltrialsarena.com/news/clinical-trials-arena/expert-insights-amgen-vs-sandoz-trial-on-enbrel-biosimilar-delayed-how-long-will-infliximab-biosimilars-dominate-the-us-anti-tnf-market-6154126-2/. Accessed November 2018.

how biologics are produced, there are slight variations between different batches of the same product including reference products. Consequently, there is potential to recognize an international reference comparator standard, leveraging shared data from multiple jurisdictions, against which future biosimilar studies could be compared.[10]

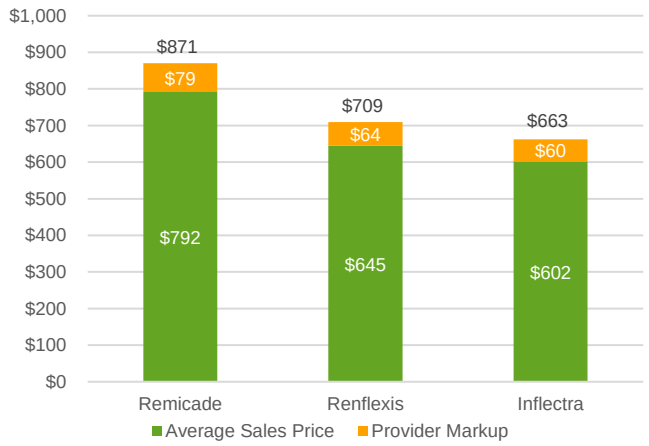
Rebates: Manufacturers negotiate their rebate agreements with Pharmacy Benefit Managers (PBMs) to ensure that their brand drug remains on the formulary or on a preferred formulary tier. Rebates for some high-cost biologics can reach or exceed 50% of WAC.[11] At any point, reference product sponsors or manufacturers can compete by increasing their rebates to encourage a payer to exclude biosimilars from the formulary. In Medicare Part D, the "rebate trap" means plans have a financial incentive to favor a higher-priced, higher-rebated reference product rather than a lower-priced, lower-rebated biosimilar. After a patient passes through the initial coverage phase in Part D, plan cost sharing decreases and federal cost sharing increases, which gives payers an incentive to encourage use of higher-priced drugs. The biologic reference drug can actually have a lower net price, so a Part D plan is financially incentivized to keep biosimilars off their formulary, as the biosimilars likely cannot offer competitive rebates.[12] Manufacturer rebates are not typically passed through to the beneficiary at the point of sale, so while rebates offset the payer costs to reduce the payer's net price, the list price, not the net price, is used to determine member cost sharing and shift members through benefit phases.

In addition, multi-year contractual rebate arrangements negotiated right before biosimilar launches can allow innovator manufacturers to retain market share.

Reimbursement: Many biologics are covered under the medical benefit and reimbursed using the "buy-and-bill" method. Under this reimbursement, drugs are administered in an outpatient facility or office by healthcare professionals who purchase the drug at a percent-of-charge or the Average Sales Price (ASP) and charge insurers the drug cost plus a markup. The markup is typically 6% to 10% on ASP for products administered in physician offices, but the markup varies by market segment (Medicare Part B, commercial, etc.).[13]

For commercial payers, drugs administered in an outpatient facility are typically reimbursed as a percent-of-charge, where payers reimburse a portion of the amount billed by providers. The percent-of-charge method usually yields a higher profit than the ASP markup, possibly over 100% of the drug cost.[14] In the commercial market, this reimbursement method disincentivizes providers from purchasing and administering biosimilars since they would lose potential profits with the lower-cost biosimilar. To avoid this disincentive in Medicare, Centers for Medicare and Medicaid Services (CMS) reimburses physicians at the biosimilar's ASP plus a markup of 6% of the reference ASP, such that the physician profit is the same whether the biosimilar or the reference product is prescribed. Figure 3 shows the provider's reimbursement amount for a typical commercial arrangement administered in a physician's office, ASP plus 10% markup, for Remicade and its two biosimilars currently on the market. The Remicade markup is about $15 to $20 more per dose than Renflexis and Inflectra.

FIGURE 3: AVERAGE SALES PRICE (AS OF Q3 2018[15]) PLUS 10% MARKUP PER DOSE FOR REMICADE, RENFLEXIS, AND INFLECTRA



Approval for Indications: Many biologics are approved for multiple indications; for example, Humira is indicated for 10 conditions of use. In the U.S., biosimilar manufacturers are required to provide their own safety and efficacy data for at least one indication. They can provide either comparative clinical data for each additional indication that they are seeking approval or scientific justification for extrapolation to other indications for which

[10] Webster, C.J., Woollett, G.R., "A 'Global Reference' Comparator for Biosimilar Development." BioDrugs. May 2017. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5541093/pdf/40259_2017_Article_227.pdf. Accessed August 2018.

[11] Hakims, A., Ross, J.S., "Obstacles to the Adoption of Biosimilars for Chronic Diseases." JAMA. June 2017. https://www.ncbi.nlm.nih.gov/pubmed/28459924. Accessed August 2018.

[12] MedPAC "Chapter 14: The Medicare Prescription Drug Program (Part D): Status Report." March 2018. http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch14_sec.pdf. Accessed August 2018.

[13] Santye, L. "Biosimilar Uptake Challenges: Low-Cost Specialty Drugs Reduce Provider Profits." July 2017. https://www.specialtypharmacytimes.com/news/biosimilar-uptake-challenges-low-cost-specialty-drugs-reduce-provider-profits. Accessed August 2018.

[14] Fein, A. "New Data: Outrageous Hospital Markups Hike Drug Spending. April 2016. https://www.drugchannels.net/2016/04/new-data-how-outrageous-hospital.html. Accessed September 2018.

[15] Serebrov, M. "Will price competition follow in the wake of incoming U.S. biosimilar wave?" Clarivate Analytics. http://www.bioworld.com/content/will-price-competition-follow-wake-incoming-us-biosimilar-wave-0. Accessed August 2018.

the reference product is already approved.[16] Biosimilars approved in the U.S. have obtained indication extrapolation. The lack of automatic extrapolation is one barrier, but separate exclusivity periods for each new indication of the originator is another barrier.

Possible paths for biosimilars

Despite the obstacles that biosimilars face in the marketplace, the FDA is modifying their policies to help remove some of the hurdles under its jurisdiction. For example, the FDA is considering allowing clinical safety and efficacy data from the EU, Japan, and Canada to be included as support in a biosimilar's Biologics License Application (BLA).[17]

BIOSIMILARS ACTION PLAN[18]

The FDA released the Biosimilars Action Plan (BAP) in July 2018, which outlined important elements to balancing innovation and competition of biosimilars in the U.S. Notable actions include the following four key strategies:

- Enhancing efficiencies around developing and approving biosimilars and interchangeable biologics, which includes developing application review templates, improving coordination with the Center for Drug Evaluation and Research (CDER), and providing tools and resources for interchangeable and high-quality biosimilars.
- Increasing clarity and support around biosimilar product development including expanding the Purple Book to include more detail about exclusivity and interchangeability. The Orange Book, the FDA's list of small-molecule drugs and their generic equivalents, is analogous to the Purple Book and is commonly referenced by providers when deciding on treatment.[19] Some have argued that this improvement to the Purple Book could increase providers' confidence in the substitutability of biosimilars. Also introduced in the BAP is the Biosimilar Product Development (BPD) program, in which the FDA provides manufacturers product-specific advice to speed up and promote biosimilar development.
- Educating healthcare professionals, patients and insurers about biosimilars and interchangeable biologics. Some recent examples of biosimilar and interchangeability education by the FDA include:
  - October 2017: Biosimilar Education and Outreach Campaign
  - December 2017: Webinar on the "Overview of the Regulatory Framework and the Development and Approval of Biosimilar Products in the U.S."
  - April 2018: Reddit AMA (Ask Me Anything) Forum
  - Updates to FDA biosimilars website
- Promoting market competition by reducing attempts at delaying approval of competitor biosimilars. The FDA will take action and work with the Federal Trade Commission and legislators, when deemed necessary, to address actions that prevent competition. In addition, the principles outlined in the Drug Competition Action Plan (DCAP), for generic drugs, will be used for biosimilar anticompetitive situations.

The BAP addresses some of the barriers to biosimilars evident in the U.S. market, but not all as the most meaningful solutions are largely beyond the authority of the FDA. In 2016, CMS announced that they would pay Part B reimbursement for biosimilars based on the ASP of the group of biosimilars for each reference product, which would decrease competition within each drug. But, in a new rule, effective January 2018, CMS decided to assign each biosimilar for the same reference product a unique HCPCS code that will be reimbursed by Medicare independently of its competition.[20] Now that biosimilars will be reimbursed at their own individual ASP, plus a markup of 6% of the reference ASP, this will incentivize more competition in the biosimilar marketplace. In addition, a proposal to shift Part B drugs to Part D, where competition is more pronounced, could further assist with increasing price competition for biosimilars.

REIMBURSEMENT ALTERNATIVES

Two other commercial reimbursement strategies that could incentivize providers to prescribe biosimilars are:

- "Fixed" reimbursement, where, regardless of which version (reference product or biosimilar) was administered, providers would be reimbursed the same dollar amount. For example, in Figure 3 above, the provider who uses any of Remicade, Inflectra, or Renflexis would receive the same "fixed" dollar amount. This would incentivize the provider to prescribe the lowest priced product.

[16] "Scientific Considerations in Demonstrating Biosimilarity to a Reference Product: Guidance for Industry." *FDA.gov*. April 2015. https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM291128.pdf. Accessed August 2018.

[17] Gottlieb, S. "Release of FDA's Biosimilar Action Plan." Brookings Institution. July 2018. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613881.htm. Accessed August 2018.

[18] U.S. Food and Drug Administration. "Biosimilars Action Plan: Balancing Innovation and Competition." July 2018. https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm613761.pdf. Accessed July 2018.

[19] "*Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book)*." *FDA.gov*. https://www.fda.gov/drugs/informationondrugs/ucm129662.htm. Accessed August 2018.

[20] Syrop, J., "CMS Reverses Its Policy on Biosimilar Reimbursement, Will Issue Unique J-Codes." The Center for Biosimilars. November 2017. https://www.centerforbiosimilars.com/news/cms-reverses-its-policy-on-biosimilars-reimbursement-will-issue-unique-jcodes. Accessed August 2018.

- "Differential" reimbursement would allow a larger markup on biosimilars so providers would not lose profits on prescribing lower cost biosimilars. For example, in the case of infliximab drugs, if providers were reimbursed a markup of 14% for either Renflexis or Inflectra, the biosimilars markup would be greater than that for Remicade at a 10% markup. Using the ASP from Figure 3, Remicade would continue to have a $79 markup (or 10% markup) while Renflexis and Inflectra would have a $90 and $84 markup, respectively (or 14% of each biosimilars ASP).[21] Under this "differential" reimbursement, commercial payers would pay more in markup for the biosimilars; however, given their much lower ASP, it would be less expensive to pay for biosimilars with a higher markup than the biologic with a lower markup. For example, Remicade, Renflexis, and Inflectra would be reimbursed at $871, $735, and $686, respectively, with a 10% markup for Remicade and 14% markup for the biosimilars (Renflexis and Inflectra). "Differential" reimbursement would result in higher biosimilar reimbursement for commercial payers but overall savings if providers were financially incentivized to prescribe biosimilars over reference products.

Recent Medicare reimbursement proposals and changes could influence biosimilars' utilization and competition:

- **International Pricing Index (IPI) model**:[22,23] The Trump administration recently proposed to shift Part B reimbursement to the International Pricing Index (IPI) model over a five-year time period, with the following notable changes:
  - Reduce drug prices to align with international drug price levels from 180% of what other countries pay to 126% over the five years. Lower prices mean lower member cost sharing as coinsurance would be applied to a lower cost.
  - Pay providers a flat payment unrelated to the cost of the drug, eliminating the incentive to prescribe higher-cost drugs under the current ASP plus 6% policy.
  - Introduce an intermediary vendor between the provider and CMS who would be responsible for obtaining drugs, distributing them to providers, and billing Medicare.
- **Part B step therapy**: Beginning January 1, 2019, CMS will allow Medicare Advantage plans to use step therapy for Part B drugs.[24] Step therapy is a type of prior authorization that can require patients to use a preferred (typically lower-cost) drug and progress to other drugs only if necessary. This change could result in plans preferring biosimilars. This step therapy exists in the commercial market where 27% of drugs with a biosimilar available required members to use a biosimilar over its reference drug in 2017.[25]
- **Indication-based formularies**:[26] In August 2018, CMS announced the allowance of Part D indicated-based formularies beginning in calendar year 2020, where plan sponsors can only provide coverage for specific indications for a certain drug. This change will encourage Part D sponsors to use biosimilars for certain indications that will lose patent protection or market exclusivity over using biologics only for all indications. In addition, this change will promote plan negotiations with manufactures for high-cost drugs and can provide reduced patient and government costs.
- **Coverage gap discount program (CGDP)**: Under the CGDP, the pharmaceutical manufacturer is liable for applicable drugs while Part D beneficiaries are in the coverage gap benefit phase. Per the Bipartisan Budget Act of 2018, the CGDP manufacturers' discount increased from 50% to 70% and removed the exclusion of certain biosimilars from the CGDP.[27] The inclusion of certain biosimilars in the CGDP will encourage Part D sponsors to consider biosimilars. However, lower-priced biosimilars may not be able to pay rebates as high as the originator, so the rebate trap may still be a deterrent despite this change.

Another potential avenue to increase biosimilar use would be to consider how rebates and bona-fide fees for Part B could be regulated for biosimilars or originator drugs.

[21] Santye, L. (n 13).

[22] Azar, A. "Remarks at Brookings on Drug Pricing," HHS. October 26, 2018. https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-at-brookings-on-drug-pricing.html. Accessed October 2018.

[23] HHS Press Office. "HHS Advances Payment Model to Lower Drug Costs for Patients," HHS. October 25, 2018. https://www.hhs.gov/about/news/2018/10/25/hhs-advances-payment-model-to-lower-drug-costs-for-patients.html. Accessed October 2018.

[24] Department of Health and Human Services. "Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage." August 7, 2018. https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf. Accessed October 2018.

[25] Macher, D., Sullivan, M., DiAngelo, L. "CS Grants Medicare Advantage Plans Flexibility to Use Step Therapy for Part B Drugs." August 15, 2018. http://avalere.com/expertise/life-sciences/insights/cms-grants-medicare-advantage-plans-flexibility-to-use-step-therapy-for-par. Accessed October 2018.

[26] Centers for Medicare & Medicaid Services. "Indication-Based Formulary Design Beginning in Contract Year (CY) 2020." August 29, 2018. https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/Downloads/HPMS-Memos/Weekly/SysHPMS-Memo-2018-Aug-29th.pdf. Accessed November 2018.

[27] Bipartisan Budget Act of 2018. February 9, 2018. https://www.congress.gov/115/plaws/publ123/PLAW-115publ123.pdf. Accessed July 2018.

Conclusion

Biosimilars have the potential to provide substantial savings in the U.S. market; however, barriers to biosimilars entry are substantial and we are already seeing manufacturers trim their pipelines even before their biosimilars are approved.

While the possible savings will vary by drug and more so by therapeutic class, biosimilars could reduce biologic drug spending in the U.S. by up to $54 billion by 2026, according to a study by the RAND Corporation using recent data.[28] In 2009, the Congressional Budget Office (CBO) forecast 2018 savings to be $1 billion; however, Avalere's 2018 estimated savings for the three launched biosimilars as of May 2018 is estimated to be $91 million—only 9% of CBO's forecast.[29] This gap is largely due to the barriers discussed above.

For biosimilars to achieve significant savings, the many barriers, which exist in separate legal, clinical, financial, and regulatory areas, will need to be reduced or eliminated.

[28] Mulcahy, A.W., Hlavka, J.P., and Case, S.R. "Biosimilar Cost Savings in the United States: Initial Experience and Future Potential." Santa Monica, CA: RAND Corporation, 2017. https://www.rand.org/pubs/perspectives/PE264.html. Accessed August 2018.

[29] Avalere Health "Use of Step Through Policies for Competitive Biologics Among Commercial U.S. Insurers" May 2018. http://avalere.com/expertise/life-sciences/insights/use-of-step-through-policies-for-competitive-biologics-among-commercial-us. Accessed June 2018.

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