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Biosimilars: Price, Policy & Outlook

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Objectives

- Identify the definition of biosimilars
- Outline the difference between biosimilars and generics
- Describe the FDA's outlook on biosimilars
- Explain the supportive policy environment being put into place for biosimilars and ability to thrive under such policies
- Discuss the outlook for biosimilars as interchangeability policies and legislation evolves

Overview of Biosimilars

- What are biosimilars or follow-on biologics?
- Hatch-Waxman
  - They are not a copy of the reference product
  - Uses living material
  - More specific handling restrictions
- How do they impact the market?
  - So far there have been a limited amount of approvals for biosimilars
  - Can be up to 30% less
  - Reference product manufacturers are using different tactics to protect patents

Biosimilars Vs Generics: What's the Difference?

Generics

Copies of brand-name drugs and are the same as those brand name drugs in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use.

- Manufactured using chemistry
- Exact copy of the formulated drug with the same chemical make-up
- Smaller clinical trials required before approval compared to biosimilars
- Relatively easy to store

Biosimilars

Biological product that is "highly similar" to the reference product or drug notwithstanding minor differences in clinically inactive components.

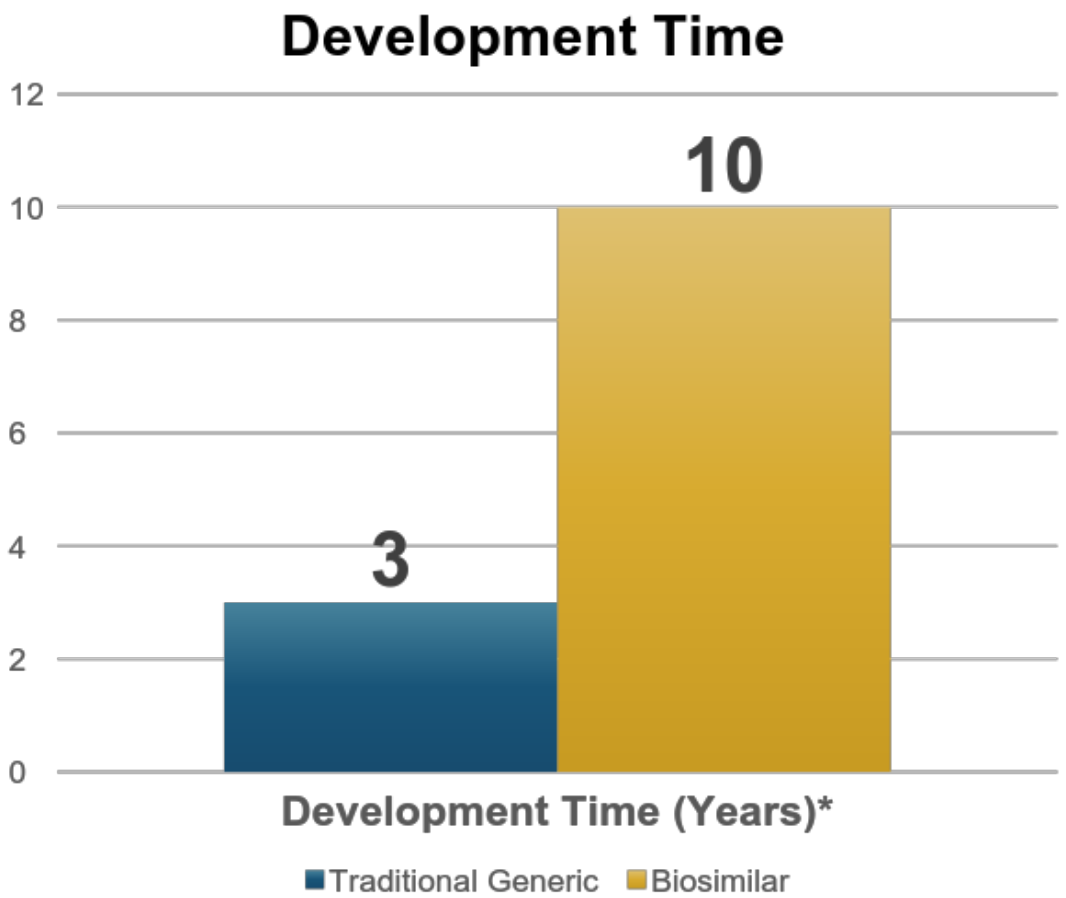
- Manufactured using living material (biology)
- Similar copy of the formulated drug biology
- Larger and longer clinical trials required before approval compared to generics
- Specific handling and storage restrictions apply more often than in generics

Amgen Biosimilars. Biosimilars vs. generics. http://www.amgenbiosimilars.com/the-basics/biosimilars-versus-generics/. Accessed September 1, 2017.

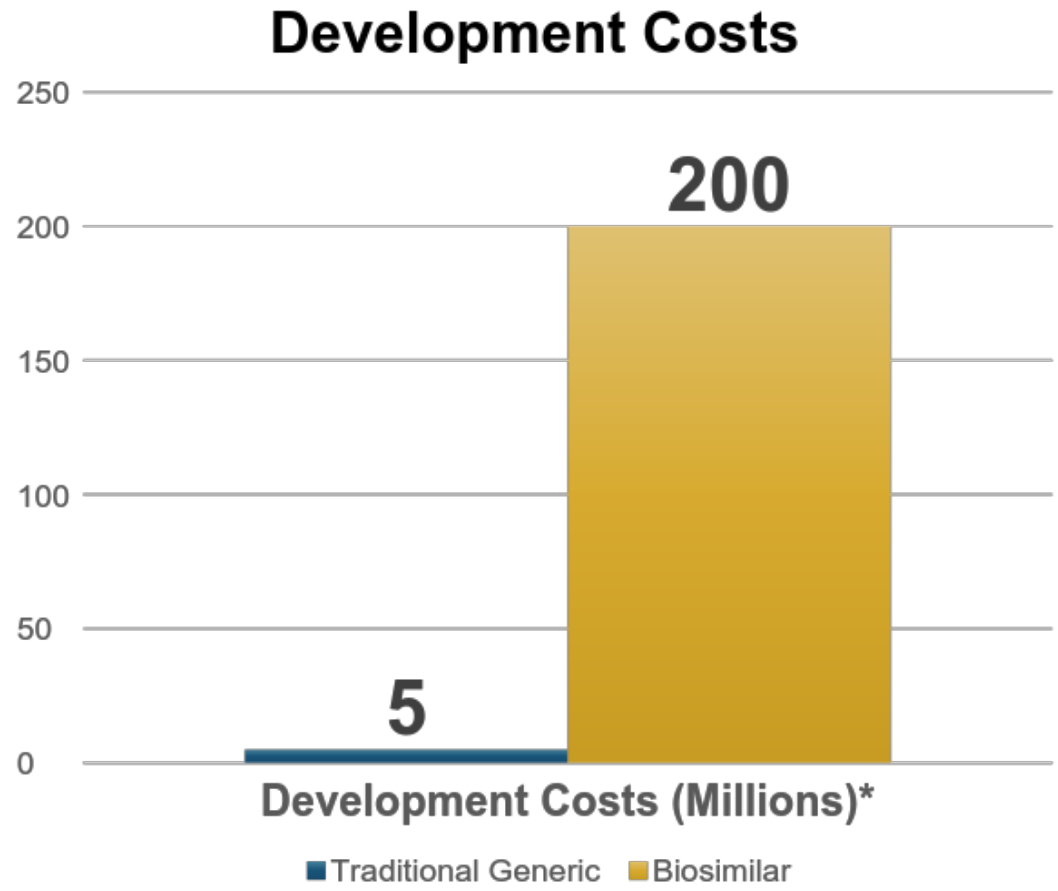
Overview of Biosimilars: Current List of Approved Biosimilars

Date of Approval	Biosimilar Product	Original Product
March 6, 2015	Zarxio (filgrastim-sndz)	Neupogen (filgrastim)
April 5, 2016	Inflectra (infliximab-dyyb)	Remicade (infliximab)
August 30, 2016	Erelzi (etanercept-szzs)	Enbrel (etanercept)
September 23, 2016	Amjevita (adalimumab-atto)	Humira (adalimumab)
April 21, 2017	Renflexis (infliximab-abda)	Remicade (infliximab)
August 25, 2017	Cyltezo (adalimumab-adbm)	Humira (adalimumab)

Biosimilars vs Generics: Development Time and Cost



*Amount of years reported are estimated; Generic = 1-3 years; Biosimilar = 8-10 years.



*Costs reported are estimated; Generic = $2-5 million; Biosimilar = $100-200 million.

Optum. Potential pitfalls for biosimilars. https://www.optum.com/resources/library/potential-pitfalls-biosimilars.html. Accessed September 1, 2017.

Price

- Biosimilars have been slow to gain approval
- Current pricing can range from 15% to 30% less than the reference product
- What goes into pricing? Challenges to approval?
- Why pricing is not as low as generics
  - The use of biologic material as opposed to chemical components
  - Longer clinical trials.
  - Higher costs spent on patent infringement cases to protect reference product
  - Biosimilars and exclusivity periods

Price

- Drug price debate
- Value-based care agreements
  - Insurers are creating pricing contracts that pair price with a drug's performance
- Marketplace partnership for development

  Companies are sharing development costs

Policy

- Biosimilars and the ACA
- FDA approval policy
  - There is a new push to approve both generics and biosimilars quickly
- Drug Competition Plan
- January 2017 FDA issued interchangeability regulatory guidance
- Naming
  - Purple Book
  - Suffixes
  - Debate between biosimilars and reference product

Policy

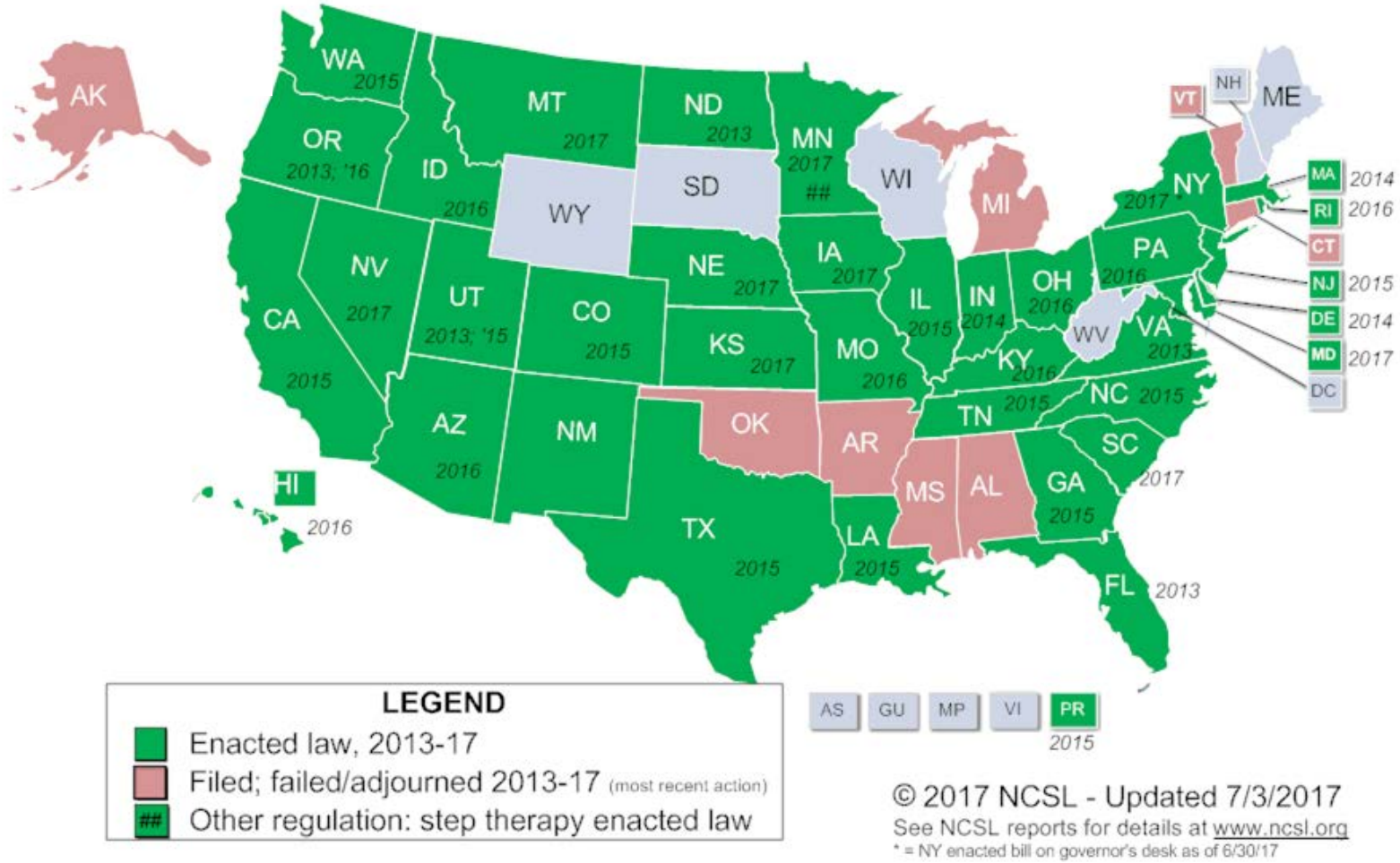
Amgen V. Sandoz

- Supreme Court ruling
- In favor of biosimilars
- Remanded to the State of California

Outlook

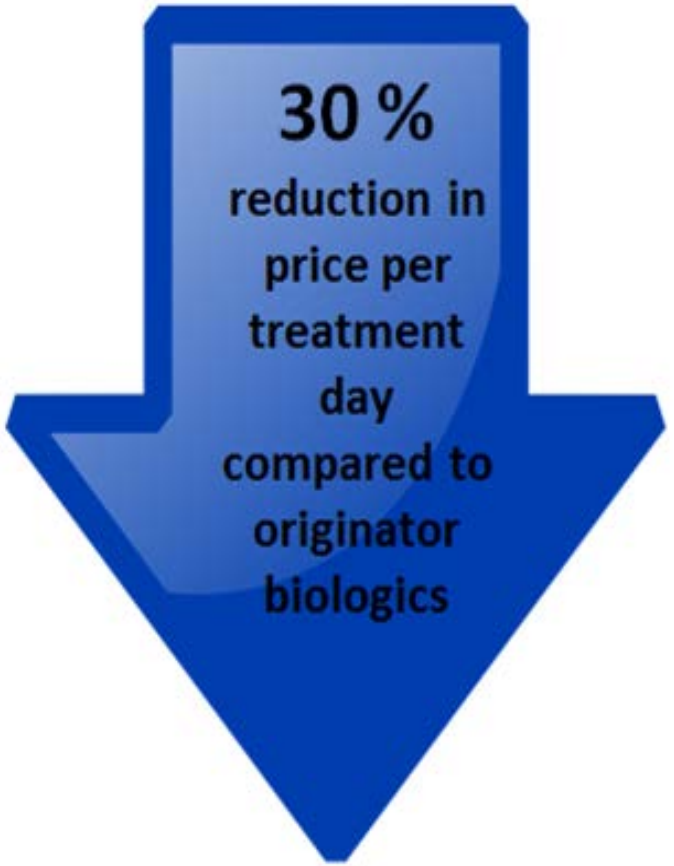
- Substitution
  - Once interchangeability policy is clear there will be ways to substitute biosimilars for the reference product
  - States are getting ready and have passed legislation allowing for substitution
- Biosimilars in the pipeline
  - Awaiting approval
  - Reference products that are the most at risk
- Labeling
  - Issues and how they may affect the market

Legislation on Biologics and Biosimilar Substitution 2013-2017



NCSL. State laws and legislation related to biologic medications and substitution of biosimilars. www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx. Accessed September 1, 2017.

What to Expect in the Future for Biosimilars



- 56 new products in clinical development
- As much as **$110 BILLION IN SAVINGS** to health systems in Europe and the U.S.

QuintilesIMS. IMS Health: Surge in biosimilars to drive significant change in health system costs, patient access, and competition by 2020. https://launchpad.imshealth.com/en_IE/thought-leadership/quintilesims-institute/news-and-press/ims-health-surge-in-biosimilars-to-drive-change-in-health-system-costs. Accessed September 1, 2017.

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