Biosimilars in the US Health Care Landscape

May 2018
PP-BIO-USA-0414

Pfizer Biosimilars

Agenda

- Introduction to Biologics and Biosimilars
- FDA Guidelines for Establishing Biosimilarity
- An Overview of Extrapolation and the US FDA Interchangeability Designation
- How Biosimilars May Help Bring Value to Patients

FDA, Food and Drug Administration

Pfizer Biosimilars

Introduction to Biologics and Biosimilars

Pfizer Biosimilars

Biologics and Biosimilars Defined[1,2]

Biologic

Wide range of products (eg, vaccines, blood and blood components, somatic cells, gene therapy, tissues, therapeutic proteins) derived from genetically engineered living cells or organisms and intended to prevent, treat, or cure a variety of medical conditions[1]

Reference biologic

Originally licensed biologic product used for comparison[2]

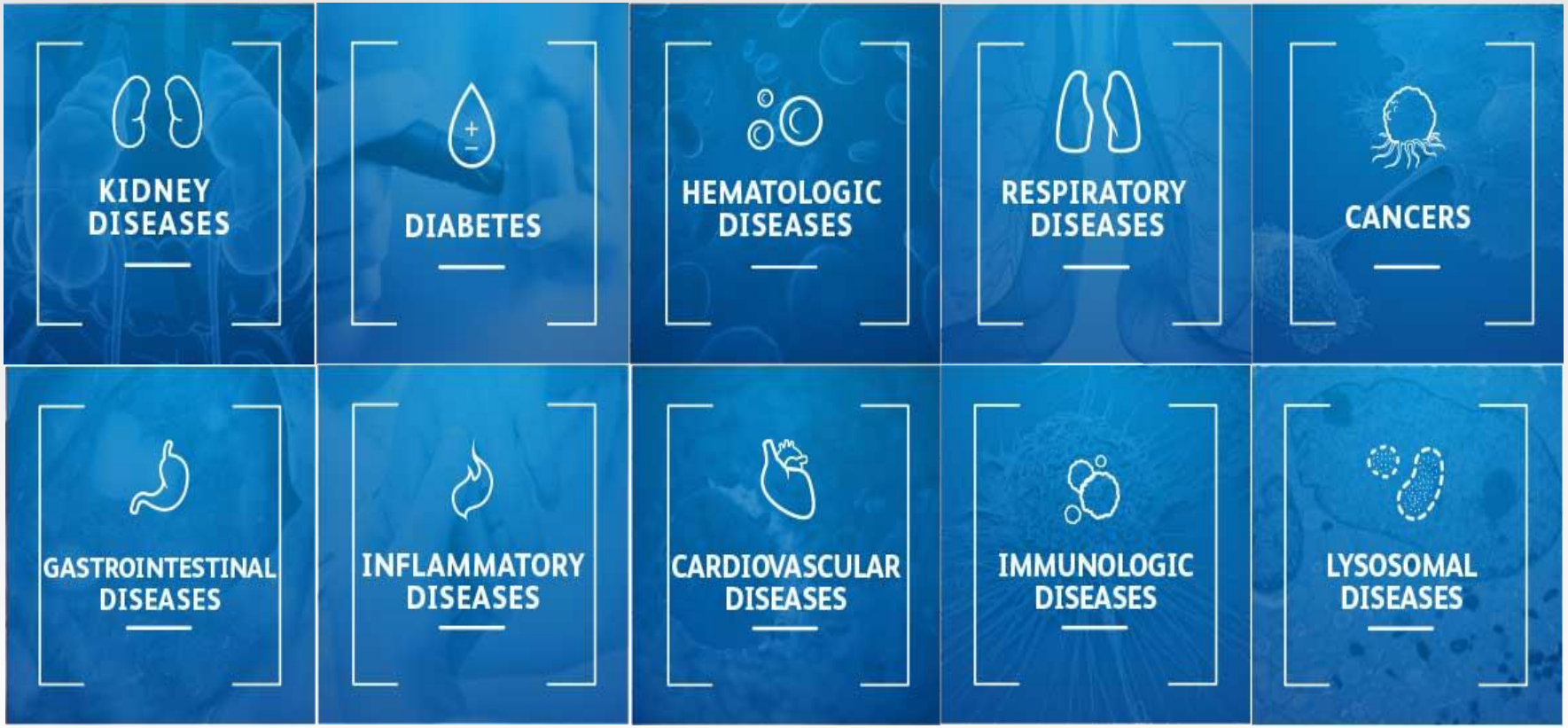
Biosimilar

Biologic that is **highly similar** to the reference product with **no clinically meaningful differences** in terms of the **safety, purity, and potency[2]**

1. US Food and Drug Administration. *What Are "Biologics" Questions and Answers*. Silver Spring, MD: FDA; 2015. https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cber/ucm133077.htm. Accessed May 10, 2018. **2.** US Food and Drug Administration. *Guidance for Industry: Scientific Considerations in Demonstrating Biosimilarity to a Reference Product*. Silver Spring, MD: FDA; 2015.

Biologics Have Had a Meaningful Impact on Patient Care[1,2]

Successfully used to treat many different life-threatening and chronic diseases[1-5]



1. Kozlowski S, et al. *N Engl J Med.* 2011;365(5):385-388. **2.** Ryan AM. *Vet Pathol.* 2015;52(2):419-426. **3.** Walsh G. *Nat Biotechnol.* 2010;28(9):917-924. **4.** Oh DB. *BMB Rep.* 2015;48(8):438-444. **5.** Pelaia G, et al. *Ther Clin Risk Manag.* 2016;12:1075-1082.

Pfizer Biosimilars

Today, Biologics Comprise 5 of the 10 Top-Selling Medications in the United States and Drive Disproportionate Costs[1,2]

"Biologic medicines are costly. While only **2% of the U.S. population** uses them, biologics account for **40% of prescription drug spending** in the United States."[2]—*The Biosimilars Council*

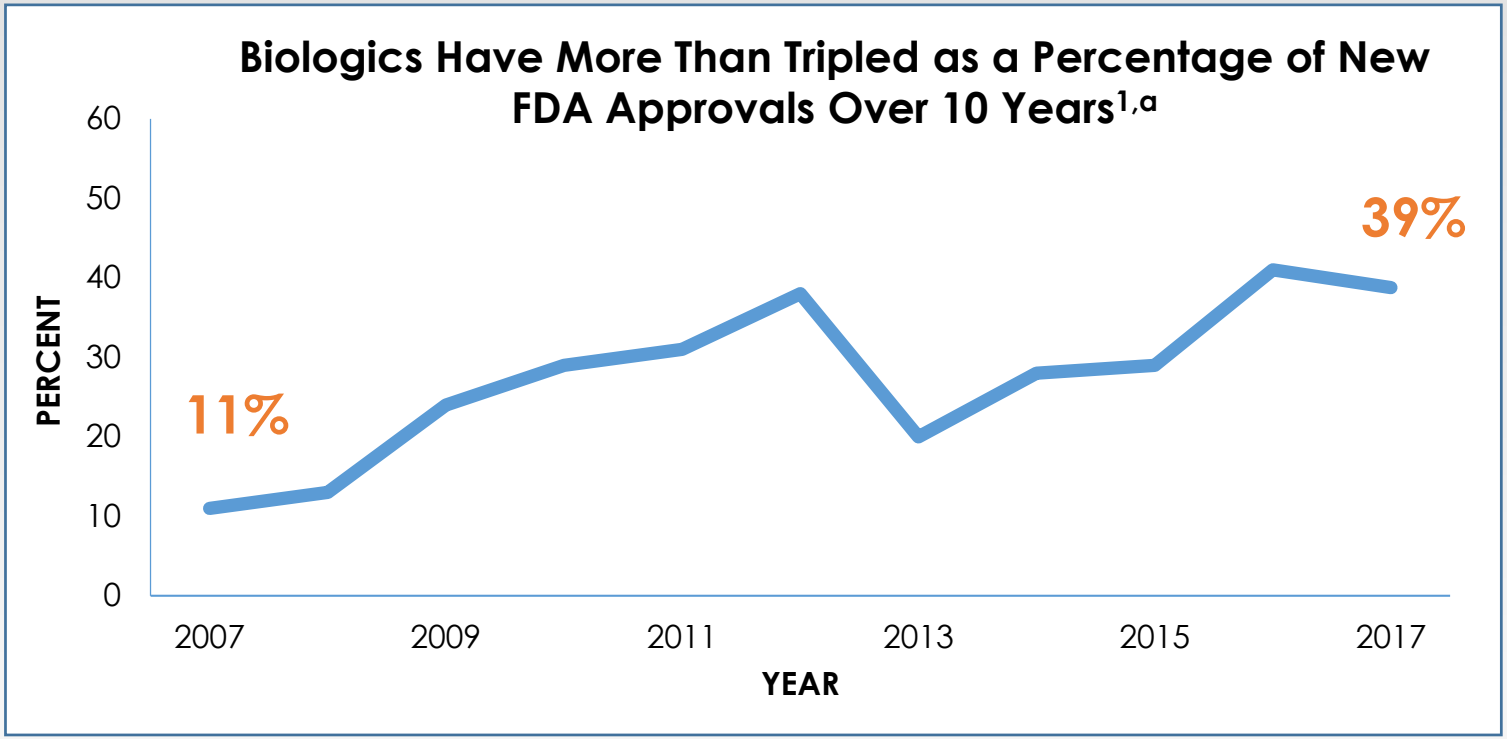
Biologics Comprise 5 of the 10 Top-Selling Medications in the United States[1]

In 2017, biologics accounted for approximately **$40 billion of $65 billion** in sales for the 10 top-selling drugs[1]

1. Data on file. Pfizer Inc, New York, NY. IMS NSP sales by brand Top 50. **2.** The Biosimilars Council. Biosimilars: A Safe & Effective Option for Patients. http://biosimilarscouncil.org/wp-content/uploads/2017/06/Biosimilars-Fact-Sheet_FINAL_5-31-17.pdf. Updated May 2017. Accessed May 10, 2018.

Pfizer Biosimilars

The Number of Biologic Therapies Is Expected to Grow, Increasing Pressure on the US Health Care System[1,2]



By 2020, **$5 out of every $10** that the country spends on prescription drugs will be spent on biologics[2]

[a]Includes biosimilars.

1. Morrison C. Fresh from the biotech pipeline-2017. *Nat Biotechnol.* 2018 Jan 22. doi: 10.1038/nbt.4068. [Epub ahead of print]. **2.** The Biosimilars Council. The Next Frontier for Improved Access to Medicines: Biosimilars and Interchangeable Biologic Products. https://www.spcma.org/wp-content/uploads/2016/06/GPhA-biosimilars-handbook.pdf. Accessed May 10, 2018.

Pfizer Biosimilars

The Potential Cost Savings From Biosimilars to Health Care Systems May Be Substantial[1]

Estimated Reduction in Direct Spending on Biologic Drugs Between 2017 and 2026 (RAND Corporation)[1,a]:

Up to $150 billion

Savings realized by patients may depend on various factors, including changes in copays, coinsurance, etc, which may be more apparent in the future.[2]

[a]Based on an assumption of constant reference biologic prices, a biosimilar market share of 50%, and biosimilar prices that are 50% of the reference biologic.

- **1.** Mulcahy AW, et al. *Biosimilar Cost Savings in the United States*. Santa Monica, CA: RAND Corporation; 2017. **2.** Mulcahy AW, et al. *The Cost Savings Potential of Biosimilar Drugs in the United States*. Santa Monica, CA: RAND Corporation; 2014.

Pfizer Biosimilars

Biosimilars May Provide Multiple Benefits to the US Health Care System[1-3]

Potential of biosimilars for patients, payers, and providers[1-3]

Additional treatment choices at potentially lower cost	**May increase access to biologics, which may lead to better health outcomes overall**
Possible savings and efficiencies	**Offer a variety of therapeutic options**

1. Strober BE, et al. *J Am Acad Dermatol*. 2012;66(2):317-322. **2.** Scheinberg MA, Kay J. *Nat Rev Rheumatol*. 2012;8(7):430-436.
3. Henry D, Taylor C. *Semin Oncol*. 2014;41(suppl 3):S13-S20.

Pfizer Biosimilars

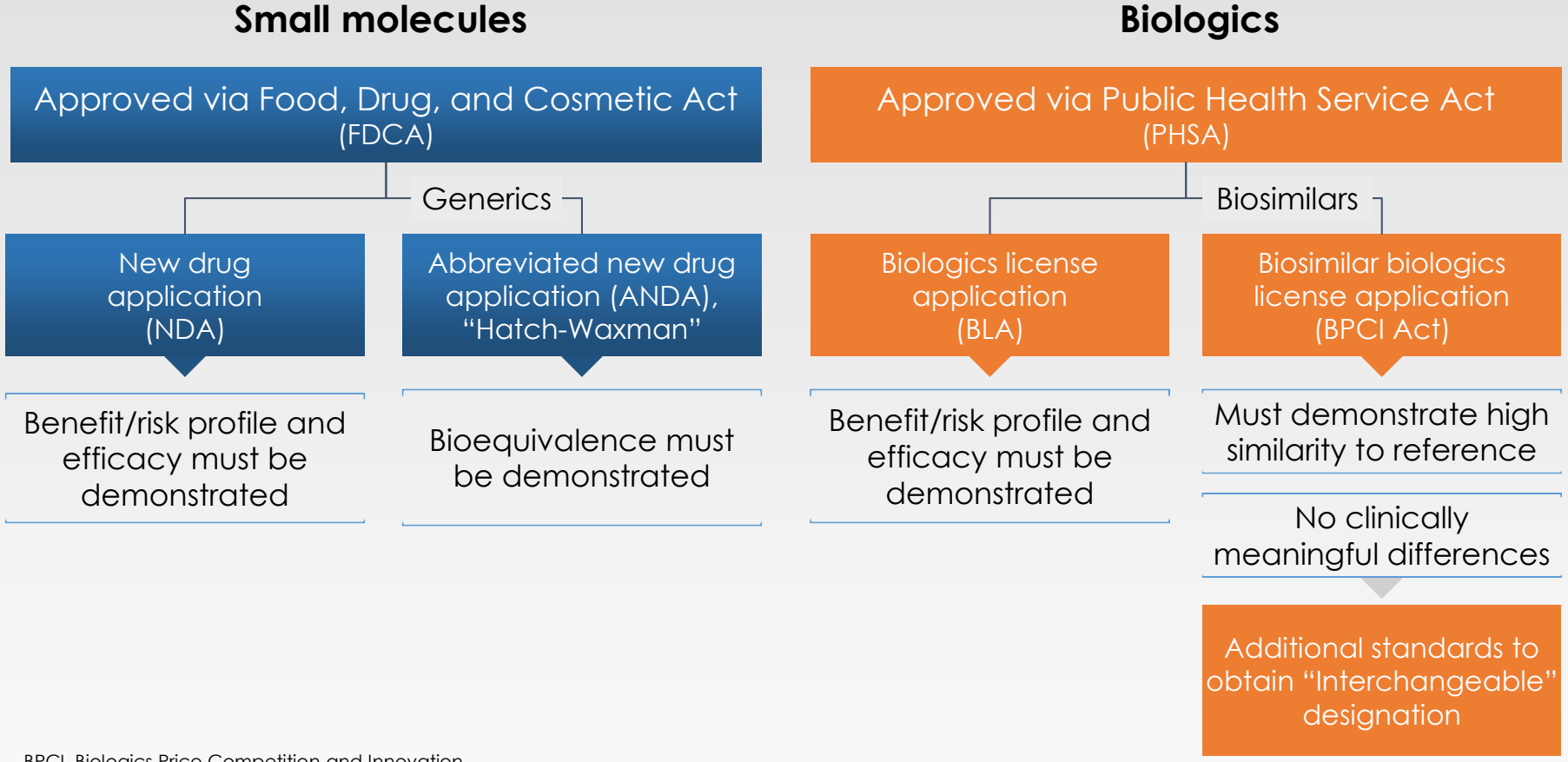
Key Points

- A biosimilar is a biologic that is highly similar to a reference product, with no clinically meaningful differences in terms of the safety, purity, and potency
- As the demand and spending for biologics continue to grow, the introduction and successful adoption of biosimilars have the potential to provide additional treatment choices at lower cost

FDA Guidelines for Establishing Biosimilarity

Pfizer Biosimilars

Standard and Abbreviated Pathways for Drug Approval in the United States[1-6]



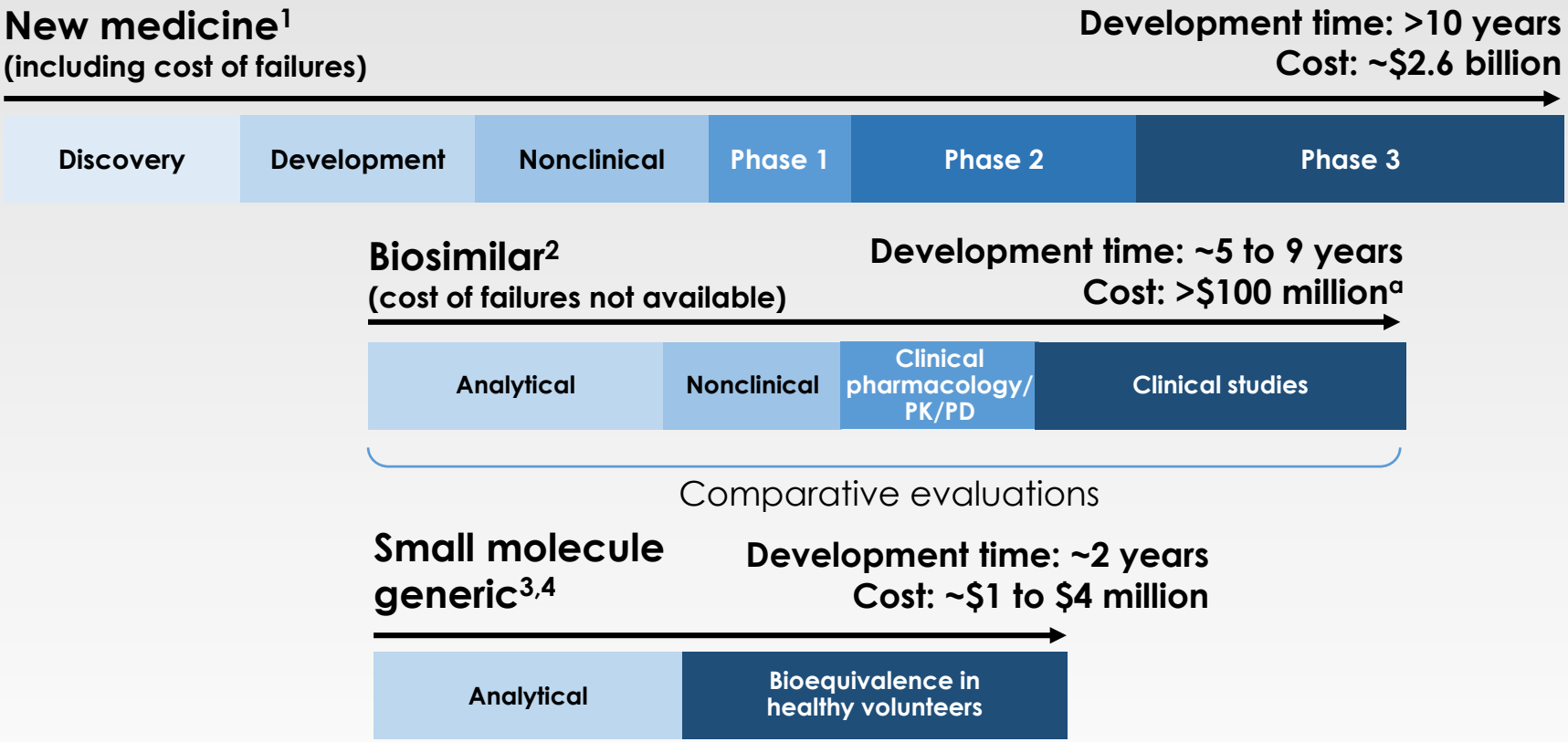
BPCI, Biologics Price Competition and Innovation.

1. US Food and Drug Administration. New Drug Application (NDA). http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/. Updated March 29, 2016. Accessed May 10, 2018. **2.** US Congress. Drug Price Competition and Patent Term Restoration Act of 1984, Title I, 98 Stat 1585 Public Law 98-417. **3.** US Food and Drug Administration. *Guidance for Industry: Scientific Considerations in Demonstrating Biosimilarity to a Reference Product*. Silver Spring, MD: FDA; 2015. **4.** Patient Protection and Affordable Care Act, March 2010. **5.** US Congress. United States Public Health Service Act, Sec. 262 Regulation of Biological Products. 42USC262. http://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/pdf/USCODE-2010-title42-chap6A-subchapII-partF-subpart1-sec262.pdf. Accessed May 10, 2018. **6.** US Food and Drug Administration. *Guidance for Industry: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009*. Silver Spring, MD: FDA; 2015.

Pfizer Biosimilars

Developing a Biosimilar Requires Substantial Investment Compared With a Small Molecule Generic[1-4]

- Despite being rigorous, the development timeline for biosimilars may be shorter than for a new medicine



PD, pharmacodynamic; PK, pharmacokinetic.

[a]Not including regulatory fees.

1. Pharmaceutical Research and Manufacturers of America. *Drug Discovery and Development: Understanding the R&D Process*. Washington, DC: PhRMA; 2007. **2.** Generics and Biosimilars Initiative. GaBI Online. Development of biosimilars. Posted July 1, 2011. http://www.gabionline.net/Biosimilars/Research/Development-of-biosimilars. Accessed May 10, 2018. **3.** Grabowski H, et al. *Health Aff (Millwood)*. 2006;25(5):1291-1301. **4.** IMS Health. Shaping the Biosimilars Opportunity: A Global Perspective on the Evolving Biosimilars Landscape. London, UK: IMS Health Incorporated; December 2011.

Pfizer Biosimilars

Biosimilar Development Is More Complex Than Establishing Comparability[1-3]

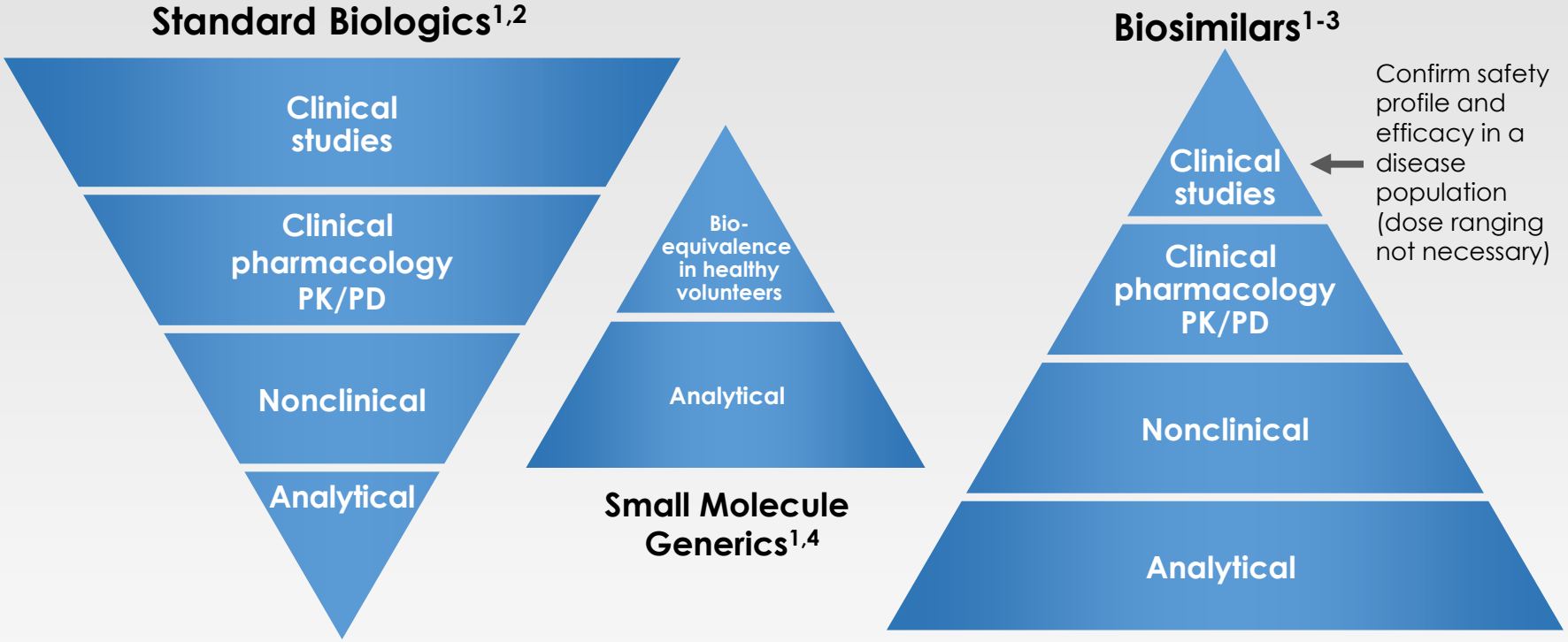
- Demonstrating biosimilarity to a reference product requires more data and information than establishing comparability between a post- and premanufacturing change[1]
- Although biosimilars are developed against a reference product, they have their own specifications, dependent on[2]:
  - Manufacturing process
  - Industry standards
  - Regulatory expectations
  - Data from comparisons with the reference product
- Rigorous control strategies are necessary to maintain consistency and help ensure biosimilars conform to specifications[3]

1. US Food and Drug Administration. *Guidance for Industry: Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product*. Silver Spring, MD: FDA; 2015. **2.** Schiestl M, et al. *Nat Biotechnol*. 2011;29:310-312. **3.** US Food and Drug Administration. *Guidance for Industry: Changes to an Approved Application for Specified Biotechnology and Specified Synthetic Biological Products*. Rockville, MD: FDA; 1997.

Pfizer Biosimilars

The Goal of Biosimilar Development Is to Demonstrate That There Are No Clinically Meaningful Differences Based Upon the **Totality of Evidence**, Not to Reestablish Benefit[1-4]

Development Pathways



- It is not scientifically necessary to repeat the entire development program of the reference product[5,6]
- A robust analytical characterization and preclinical foundation reduces the need for extensive animal and clinical testing[7]

1. Schneider CK, et al. *Nat Biotechnol*. 2012;30:1179-1185. **2.** McCamish M. Presented at EMA Workshop on Biosimilars; London; October 2013. **3.** Berghout A. *Biologicals*. 2011;39:293-296. **4.** US Food and Drug Administration. Abbreviated New Drug Applications (ANDA): Generics. https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/default.htm. Updated November 28, 2017. Accessed May 10, 2018. **5.** Kozlowski S, et al. *N Engl J Med*. 2011;365:385-388. **6.** Noaiseh G, Moreland L. *Biosimilars*. 2013;3:27-33. **7.** US Food and Drug Administration. *Guidance for Industry: Scientific Considerations in Demonstrating Biosimilarity to a Reference Product*. Silver Spring, MD: FDA; 2015.

Pfizer Biosimilars

Robust Analytical Testing Is Used to Establish High Similarity to the Reference Product

- Analytical testing is a major focus throughout biosimilar development

  - New techniques and advancements in analytics are available
  - More than 1 test method may be used to measure a single quality attribute

Analytical tests maximize the potential for detecting differences between the proposed biosimilar and the reference product

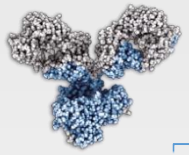
US Food and Drug Administration. *Guidance for Industry: Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product*. Silver Spring, MD: FDA; 2015.

Pfizer Biosimilars

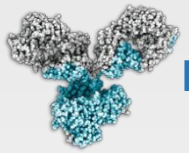
Any Comparative Clinical Evaluation Is Designed on a Case-by-Case Basis

- Comparative safety and effectiveness data are necessary if there are residual uncertainties about the biosimilarity of the 2 products

Reference biologic



Degree of analytical and functional similarity



Biosimilar

The need for additional studies may be influenced by many factors

- Mechanism of action
- Complexity and heterogeneity
- Structure/ function relationship to clinical outcomes
- Relevance of clinical pharmacology to predicting outcomes
- Clinical experience in therapeutic class

US Food and Drug Administration. *Guidance for Industry: Scientific Considerations in Demonstrating Biosimilarity to a Reference Product*. Silver Spring, MD: FDA; 2015.

Pfizer Biosimilars

FDA Biosimilar Guidelines and Resources for Health Care Providers, Patients, and the Industry

"As more biosimilars are approved by FDA, we want health care providers to understand what these drugs are, and how they can help patients."[1]

—Scott Gottlieb, MD, Commissioner of the US Food and Drug Administration

The FDA has developed educational materials to help health care providers better understand biosimilars and their approval process[2]

- **Biosimilar and Interchangeable Products**
- **Biosimilar Product Information**
- **Biosimilar Development, Review, and Approval**
- **Industry Information and Guidance**
- **Prescribing Biosimilar and Interchangeable Products**
- **Online Courses, Webinars, and Presentations**
- **Patient and Prescriber Outreach Materials**

1. US Food and Drug Administration. FDA Taking New Steps to Better Inform Physicians About Biosimilars Through Education About These Potentially Cost-Saving Options. https://blogs.fda.gov/fdavoice/index.php/2017/10/fda-taking-new-steps-to-better-inform-physicians-about-biosimilars-through-education-about-these-potentially-cost-saving-options/. Accessed May 10, 2018.

2. US Food and Drug Administration. Biosimilars. https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/default.htm. Updated November 14, 2017. Accessed May 10, 2018.

Pfizer Biosimilars

Key Points

- The BPCI Act established an abbreviated pathway for biosimilar approval, focusing on high similarity to a reference product
- Demonstrating biosimilarity requires substantial investment and goes beyond establishing comparability between a post- and premanufacturing change
- Biosimilars undergo a rigorous development process and are evaluated by the FDA based on a "totality of evidence" approach
  - A major focus of biosimilar development is thorough analytical testing used to establish high similarity to the reference product
  - Decisions about the approach to comparative clinical analyses are made on a case-by-case basis and are based on the determination of residual uncertainty

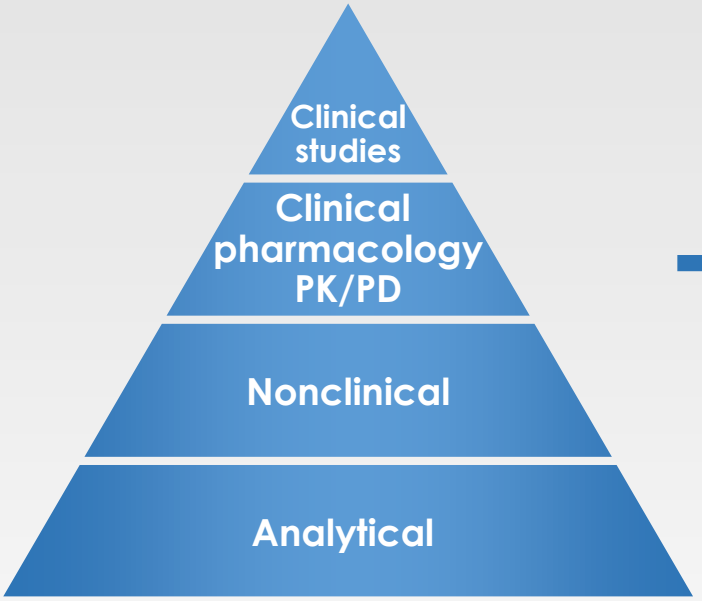
Pfizer Biosimilars

An Overview of Extrapolation and the US FDA Interchangeability Designation

Pfizer Biosimilars

Scientific Justification Is Required to Support Extrapolation to Indications Not Clinically Studied[1-3]

Biosimilar Pathway[1,2]



Convincing scientific justification to support extrapolation to a reference biologic's approved indications[3]

Extrapolated indications

Biosimilar extrapolation occurs from the reference biologic to the biosimilar, when scientifically justified, based on all available data—not from the indication(s) studied with the biosimilar to other indications[4]

1. US Food and Drug Administration. *Guidance for Industry: Scientific Considerations in Demonstrating Biosimilarity to a Reference Product*. Silver Spring, MD: FDA; 2015. **2.** McCamish M. Presented at EMA Workshop on Biosimilars; London; October 2013. **3**. Weise M, et al. *Blood*. 2012;120(26):5111-5117. **4.** Jenkins J. Biosimilars in the US: Progress and Promise. October 27, 2016. https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM526935.pdf. Accessed May 10, 2018.

Pfizer Biosimilars

Interchangeability Designation Is an Additional Standard, and Is Not Required for a Physician to Change Therapy to a Biosimilar

To be designated interchangeable[1,2]:

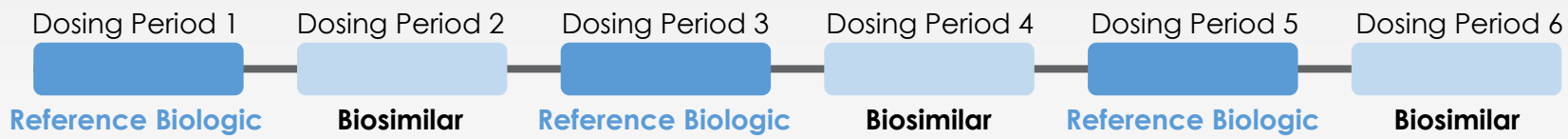
The biological product:

- Must be biosimilar to the reference biologic
- Must be expected to produce the same clinical result as the reference biologic in any given patient

For a biological product administered more than once to a patient:

- The risk in terms of safety or diminished efficacy of alternating or switching between the use of the biological product and the reference biologic is not greater than the risk of using the reference biologic without such alternating or switching

Alternation:



The FDA issued draft guidance related to interchangeability designation in January 2017[2]

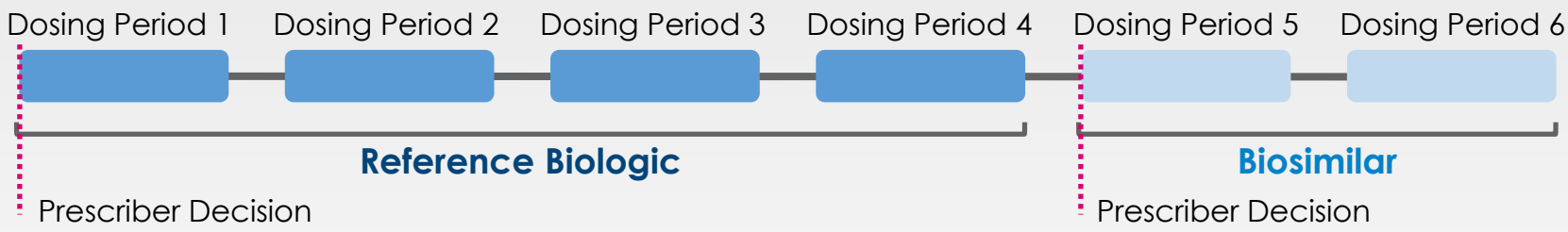
1. US Food and Drug Administration. *Guidance for Industry: Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009.* Silver Spring, MD: FDA; 2015. **2.** US Food and Drug Administration. *Guidance for Industry: Considerations in Demonstrating Interchangeability With a Reference Product.* Silver Spring, MD: FDA; 2017.

Pfizer Biosimilars

Physicians May Prescribe a Biosimilar in the Same Manner as Other Medications

Physicians may prescribe a biosimilar in the same manner as they would prescribe other medications—including prescribing a biosimilar for patients currently stable on the reference biologic[1]

Physician-Directed Switching:



Decisions to prescribe a biosimilar to patients currently stable on the reference biologic are not restricted by FDA guidance or the Biologics Price Competition and Innovation Act[1-3]

1. US Food and Drug Administration. *Purple Book: Lists of Licensed Biological Products With Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations.* https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/ucm411418.htm. Accessed May 10, 2018. **2.** US Food and Drug Administration. *Guidance for Industry: Considerations in Demonstrating Interchangeability With a Reference Product.* Silver Spring, MD: FDA; 2017. **3.** US Congress. United States Public Health Service Act, Sec. 262 Regulation of Biological Products. 42USC262. http://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/pdf/USCODE-2010-title42-chap6A-subchapII-partF-subpart1-sec262.pdf. Accessed May 10, 2018.

Pfizer Biosimilars

Substitution of Biosimilars With an Interchangeability Designation May Be Addressed by State Law[1-3]

Substitution at the Pharmacy[1-4]

- According to the FDA, products designated interchangeable may be substituted at the pharmacy level for the reference biologic without the intervention of the prescribing health care provider[1]
- Many states have considered legislation establishing standards for substitution of a biosimilar product to replace the reference biologic[2,a]
- Such legislation may include the following features[2-4]:
  - Any substituted biosimilar must first be designated "interchangeable" by the FDA
  - The prescriber would be able to prevent substitution by stating "dispense as written"
  - The prescriber must be notified of any substitution made by the pharmacy
  - Requirements for pharmacy record keeping when a biosimilar is substituted for a reference product

Many states have enacted laws concerning biosimilars and biosimilar substitution—specific legislation may vary by jurisdiction[2]

[a]**Additional information on US states that have enacted laws on substitution:** http://www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx

1. US Food and Drug Administration. *Guidance for Industry: Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009*. Silver Spring, MD: FDA; April 2015. **2.** National Conference of State Legislatures. http://www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx. Accessed May 10, 2018. **3.** Benedict AL. *J Law Biosci*. 2014;1(2):190-201. **4.** Li E, et al. *J Manag Care Spec Pharm*. 2015;21(7):532-539.

Pfizer Biosimilars

FDA Purple Book: A List of Licensed Biological Products

- The FDA Purple Book provides a list of all **biological products licensed by the FDA**, including biosimilars and interchangeable biologics
- The list provides information on:

  - **Date of product licensure** under the 351(a) of the PHS Act and whether the biological product was evaluated for reference product exclusivity under section 351(k)(7)
  - Whether the biological product has been determined by FDA to be **biosimilar to or interchangeable** with a reference biological product (an already-licensed FDA biological product)

- Biosimilars may still be designated interchangeable by the FDA while final guidance is underway

US Food and Drug Administration. *Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations.* https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredeveloped andapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/ucm411418.htm. Accessed May 10, 2018.

Pfizer Biosimilars

Key Points

- The FDA has stated that a biosimilar may be licensed for one or more indications of the reference product not studied clinically with the biosimilar
  - Biosimilar extrapolation occurs from the reference biologic to the biosimilar, when scientifically justified, based on all available data—not from the indication(s) studied with the biosimilar to other indications
  - Extrapolation is not automatic and will be determined based on the "totality of evidence" and scientific justification
- Interchangeability designation is an additional standard, and is not required for a physician to switch a patient to a biosimilar
  - Physicians may prescribe a biosimilar in the same manner as they would prescribe other medications—including prescribing a biosimilar for patients currently stable on the reference biologic
  - According to the FDA, products designated interchangeable may be substituted at the pharmacy level for the reference biologic without the intervention of the prescribing health care provider
  - State law will govern substitution of biosimilars that have an interchangeability designation

How Biosimilars May Help Bring Value to Patients

Pfizer Biosimilars

Many Commercially Insured Patients Have High Coinsurance Requirements for Medical Specialty Drugs

>50% of commercial payers **required coinsurance** for specialty drugs covered under the medical benefit in 2016[1]

Coinsurance for Specialty Drugs in Medical Sites of Care[2]

	Physician Office	Home Infusion	Outpatient Hospital
Coinsurance % (mean)	21%	21%	22%

In many cases—especially for economically vulnerable patients—**out-of-pocket (OOP) costs reduce or prevent access to prescribed medications**, and this **negatively impacts both quality of life and the course of disease**[3]

1. Magellan RX Management. *Medical Pharmacy Trend Report.* 2016. 7th ed. https://www1.magellanrx.com/media/604882/2016mrxtrendreport_final.pdf. Accessed May 10, 2018. **2.** EMD Serono, Inc. EMD Serono Specialty Digest. Managed Care Strategies for Specialty Pharmaceuticals. 2017. 13th ed. https://specialtydigestemdserono.com. Accessed May 10, 2018. **3.** Patient Access Network Foundation. Cost Sharing and Access to Prescription Medications. https://panfoundation.org/files/PAN-Issue-Brief-1.pdf. December 2016. Accessed May 10, 2018.

Pfizer Biosimilars

For Medicare Patients, Annual OOP Costs Associated With Biologic Therapy May Be Substantial[1]

Medicare beneficiaries

- Pay **20%** coinsurance for most outpatient therapies, after deductibles are met[2]
- **14%** do not have supplemental coverage[3]

Depending on the therapy, the top 10 Medicare Part B-covered biologics with the highest OOP expenses may[1,a]:

Impact nearly **300,000 patients** annually

Incur annual OOP costs of **~$2,500-$15,000** for 14% of beneficiaries

Annual OOP costs may reach up to

~58% of the median income of Medicare beneficiaries[1,4,b]

[a]Based on average annual OOP costs per patient; excludes small molecules, hormones, and human immunoglobulin G therapies.
[b]Percentage based on the annual OOP cost for a biologic costing $15,119 and a median per capita income of $26,200 reported for Medicare population in 2016.[4]

1. Centers for Medicare & Medicaid Services. Medicare Drug Spending Dashboard. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Dashboard/2015-Medicare-Drug-Spending/medicare-drug-spending-dashboard-2015-data.html. Accessed May 10, 2018. **2.** Medicare.gov. Medicare 2018 costs at a glance. https://www.medicare.gov/your-medicare-costs/costs-at-a-glance/costs-at-glance.html. Accessed May 10, 2018. **3.** Kaiser Family Foundation. A Primer on Medicare – Key facts about the Medicare program and the people it covers. http://files.kff.org/attachment/report-a-primer-on-medicare-key-facts-about-the-medicare-program-and-the-people-it-covers. March 2015. Accessed May 10, 2018. **4.** Kaiser Family Foundation. Issue Brief. Income and assets of Medicare beneficiaries, 2016–2035. http://files.kff.org/attachment/Issue-Brief-Income-and-Assets-of-Medicare-Beneficiaries-2016-2035. April 2016. Accessed May 10, 2018.

Pfizer Biosimilars

How Biosimilars May Help to Bring Value to Patients

Biosimilars may…

Improve access to biologics

- Biosimilars have the potential of offering additional treatment choices to patients, physicians, and payers at a lower cost to the health care system[1-3]
  - These savings to the health care system may **enable more patients to have access to biologics**, which could result in improved health outcomes for patients

Help reduce the OOP costs of biologic medicines

- It is expected that health care providers, such as clinics or hospitals, will be able to acquire biosimilars at a lower wholesale cost than their reference products[2,3]
  - Because of this, biosimilars may have the **potential to lower OOP costs for patients with cost-sharing requirements**, such as coinsurance and copayments

Patients who may pay less in the form of coinsurance:

Patients with Medicare Part B without supplemental coverage[4,5]

Patients with private insurance required to pay coinsurance for specialty drugs, including biologics[2,6]

1. IMS Health. Delivering on the Potential of Biosimilar Medicines: The Role of Functioning Competitive Markets. London, UK: IMS Health Incorporated; March 2016. **2.** Mulcahy AW, et al. *The Cost Savings Potential of Biosimilar Drugs in the United States*. Santa Monica, CA: RAND Corporation; 2014. **3.** US Food and Drug Administration. Biosimilar development, review and approval. https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm580429.htm. Accessed May 10, 2018. **4.** Medicare.gov. Medicare 2018 costs at a glance. https://www.medicare.gov/your-medicare-costs/costs-at-a-glance/costs-at-glance.html. Accessed May 10, 2018. **5.** Kaiser Family Foundation. A Primer on Medicare – Key facts about the Medicare program and the people it covers. http://files.kff.org/attachment/report-a-primer-on-medicare-key-facts-about-the-medicare-program-and-the-people-it-covers. March 2015. Accessed May 10, 2018. **6.** Magellan RX Management. *Medical Pharmacy Trend Report*. 2016. 7th ed. https://www1.magellanrx.com/media/604882/2016mrxtrendreport_final.pdf. Accessed May 10, 2018

Key Points

- Patients treated with specialty drugs, including biosimilars, may have high cost-sharing requirements, such as coinsurance and copayments
- Biosimilars have the potential of offering additional treatment choices at lower cost to the health care system
  - Savings to the health care system may enable more patients to have access to biologics, which could result in improved health outcomes overall
- It is expected that health care providers, such as clinics or hospitals, will be able to acquire biosimilars at a lower wholesale cost than their reference products
  - Hence, biosimilars may have the potential to lower OOP costs for patients with cost-sharing requirements

Program Summary

Extrapolation and interchangeability designation

- Extrapolation is not automatic and requires scientific justification in each indication not studied clinically
  - Biosimilar extrapolation occurs from the reference biologic to the biosimilar, when scientifically justified, based on all available data—not from the indication(s) studied with the biosimilar to other indications
- Draft guidance on interchangeability designation was issued by the FDA in January of 2017
  - An interchangeability designation is not required for a physician to switch a patient to a biosimilar

Potential value to patients and the health care system

- Biosimilars may have the potential to lower OOP costs for patients with cost-sharing requirements
- Savings to the health care system may enable more patients to have access to biologics, which could result in improved health outcomes overall
- As the demand and spending for biologics continue to grow, the introduction and successful adoption of biosimilars have the potential to provide additional treatment choices at a lower cost to the health care system

Pfizer Biosimilars

For More Information

- To provide clinicians with an in-depth look into the science of biosimilars, Pfizer Biosimilars has established a peer-to-peer professional speakers' bureau
- Available speaker programs include:
  - Biosimilars: An Overview for Health Care Professionals
  - A Practical Approach to Biosimilar Implementation
  - Beyond Being Biosimilar: A Closer Look at the US FDA Interchangeability Designation, Substitution, and Extrapolation of Biosimilarity
- For more information or to arrange a speaker program, contact your Pfizer Biosimilars Representative
- **For more information on biosimilars, also visit PfizerBiosimilars.com**

Pfizer Biosimilars

Thank You!

For more information on biosimilars, visit PfizerBiosimilars.com

May 2018
PP-BIO-USA-0414

Pfizer Biosimilars