Biosimilar Overview

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Neither I nor Walgreens have received any financial support or commitment from the NH Prescription Drug Affordability Board.

Basics about biosimilars

Biosimilars are biologics that are "highly similar" to the previously approved biologic (aka reference product).

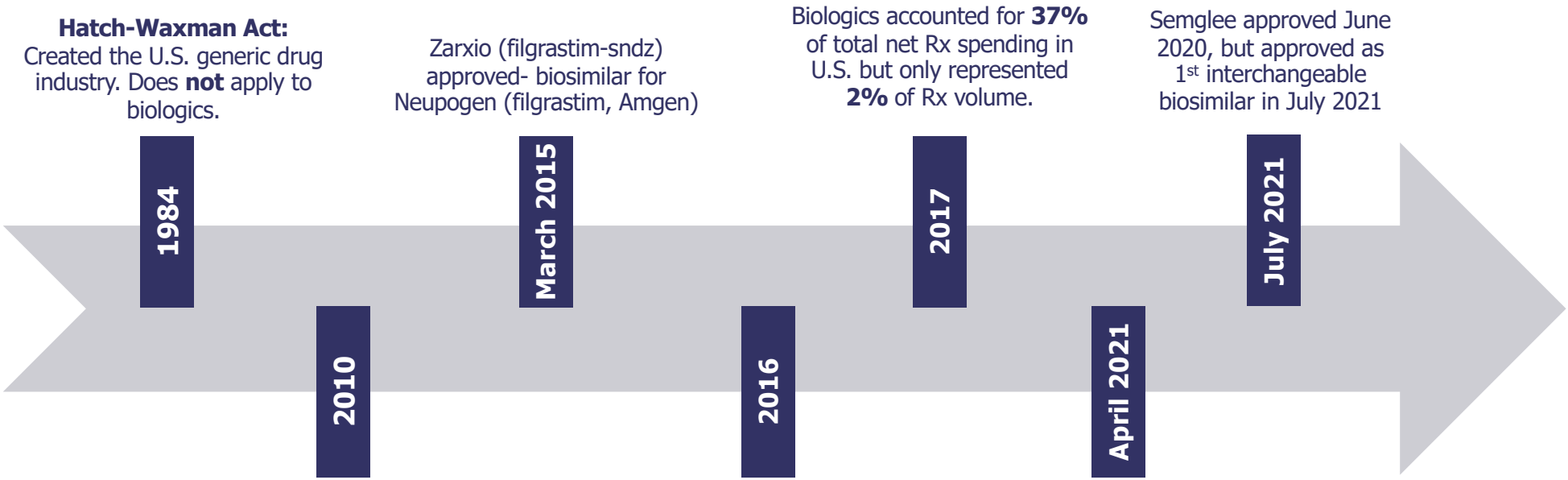
- Biosimilars must have the **same**: mechanism, administration route, dosage, form, & strength.
- Biosimilars may **differ** in: medical indications, product presentations (e.g. vial vs. pen).
- Even interchangeable biosimilar substitutions are still prone to **state specific regulations**.

Table 2: Differences between generics and biosimilars

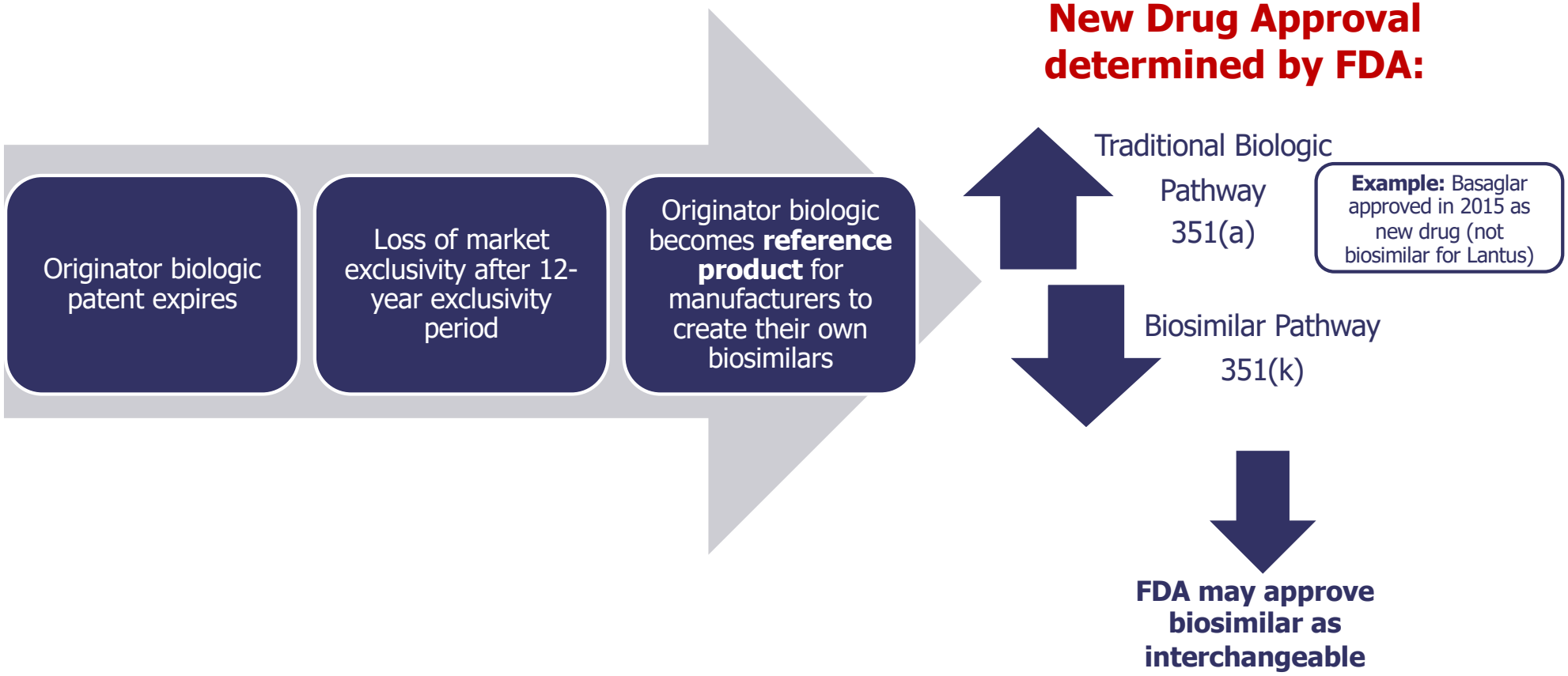
Generic	Biosimilar
A product that has been shown to be bioequivalent (i.e., performs in the same manner) to the brand-name drug	A biological product that has been demonstrated to be highly similar to the reference product
Is identical to the brand name reference product	Is not identical, but the variances pose no clinically meaningful differences
Applies only to small molecule drugs	Applies to biologics
FDA Orange Book • AB Rating means therapeutically equivalent • First published in 1980	FDA Purple Book • List of biologic products, and if that biologic is biosimilar and/or interchangeable • First published in 2011
Pharmacists may substitute a brand name for its generic in most situations	Unless it is designated as interchangeable, a biosimilar cannot be automatically substituted for the reference product

Biosimilars are part of a key strategy to introduce competition and bring down costs by influencing insurance formularies and utilization management.

Biosimilar history

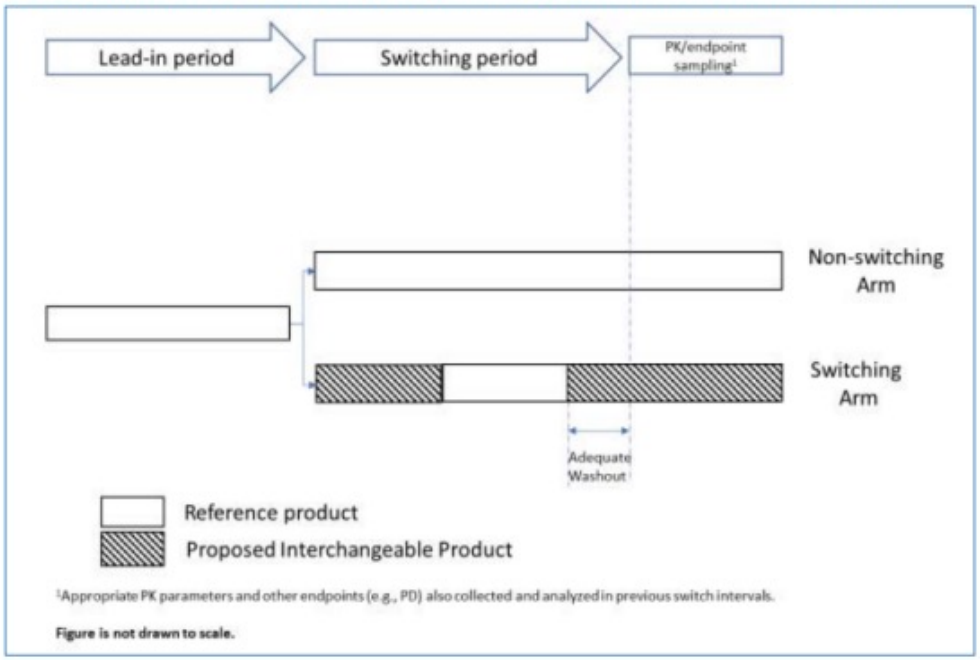


Biosimilar approval process



Biosimilar interchangeability

Figure 5: Example of a switching study design for interchangeable biosimilars[16]



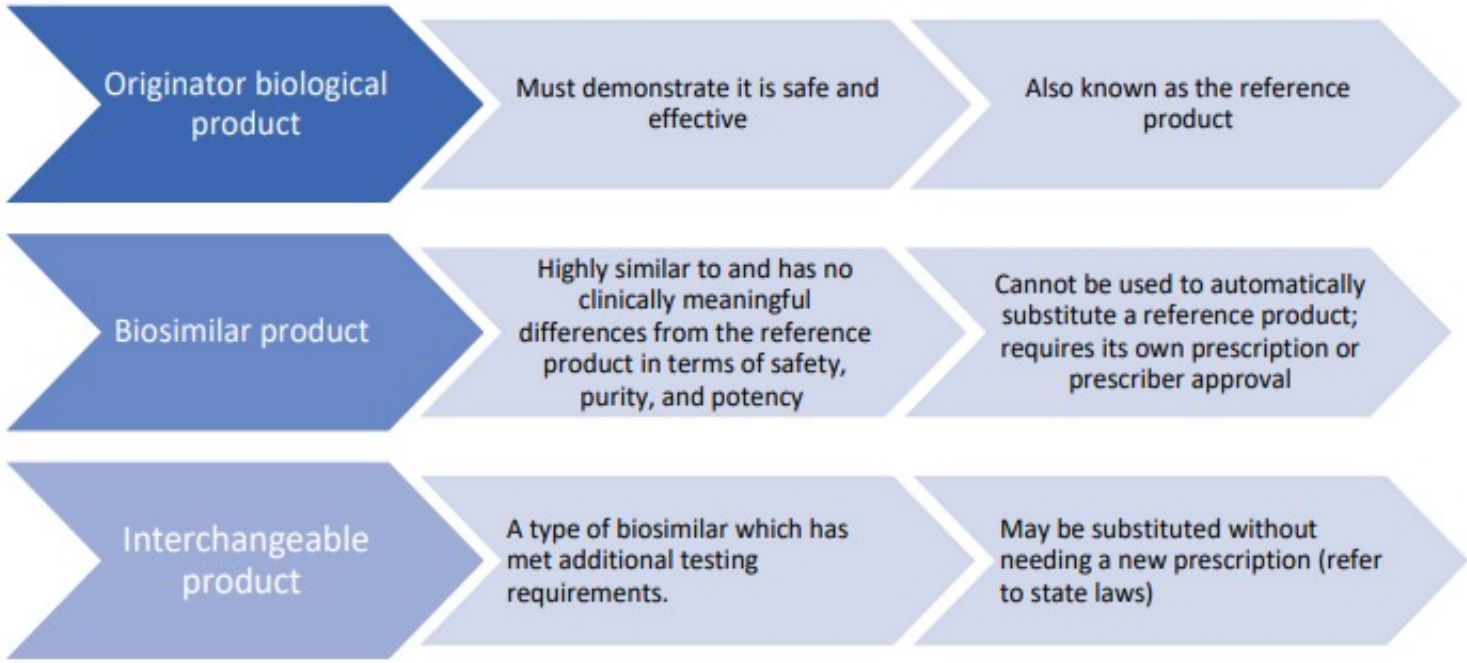
Walgreens University. May 8th 2023. *Basics in Biologics and Biosimilars.* *4d2282e5-3adf-493a-86a5-fc95a3b429cd_Basics_in_Biologics_and_Biosimiliars_Content_Pharm___Final.pdf (csod.com)

The FDA may approve a biosimilar as interchangeable if, based on switch studies:

- It achieves the **same clinical results** as the reference product in **any given patient**.
- Safety and efficacy-related risks of switching between the biosimilar and reference product are **no greater** than remaining on the reference product continuously.

Biologics & biosimilars in summary

There are 3 types of biologics regulated by the FDA



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Biosimilar overview

- The first biosimilar launched in 2007 and 40 biosimilars have launched across 12 molecules in the U.S. since, including biosimilars for the best-selling biologic molecule, adalimumab (Humira), in 2023.
- Biosimilar uptake in the US has lagged that in the EU
  - The European Medicines Agency and Heads of Medicines Agencies allow all biosimilars that are approved in the EU to be used interchangeably with their reference products and other biosimilars equivalent to the same reference product. There are no additional requirements and separate designation for interchangeable biosimilars.
- *With significant launches expected in the next five years, it is important to understand the state of the market and the factors that influence their use, and to also consider how these factors may impact future biosimilars. Ultimately, it is expected that biosimilars will generate significant savings in the future, enhancing the sustainability of the U.S. healthcare system* ("Biosimilars in the United States", 2023).

Barriers to uptake

In 2020 AMCP Foundation conducted a survey, top 3 barriers to biosimilar:

1. **State laws/regulations for substitution and interchangeability**
2. **Pricing and contracting**
3. **Prescriber's concerns about safety and efficacy**

Barriers to uptake (cont'd)

1. State laws and regulations for substitution and interchangeability:

- The designations of "biosimilar" and "interchangeable" cause confusion. Interchangeability designation is unique to the US.
  - Biosimilar ≠ Generic
  - Interchangeable = Substitutable
- State laws and regulations around substitution and interchangeability are not consistent.
  - Prescriber notifications
    - Varying time-frame requirements
  - RX Labeling requirements
    - "Substituted for XXX"
    - "Interchangeable biological product for XXX"
    - "Interchangeable with XXX"
  - Current law does not allow substitution of one interchangeable biologic for another interchangeable biologic

Barriers to uptake (cont'd)

2. Pricing and contracting:

- Payors:
  - Some of the complexities with health plans or PBMs including contracting arrangements, may reduce or remove the anticipated cost savings of a biosimilar versus the reference biologic.
    - Insulin glargine biosimilars at 28% share in 2022, 6 years after launch
    - Insulin lispro biosimilars at 8% in 2022, 4 years after launch.
- Prescribers:
  - Prescriber-specific economic challenges noted by participants might also be influenced by health plan/PBM decisions; these included no difference in reimbursement to providers between a biosimilar and its reference product.
- Biosimilar penetration in pharmacies has been relatively low to date, relating only to insulin glargine and insulin lispro. However, with the recent launch of several biosimilars for the molecule adalimumab, expectations are for a more significant biosimilar uptake in pharmacies.

Barriers to uptake (cont'd)

3. Prescriber Concerns:

- Perspectives on biosimilars may vary by physician specialty. This may be related to hesitance from some organizations to embrace biosimilars in their guidelines or position statements, or to the nature of various conditions.
  - Chronic Patients:
    - Rheumatology- longer term, chronic therapy. Biosimilar uptake would require switching existing patients.
  - Acute Patients:
    - Oncology- shorter term therapies, more new to therapy patients that would not require switching from an existing medication to a biosimilar.

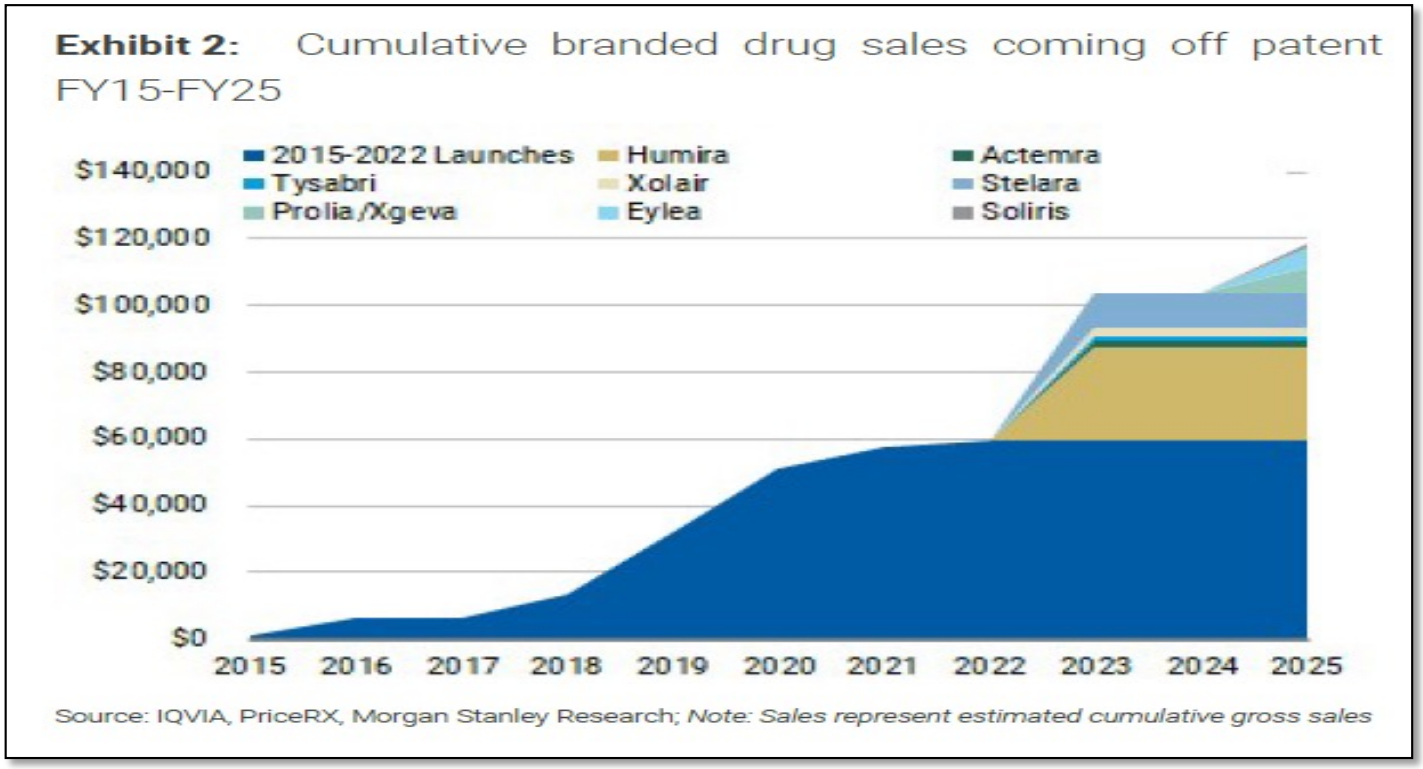
Opportunities to increase uptake

Savings over the next 5 years as a result of biosimilars are projected to exceed **$180BN**, though uncertainties remain as market events to date suggest a wide range of market outcomes are still possible.

- **Education:**
  - Simplify the language used to describe biosimilars- "Safe and effective" and "therapeutically equivalent to" vs "biosimilar" and "interchangeable".
  - Use Real World Experiences to provide outcomes data to prescribers.
  - Build positive evidence-based communications and educational materials for patients, prescribers and payers.
- **Legislation/Policy**
  - The Inflation Reduction Act (IRA) enacted October 1st, 2022. CMS to provide a 2% payment increase for using qualifying biosimilars to Medicare Part B entities over the next 5years.
  - Harmonize state substitution regulations.
  - Continue to promote interchangeability approval.
  - Enable substitution of one interchangeable biologic with another interchangeable biologic

Biosimilar pipeline

We need to maximize cost savings for patients and the healthcare marketplace.



Q & A

Appendix

Reference Page

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- Walgreens University. May 8th 2023. *Basics in Biologics and Biosimilars.* *4d2282e5-3adf-493a-86a5-fc95a3b429cd_Basics_in_Biologics_and_Biosimiliars_Content_Pharm___Final.pdf (csod.com)
- Understanding Interchangeable Biosimilars at the Federal and State Levels

  Understanding Interchangeable Biosimilars at the Federal and State Levels (ajmc.com)