Biosimilar vs. Generic, What's the Difference?

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Disclosures

- The presenter has no financial relationships with any commercial interests pertinent to this presentation.

- This program may contain the mention of drugs or brands presented in a case study or comparative format using evidence-based research. Such examples are intended for educational and informational purposes and should not be perceived as an endorsement of any particular supplier, brand or drug.

Pharmacist Learning Objectives

At the end of this session, participants should be able to:

- Describe the process for approval of biosimilar products
- Recall the differences between generic and biosimilar products
- Identify newly approved biosimilar products in the United States

Pharmacy Technician Learning Objectives

At the end of this session, participants should be able to:

- Determine the regulatory requirements for a biosimilar product to be approved

- Identify three biosimilars currently on the U.S. market

Overview

- Terminology Review
- History of Generic and Biosimilar Regulations
- Comparison of Generic vs. Biosimilar vs. Interchangeable
- Approval Process for Biosimilars
- Naming of Biosimilars
- Prescribing and Substitution of Biosimilar Products

Definitions

- **Generic product**
  - Medication created to be same as existing approved medication in dosage form, safety, strength, route of administration, quality and performance characteristics

- **Biological product ("biologic")**
  - "Virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesizedpolypeptide) or analogous product used to diagnose, prevent, treat and cure diseases and medical conditions"

- **Reference product**
  - Single biological product against which a proposed biosimilar is compared

- **Biosimilar biological product ("biosimilar")**
  - Highly similar to AND no clinically meaningful differences from reference product

Source: Biosimilar and interchangeable products. U.S. Food and Drug Administration web site. Updated October 23, 2017. Accessed November 2, 2018.

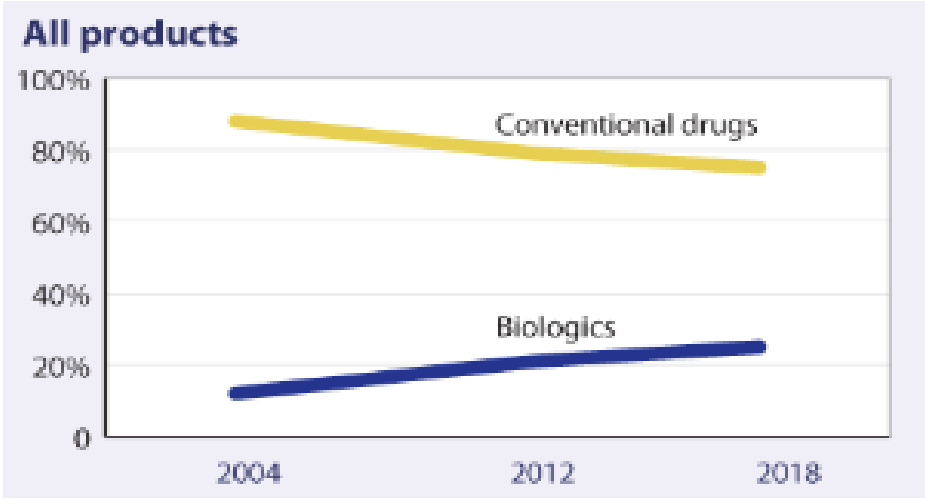
Relevance of Biosimilar Products

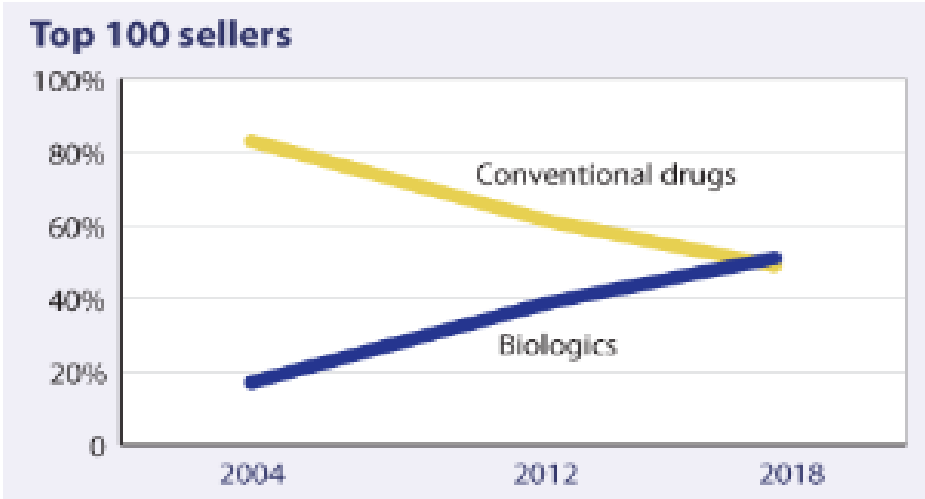
- In 2016, the United States spent $3,337 billion on healthcare
  - 18% of the gross domestic product (GDP) or $329 billion spent on prescription drugs!

- Biological products represent ~40% of prescription drug spending
  - Accounted for 70% of growth in spending from 2010 to 2015

Source: Biosimilars action plan: balancing innovation and competition. US Food and Drug Administration website. Updated July 2018. Accessed November 9, 2018.

Conventional Drug vs. Biologic Sales, Worldwide





*Percentage of sales attributable to each

Source: Image available at https://www.managedcaremag.com/archives/2013/10/5-years-50-top-selling-drugs-will-be-biologics.

10 Best-selling Drugs Globally in 2017

1. Humira® (adalimumab)
2. Eylea® (aflibercept)
3. Revlimid® (lenalidomide)
4. Rituxan® (rituximab)
5. Enbrel® (etanercept)
6. Herceptin® (trastuzumab)
7. Eliquis® (apixaban)
8. Avastin® (bevacizumab)
9. Remicade® (infliximab)
10. Xarelto® (rivaroxaban)

Source: Dezzani L. 20 best selling drugs 2018. Igea Hub Pharmaceutical Club website. Updated April 7, 2018. Accessed November 10, 2018.

Top 10 Branded Drugs in U.S. for Invoice Spending & Prescriptions in 2016

Rank	Medicine	2012 ($ in Billions)	2016 ($ in Billions)
	Total US market	317.8	450.0
1	*Humira* (adalimumab, AbbVie)	4.5	13.6
2	*Harvoni* (ledipasvir sofosbuvir, Gilead)	0.0	10.0
3	*Enbrel* (etanercept, Amgen)	4.2	7.4
4	*Lantus Solostar* (insulin glargine injection, Sanofi)	2.3	5.7
5	*Remicade* (infliximab, Janssen Biotech)	3.8	5.3
6	*Januvia* (sitagliptin, Merck)	2.6	4.8
7	*Advair Diskus* (fluticasone/salmeterol, GlaxoSmithKline)	4.6	4.7
8	*Lyrica* (pregabalin, Pfizer)	1.9	4.4
9	*Crestor* (rosuvastatin, AstraZeneca)	4.8	4.2
10	*Neulasta* (pegfilgrastim, Amgen)	3.4	4.2

- 5 of top 10 prescription meds were biologic products

Source: Frellick M. Top-selling, top-prescribed drugs for 2016. Medscape web site. Written October 2, 2017. Accessed November 2, 2018.

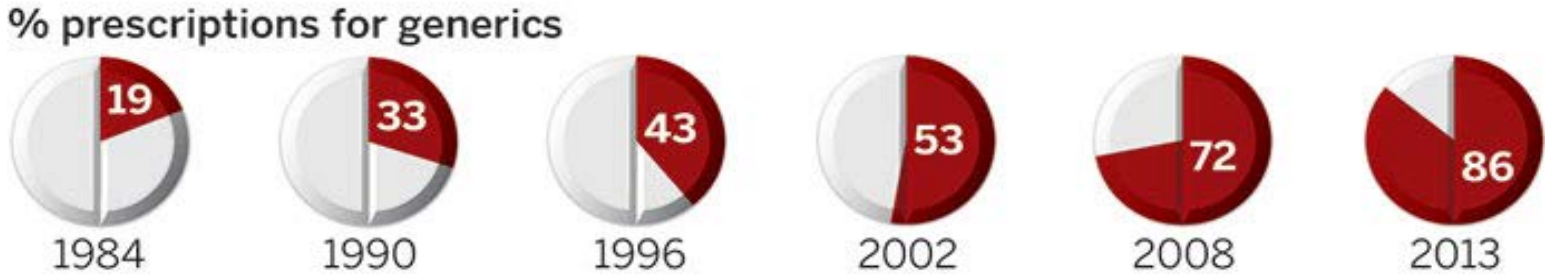
History of Generic Drugs

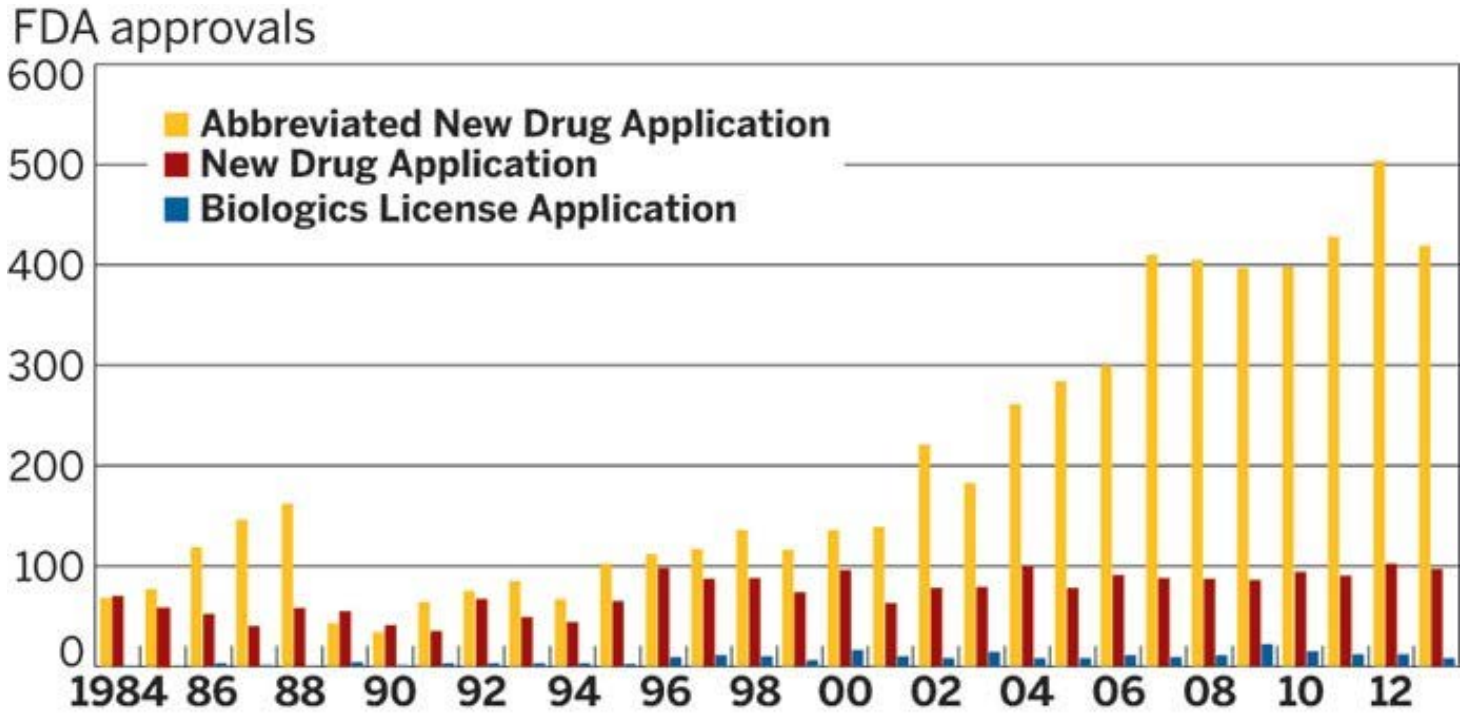
- Drug Price Competition and Patent Term Restoration Act of 1984
  - Also known as "Hatch-Waxman Act"
  - Two goals of this law:
    Encourage greater public access to generic drugs
    Support new pharmaceutical research and development

Enable Generic Competition	Reward Technological Advance
Established abbreviated new drug application (ANDA)	Patent term extension allowed- relative to regulatory review length
Allows testing before brand patent expires	Non-patent exclusivity benefits (NDA data proprietary thru FDA, etc.)
Incentive 180 day exclusivity- for first successful ANDA filer	Established process for patent challenges

Sources: Rumore MM. The Hatch-Waxman Act—25 years later: keeping the pharmaceutical scales balanced. Pharmacy Times website. Updated August 15, 2009. Accessed November 11, 2018. Sokal AM and Gerstenblith BA. The Hatch-Waxman Act: encouraging innovation and generic drug competition. Finnegan website. Accessed November 10, 2018.

Generic Drugs Today





Source: Image from https://cen.acs.org/articles/92/i39/30-Years-Generics.html

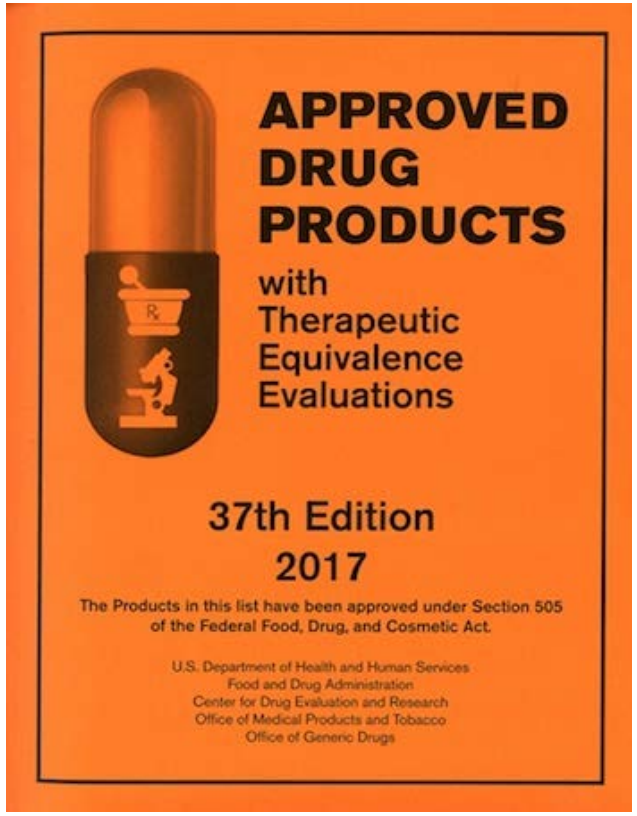
Source: Image from https://cen.acs.org/articles/92/i39/30-Years-Generics.html

The “Orange Book”

- *Approved Drug Products with Therapeutic Equivalence Evaluations*
  - Official name of the publication
  - First distributed as a proposal in January 1979

- Identifies drug products approved by FDA
  - Lists therapeutic equivalence evaluations (AA, AB, etc.)

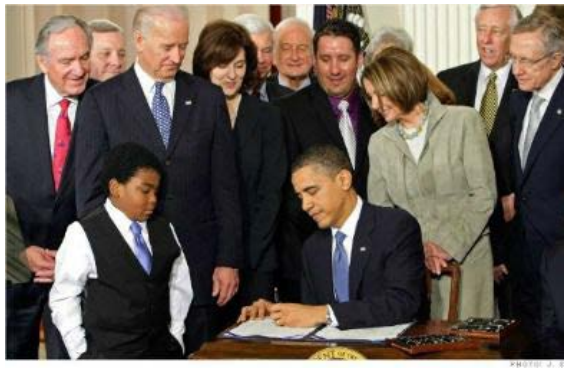
- Provides drug patent and exclusivity information
  - Updated as part of Hatch-Waxman Act



https://www.ipwatchdog.com/2018/04/04/abuse-orange-book-listings/id=95555/

Source: Orange book: approved drug products with therapeutic equivalence evaluations. U.S. Food and Drug Administration website. Updated October 31, 2018. Accessed November 10, 2018.

History of Biosimilar Products



- European Medicines Agency
  - Biosimilar regulatory framework in place since 2006

- Biologics Price Competition and Innovation (BPCI) Act of 2009
  - Part of Patient Protection and Affordable Care (PPAC) Act of 2010
  - Created abbreviated approval pathway for biological products that are:

    "Highly similar" OR

    "Interchangeable" to reference biological product

- Goal of legislation similar to Hatch-Waxman Act
  - Enhance competition and patient access, lower cost
  - History repeats itself…

Sources: Implementation of the Biologics Price Competition and Innovation Act of 2009. US Food and Drug Administration web site. Accessed November 9, 2018. Schiestl M, et al. *Drug Des Devel Ther*. 2017; 11: 1509–1515. Image accessed at https://chicagodefender.com/2013/09/09/taxpayer-guide-obamacare/

Defining Biosimilar

"Highly similar"

- Structural and functional analysis of reference product and proposed biosimilar
- Comparison for purity, chemical identity, bioactivity
- Minor differences allowed, such as differences in *stabilizer or buffer*

No clinically meaningful differences

- Refers to differences in safety, purity and potency
- Demonstrated through human pharmacokinetic (exposure) and pharmacodynamic (response) studies, clinical immunogenicity assessment and if needed, additional clinical studies

Source: Biosimilar and interchangeable products. US Food and Drug Administration website. Updated October 23, 2017. Accessed November 10, 2018.

Biological Product vs. Small Molecule Drug

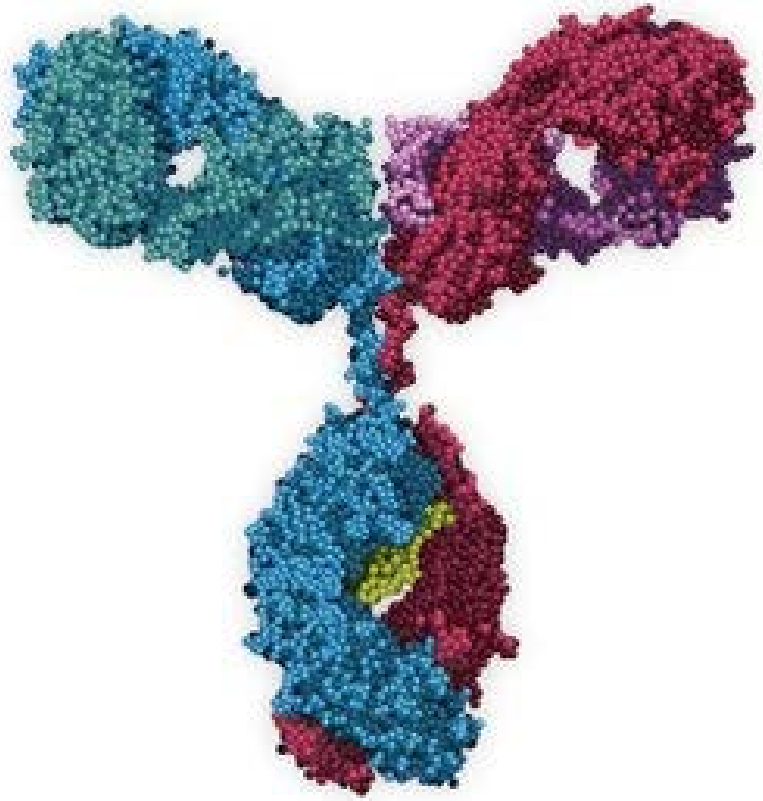
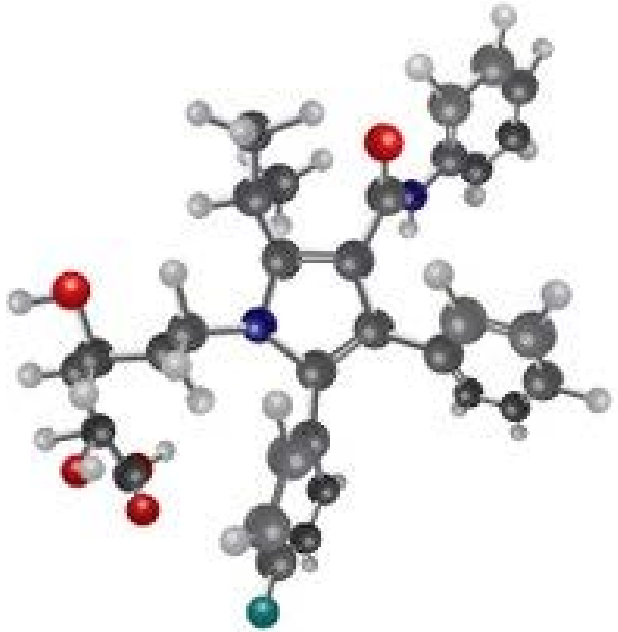
BIOLOGICAL PRODUCT

- Larger, complex molecules
- Chemical structure less easily characterized
- Produced through biotechnology methods in a living system (microorganism, plant or animal cell)
  - Inherent variations from manufacturing process
- Can be immunogenic
- Approved under Public Health Services (PHS) Act

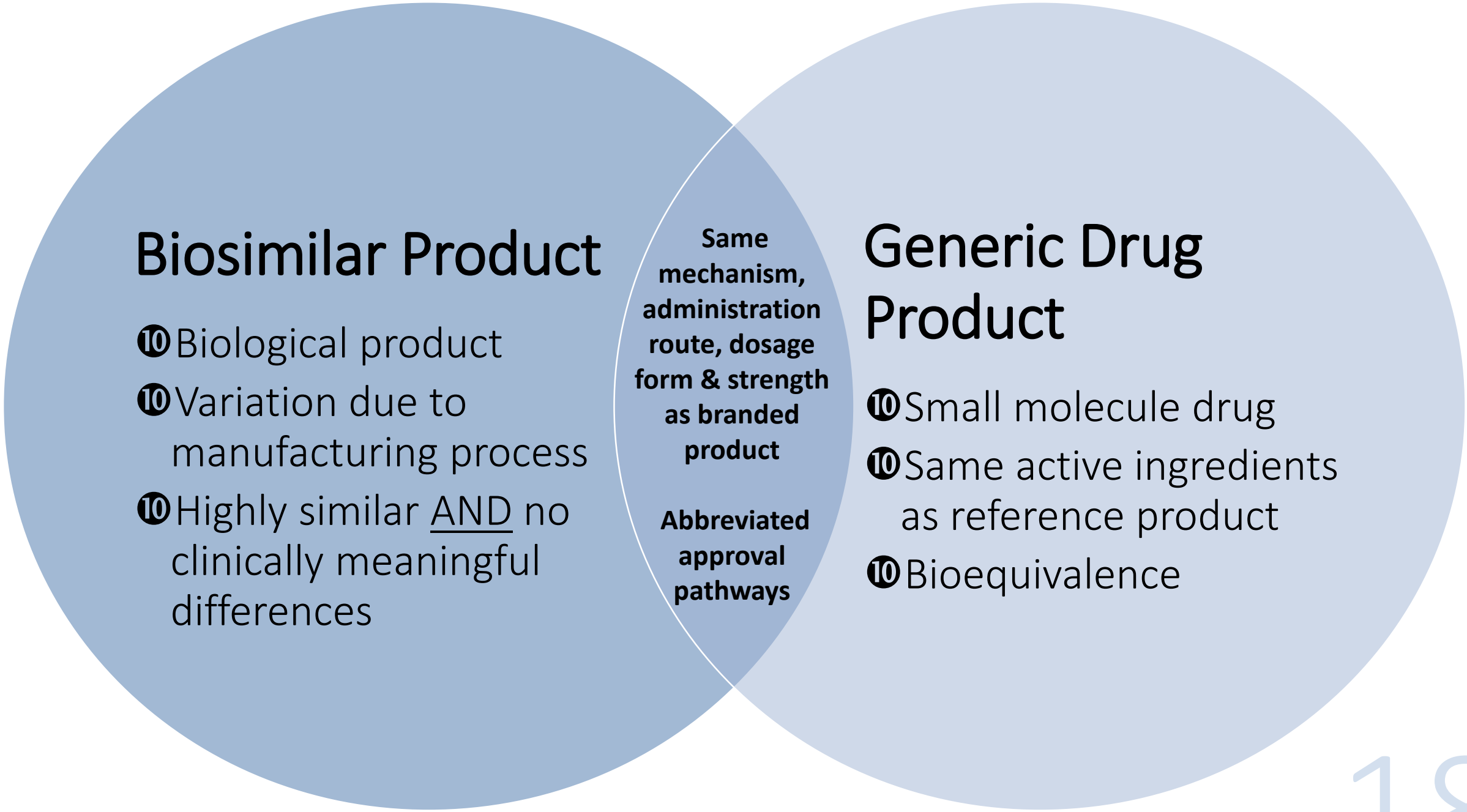
SMALL MOLECULE DRUG

- Small molecule drug made from pure chemical substances
- Chemical structure easily identified and characterized
- Synthesized through predictable chemical process according to a reproducible "recipe"
- Usually not immunogenic
- Approved under Food, Drug, Cosmetic (FDC) Act

Source: What are biologics? Academy of Managed Care Pharmacy website. https:///www.biosimilarsresourcecenter.org/faq. Accessed November 12, 2018.

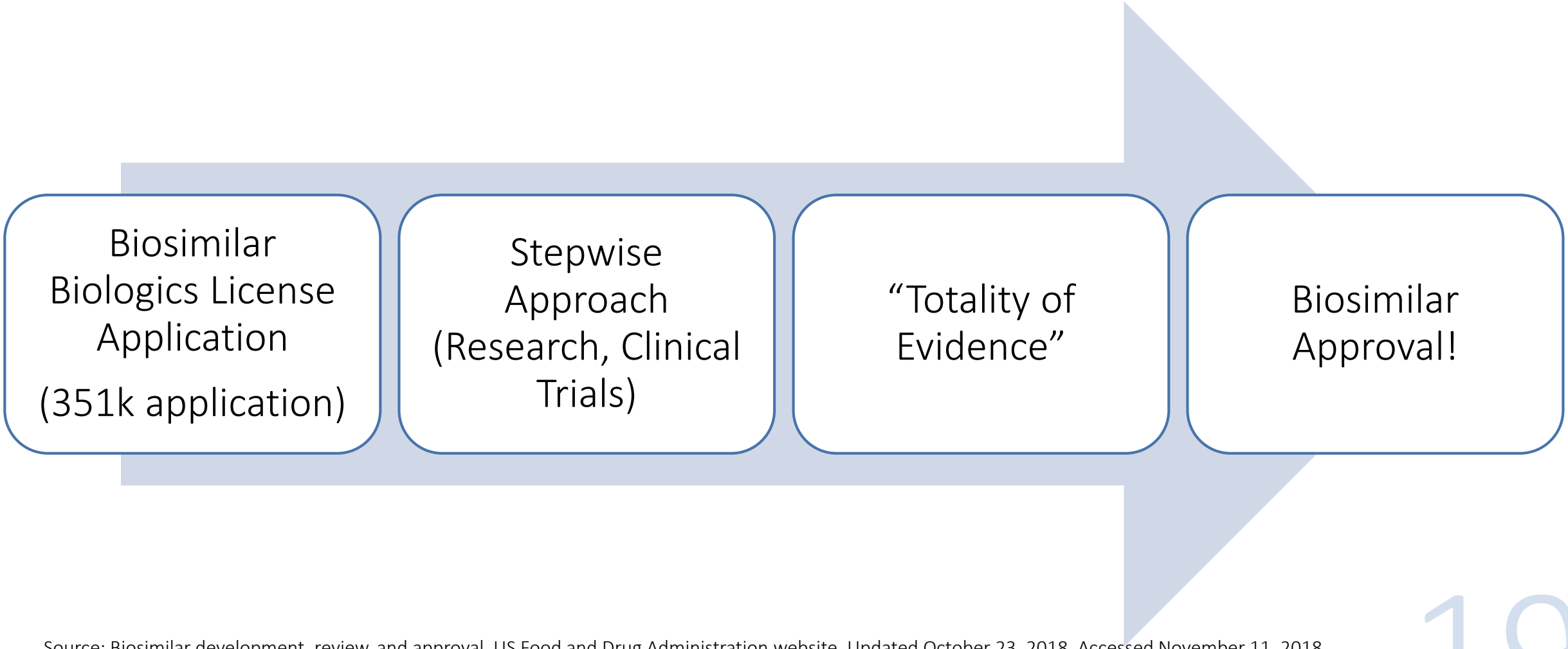
Biologic	Traditional Drug
	
Herceptin (breast cancer) molecular weight = 185,000 daltons	**Lipitor (hypercholesterolemia)** molecular weight = 559 daltons

Source: Image accessed at https://blogs.scientificamerican.com/guest-blog/will-ldquo-biosimilar-rdquo-medications-reduce-the-cost-of-biologic-drugs/



Source: What are biologics? Academy of Managed Care Pharmacy website. Accessed November 12, 2018.

Approval Process for Biosimilars



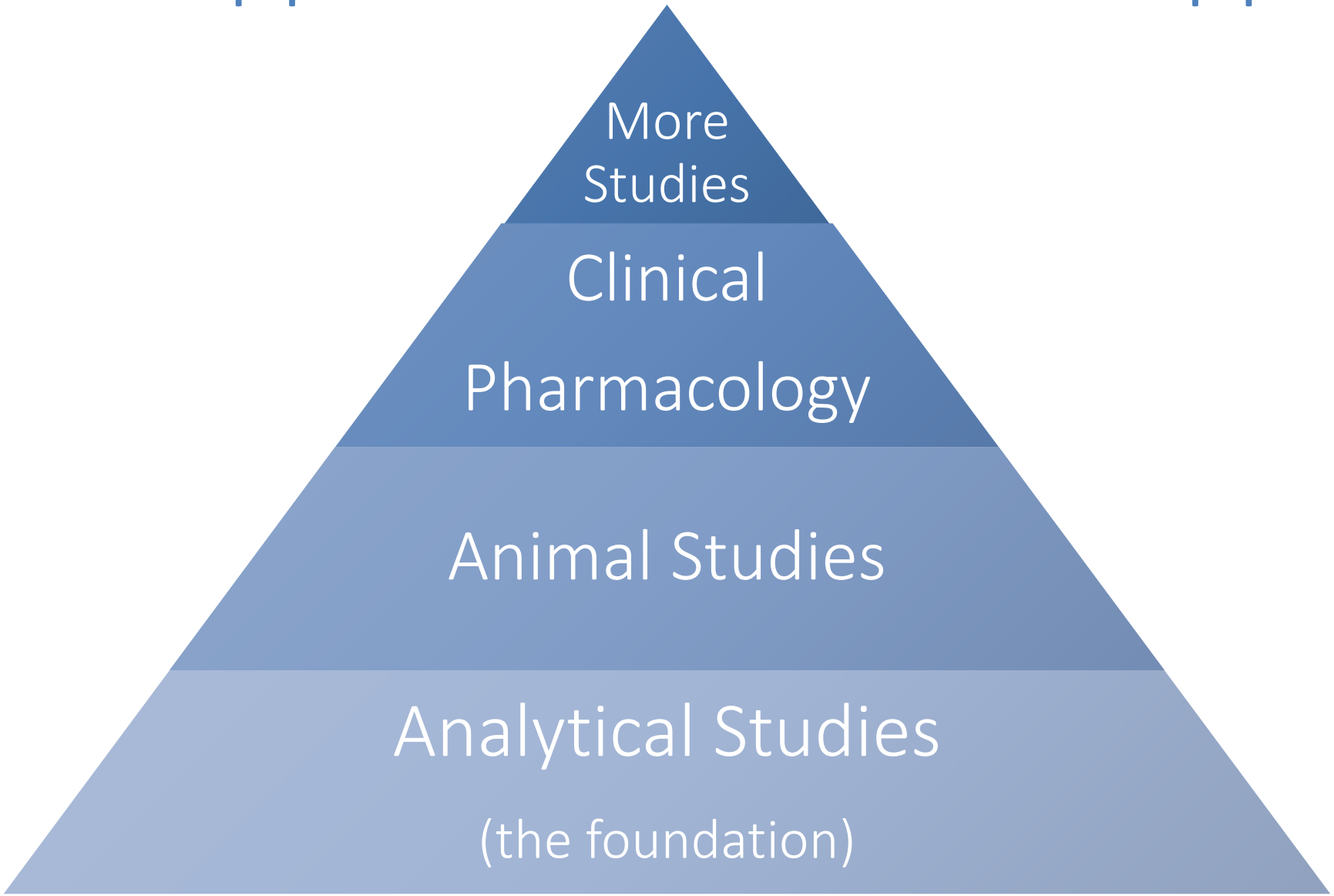
Source: Biosimilar development, review, and approval. US Food and Drug Administration website. Updated October 23, 2018. Accessed November 11, 2018.

Approval Process for Biosimilars–a **CAVEAT**

- The Agency has the discretion to determine that an element described above is "*unnecessary in a 351(k) application*"
  - Biosimilar application can rely on certain existing scientific knowledge about the safety, purity and potency of the reference product to support licensure

Source: Biosimilar development, review and approval. US Food and Drug Administration website. Updated October 23, 2018. Accessed November 11, 2018.

Stepwise Approach to Biosimilar Approval



Source: Biosimilar development, review, and approval. U.S. Food and Drug Administration website. Updated October 23, 2018. Accessed November 11, 2018.

Stepwise Approach to Biosimilar Approval

Structural Analysis & Functional Assays	Characterize structural and mechanistic differences between proposed biosimilar and reference product
Animal Studies	Assess toxicity and potentially some immunogenicity
Clinical Pharmacokinetic, Pharmacodynamic & Immunogenicity Studies	Demonstrate safety, purity and potency in appropriate conditions

Source: Biosimilar development, review, and approval. US Food and Drug Administration website. Updated October 23, 2018. Accessed November 11, 2018.

"Totality of Evidence"

- No single study will demonstrate biosimilarity!
- FDA will license proposed biological product if FDA **"determines that the information submitted in the application… is sufficient to show that the biological product is biosimilar to the reference product"**
- Risk-based approach to evaluate data and information

Source: Biosimilar development, review, and approval. US Food and Drug Administration website. Updated October 23, 2018. Accessed November 11, 2018. How does a manufacturer demonstrate biosimilarity? Academy of Managed Care Pharmacy website. Accessed November 10, 2018.

What About Interchangeable Products?

- Interchangeable expected to produce same clinical result as reference product *in any given patient*
  - Additional requirements for approval

- Switching studies for products administered more than once
  - Evaluate safety and efficacy risks for switching between interchangeable and reference product

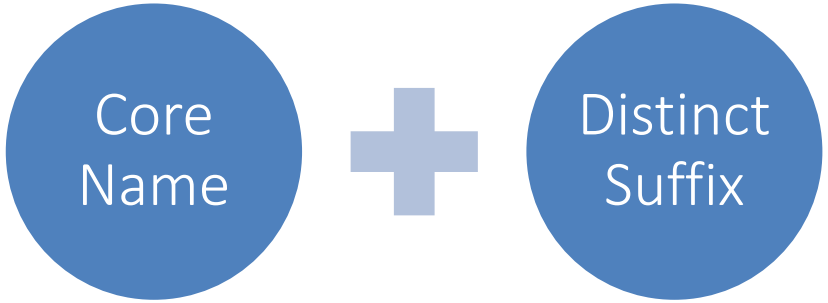
- Why be more stringent with interchangeable approval?
  - Interchangeable product may be substituted for the reference product WITHOUT prescriber involvement

Source: Biosimilar development, review, and approval. US Food and Drug Administration website. Updated October 23, 2018. Accessed November 11, 2018.

Naming Biosimilars

- Biosimilar naming rules not established with initial approval in 2015
  - Zarxio® (filgrastim-sndz) given placeholder nonproprietary name

- Final industry guidance issued in January 2017
  - **Core name + four letter distinguishing suffix**
  - Suffix must be lowercase, three of four letter distinct



- What about biosimilars which were approved before the guidance?
  - Changes in names of already approved biosimilar products
  - Example- Erelzi® (etanercept-szzs) will need suffix with three distinct letters

Source: How are biosimilars named and identified. Biosimilars Resource Center website. Accessed November 11, 2018.

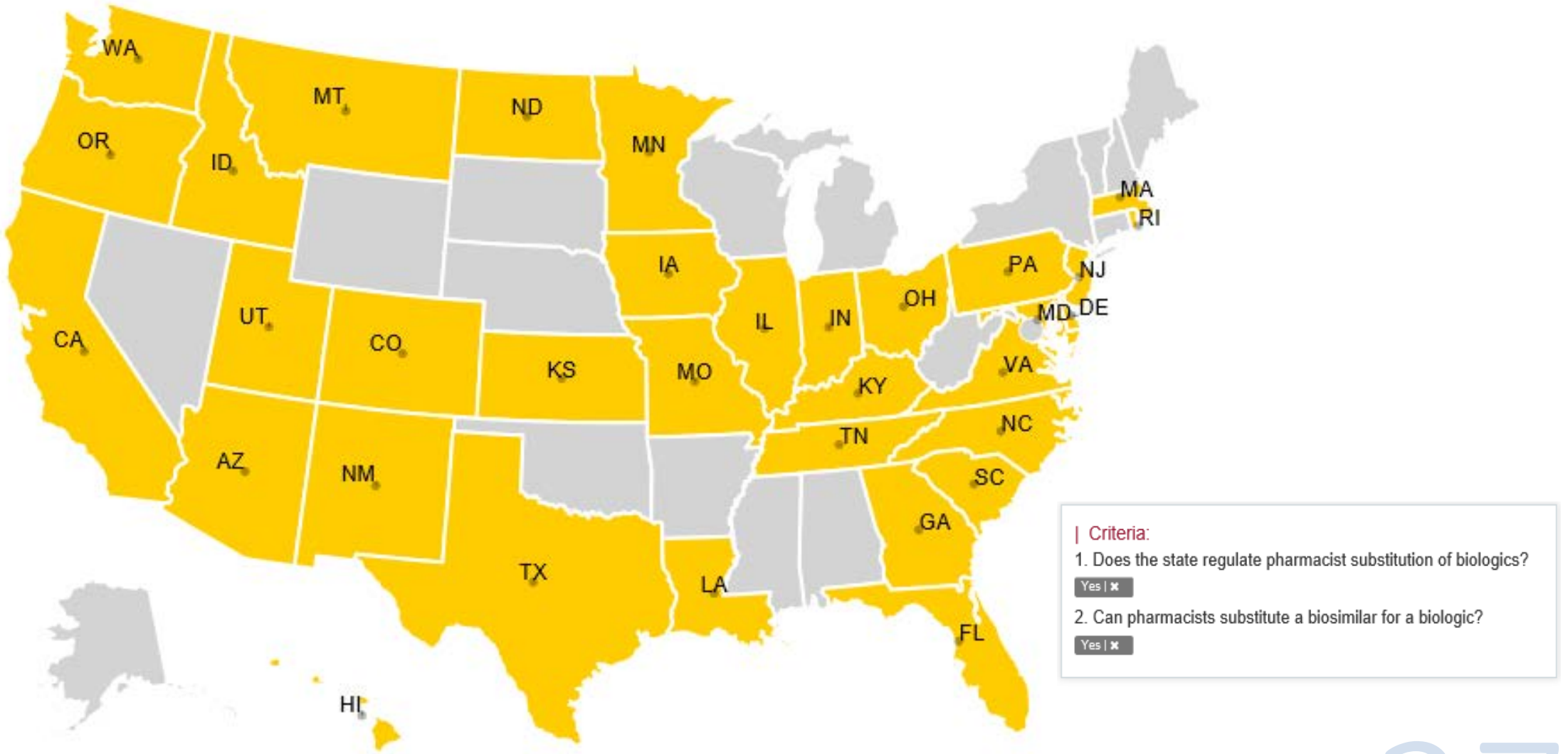
Outpatient Prescribing of Biosimilars

- Pharmacist substitution of biosimilars for reference biological product
  - Dependent on state law

- United States Overview
  - Most states require the biologic drug be deemed “interchangeable” for pharmacist substitution to occur
  - Some states have additional notification and record keeping requirements
    Can require prescriber and/or patient notification about substitution
  - Some states have requirements for when substitution required (i.e., if public dollars are being used)

Source: The policy surveillance program: a LawAtlas project. LawAtlas website. Updated October 1, 2017. Accessed November 13, 2018.

States With Regulations Surrounding Pharmacist Substitution of Biologics



Source: Image accessed at http://lawatlas.org/datasets/biosimilars-laws

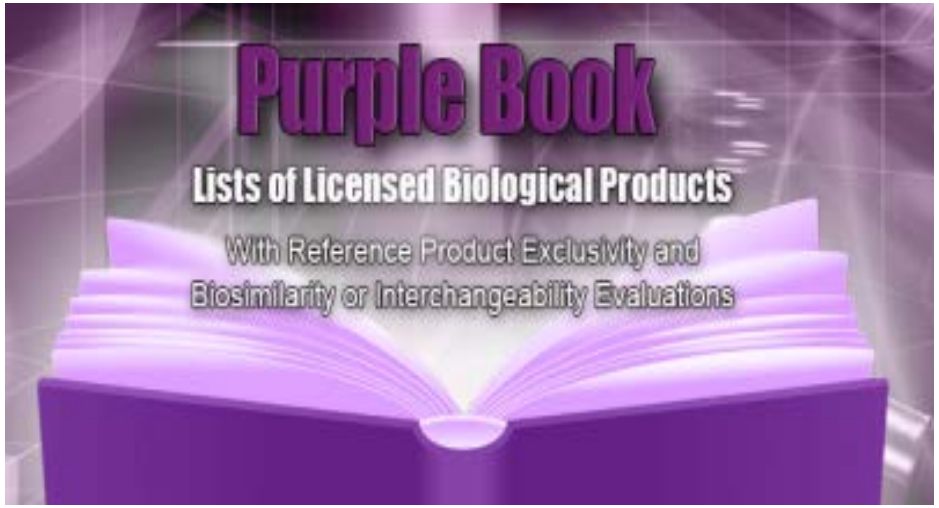
Inpatient Prescribing of Biosimilars

- Pharmacist substitution of biosimilars for reference biological product
  - Dependent on hospital or health system policies
  - Refer also to state regulations

- Several clinical considerations for Pharmacy and Therapeutics Committees
  - Evaluation of efficacy, safety
  - Manufacturer and supply chain considerations
  - Financial considerations
  - Processes to facilitate or limit substitution
  - Etc.

Source: Ventola CS. Evaluation of biosimilars for formulary inclusion: factors for consideration by P&T committees. P&T. 2015 Oct; 40(10): 680–689.

Purple Book: "Lists of Licensed Biological Products"

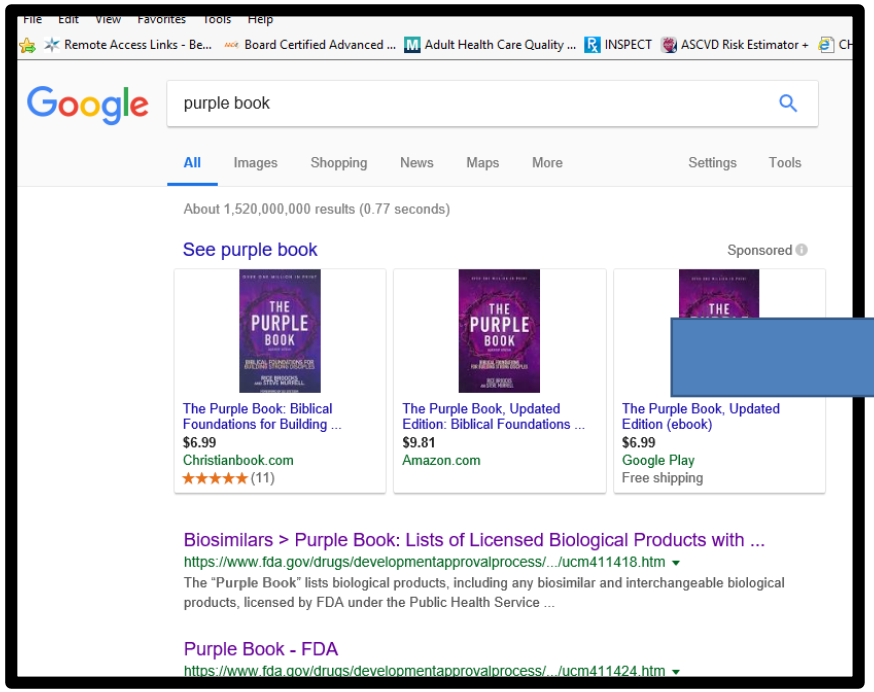


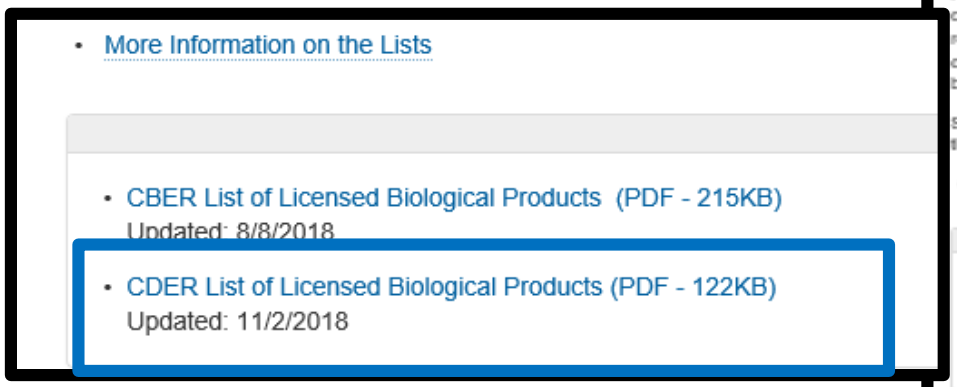
- Similar to Orange Book
  - Specific to biological products

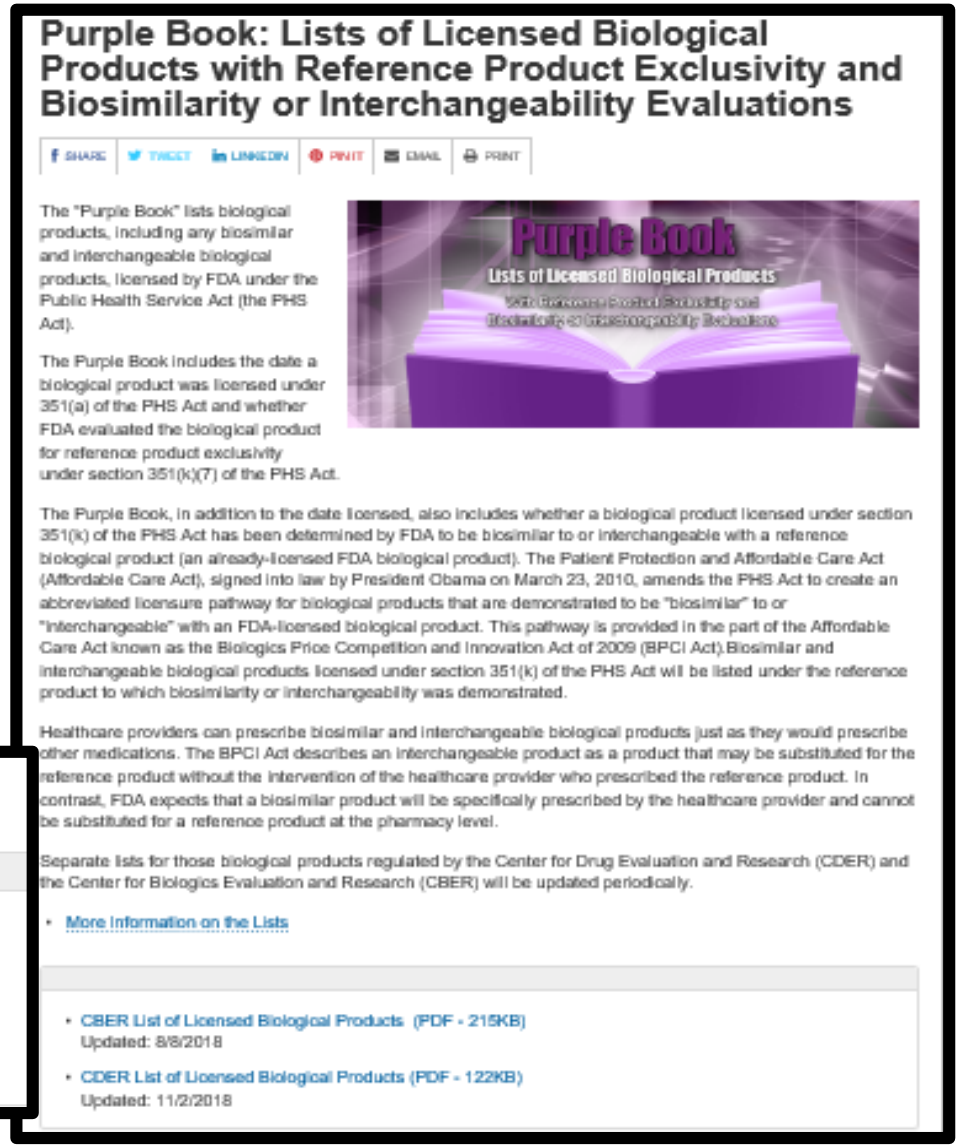
- Includes information about:
  - Reference product exclusivity period (original licensing date, exclusivity expiration date)
  - Biosimilar or interchangeable biological products

- Lists updated "periodically" when FDA licenses a biological product
  - As resources permit

Source: Purple book: lists of licensed biological products with reference product exclusivity and biosimilarity or interchangeability evaluations. US Food and Drug Administration website. Updated November 2018. Accessed November 13, 2018.







Source: Purple book: lists of licensed biological products with reference product exclusivity and biosimilarity or interchangeability evaluations. US Food and Drug Administration website.

Center for Drug Evaluation and Research

List of Licensed Biological Products with (1) Reference Product Exclusivity and (2) Biosimilarity or Interchangeability Evaluations to Date

BLA STN	PRODUCT (PROPER) NAME	PROPRIETARY NAME	DATE OF LICENSURE (mo/day/yr)	DATE OF FIRST LICENSURE (mo/day/yr)	REFERENCE PRODUCT EXCLUSIVITY EXPIRY DATE (mo/day/yr)	INTERCHANGEABLE (I)/ BIOSIMILAR (B)
125118	abatacept	Orencia	12/23/05	NA	NA	
103575	abciximab	ReoPro	12/22/94	NA	NA	
125274	abobotulinumtoxinA	Dysport	04/29/09			
125057	adalimumab	Humira	12/31/02	NA	NA	
761071	adalimumab-adaz	Hyrimoz	10/30/18			B
761058	adalimumab-adbm	Cyltezo	08/25/17			B
761024	adalimumab-atto	Amjevita	09/23/16			B
125427	ado-trastuzumab emtansine	Kadcyla	02/22/13			
125387	aflibercept	Eylea	11/18/11			
103979	agalsidase beta	Fabrazyme	04/24/03	NA	NA	
125431	albiglutide	Tanzeum	04/15/14			

Source: Purple book: lists of licensed biological products with reference product exclusivity and biosimilarity or interchangeability evaluations. US Food and Drug Administration website. Updated November 2018. Accessed November 13, 2018.

FDA-approved Biosimilars in the U.S.

Reference Product Name	Biosimilar Product Name
Adalimumab (Humira®)	Adalimumab-adaz (Hyrimoz®) Adalimumab-adbm (Cyltezo®) Adalimumab-atto (Amjetiva®)
Bevacizumab (Avastin®)	Bevacizumab-awwb (Mvasi®)
Epoetin alfa (Epogen®, Procrit®)	Epoetin alfa-epbx (Retacrit®)
Etanercept (Enbrel®)	Etanercept-szzs (Erelzi®)
Filgrastim (Neupogen®)	Filgrastim-aafi (Nivestym®) Filgrastim-sndz (Zarxio®)
Infliximab (Remicade®)	Infliximab-abda (Renflexis®) Infliximab-dyyb (Inflectra®) Infliximab-qbtx (Ixifi®)
Pegfilgrastim (Neulasta®)	Pegfilgrastim-cbqv (Udenyca®) Pegfilgrastim-jmdb (Fulphila®)
Trastuzumab (Herceptin®)	Trastuzumab-dkst (Ogivri®)

FDA Approves Sandoz's Zarxio, The First Biosimilar Approved in the U.S.

By **Thomas Sullivan** — Last Updated **May 5, 2018**

BIOSIMILAR FDA

- Zarxio® (filgrastim-sndz) approved March 6, 2015

- Approved for same 5 indications as reference product (Neupogen®)

- Studies conducted prior to approval
  - Structural and functional characterization
  - Animal study data
  - Human pharmacokinetic
  - Clinical immunogenicity data
  - Other clinical safety and efficacy- PIONEER, phase IV studies

Source: Sullivan T. FDA approves Sandoz's Zarxio (filgrastim-sndz), the first biosimilar approved in the US. Last updated May 5, 2018. Policy and Medicine website. Accessed November 12, 2018.

A Comparison of Proposed Biosimilar and Originator Filgrastim for the Prevention of Neutropenia in Patients with Breast Cancer Receiving Myelosuppressive Adjuvant or Neoadjuvant Chemotherapy: Phase III, Randomized, Double–Blind Trial (The PIONEER study)

Kimberly Blackwell, Vladimir Semiglazov, Pedro Gascon, Roumen Nakov, Stefan Kramer, Arnd Schwebig, and Nadia Harbeck

Blood 2014 124:5133;

- Purpose
  - Compare safety and efficacy of filgrastim versus biosimiliar, EP2006, with respect to mean duration of severe neutropenia following Cycle 1chemotherapy
- Methods
  - Randomized, double-blind, multi-center, non-inferiority trial
  - 4 treatment groups
    - *Filgrastim alone*
    - *EP2006 alone*
    - *EP 2006 initially then cycle between filgrastim and EP2006*
    - *Filgrastim initially then cycle between filgrastim and EP2006*
  - Included women > 18 years old with histologically-proven breast cancer eligible for neoadjuvant or adjuvant chemotherapy treatment

PIONEER Trial

- Results
  - 218 patients randomized
  - Mean DSN in Cycle 1: 1.17±1.11 days (EP2006) vs. 1.20±1.02 days (filgrastim)

    Mean difference in DSN= 0.04 days (97.5% CI, lower limit -0.26 days)
  - Febrile neutropenia incidence over 6 cycles chemotherapy

    EP: 2/40, 5.0%, EPNEU: 5/45, 11.1%, NEUEP: 1/44, 2.3%, NEU: 0/46, 0.0%)
  - No obvious difference in treatment emergent adverse events

    EP: 5/53, 9.4% patients; EPNEU: 4/54, 7.4%; NEUEP: 1/55, 1.8%; NEU: 2/52, 3.8%)
  - No subjects developed anti-drug antibodies
- Conclusion
  - Biosimilar result met predefined non-inferiority criteria

Source: Blackwell K, Semiglazov V, Gascon P, et al. *Blood.* 2014;124:5133.

Cost of Biosimilar Products

- Biosimilars expected to cost 10 to 40% less than reference product

- Insurance Coverage of Biosimilar Products
  - Varies by state and health plan
  - Center for Medicare and Medicaid Services (CMS) finalized proposal in April 2018 to allow biosimilars to be covered at generic copay level
  - Several state Medicaid programs placing biosimilar as "preferred" product

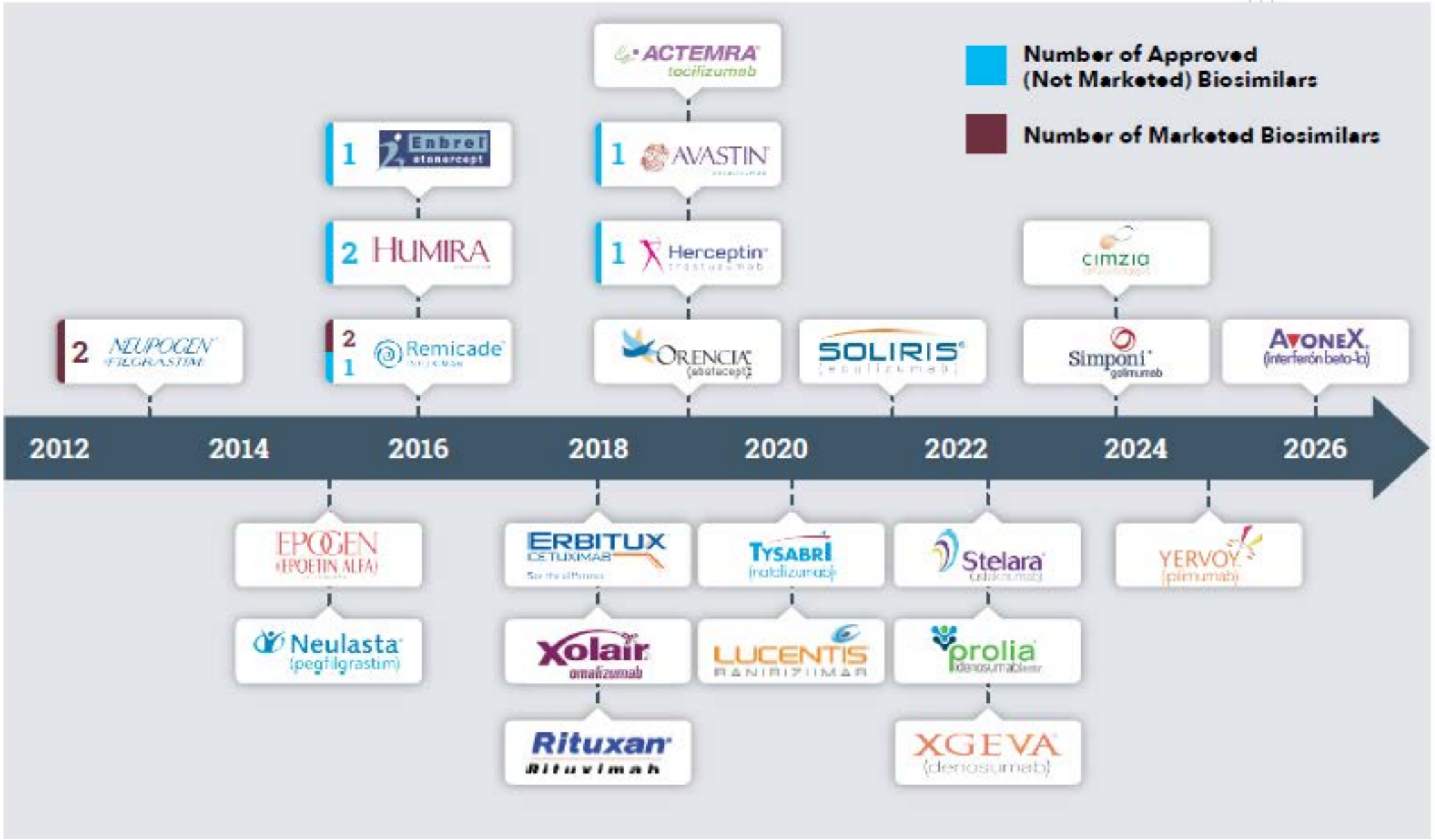
Comparison of U.S. Biosimilar and Generic Drug Average Share of Sales and Price Discount
(Six Months After Launch)

	Share of sales vs. originator	Price discount vs. originator*
Generic Drug Average	≥75%	≥40%
Zarxio (biosimilar Neupogen)	~10%	15%
Granix (quasi-biosimilar Neupogen)	5-10%	~11-23%

* Does not include rebates or other contracted reductions.
SOURCES: Generic Drug Average: Berndt et al. Health Affairs, 26, no. 3, (2007); Grabowski et al. Journal of Medical Economics, (2016). Zaxio and Granix: Publicly available data.

Source: Image accessed at https://blogs.scientificamerican.com/guest-blog/will-ldquo-biosimilar-rdquo-medications-reduce-the-cost-of-biologic-drugs/

Figure 1: LOE and Biosimilar Entry Timeline as of January 2018



Source: Simmons-Stern N. The state of US biosimilars market access: payer perceptions of past, present and future hurdles to adoption. Trinity Partners website. Updated January 2018. Accessed November 12, 2018.

What About Biosimilar Insulin Products?

- Basaglar® (insulin glargine) and Admelog® (insulin lispro) **NOT** approved as biosimilars
  - FDA refers to it as a "follow-on" insulin
  - Some protein products licensed under Food, Drug and Cosmetic (FDC) Act rather than Public Health Services (PHS) Act
  - Insulin and human growth hormones, historically, approved under the FDC Act

- What about the future for biologic protein products?
  - In 2020, these applications for protein biological products will fall under PHS Act

Source: Is biosimilar insulin available. Biosimilars Resource Center website. https://www.biosimilarsresourcecenter.org/faqs/ Accessed November 13, 2018.

Currently Approved “Follow-on” Insulin Products

“Reference” Insulin Product	“Follow-On” Insulin Product
Lantus® (insulin glargine)	Basaglar® (insulin glargine)
Novolog® (insulin lispro)	Admelog® (insulin lispro)

Future Discussion About Biosimilar Products

- Prescribing and pharmacist substitution
- Efficacy studies and extrapolation
- Additions to hospital or health plan formularies

Helpful Resources

- Academy of Managed Care Pharmacy Biosimilars Resource Center
  - Laws and Regulations https://www.biosimilarsresourcecenter.org
  - FAQs Section, https://www.biosimilarsresourcecenter.org/faqs/

- U.S. Food and Drug Administration website
  - Guidances on Biosimilars, https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm290967.htm
  - Biosimilars section, https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/default.htm

- State Board of Pharmacy websites

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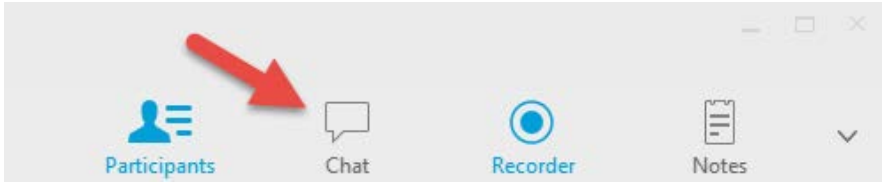
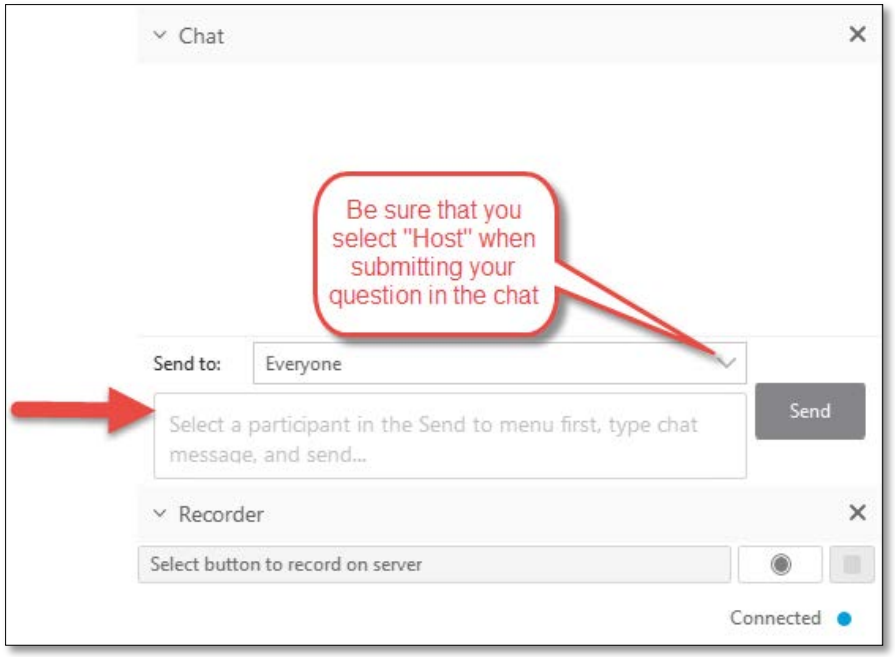
Q & A

To ask the presenter a question, simply type it into the “chat” box within the WebEx tool bar. Be sure that you select “Host” when submitting your question in chat.





Thank you!

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