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RHEUMATOLOGY ADVANCED PRACTICE PROVIDERS

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VIRTUAL CONFERENCE

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Biosimilars

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Disclosure

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Faculty Disclosures

Tanya Golovanoff, PharmD, BCSCP

- There are no relationships to disclose.

Learning Objectives

- Define Biosimilar
- Review the History of Biosimilar market
- Understand how FDA approves Biosimilar agents
- Appreciate the need for Biosimilars
- Apply Biosimilar understanding to your practice

Biotherapeutics or Biologicals

- Drug therapy products where the active substance is extracted or produced from a biological source
- Recombinant proteins and hormones, monoclonal antibodies (mAbs), cytokines, growth factors, gene therapy products, vaccines, cell-based products, gene-silencing/editing therapies, tissue-engineered products, and stem cell therapies

FDA Definition of a Biosimilar

An FDA-approved biosimilar is a biological product that is highly similar to and has no clinically meaningful differences in terms of safety, purity and potency (safety and effectiveness) from an already FDA-approved product, called the reference product.

Biological products are highly complex, and often used to treat patients with serious and life-threatening conditions. The law allowing FDA to approve biosimilars was designed to create competition, increase patient access, and potentially reduce cost of important therapies.

Biosimilar Definition

- US FDA [53]: “A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product.”
- EU EMA [5]: “A biosimilar is a biological medicine highly similar to another already approved biological medicine.”
- WHO [31]: “Similar biotherapeutic product (SBP). A biotherapeutic product that is similar in terms of quality, safety and efficacy to an already licensed reference biotherapeutic product.”

The First Biologics

- 1980s: The first biological medicinal products produced by DNA recombinant techniques were approved
- 1986: First monoclonal antibody receives FDA approval
- 1998: First biologic for rheumatoid arthritis is introduced: Omnitrope

2010-2014

- 2010: The Biologics Price Competition and Innovation Act (BPCIA), enacted in 2010, provided a framework for biosimilars approval, adoption and access in the U.S.
- 2014: FDA's first guidance issued on Development and Approval of Biosimilar Products in the U.S., creating clear regulatory expectations for biosimilar products. This guidance provides information on developing biosimilarity, safety and efficacy.

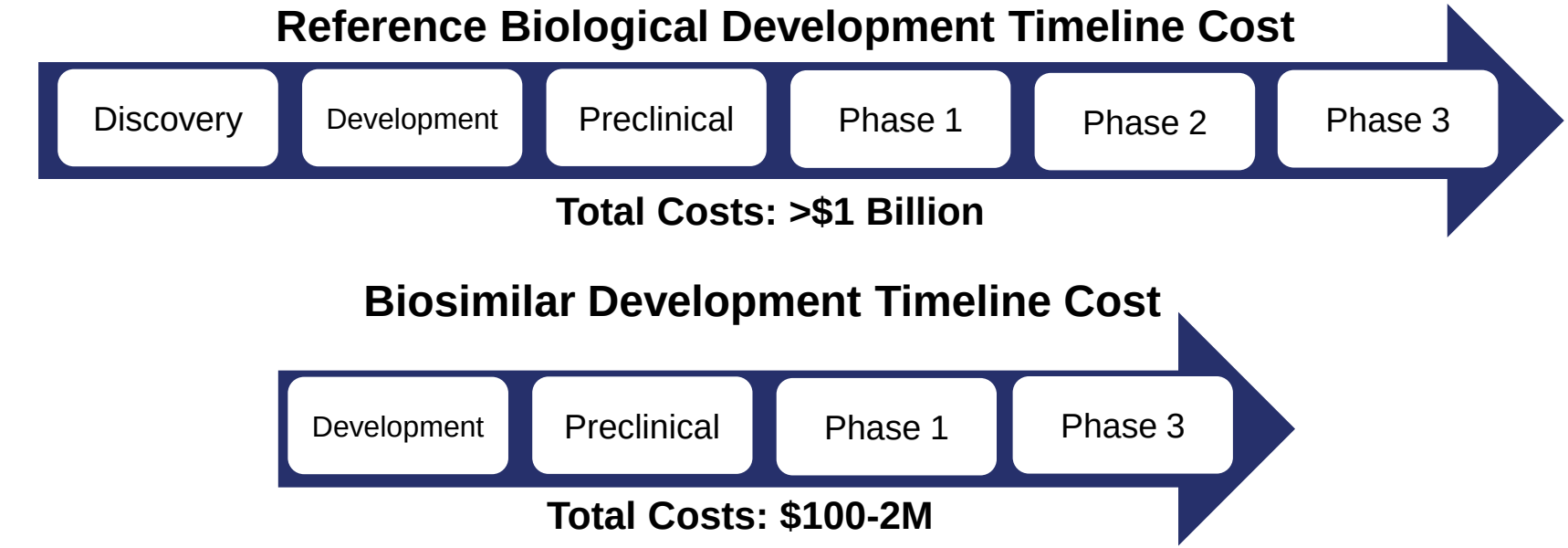
2015

- 2015: FDA Final Guidance issued on demonstrating biosimilarity with a reference product
- March 2015: First US biosimilar approved: ZARZIO (filgrastim-sndz) for patients with cancer receiving chemotherapy and radiation to support white blood cell creation

2016-2019

- 2016: FDA Final Guidance issued on naming and labeling for biosimilar products
- 2017: Centers for Medicare & Medicaid Services issues policy on biosimilars reimbursement, giving each biosimilar its own average sales price
- 2018: FDA Revised Guidance on biosimilar extrapolation of indications and biosimilar interchangeability
- 2019: Bipartisan members of Congress introduced multiple pieces of legislation to incentivize biosimilar use and adoption

Biosimilar Approval Process



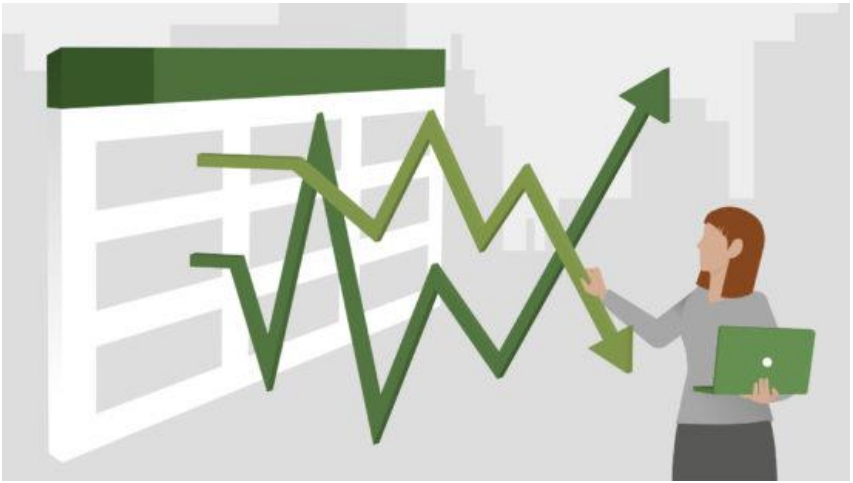
Social and Economic Challenges

- Population is aging → rising prevalence of Chronic Conditions
- Global spending on pharmaceutical products continues to increase (~81 billion in 2018)
- Biologics are an important but expensive portion of new drugs (40% of US pharmaceutical spending)

Generic Drug Landscape

- 1984 – Hatch-Waxman Drug Price Competition and Patent Term Restoration Act
  - Generic Share is nearly 90% today
  - ~293 BILLION Saved in 2018 alone

RAND Reports Cost Savings



- Cost savings potential of biosimilars to be $54 billion over ten years.
- Lower- to upper-bound range of $25 billion to $150 billion.

Reality for Biosimilars

- Patent Abuse Blocking access due to delayed launch of biosimilars
  - Cost US health system $7.6 billion in lost savings since 2015
- Adoption Barriers – brand-name biologic company anti-competitive tactics
  - Additional $2.2 billion in lost savings

Reactions

- More and more commercial payors are dictating what medication will be approved
  - In some cases they do not let you know the biosimilar must be prescribed
- The infusion center of choice may have specific formularies
- Some medical benefits differ from drug benefit coverage (office vs home infusion)

Change Begins With YOU

- Keeping up to date with the Biosimilar Market
  - Ask your Pharmacist!
- Attitudes when talking with patients when making therapy choices
  - Explain biosimilar availability
- Using generic names vs brand
  - Infliximab vs Remicade

Keep up to Date

- Biosimilarscouncil.org
- FDA website:
  - https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars
- FDA Purple Book: Database of Licensed Biological Products
  - https://purplebooksearch.fda.gov/

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Thank you.