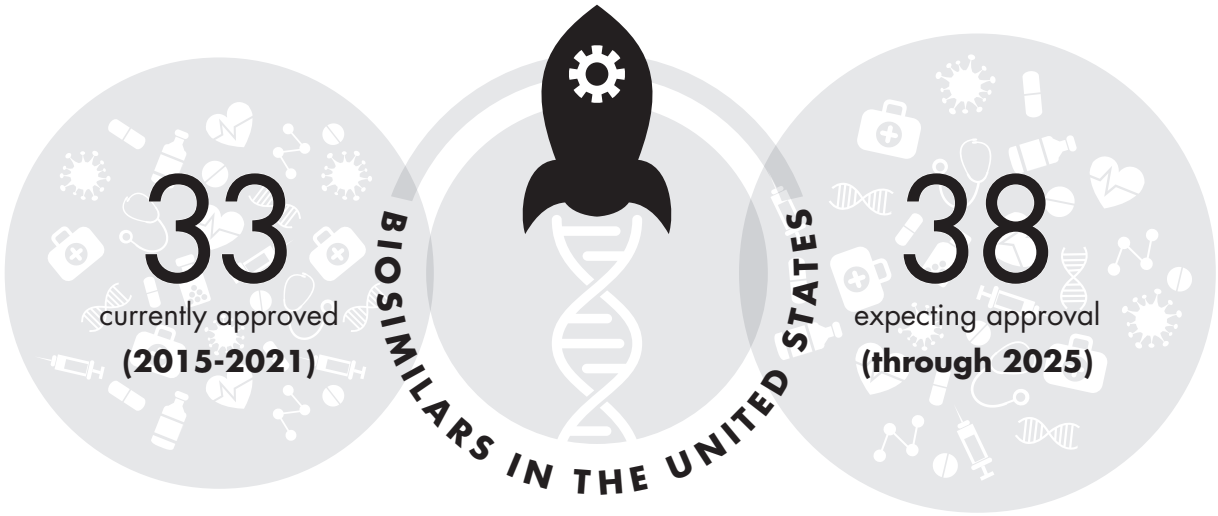
BIOSIMILARS IN THE US:
CURRENT PERSPECTIVES AND IMPLICATIONS

WHAT LEVEL OF BIOSIMILAR GROWTH IS EXPECTED?

The entry of biosimilars in the marketplace has been highly anticipated based on the promise to promote competition and alleviate financial pressures in the health system. Manufacturers continue to see opportunities for growth as demonstrated by their commitment to bring new biosimilars to market.[1,2]

Looking ahead, biosimilar growth will continue, particularly in 2023. A significant market disruption is expected in the immunology category in 2023 when up to 10 adalimumab, 5 ustekinumab, and 1 tocilizumab biosimilar products are anticipated to launch.[3]



HOW ARE POLICY EFFORTS DRIVING BIOSIMILAR INVESTMENT?

US policymakers view biosimilars as a tool to help reduce drug spending and have passed legislation to further promote biosimilar uptake. Policy efforts to promote biosimilar utilization have largely been successful as physicians have become increasingly comfortable prescribing biosimilars, paving the way for new biosimilar market entrants.

The Biologics Price, Competition, and Innovation Act (BPCIA)
created pathways for biosimilar development and to promote competition[4]

The Advancing Education on Biosimilars Act of 2021
provided additional clarification on biosimilars to reduce market confusion, including providing guidance on interchangeability designation and regulatory considerations[5]

McCANN HEALTH MANAGED MARKETS | POINTS *of* VIEW

HOW DO PROVIDERS UTILIZE AND PERCEIVE BIOSIMILARS?

Market share data reflect providers' **increased willingness to prescribe biosimilar therapies**, as biosimilars continue to gain share vs the originator product. In at least one case, the biosimilar has displaced the originator (ie, Neupogen®).[3]

Although initially skeptical, providers' familiarity and experience with biosimilars have increased their prescribing comfort, according to a recent Cardinal Health provider survey.[3]

85% of surveyed **oncologists are comfortable** prescribing biosimilars

90% of surveyed **rheumatologists are comfortable** prescribing biosimilars

HOW ARE PAYERS LEVERAGING BIOSIMILARS OPTIONS?

Population health decision makers (PHDM) are taking different approaches to leverage the potential cost benefits of increased biosimilar utilization.

PDHM tools include biosimilar-first formulary offerings, originator exclusions, and mandated conversion from originator to preferred biosimilar product.

Biosimilar-first formulary offerings

CVS Caremark is offering a biosimilar-first Part D formulary[6] | Mayo Clinic has biosimilar-first policies[7] | Providence St Joseph Health has biosimilar-first policies[8]

2022 PBM originator exclusions[9]

Express Scripts–Remicade® | CVS Caremark–Lantus®

Mandated conversion from originator to preferred biosimilar product

Payer-mandated switching | Patient incentives (ie, gift cards)

WHAT OPTIONS ARE AVAILABLE FOR PHARMACEUTICAL MANUFACTURERS FACING BIOSIMILAR COMPETITION?

As controlling rising health care costs continues to be a public priority, the demand for biosimilar utilization will continue to grow. Despite this demand, **originator manufacturers can take steps to protect market share** as the number of biosimilar entrants in the marketplace increases.

- **Enhance brand value story** by leveraging real-world evidence (RWE) data to reinforce proven efficacy and outcomes
- **Identify hard-to-treat or underserved sub-populations** where brand has a compelling clinical story
- **Deliver best-in-class patient assistance programs** as an experience differentiator
- **Explore opportunities** that communicate the clinical and economic implications related to switching stable patients to therapeutic alternatives

McCANN HEALTH MANAGED MARKETS
AN IPG HEALTH COMPANY

Turn to McCann Health Managed Markets to help you navigate the evolving biosimilar market.

McCANNMANAGEDMARKETS.COM

References: 1. How many biosimilars have been approved in the United States? (drugs.com) **2.** https://www.cardinalhealth.com/content/dam/corp/web/documents/Report/cardinal-health-biosimilar-launches.pdf **3.** https://www.cardinalhealth.com/en/product-solutions/pharmaceutical-products/biosimilars/biosimilars-report.html **4.** Biologics Price Competition and Innovation Act of 2009, 42 U.S.C section 262 (k). https://www.govinfo.gov/content/pkg/USCODE-2020-title42/pdf/USCODE-2020-title42-chap6A-subchapII-partF-subpart1-sec262.pdf **5.** https://www.bioprocessonline.com/doc/new-us-legislation-creates-momentum-for-biosimilars-0001 **6.** https://globalhealth.com/media/ihpfscmw/2022-biosimilars-first-medical-preferred-drug-list-medicare-part-b.pdf **7.** https://www.drugtopics.com/view/-biosimilar-first-policy-at-mayo-clinic-nets-big-cost-savings **8.** https://www.futuremedicine.com/doi/10.2217/fon-2021-1584 **9.** https://www.drugchannels.net/2022/01/five-takeaways-from-big-three-pbms-2022.html