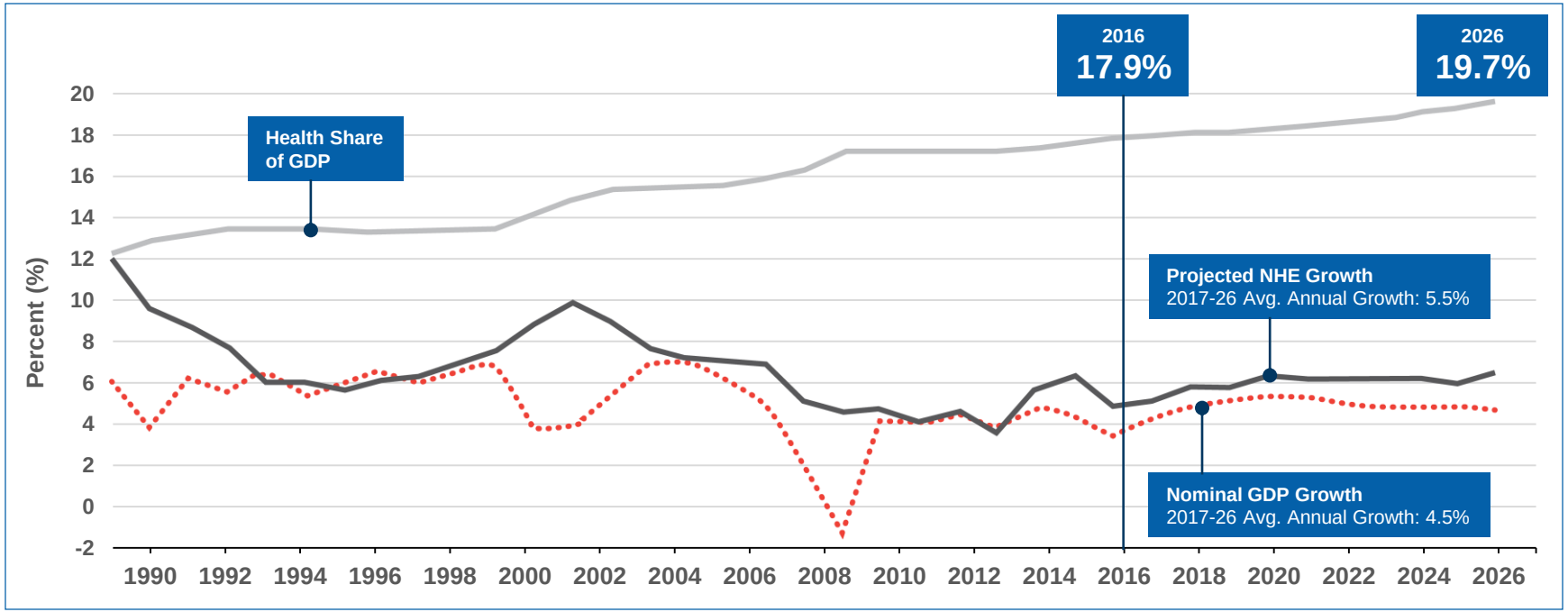
Biosimilars Shenanigans – Can They Be Stopped?

Carol Lynch
President Sandoz US, Head of North America

February 5, 2019

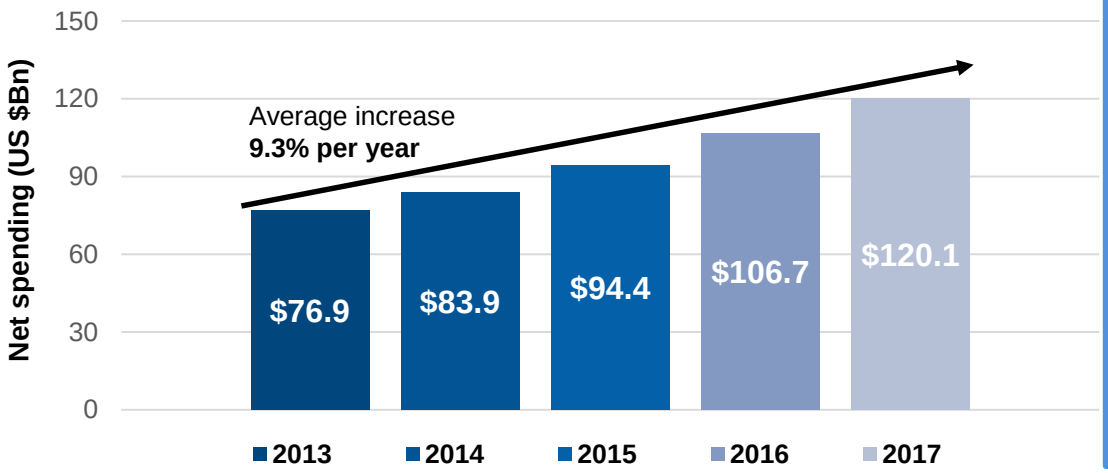
Today's healthcare system is unsustainable

US national health spending is expected to grow **5.5 percent** per year from 2017 to 2026, reaching $5.7 trillion in total spending



Biologics are expensive and contribute to the increasing cost of healthcare

Biologic spending in the US grew by more than 56% from 2013-2017[1]

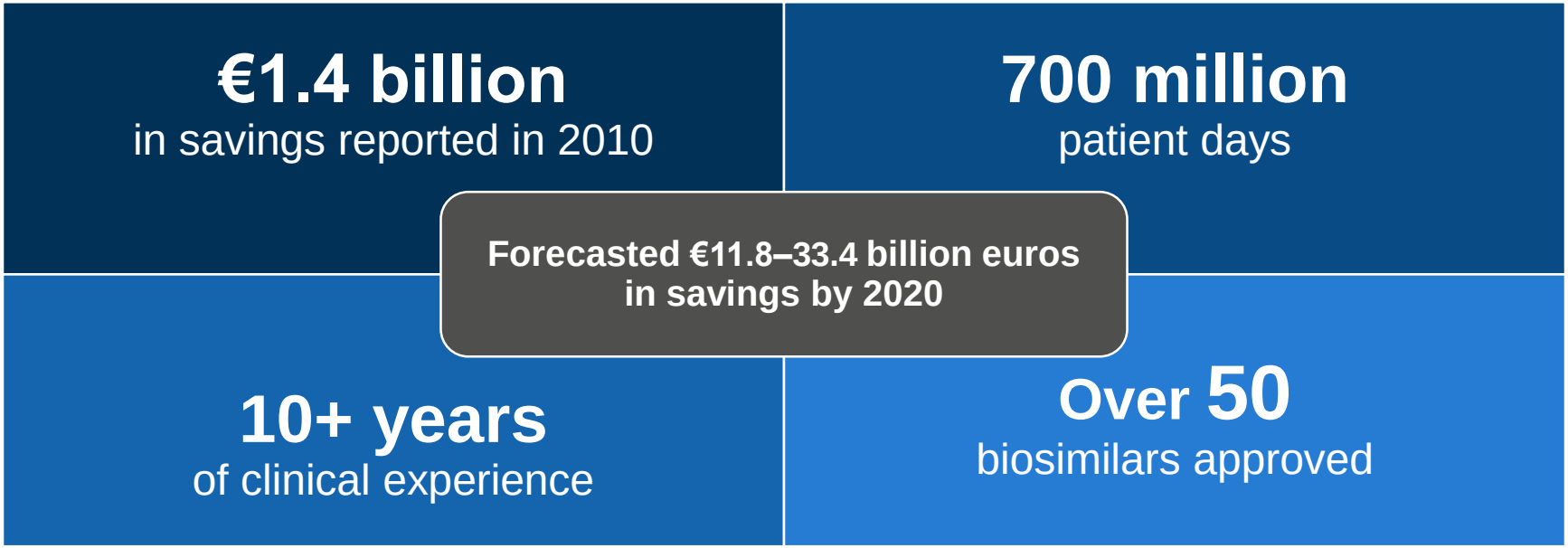


If all approved biosimilars had been marketed in a timely manner, Americans could have saved $4.5 billion[1,2]

References: 1. IQVIA Medicine Use and Spending in the US 2017. page 11/chart 8, Column 1, Bullet 1. **2.** U.S. Food and Drug Administration. Remarks from FDA Commissioner Scott Gottlieb, M.D., as prepared for delivery at the Brookings Institution on the release of the FDA's Biosimilar Action Plan [press release]. July 18, 2018

Biosimilars are part of the solution

Biosimilars have made an impact in Europe



References: 1. European Generic Medicines Association: Vision 2015. The EGA's thoughts on how to improve the legal and regulatory framework for generic and biosimilar medicines, 2010. Available at: http://www.egagenerics.com/images/publication/PDF/EGA_Vision_2015.pdf. Accessed February 10, 2018. **2.** Biosimilar medicines today. Medicines for Europe website. medicinesforeurope.com/ biosimilar-medicines/. Accessed August 23, 2018. **3.** FDA approves first biosimilar Zarxio (filgrastim-sndz) from Sandoz [news release]. Holzkirchen, Germany: Sandoz; March 6, 2015. sandoz.com/news/media-releases/fda-approves- first-biosimilar-zarxiotm-filgrastim-sndz-sandoz. Accessed August 23, 2015. **4.** European Medicines Agency, European Commission. Biosimilars in the EU: information guide for healthcare professionals. ema.europa.eu/docs/en_GB/document_library/Leaflet/ 2017/05/WC500226648.pdf. Updated April 27, 2017. Accessed September 1, 2017.

Substantial opportunity for biosimilars to create savings in the US

Approximately

$100 billion worth of biologics expected to be off-patent by 2020[1]

An estimated

1.2 million US patients could gain access to biologics by 2025

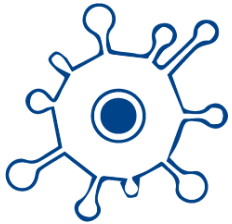
References: 1. GBI Research. $100 billion of revenues up for grabs for drug manufacturers by 2020 as patents for key biologics expire [press release). March 13, 2017. https://drug-dev.com/100-billion-of-revenues-up-for-grabs-for-drug-manufacturers-by-2020-as -patents-for-key-biologics-expire/. Accessed December 14, 2018. **2.** The Biosimilars Council. Biosimilars in the United States: providing more patients greater access to lifesaving medicine. http://biosimilarscouncil.org/wp-content/uploads/2017/09/Biosimilars-Council-Patient-Access-Study-090917.pdf. Accessed December 14,2018.

Switching to a biosimilar is proven safe & efficacious

Systematic literature review confirms safety of switching[1]

90
Studies[1]

7
Biosimilars[1]

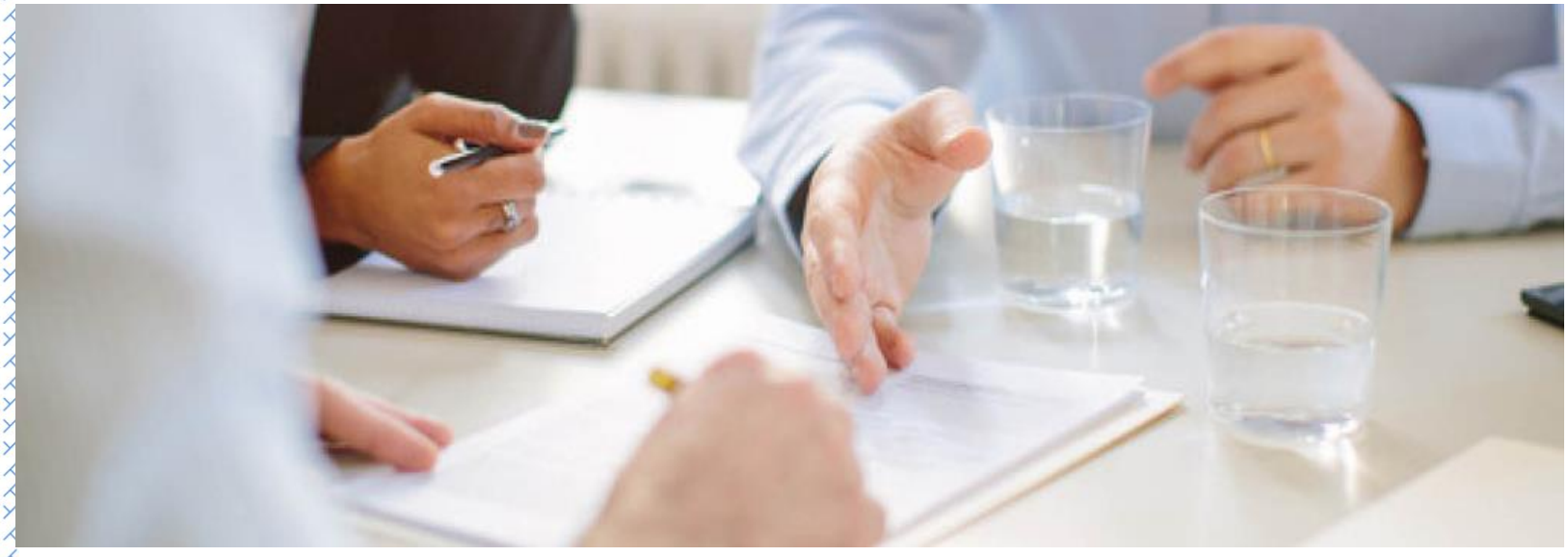


14
Diseases[1]

14,255
Subjects[1]

No new safety and efficacy concerns detected in over 10 years and >700 million days of patient experience with biosimilars[2]

References: 1. Cohen HP, et al. *Drugs*. 2018;78:463-478. **2.** Comment from Biosimilars Medicines Group, A Medicines for Europe sector group. Presented at: Oncologic Drugs Advisory Committee Meeting; July 13, 2017. Docket FDA-2017-N-2732. https://www.regulations.gov/document?D=FDA-2017-N-2732-0006. Accessed November 21, 2017.



Biosimilars: Real barriers impact uptake!

Barriers to success in the US market

Clinical Barrier

- What are biosimilars?
- Is the manufacturer as good as the innovator?
- Is the biosimilar drug as effective and safe as the reference medicine?
- Can I switch existing patients?
- Can I use the drug for all indications?
- What real world evidence can I use?
- Can I trust the quality of a biosimilar

Ease-of-Use Barrier

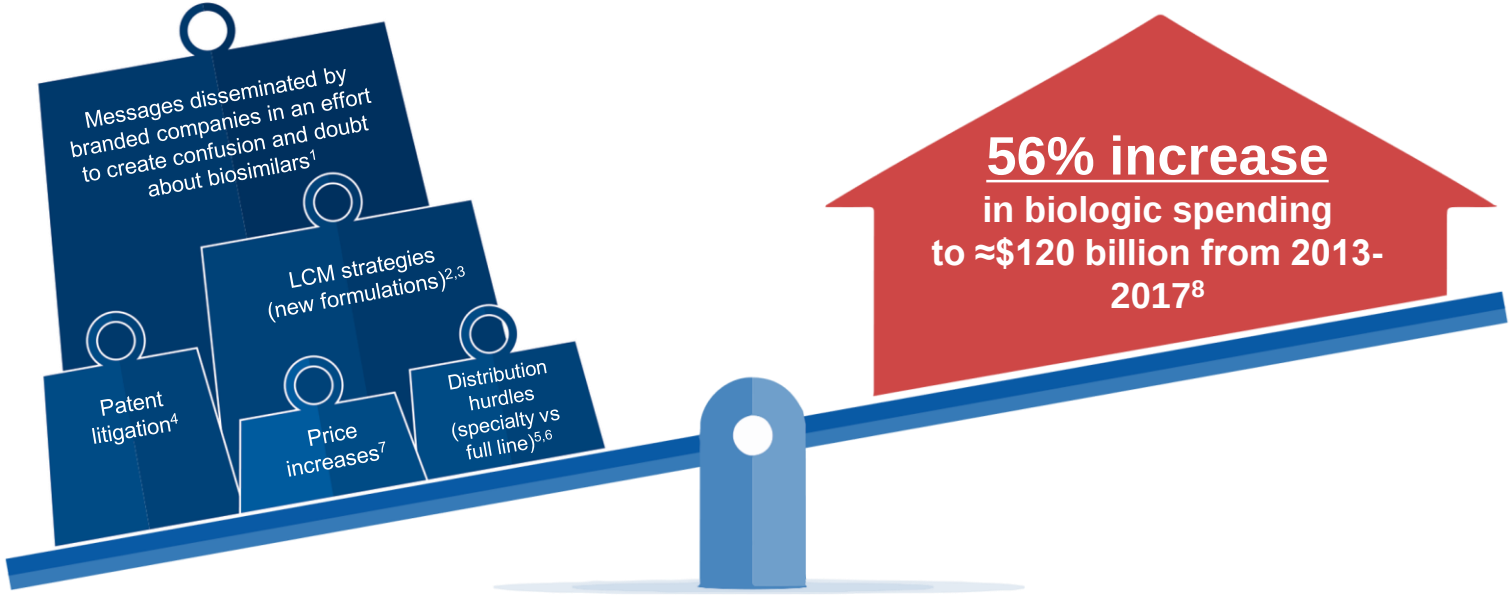
- Is the biosimilar cost-effective?
- How much of this cost will I recover?
- How will that change over time?
- Can I easily integrate my patients' information into electronic medical records?

Economic Barrier

- Does this have the same support services as the brand?
- Will payers cover it?
- Is this a better deal for my patient?
- Will using this create more hassle for my clinic and my patients?

Reference: http://www.onclive.com A Perfect Storm Brews for Biosimilar Marketing

Reference BIOLOGIC Business Strategies May Contribute to Rising Costs OF TREATMENT[1-7]



LCM=life cycle management.

References: 1. Rowland C. 'Marketers are having a field day': patients stuck in corporate fight against generic drugs. *Washington Post*. January 9, 2019. https://www.washingtonpost.com/business/economy/drugmakers-alleged-scare-tactics-may-hold-back-competition/2019/01/09/612ac994-046d-11e9-9122-82e98f91ee6f_story.html?noredirect=on&utm_term=.7462b1e40887. Accessed January 22, 2019. **2.** New rituximab formulation approved for some lymphomas, leukemia. National Cancer Institute website. https://www.cancer.gov/news-events/cancer-currents-blog/2017/fda-rituxan-hycela. Published July 14, 2017. Accessed October 5, 2018. **3.** FDA approves Roche's Gazyva for previously untreated advanced follicular lymphoma [press release]. Basel, Switzerland: Roche; November 17, 2017. https://www.roche.com/media/releases/med-cor-2017-11-17.htm. Accessed October 5, 2018. **4.** Mehr SR. Pharmaceutical patent litigation and the emerging biosimilars: a conversation with Kevin M. Nelson, JD. *Am Health Drug Benefits*. 2017;10(1):23-26. **5.** Genentech's controversial distribution move deemed a failure. P&T Community website. https://www.ptcommunity.com/news/20150304/genentech-s-controversial-distribution-move-deemed-failure. Published March 4, 2015. Accessed October 5, 2018. **6.** Furlow B. US hospitals object to changes in Genentech drug distribution. *Lancet Oncol*. 2014;15(13):e591. doi:10.1016/S1470-2045(14)71040-X. **7.** IQVIA Institute for Human Data Science. Global oncology trends 2017: advances, complexity, and cost. https://www.iqvia.com/institute/reports/global-oncology-trends-2017-advances-complexity-and-cost. Accessed October 23, 2018. **8.** IQVIA Institute for Human Data Science. Medicine use and spending in the U.S.: a review of 2017 and outlook to 2022. https://www.iqvia.com/institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022. Accessed October 23, 2018.

Antitrust lawsuit impact

"Pfizer's Complaint sufficiently alleges that it has suffered an antitrust injury as the result of J&J's anticompetitive conduct. J&J's efforts to foreclose Pfizer from the market, as Pfizer has alleged, have led to increased prices for consumers and limited competitive options for end payors, providers, and patients."
- Court for Eastern District of Pennsylvania

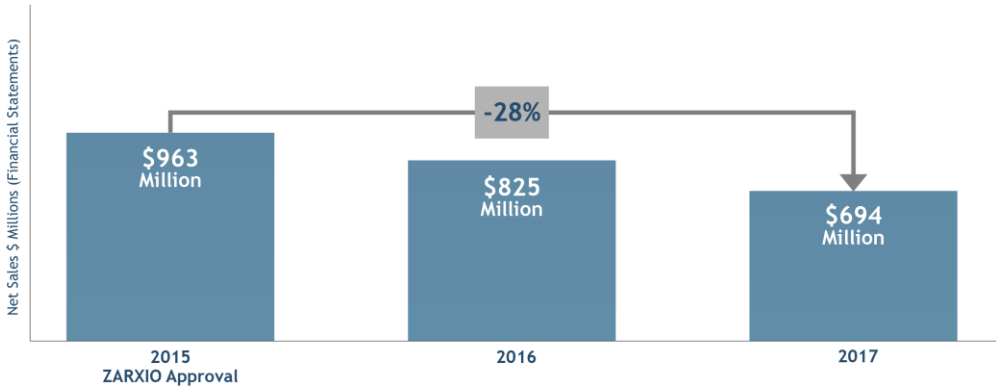
Reference: Centerforbiosimilars.com; https://www.mmm-online.com/home/channel/commercial/pfizer-lawsuit-could-clear-path-for-biosimilars/

Biosimilars: Favorable shift in momentum!

One biosimilar, Zarxio®, has already proven cost savings in the US

Filgrastim spending has declined since ZARXIO launched in 2015[1]

Estimated net sales ($M) for filgrastim products in the US from 2015-2017[1]



Switching to ZARXIO from Neupogen® may expand the use of ZARXIO and novel immunotherapies in a budget-neutral manner[2*†]

Neupogen is a registered trademark of Amgen Inc.
Zarxio is a registered trademark of Novartis AG

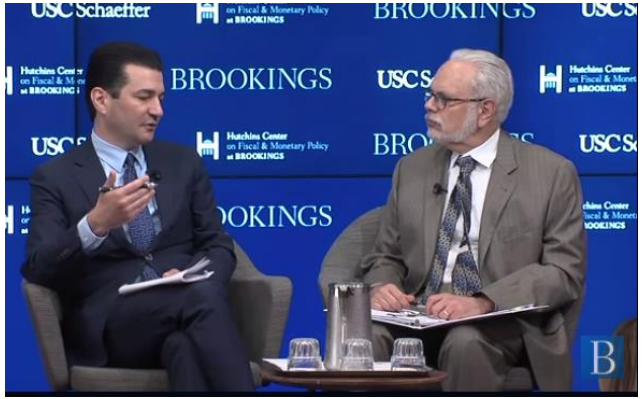
*In a simulation model, 20,000 patients were switched from Neupogen® to ZARXIO.
†Novel immunotherapies include obunutuzomab and pembroluzimab (calculated at a 5-day cycle).

References: 1. Data on file. Filgrastim Net Sales Analysis Model. Sandoz Inc. 2018. **2.** McBride A, et al. Expanded access to cancer treatments from conversion to neutropenia prophylaxis with biosimilar filgrastim-sndz. Future Oncol. 2017;13(30):2285–2295.

Healthcare organizations recognizing importance and savings potential of biosimilars

References: 1. American Society of Rheumatology. American College of Rheumatology Recommends Biosimilar Use in New White Paper. Available at: https://www.rheumatology.org/About-Us/Newsroom/Press-Releases/ID/875. Accessed January 28, 2019. **2.** Arthritis Foundation. Biosimilars. https://www.arthritis.org/advocate/our-legislative-position-statements/biosimilars.php. Available at: https://www.arthritis.org/advocate/our-legislative-position-statements/biosimilars.php. Accessed January 28, 2019. **3.** National Psoriasis Foundation. Biosimilar Substitution. Available at: https://www.psoriasis.org/about-psoriasis/treatments/statement-on-biosimilars. Accessed January 28, 2019. **4.** Leukemia and Lymphoma Society. Biosimilars. http://www.lls.org/treatment/types-of-treatment/chemotherapy-and-other-drug-therapies/types-of-drug-therapies/biosimilars. Accessed July 1, 2018. **5.** Cancer Care. Biosimilars and their role in cancer treatment. https://www.cancercare.org/publications/353-biosimilars_and_their_role_in_cancer_treatment. Accessed July 17, 2018. **6.** Association for Accessible Medicine's Biosimilars Council Releases Roadmap for Biosimilars Market Development in US. https://biosimilarscouncil.org/association-for-accessible-medicines-biosimilars-council-releases-roadmap-for-biosimilars-market-development-in-u-s/. Accessed August 14, 2018. **7.** American Academy of Dermatology. Dermatology World. Available at: https://www.aad.org/dw/monthly/2016/november/will-the-biosimilars-pathway-lead-to-savings. Accessed January 28, 2019. **8.** American Cancer Society Cancer Action Network. Increasing Access to Treatment Options Through Biosimilar Legislation. https://www.acscan.org/cancer-candor/increasing-access-treatment-options-through-biosimilar-legislation. Accessed July 2018. **9.** America's Health Insurance Plans (AHIP). 6 policy changes to reduce drug costs through a robust biosimilars market. https://www.ahip.org/6-policy-changes-to-reduce-drug-costs-through-a-robust-biosimilars-market/. Accessed July 1, 2018. **10.** McCaslin TL, Campbell JA. Biosimilars: a checklist. Is your organization prepared to achieve savings through biosimilar utilization? The National Business Group on Health. Washington, DC: The National Business Group on Health; 2017.

FDA outspoken in support of biosimilars



FDA's Scott Gottlieb speaking about biosimilars at an event hosted by USC-Brookings Schaeffer Initiative for Health Policy and the Hutchins Center on Fiscal and Monetary Policy July 2018.

POLITICS

FDA's Gottlieb slams drug makers for stalling release of biosimilars

By ERIN MERSHON @eemershon / JULY 18, 2018

In JPM interview, Gottlieb outlines FDA efforts to promote biopharma competition

The agency plans to release several guidances on complex generics and biosimilars, along with taking a deep dive into the Orange Book patent and exclusivity database.

Scott Gottlieb, M.D. @SGottliebFDA · Jul 8

The BPCI Act provides a pathway for increased biologics competition to emerge, similar to the pathway created under Hatch Waxman for generic drugs, which has saved the US health care system more than $1.67 trillion in the last decade bit.ly/2ua5ugE @AccessibleMeds

Scott Gottlieb, M.D. Retweeted

Scott Gottlieb, M.D. @SGottliebFDA · Jan 10

#FDA continues to be concerned about branded companies creating confusion about the safety and effectiveness of biosimilars and we'll take action if we determine a company is deliberately misleading the public about the safety of these important products.

"I am worried that there are either deliberate or unintentional efforts by branded companies to create confusion" about the safety and effectiveness of unbranded biologic drugs, FDA Commissioner Scott Gottlieb said in an interview with The Washington Post. The messages "can potentially undermine consumer confidence in biosimilars in ways that are untrue."

Recent efforts have had impact

Reimbursement

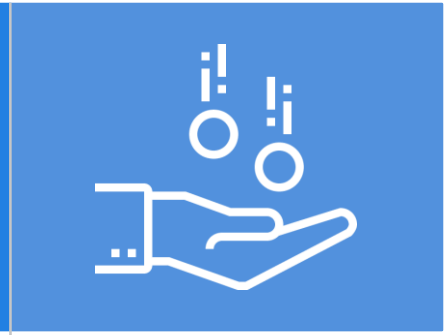
- Improvements to Medicare parts B & D
- Possible future changes to help shift part B biologic products to part D

Regulatory

- Improve use of non-U.S.-licensed comparator
- Initiate an exercise to identify product quality attributes
- Strengthen partnership and data sharing with EU/CDN/JPN authorities

Intellectual Property

- FDA committed action to clarify position on anti-competitiveness with coordination from FTC
- Chairman of senate judiciary committee urging FTC to act against anti-competitive tactics from large biologic players



Payers

- Some rebates now being partially passed by some insurers to patients
- US administration draft white paper on pharma pricing

Greater healthcare access is possible in the US…

Future

- All stakeholders must work together to make biosimilars more accessible
- Collectively we can **ALL** make a difference

Present

- Demonstrated success in Europe and the US
- Sandoz is continuing to deliver on the promise of biosimilars

Past

- An unsustainable healthcare system

...and we can all agree that it's worth it!

Thank you.