



**NABP**

National Association of  
Boards of Pharmacy

# A Closer Look at FDA's Interchangeable Biosimilar Approvals

Friday, February 11, 2022



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National Association of  
Boards of Pharmacy

## Financial Disclosures

Our speakers Ilisa Bernstein and John Clay Kirtley declare that they do not have a current affiliation or financial arrangement with any ineligible companies that may have a direct interest in the subject matter of this continuing pharmacy education (CPE) activity within the past 24 months.

Our speaker Robert Popovian declares that he currently has an affiliation or financial arrangement with Pfizer, Inc, as a shareholder and with Boehringer Ingelheim as a consultant.

Additionally, NABP staff involved in the planning of this activity do not have any current affiliation or financial arrangement with any ineligible companies that may have a direct interest in the subject matter of NABP's CPE program within the past 24 months.

All relevant financial relationships have been mitigated.



# Regulatory Pathways for Biosimilars

**Ilisa BG Bernstein, PharmD, JD, FAPhA**

Senior Vice President, Pharmacy Practice and Government Affairs  
American Pharmacists Association

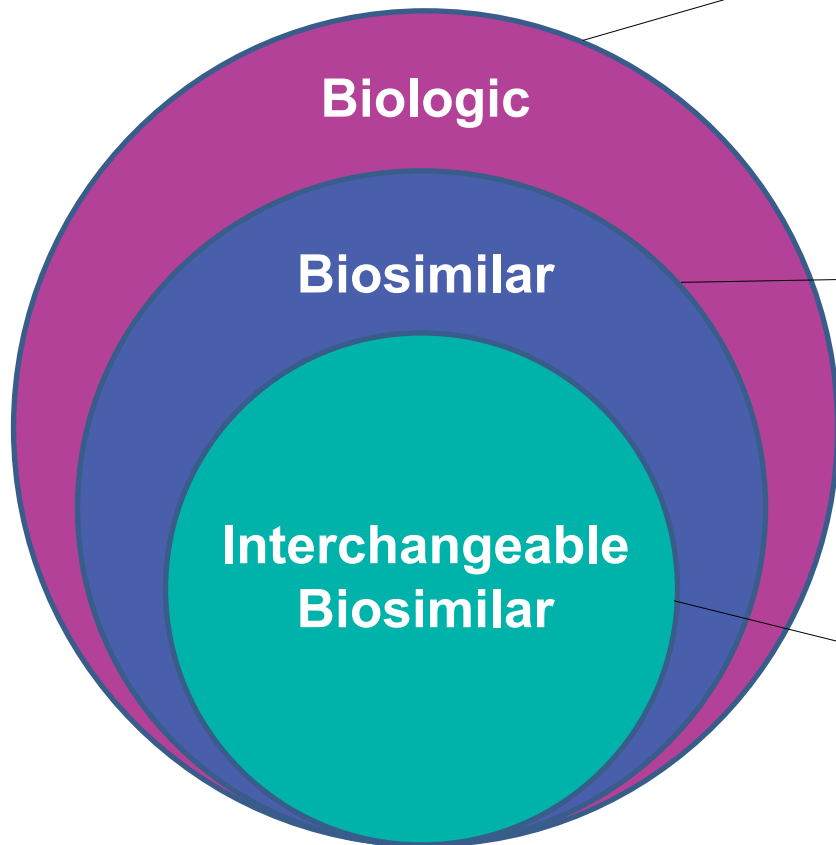
February 11, 2022

NABP webinar: A Closer Look at FDA's Interchangeable Biosimilar Approvals

*For Every Pharmacist. For All of Pharmacy.*

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# Definitions

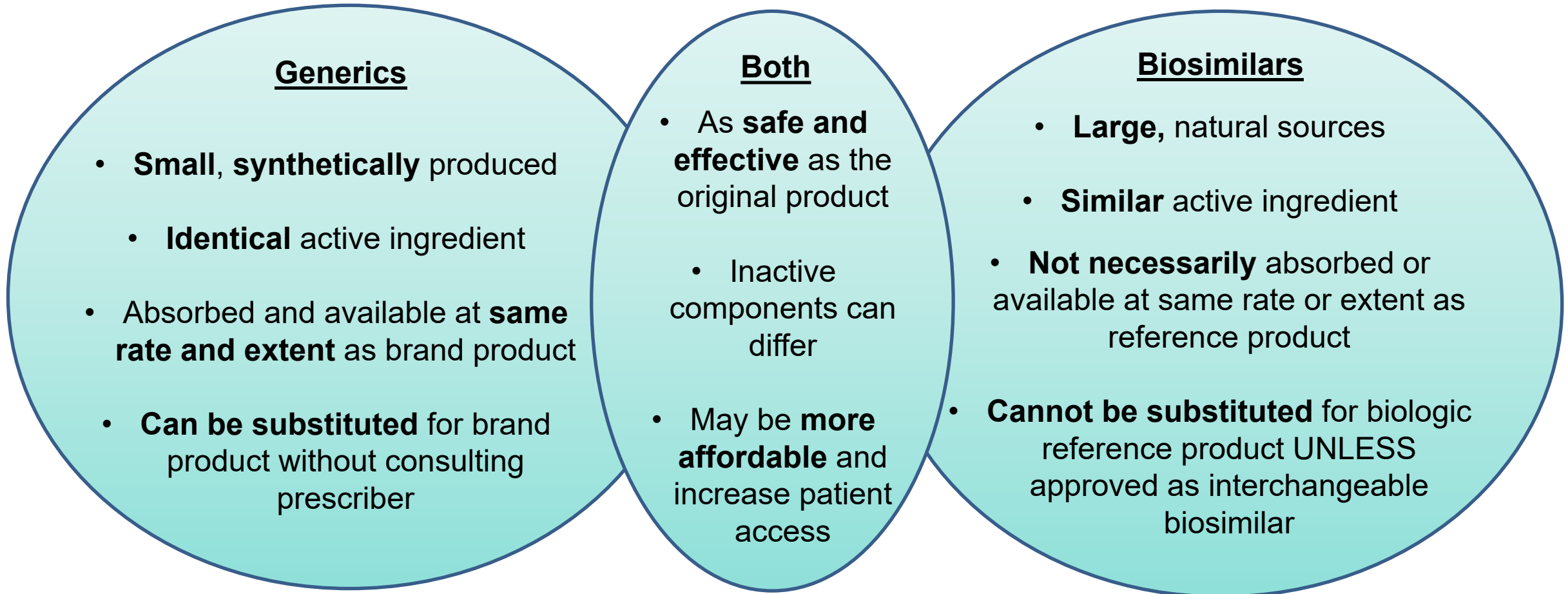


A large, complex molecule made from living cells.

A biologic that is *highly similar* compared to the biologic reference product.

A biosimilar that produces the same clinical outcome as the biologic reference product in any given patient.

# Generics vs. Biosimilars



# Generic vs. Biosimilar Approval Process

Generics	Biosimilars
<p>Both have <b>abbreviated</b> pathways (avoid repeating costly trials) compared to their original products, but must meet <b>rigorous standards</b> to ensure safety, efficacy, and quality.</p>	
<ul style="list-style-type: none"> <li>• <b>Less intensive</b> process               <ul style="list-style-type: none"> <li>• Abbreviated New Drug Application (ANDA)</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• <b>More intensive</b> process               <ul style="list-style-type: none"> <li>• Application comparing product to reference product</li> </ul> </li> </ul>
<ul style="list-style-type: none"> <li>• Must prove <b>bioequivalence</b> to brand product               <ul style="list-style-type: none"> <li>• Small, short <b>clinical study</b> showing same bioavailability of same active ingredient</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Must prove <b>highly similar</b> in purity, chemical identity, and bioactivity to reference product               <ul style="list-style-type: none"> <li>• <b>Drug analytical studies</b></li> </ul> </li> <li>• Must prove <b>no clinically meaningful differences</b> in safety and effectiveness to reference product               <ul style="list-style-type: none"> <li>• <b>Clinical studies</b></li> </ul> </li> </ul>

FDA. Biosimilar and interchangeable products. [www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products](http://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products).

FDA. Biosimilar and interchangeable biologics: more treatment choices. [www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices](http://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices).

Baghdadi R. Health policy brief: biosimilars. Health Affairs. 2017. doi:10.1377/hpb20170721.487227.

FDA. Interchangeable biologic products. <https://www.fda.gov/media/151094/download>.

# Interchangeable Biosimilar Approval Process

- FDA reviews biosimilars for interchangeability upon manufacturer application submission.
- Must meet **biosimilar approval requirements PLUS** additional testing to confirm:

Produces the **same clinical result** as the biologic reference product in any given patient.



When administered to a patient more than once, **safety and efficacy risks of switching** with the reference product are **not greater than** solely using the reference product.

- Once approved, **may be substituted** by a pharmacist for the reference product, subject to state laws (prescriber consultation/approval, communication, and documentation).

# Approval for One Indication May Be Extrapolated for Others

## The concept of extrapolation is based on:

- ✓ All available data and information in the biosimilar application
- ✓ FDA's previous finding of safety and efficacy for other approved indications for the reference product
- ✓ Knowledge and consideration of various scientific factors for each indication



- Approval without direct studies
- Totality of evidence
- Improves access and options

## What's Next?

### Biosimilar User Fee Amendments III

- Reauthorizes collection of user fees from 2023-2027
- Performance goals for application review, meetings, communications, guidances, facility assessments, resource management, hiring, IT

## Self-assessment Question 1

Which statement is correct about biosimilars?

- a. Biosimilars must meet a lower standard for safety, efficacy, and quality compared to the reference product.
- b. Biosimilars have the same standard for safety, efficacy, and quality compared to the reference product.
- c. Biosimilars must meet a higher standard for safety, efficacy, and quality as an interchangeable biosimilar.
- d. Biosimilars do not need to meet any standard for safety, efficacy, and quality.

## Self-assessment Question 2

True or False:

An interchangeable biosimilar must demonstrate that it is bioequivalent to the reference product.

# Robert Popovian, PharmD, MS

## Founder, Conquest Advisors

Health Matters Podcast

Apple Podcasts: <https://cutt.ly/5TLK3ce> Spotify: <https://cutt.ly/ATLKiIM>

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# Brand Biologics and Biosimilars Market

- Biologics represent 43% of invoice-level medicine spending in the United States, reaching \$211 billion in 2019 <sup>1</sup>
- Humira revenue in the U.S. in 2020 = >\$16 billion <sup>2</sup>
- 7 biosimilars of Humira will launch in 2023 <sup>3</sup>
- For 2019, 4 out of top 10 selling drugs in Medicare Part B have biosimilars available in the market, 3 other biosimilars are approved not yet available in the market <sup>4,5</sup>
- In the past 5 years, biosimilars have created \$9.8 billion in savings with an average of \$238 million annual out-of-pocket savings for patients <sup>6</sup>

1. <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/iqvia-institute-biosimilars-in-the-united-states.pdf>

2. <https://www.prnewswire.com/news-releases/abbvie-reports-full-year-and-fourth-quarter-2020-financial-results-301221231.html>

3. <https://www.cardinalhealth.com/en/product-solutions/pharmaceutical-products/biosimilars/biosimilars-report.html>

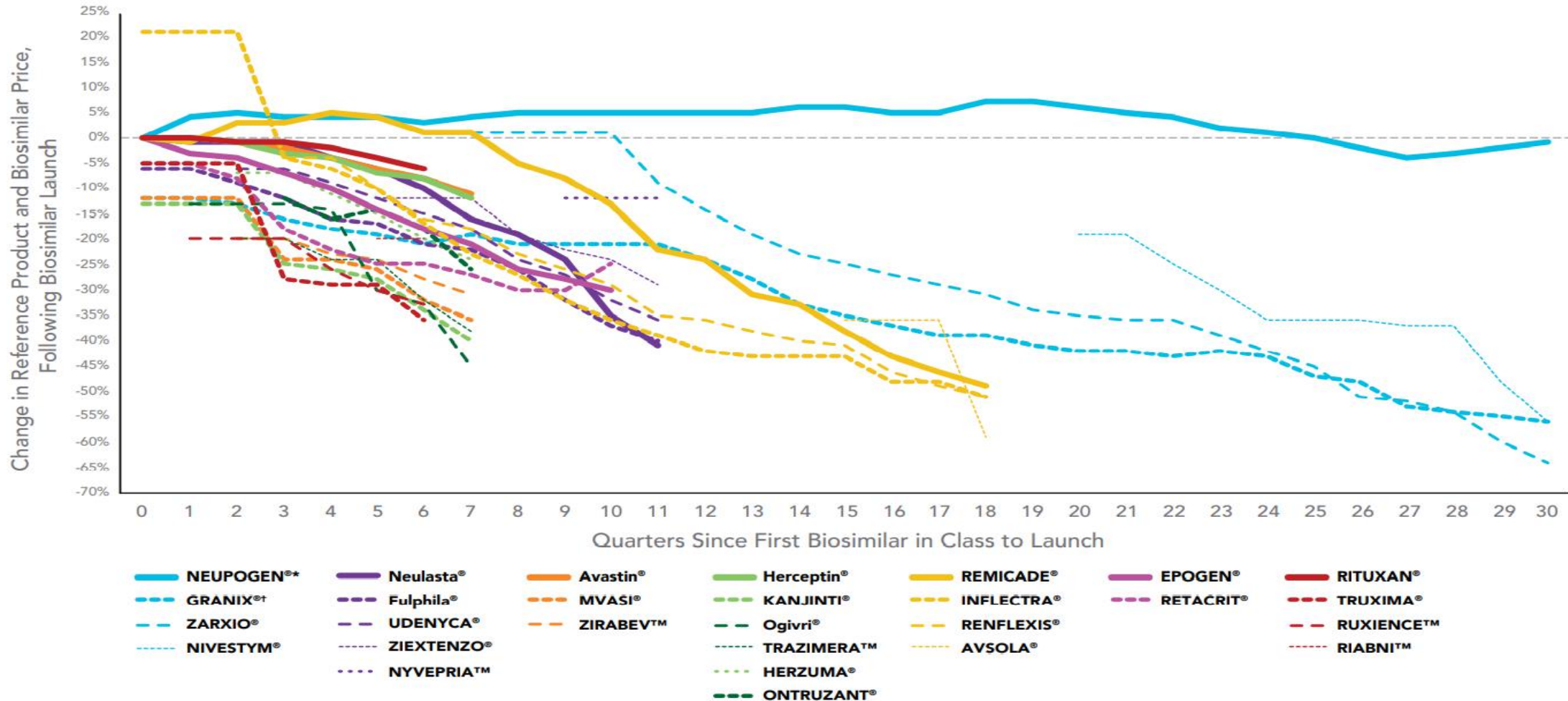
4. <https://www.kff.org/medicare/issue-brief/relatively-few-drugs-account-for-a-large-share-of-medicare-prescription-drug-spending/>

5. <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/iqvia-institute-biosimilars-in-the-united-states.pdf>

6. [https://www.amgenbiosimilars.com/commitment/-/media/Themes/Amgen/amgenbiosimilars-com/Amgenbiosimilars-com/pdf/USA-CBU-80962\\_Amgen-2021-Biosimilar-Trends-Report.pdf](https://www.amgenbiosimilars.com/commitment/-/media/Themes/Amgen/amgenbiosimilars-com/Amgenbiosimilars-com/pdf/USA-CBU-80962_Amgen-2021-Biosimilar-Trends-Report.pdf)

# Biosimilar Competition Does Drive Down Prices

**Figure 5.** Downward Trend in ASP for Biosimilars and Reference Products Over Time<sup>2</sup>



[https://www.amgenbiosimilars.com/commitment/-/media/Themes/Amgen/amgenbiosimilars-com/Amgenbiosimilars-com/pdf/USA-CBU-80962\\_Amgen-2021-Biosimilar-Trends-Report.pdf?](https://www.amgenbiosimilars.com/commitment/-/media/Themes/Amgen/amgenbiosimilars-com/Amgenbiosimilars-com/pdf/USA-CBU-80962_Amgen-2021-Biosimilar-Trends-Report.pdf?)

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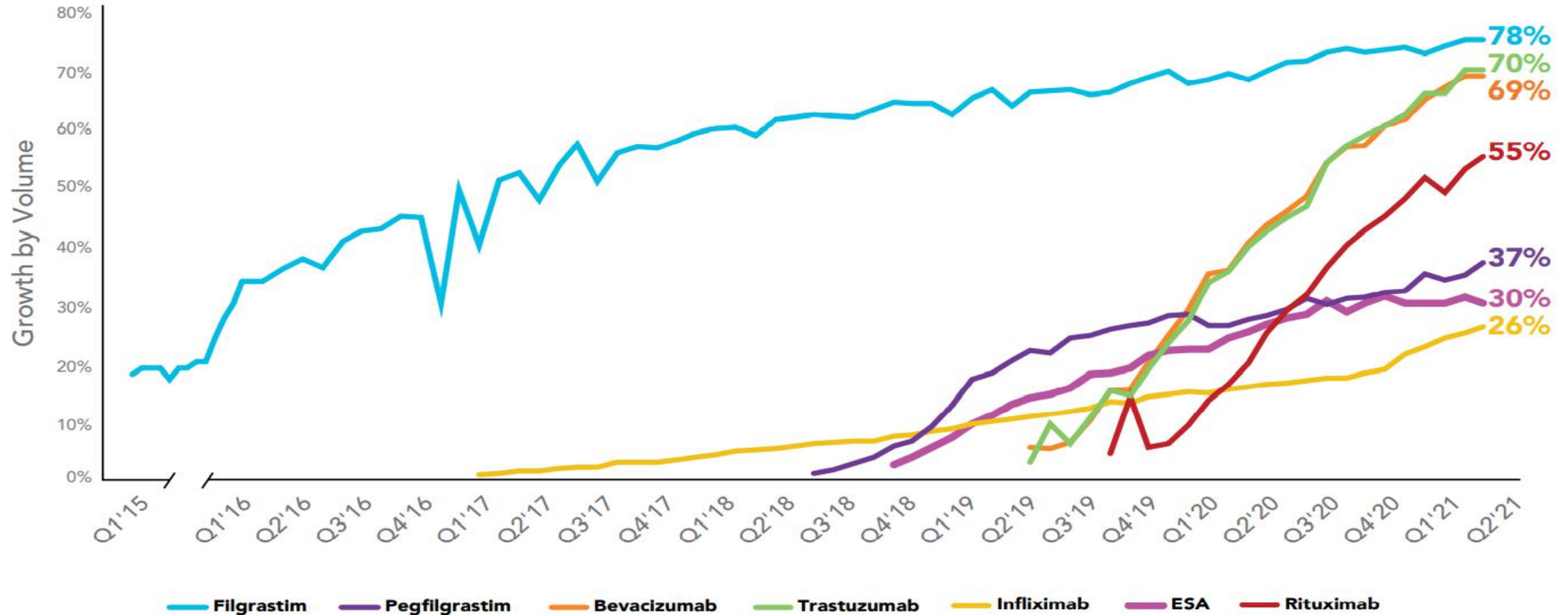
Apple Podcasts: <https://cutt.ly/5TLK3ce> Spotify: <https://cutt.ly/ATLKiIM>

rpopovian@gmail.com  
Twitter: @PopovianPharmD



# Competition Is Robust With Certain Classes

**Figure 6. Biosimilars Uptake Curve<sup>5</sup>**



[https://www.amgenbiosimilars.com/bioengage/-/media/Themes/Amgen/amgenbiosimilars-com/Amgenbiosimilars-com/pdf/USA-CBU-80961\\_Amgen-Biosimilars-Trend-Report.pdf](https://www.amgenbiosimilars.com/bioengage/-/media/Themes/Amgen/amgenbiosimilars-com/Amgenbiosimilars-com/pdf/USA-CBU-80961_Amgen-Biosimilars-Trend-Report.pdf)

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rpopovian@gmail.com  
Twitter: @PopovianPharmD

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# Payment Incentives Matter

Figure 13. Biosimilar Uptake Curve for Trastuzumab Products<sup>5</sup>

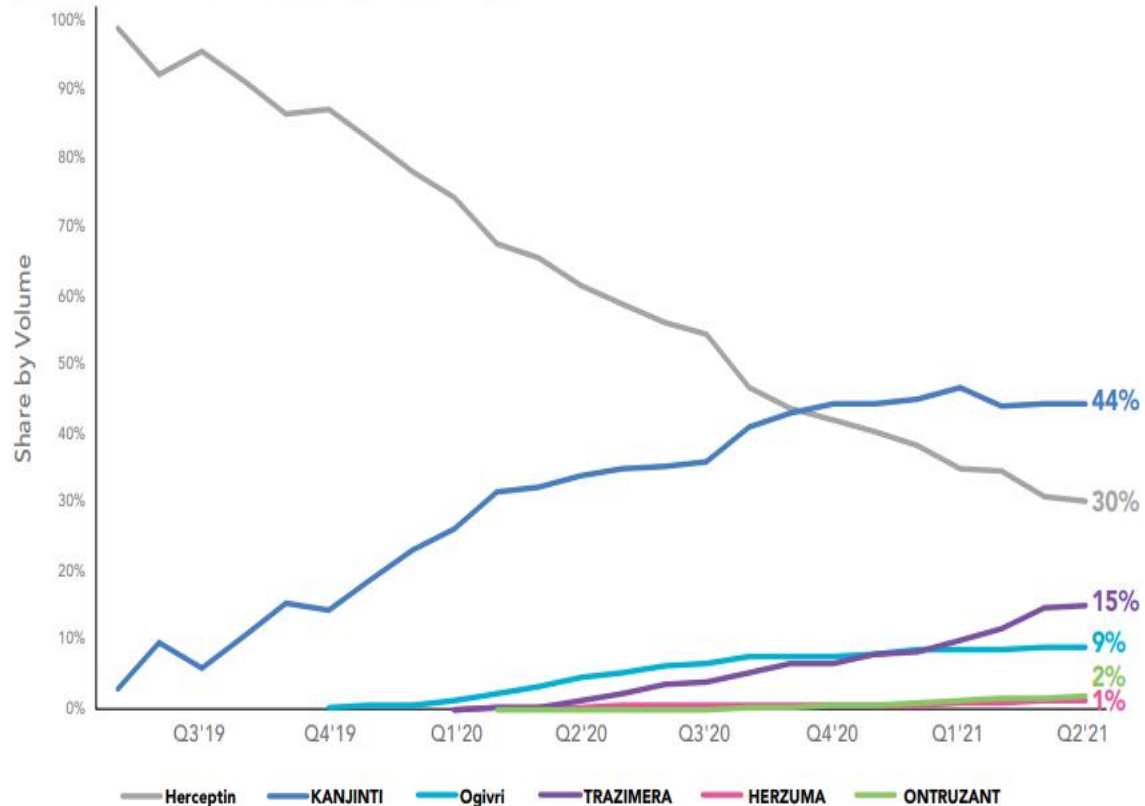
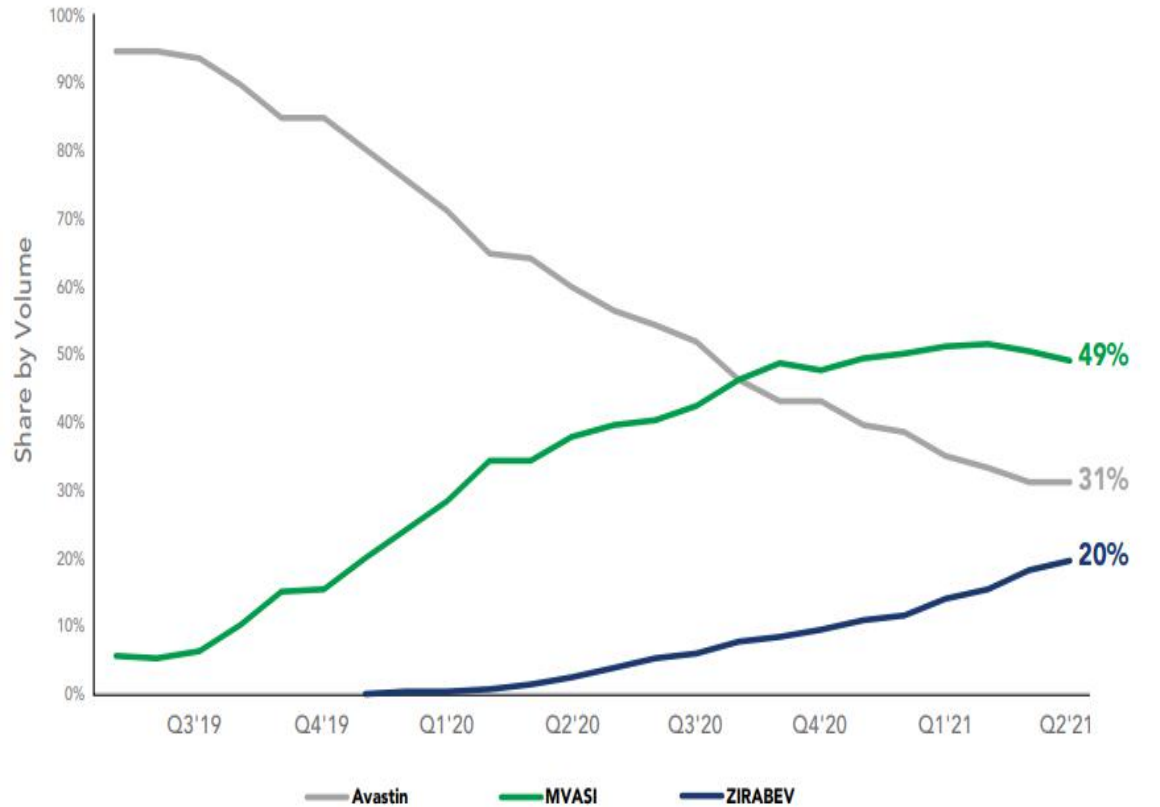


Figure 17. Biosimilar Uptake Curve for Bevacizumab Products<sup>5</sup>



[https://www.amgenbiosimilars.com/bioengage/-/media/Themes/Amgen/amgenbiosimilars-com/Amgenbiosimilars-com/pdf/USA-CBU-80961\\_Amgen-Biosimilars-Trend-Report.pdf](https://www.amgenbiosimilars.com/bioengage/-/media/Themes/Amgen/amgenbiosimilars-com/Amgenbiosimilars-com/pdf/USA-CBU-80961_Amgen-Biosimilars-Trend-Report.pdf)

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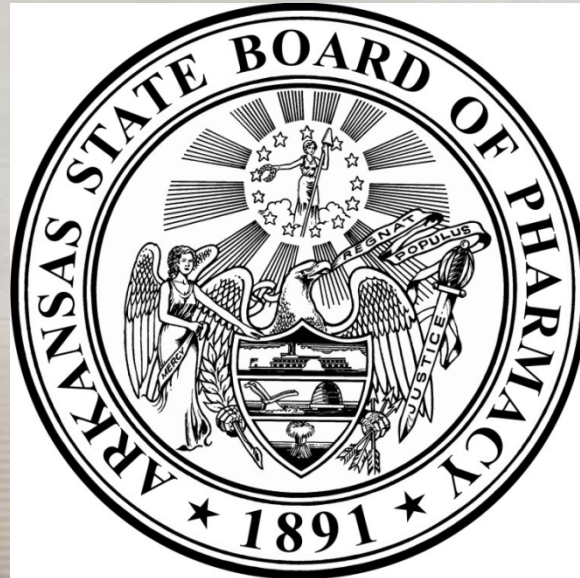
# Interchangeable Biosimilars

- Interchangeability for biosimilars is a regulatory designation
- Lack of interchangeability designation is NOT related to the safety and efficacy of a biosimilar
- State laws allow pharmacists to substitute a brand biologic with an interchangeable biosimilar without prior notification to the prescriber
- Lack of interchangeability designation does NOT prohibit a pharmacist from substituting a brand biologic with a biosimilar, the pharmacist is required to get authorization from the prescriber prior to substitution
- In all cases, pharmacists are required to inform the patient

# Self-Assessment Questions

- True or False? The ASP of most brand biologics have plummeted when a biosimilar is approved and introduced in the United States market.
- True or False? The lack of interchangeability designation impacts safety and efficacy assessment of a biosimilar.

# Arkansas Pharmacy Board Update



John Clay Kirtley, PharmD  
Executive Director

Arkansas State Board of Pharmacy

# Objectives

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- Explain the background for proving safety of biosimilar products in the US.
- Review different types of misinformation that is often seen when discussing biosimilar and interchangeable biologic products.

# Quick Thoughts in Health Care

- Why do we fight each other?
  - Money, Bad information, Bad attitudes
- Why do we lack updated knowledge?
  - Often, we fail to seek knowledge and have the attitude that it should be brought to us
- Why don't we help each other learn?
  - See Above
- What can we work together on?
  - Everything, Opioids, Scope
- How can we support each other?
  - Communication, Education

# Let's Talk – BIAS

A faded, sepia-toned background image of a classical building with a series of tall, fluted columns and a pedimented roof. The image is positioned on the right side of the slide, partially obscured by the text.

- Who is driving the information?
- Where are they driving the information?
- Why are they driving the information?

# Want a Similar Story?

- Ask your mentors about the arguments regarding generic drugs decades ago.
- Narrow Therapeutic Index Drugs

# ODD Arguments

- Attempts at statutes that limit this across all practice settings: this included limiting any formulary management approaches in hospitals
- Absolute misinformation via manufacturer organizations:
  - Risk for immunogenicity for alternate products or biosimilars
  - Biologics are not drugs and therefore the Board of Pharmacy has no authority without their statutory requests

# Biologics Aren't Drugs???

- **Biologics**—In the United States, all biologics are considered a subset of drugs, whether they are approved by FDA under the FD&C Act [and receive a new drug application (NDA)] or under the Public Health Service Act [PHS Act, where they receive a biologics license application (BLA)]. As a result, all PHS Act biologics are subject to the drug regulatory requirements of the FD&C Act, which means they are required to comply with the adulteration and misbranding provisions of the FD&C Act, including USP–NF compendial requirements. This is equally so for biologics approved under the longstanding PHS Act "351(a)" pathway, as well as the new "351(k)" pathway for biosimilars added by the 2010 healthcare reform legislation.

<https://www.usp.org/about/legal-recognition/standard-categories#biologics>

# 2014 Idaho

First, the biotechnology industry fully supports the substitution of biologics that have been deemed interchangeable by the Food and Drug Administration ("FDA"). We are not in favor of provisions – other than the universally supported prescriber "dispense as written" privilege, which is included in the Idaho draft rule – that would prevent the automatic substitution of an interchangeable biologic. As such, we are aligned with physicians and patients. There are no medical societies or patient groups that oppose substitution or propose restrictions on the substitution of interchangeable biologics.

Third, your letter inaccurately implies that FDA has taken a position on the merits of an after-the-fact communication of dispensing information to a prescriber. FDA has stated that substitution should occur without the intervention of the provider, but an after the fact communication is *not* an intervention. When specifically asked about the state pharmacy practice acts, FDA has stated that it *takes no position*.

Fourth, automatic substitution is not practiced in any well-regulated market outside the U.S. In fact, automatic substitution is not currently permitted in Europe, Canada or Japan. We do not suggest that automatic substitution would be unsafe in the U.S., but – contrary to the claim made in your letter – there is currently no experience with safe automatic substitution. Payer-mandated switching has occurred and has not resulted in reported safety issues. But, such switching occurs with the *knowledge of the provider and is not the same as automatic pharmacy substitution*.

# Overview of the Regulatory Framework and FDA's Guidance for the Development and Approval of Biosimilar and Interchangeable Products in the US

Leah Christl, Ph.D., Director of the Therapeutic Biologics and Biosimilars Staff/CDER/FDA

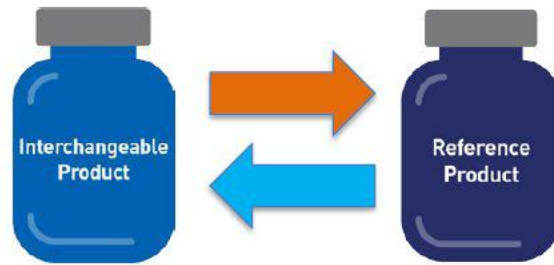
Sue Lim, M.D., Director of the Scientific Staff, TBBS/CDER/FDA



# FDA CE December 5, 2017

- **Interchangeability**
- Interchangeable or Interchangeability:
  - \*the biological product is **biosimilar** to the reference product;
  - \*it **can be expected** to produce the **same clinical result** as the reference product in **any given patient**; and
  - \***for a product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the product and its reference product is not greater than the risk of using the reference product without such alternation or switch.**
- An interchangeable product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

# Considerations in Demonstrating Interchangeability With a Reference Product



**Draft Guidance for Industry**

# Interchangeability

## Interchangeable or Interchangeability:

- the biological product is **biosimilar** to the reference product;
- it **can be expected** to produce the **same clinical result** as the reference product **in any given patient**; and
- for a product that is administered more than once to an individual, the risk in terms of **safety or diminished efficacy of alternating or switching** between use of the product and its reference product is not greater than the risk of using the reference product without such alternation or switch.

An interchangeable product **may be substituted** for the reference product without the intervention of the health care provider who prescribed the reference product.

# General Principles



- When a product is first licensed as a **biosimilar**, that licensure may be referenced to support a showing for this statutory criterion for demonstrating interchangeability
- FDA expects that sponsors will submit data and information to support a showing that that the proposed interchangeable product **can be expected** to produce the same clinical result as the reference product in ***all*** of the reference product's licensed conditions of use
  - The data and information may vary depending on the nature of the proposed interchangeable product.
  - The data and information should include a scientific justification as to why **any differences** that exist between the reference product and the proposed interchangeable product, with respect to the factors described in the guidance, **do not preclude a showing** that the proposed interchangeable product **can be expected** to produce the same clinical result as the reference product in any given patient.

## Additional Data and Information Needed to Support a Demonstration of Interchangeability

**Switching Study** to demonstrate that **the risk in terms of safety or diminished efficacy of alternating or switching** between use of the proposed interchangeable product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

# Biosimilars

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## Biosimilars

[Biosimilar and Interchangeable Products](#)

[Biosimilar Development, Review, and Approval](#)

[Prescribing Biosimilar and Interchangeable Products](#)

[Biosimilar Product Information](#)

[Industry Information and Guidance](#)

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[Curriculum Materials for Health Care Degree Programs | Biosimilars](#)



Content current as of:  
07/28/2021

Congress, through the Biologics Price Competition and Innovation Act (BPCI Act) of 2009, created an abbreviated licensure pathway for biological products that are demonstrated to be biosimilar to or interchangeable with an FDA-approved biological product. This pathway was established as a way to provide more treatment options, increase access to lifesaving medications, and potentially lower health care costs through competition.

FDA requires biosimilar and interchangeable biological products meet the Agency's rigorous approval standards. That means patients and health care professionals will be able to rely upon the safety (and effectiveness of the biosimilar or interchangeable product, just as they would the reference product.

[New Fact Sheets for Health Care Providers \(New\)](#)

[Consumer Update \(CU\)](#)

[Joint FDA/FTC Statement](#)

[Biosimilars Action Plan \(BAP\)](#)

[Educational Materials for Patients](#)

# Biosimilars: Clinical Considerations and Educational Needs



*87<sup>th</sup> Annual Meeting: NABP/AACP District VI, VII, VIII  
October 23, 2012*

*Cynthia Reilly, BSP Pharm  
Director, Practice Development Division  
American Society of Health-System Pharmacists*



**American Society of  
Health-System Pharmacists®**

**TOGETHER WE MAKE A GREAT TEAM**



# Barriers and Challenges to Adoption of Biosimilars in the US

16 January 2019, 9:45am – 10:45am  
Gillian Woollett, MA, DPhil. [gwoollett@Avalere.com](mailto:gwoollett@Avalere.com)  
**Avalere Health** | An Inovalon Company

# Working Definitions for Biologics

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US HAS THREE OPTIONS - BIOLOGIC, BIOSIMILAR, INTERCHANGEABLE BIOLOGIC; MOST PLACES HAVE TWO OPTIONS - BIOLOGIC, BIOSIMILAR

**Biologic**: Worldwide, a simple and practical definition of a biologic is a product **the active ingredient of which is made in a living system**

**Biosimilar**: A **biological product** that is approved based on a showing that it is **highly similar** to an already approved biological product, and has **no clinically meaningful differences** in terms of safety and effectiveness from the reference product

**Interchangeable Biologic**: FDA designation that switching patients between such products can be made by a pharmacist

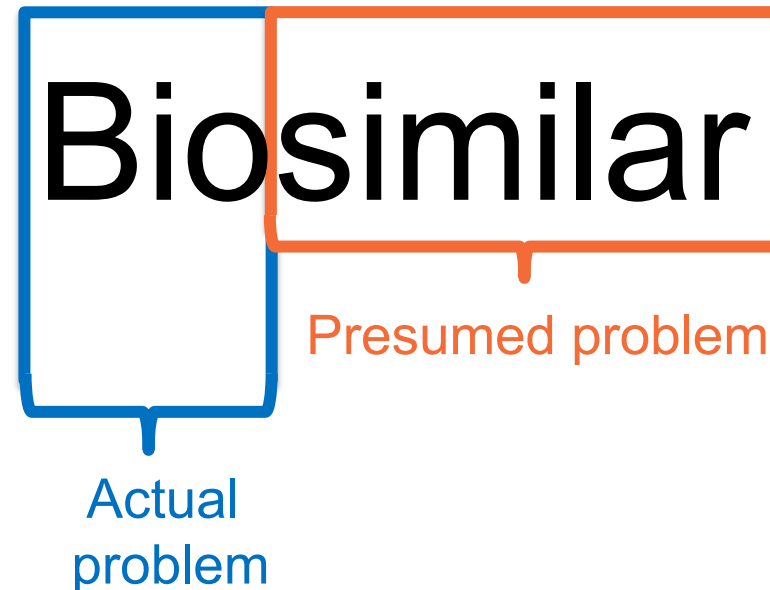
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 In many ways, Biosimilars are to Biologics, as Generics are to Drugs


# The Name Does Not Change The Product in the Tube

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SCIENTIFIC AND REGULATORY PRINCIPLES ARE ESTABLISHED  
FOR ALL BIOLOGICS



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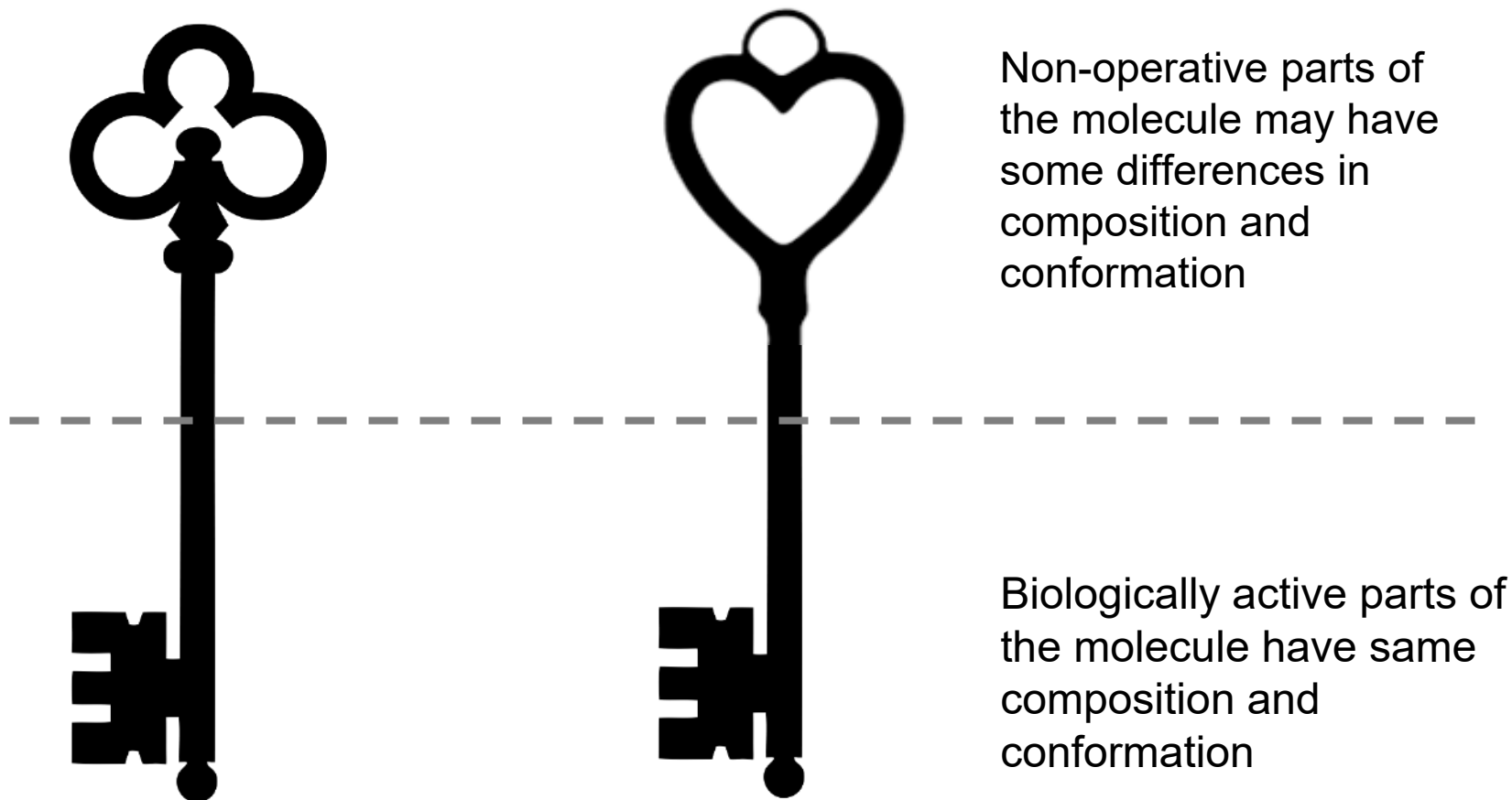
 **Solved by Comparability<sup>1</sup> in 1996, which established the “highly similar” analytical standard as a way to define a biologic**

Created through discussions with Ken Williams, Avalere


1. Demonstration of Comparability of Human Biological Products, Including Therapeutic Biotechnology-derived Products April 1996 [here](#)

# Tertiary Structures (“Folds”) of Biologics May Differ, But the Key Functional Groups Remain the Same

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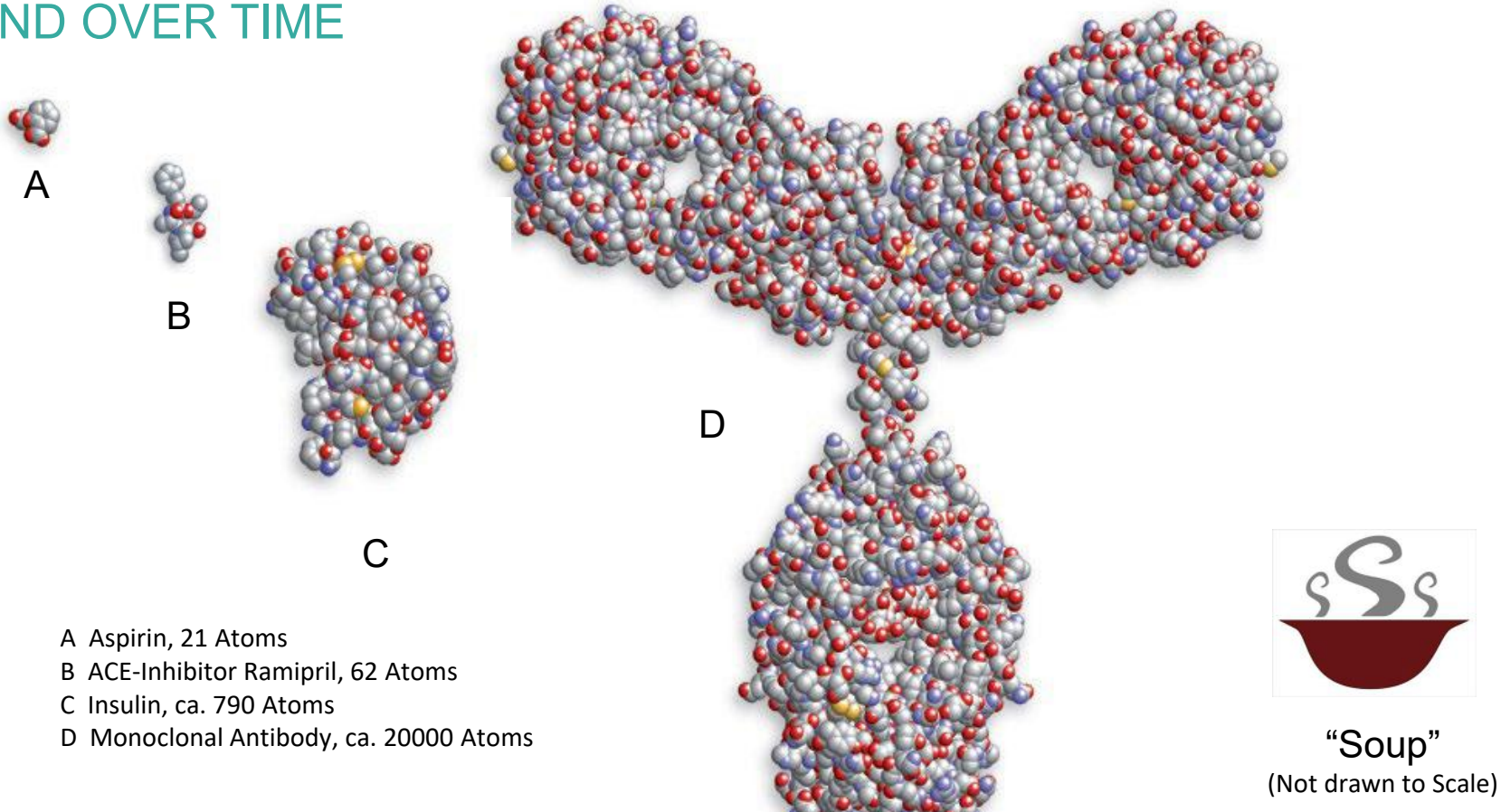


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 **Non-operative changes may occur in all biologics, not only biosimilars, based on manufacturing conditions**

# Biologics Vary in Complexity – Even Recombinant Ones

AND MANY ARE COMPLEX MIXTURES THAT VARY BATCH-TO-BATCH AND OVER TIME



Once approved, complexity is no longer a relevant argument

# Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product

Therapeutic protein products can be produced in microbial cells (prokaryotic or eukaryotic), cell lines (e.g., mammalian, avian, insect, plant), or tissues derived from animals or plants. **It is expected that the expression construct for a proposed product will encode the same primary amino acid sequence as its reference product.** However, minor modifications, such as N- or C terminal truncations (eg, the heterogeneity of C-terminal lysine of a monoclonal antibody) that are not expected to change the product performance, may be justified and should be explained by the sponsor.

# Scientific Considerations in Demonstrating Biosimilarity to a Reference Product

SAME LANGUAGE AGAIN

# Manufacturing Changes Are a Regulatory Norm – Subject to Review in Each Market and Each Biologic Becomes “Biosimilar” to Itself

A PRODUCT THAT IS “HIGHLY SIMILAR” HAS THE “SAME” ACTIVE INGREDIENT, AND THE CLINICAL OUTCOME IS EXPECTED TO BE THE “SAME” (see ICH Q5E)

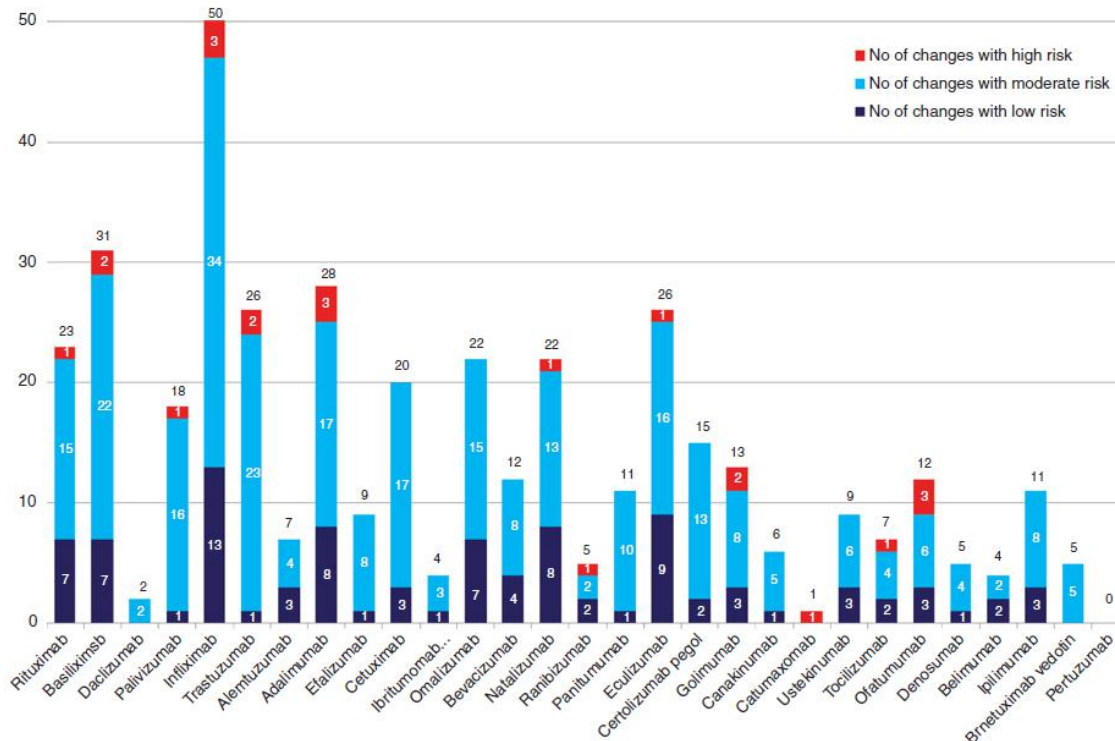


Figure 2. Number of manufacturing changes for monoclonal antibodies in their European Public Assessment Reports according to risk category (during the search period all non-proprietary names relate only to the trade named medicines listed in Table 1).

Each manufacturing change is approved by the regulators in that jurisdiction:

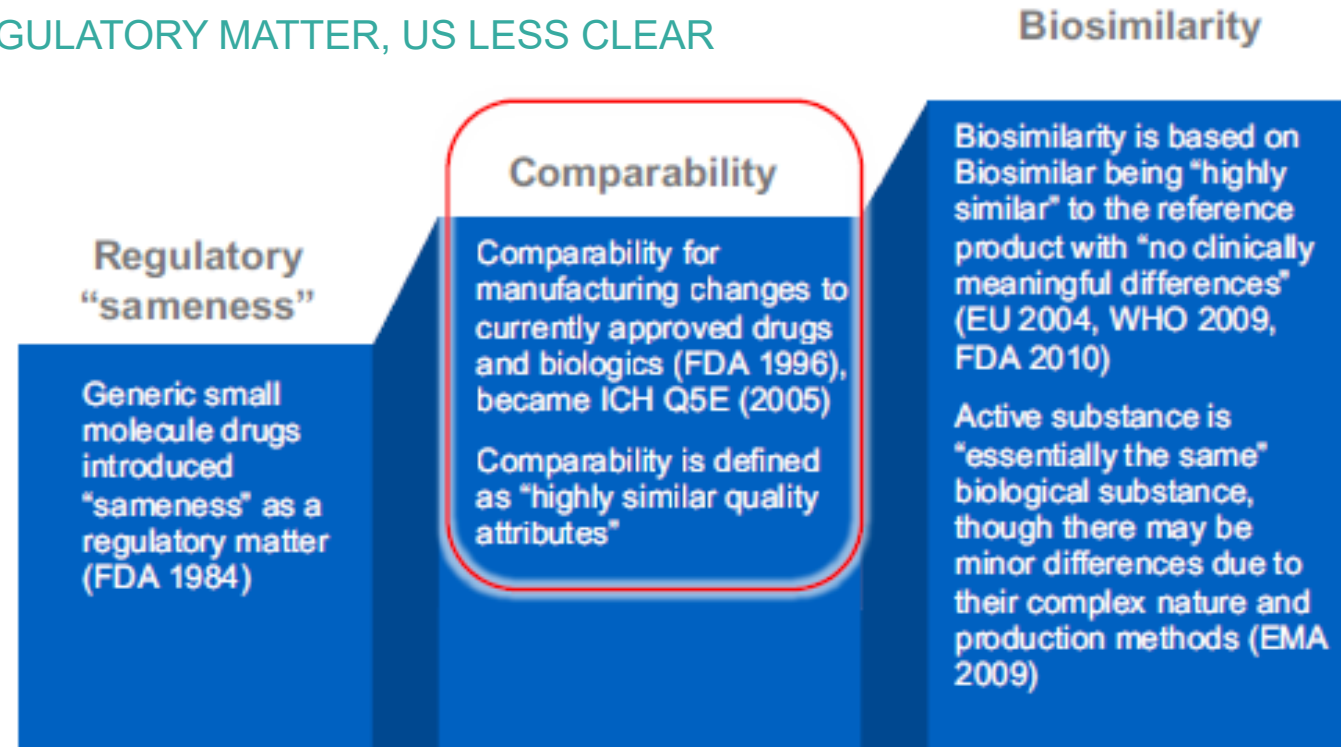
- Complete **extrapolation** between all indications
- **Interchangeability**
- The patient/HCP is not informed of the change because **the label on the product does not change** - the nonproprietary name stays the same when high similarity is established



**THE GOOD NEWS: Extensive experience with the reference products among all stakeholders, including regulators**

# Comparability and Biosimilarity Both Require High Similarity

AS A SCIENTIFIC MATTER, COMPARABILITY AND BIOSIMILARITY ARE THE SAME  
AS A REGULATORY MATTER, THEY ARE THE SAME IN EU  
AS A REGULATORY MATTER, US LESS CLEAR



 **Consistency in the application of regulatory science in increasingly important, and core to regulators credibility**

# How Safe Are Biosimilars?

- Biosimilars have been used for years in the US and Europe. They are regarded as having the same safety profile as the innovator products. In fact, the April 27, 2017, publication from “Biosimilars in the EU” Information guide for healthcare professionals, Prepared jointly by the European Medicines Agency and the European Commission clearly summarized,
- “The evidence acquired over 10 years of clinical experience shows that biosimilars approved through EMA can be used as safely and effectively in all their approved indications as other biological medicines.”
- “Because biosimilars are made in living organisms there may be some minor differences from the reference medicine. These minor differences are not clinically meaningful, i.e., no differences are expected in safety and efficacy. Natural variability is inherent to all biological medicines and strict controls are always in place to ensure that it does not affect the way the medicine works or its safety.”

# Interchangeable Biologic Products?

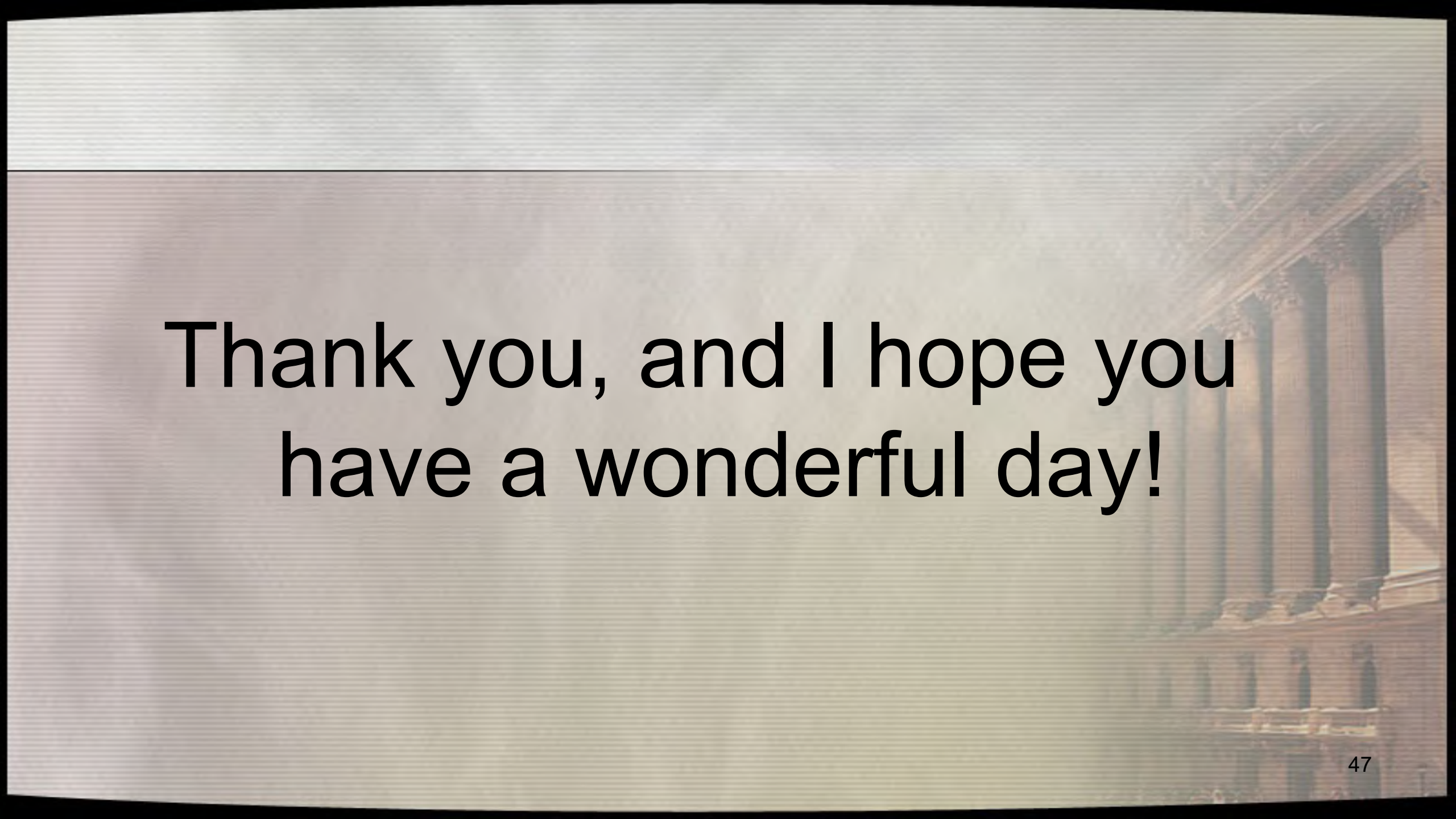
- The designation ‘Interchangeable Biologic’ is a step above and beyond that of the designation ‘Biosimilar’ and should prove that there is additional proof of patient safety beyond that of a drug simply designated as a ‘Biosimilar’.
- Products in the Purple Book designated as Interchangeable Biologics are determined by the FDA to have no clinically meaningful differences between safety, purity and potency of the product, and can be expected to produce the same clinical result as the reference product in any given patient. Manufacturers must prove that not only are these products clinically equivalent but that they also pose no additional safety risks to patients even if the patient switches between multiple interchangeable products multiple times.

# Questions for Feedback

The background of the slide features a faded, sepia-toned photograph of a grand classical building with a series of tall, fluted columns and a prominent pediment. The image is positioned on the right side of the slide, partially overlapping the text area.

## True or False?

- Biosimilars are less safe than reference biologic products.
- Reference products today remain unchanged from the originally approved product with the same name.

The background of the slide is a faded, sepia-toned photograph of a grand classical building. The building features a prominent portico with several tall, fluted columns supporting a decorative entablature. The perspective is from a low angle, looking up at the structure. The overall tone is warm and historical.

Thank you, and I hope you  
have a wonderful day!



**NABP**

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# Panelist Discussion

Ilisa Bernstein, PharmD, JD

Senior Vice President of Pharmacy Practice and Government Affairs,  
American Pharmacists Association

John Clay Kirtley, PharmD

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## Q&A

You may use the chat tool on your screen to submit questions to the presenter.

**Please change the “To” field in the chat box to “All panelists and attendees” so that everyone can see your question or comment.**

Our host will read the questions out loud in the order they are received.



**NABP**

National Association of  
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## Submit Your CPE Claim

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2. Click on the "Live CPE" tab
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4. Enter the session code provided on the next slide
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**Claims must be submitted by noon on April 12, 2022.**

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1.5 contact hours (0.15 CEU)  
0205-0000-21-006-L03-P  
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Questions about submitting your claim? Please contact [CPE@nabp.pharmacy](mailto:CPE@nabp.pharmacy).