Biosimilars in Supportive and Therapeutic Cancer Care

Key Issues and Considerations for Pharmacists

A Midday Symposium and Live Webinar conducted at the 2018 ASHP Midyear Clinical Meeting and Exhibition

Monday, December 3, 2018
11:30 a.m.–1:00 p.m.
Room 260, 200 Level, ACC North
Anaheim Convention Center

www.ashpadvantagemedia.com/biosimilars

AGENDA

11:30 a.m. – 11:35 a.m.

Welcome and Introductions

Ali McBride, Pharm.D., M.S., BCPS, BCOP

11:35 a.m. – 11:55 a.m.

Key Considerations with the Use of Biologics and Biosimilars for Supportive and Therapeutic Treatment of Cancer

Ali McBride, Pharm.D., M.S., BCPS, BCOP and Sandra Cuellar, Pharm.D., BCOP

11:55 a.m. – 12:20 p.m.

Use of Biosimilars in Patients with Cancer: Overview of Important Clinical, Product, and Institutional Parameters

Ali McBride, Pharm.D., M.S., BCPS, BCOP and Sandra Cuellar, Pharm.D., BCOP

12:20 p.m. – 12:50 p.m.

Incorporating Biosimilars for Supportive and Therapeutic Care of Cancer into Practice: Potential Impact on Patients and Formulary Decision-making

Ali McBride, Pharm.D., M.S., BCPS, BCOP and Sandra Cuellar, Pharm.D., BCOP

12:50 p.m. – 1:00 p.m.

Faculty Discussion and Audience Questions

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Biosimilars in Supportive and Therapeutic Cancer Care

Key Issues and Considerations for Pharmacists

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Provided by ASHP

Supported by an educational grant from Coherus BioSciences

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- Ali McBride
  - Amgen and Sandoz: Advisory Board Member
- Sandra Cuellar
  - Tesaro and Genentech: Speakers Bureau
  - Eisai and Amgen: Advisory Board Member

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Learning Objectives

- Evaluate the safety and efficacy data for available and emerging biosimilars and reference biologics for supportive and therapeutic cancer care.
- Describe the issues related to switching between/transitioning from the reference product and a biosimilar product in patients with cancer.
- Identify approaches to educating healthcare providers about biosimilars for patients with cancer and their effective use within the health system.
- Identify approaches to educating patients with cancer on the appropriate, effective and safe use of biosimilars.

Background

Biologics

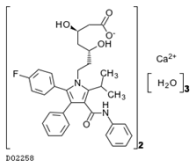
A wide range of products, such as vaccines, blood and blood components, and recombinant therapeutic proteins derived from living cells or organisms and intended to prevent, treat, or cure a disease.

Therapeutic biologics treat a variety of conditions, such as cancer, hemophilia, and chronic inflammatory conditions.

Development and manufacture of biologics is vastly more complex and costly compared with small molecule drugs.

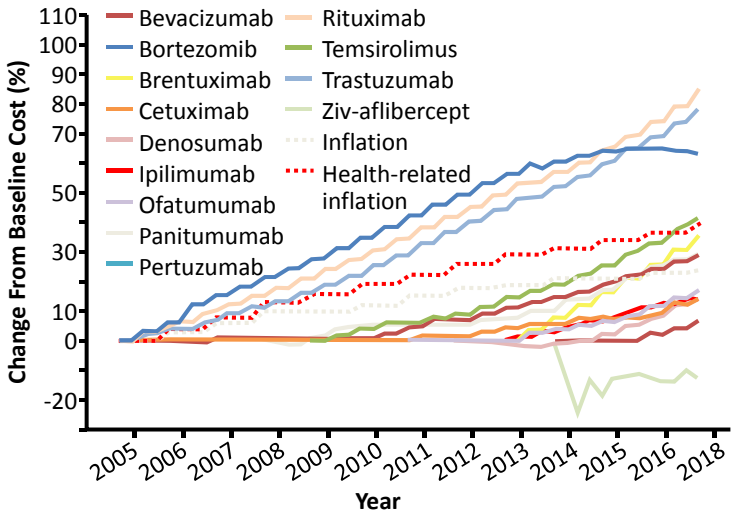
Kozlowski S, et al. *N Engl J Med*. 2011; 365:385-8.

Small Molecules vs. Biologics

	Small Molecule Drugs	Biologics
Size (MW)	Small (<1,000 Daltons)	Large (>10,000 Daltons)
Source	Chemical synthesis	Cultures of living cells
Structure	Simple, well defined, independent of manufacturing process	Complex (heterogeneous), defined by the exact manufacturing process
Characterization	Easy to characterize	Cannot be characterized completely
Immunogenicity	Mostly non-immunogenic	Immunogenic
Example	Atorvastatin  MW = 558.64	Trastuzumab  MW = 185,000

Declerck PJ. *Generics and Biosimilars Initiative Journal*. 2012;1:13-6. http://gabi-journal.net/biologicals-and-biosimilars-a-review-of-the-science-and-its-implications.html.

Changes in Cost of Biologic Oncology Agents Over Time



- Trastuzumab increased 78% over 10 years
- Cost of biologics
  - 2005: 32% of $9.5B, Medicare Part B
  - 2014: 62% of $18.5B, Medicare Part B

Gordon N, et al. *J Clin Oncol*. 2017;36:319-25. Nabhan C, et al. *JAMA Oncol*. 2018;4:241-7.
Slide credit: clinicaloptions.com

Top 10 Drugs by Expenditures in Clinic: 2017

Drug	2017 Expenditures ($ Thousands)	% Change from 2016
Infliximab	3,743,397	8.0
Pegfilgrastim	3,199,813	1.8
Rituximab	2,802,604	3.8
Nivolumab	2,533,504	21.8
Bevacizumab	2,348,893	-3.3
Trastuzumab	2,266,471	7.8
Epoetin alfa	1,839,876	1.6
Denosumab	1,823,997	13.3
Pembrolizumab	1,787,354	219.0
Ranibizumab	1,457,852	4.1

Trends in Biosimilars

- Total G-CSF product expenditures ↓ by 10.9% likely due to biosimilars
- Filgrastim-sndz 24.9% & tbo-filgrastim 18.8% of 4th quarter expenditures

Schumock et al. *Am J Health-Sys Pharm*. 2018;75:1023-38.

Disrupting Pharmaceutical Biologic Ecosystem

- **Biologics are estimated to account for ~50% of US prescription drug expenditure in 2018**
- **Biologics Price Competition and Innovation Act of 2009**
- **Increased competition with biologic medications**
- **Decreased prices, increased access, & increased innovation**

Li EC, et al. *J Manag Care Spec Pharm*. 2015; 21:532-9.

Regulatory Definitions of Biosimilar

US Food and Drug Administration (FDA)

Biosimilarity means "that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components . . . there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency."[.]"

European Medicines Agency (EMA)

"A biosimilar is a biological medicinal product that contains a version of the active substance of an already authorised original biological medicinal product (reference medicinal product) . . . Similarity to the reference medicinal product in terms of quality characteristics, biological activity, safety, and efficacy based on a comprehensive comparability exercise needs to be established."

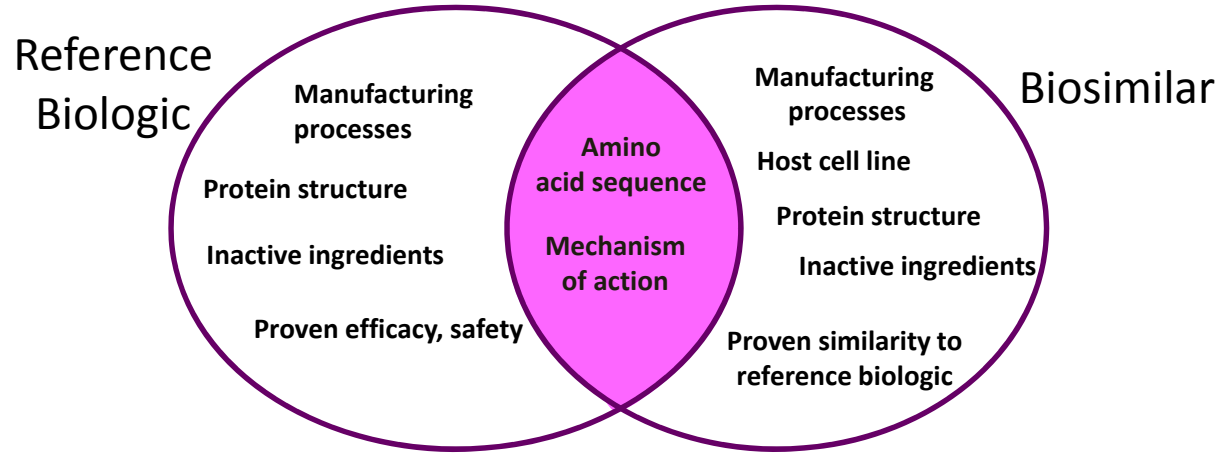
FDA. Guidance for industry on biosimilars, part I. March 2016.
EMA. Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues. December 2014.

Similarity Assessment

Highly similar with fingerprint-like similarity	• Very high confidence in similarity based on integrated, multi-parameter approaches that are extremely sensitive in identifying analytical differences
Highly Similar	• Results of comparative analytical characterization permit high confidence in similarity • Targeted and selective studies recommended to resolve residual uncertainty
Similar	• Additional analytical data or other studies needed to determine if product highly similar to reference product
Not Similar	• Future development through section 351(k) of the Public Health Service Act not recommended unless developer pursues changes in manufacturing process

Sullivan PM, DiGrazia LM. *Am J Health-Syst Pharm*. 2017; 74:568-79.

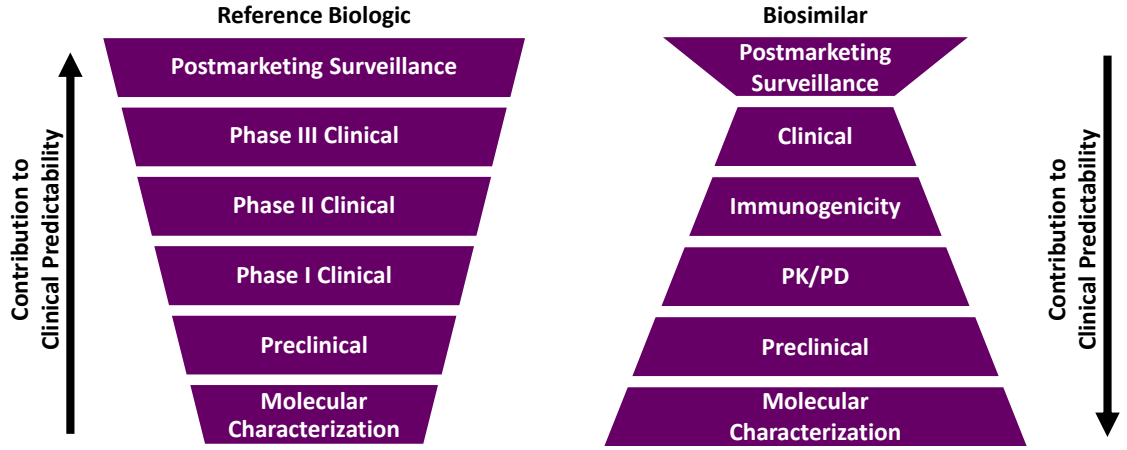
Reverse Engineering



Biologics/biosimilars have inherent heterogeneity, and slight differences in structure and clinically inactive components are expected

Li E, et al. *J Manag Care Spec Pharm*. 2015; 21:532-9. Weise M, et al. *Blood*. 2012; 120:5111-7. Lucio SD, et al. *Am J Health Syst Pharm*. 2013; 70:2004-17. FDA. Information on biosimilars. 2016

Biosimilars Represent Paradigm Shift in Product Development



FDA. Drug development overview. 2012. FDA. Scientific considerations in demonstrating biosimilarity to a reference product: guidance for industry. 2015.

Biosimilar Development & Extrapolation

Development of innovator product includes extensive preclinical and clinical studies for all indications versus development of biosimilar includes stepwise approach to demonstrating biosimilarity to reference product based on analytical studies, animal studies, and clinical studies

Demonstrating analytical & functional similarity b/w biosimilar candidate and its reference product can reduce the number and scope of subsequent clinical trials

If a biosimilar meets the requirements for biosimilarity, **extrapolation of data** may allow for approval of **additional indications** for which the reference product is indicated w/o other dedicated clinical studies

Lyman GH, et al. *N Engl J Med*. 2018;378(21):2036-44.

Extrapolation: FDA Guidance

- Scientific justification for extrapolation should consider:
  - MOA in each condition
    - Target/receptor(s) for product relevant activity/function
    - Binding, dose/concentration response, and pattern of molecular signaling when product engages with target/receptor(s)
    - Relationships b/w target/receptor interactions and product structure
    - Target/receptor location and expression
  - PK,PD, and biodistribution of product in different populations
  - Immunogenicity of product in different patient populations
  - Differences in expected toxicities for each condition & patient population
  - "any other factor that may affect the safety or efficacy f the product in each condition of use and patient population for which licensure is sought"

FDA. Scientific considerations in demonstrating biosimilarity to reference product: guidance for industry. April 2015.

Extrapolation: Summary

Extrapolation of indication must be scientifically justified and based on the totality of the evidence from the comparability exercise with reference product

When seeking extrapolation indications, pivotal clinical studies to assess efficacy and safety (including immunogenicity) should be conducted in the most sensitive patient population, using endpoints that can detect clinically meaningful differences

Goal of clinical program is not to re-establish patient benefit but to confirm similarity established by the structural and functional characterization

Kozlowski S, et al. *N Engl J Med*. 2011; 365:385-8.

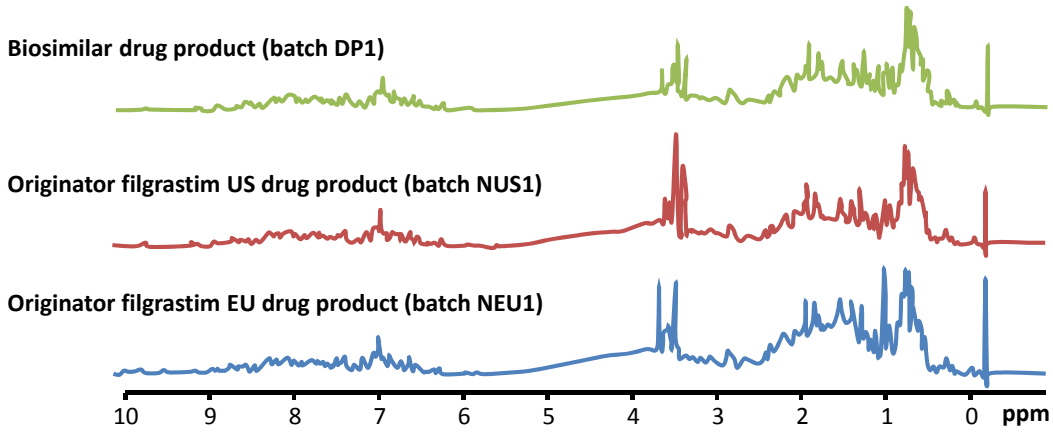
Example: Zarzio®Biosimilar of Filgrastim

- Extrapolation of indications for reference product (Neupogen) indications
- Based on
  - Overall data from the comparability exercise that included head-to-head comparison to reference product using analytical methods showing
    - similar molecular structure and in vitro functioning
    - PK studies showing similar exposure
    - PD studies showing effect on absolute neutrophil and CD34+ cell counts
    - Efficacy and safety (including immunogenicity) studies in cancer patients
    - MOA (binding to GCSF receptor and mediating the same biological activity
- Concerns with extrapolating for use for peripheral blood stem cell mobilization in healthy donors
- Pooled analysis of 5 post-approval studies
  - Similar in efficacy and safety

Curigliano G et al. *Crit Rev in Oncology/Hematology* 2016:104;131-37.

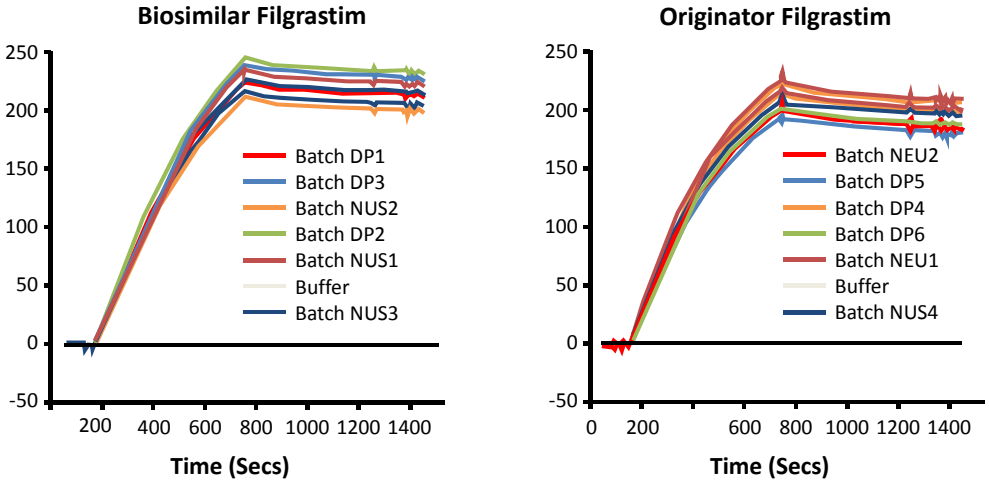
Comparability of Biosimilar Filgrastim With Originator Filgrastim: Protein Characterization

- Protein characterization by NMR spectroscopy



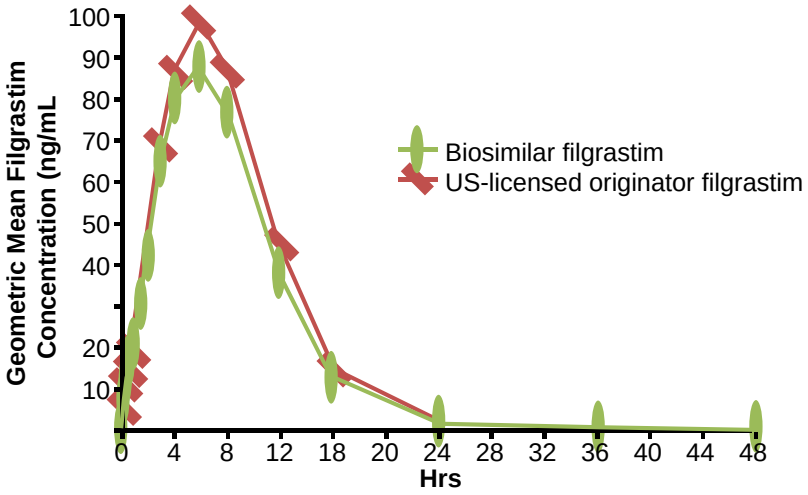
Sorgel F, et al. *BioDrugs*. 2015;29:123-31.

Comparability of Biosimilar Filgrastim With Originator Filgrastim: Receptor-Binding Affinities



Sorgel F, et al. *BioDrugs*. 2015;29:123-131.

Comparability of Biosimilar Filgrastim With Originator Filgrastim: Pharmacokinetics

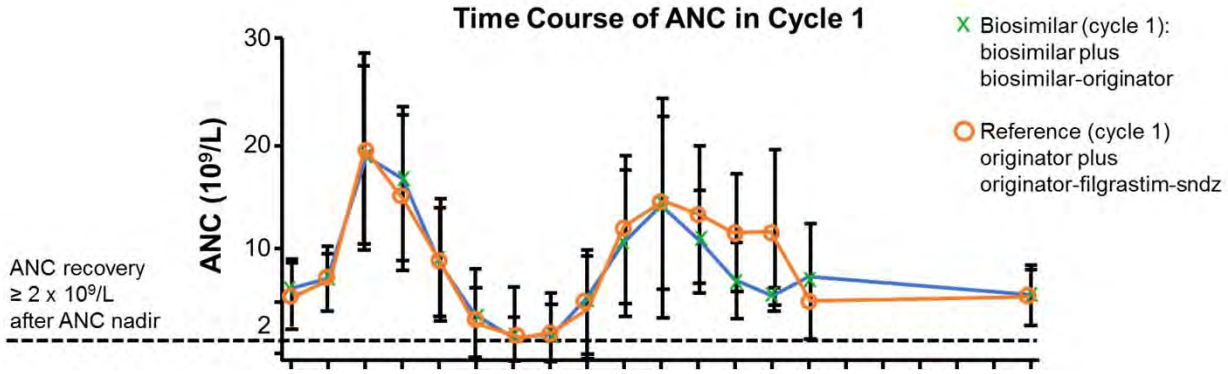


Analysis: no significant differences between the biosimilar and originator product

Sorgel F, et al. *BioDrugs*. 2015;29:123-131.

Biosimilar Filgrastim (Filgrastim-sndz) vs Reference Filgrastim: ANC Recovery

- N = 218 pts with breast cancer receiving myelosuppressive chemotherapy
- Filgrastim 5 µg/kg/day administered over 6 chemotherapy cycles
- Conclusion: biosimilar filgrastim noninferior to originator filgrastim at improving ANC counts



Blackwell K, et al. *Ann Oncol*. 2015;26:1948-1953.

Biosimilar Filgrastim: Extrapolation

- **ODAC recommended the FDA approve filgrastim-sndz for <u>all current indications</u>**
- **Patients with cancer receiving myelosuppressive chemo or bone marrow transplant**
- **AML patients receiving induction or consolidation chemo or undergoing mobilization**
- **Patients with severe chronic neutropenia**

CEDR Summmary Review for Regulatory Action. 2014.

Clinician Perspective on Extrapolation on Therapeutic Biosimilars

PK analysis is essential to show equivalent drug exposure

- PK can differ by the clinical context (eg rituximab for lymphoma vs rheumatoid arthritis)

Monitoring for anti-drug antibodies is a major safety measure

- Immunogenicity
- Neutralizing antibodies or cytokine release

Clinical efficacy should be demonstrated in appropriate patient populations

- Independent trials in NHL and non-malignant disease (rituximab)
- Single agent activity in first line follicular lymphoma as sensitive indicator of sensitivity (rituximab)
- Activity in the metastatic setting (for trastuzumab)

CEDR Summary Review for Regulatory Action. 2014.

Oncology Biosimilars

FDA Approved Oncology Biosimilars

- **Procrit**
  - Epoetin alfa-epbx (Retacrit)
- **Neupogen**
  - Filgrastim-sndz (Zarxio)
  - Filgrastim-aafi (Nivestym)
- **Neulasta**
  - Pegfilgrastim-jmdb (Fulphila)
  - Pegfilgrastim-cbqv (Udenyca)
- **Avastin**
  - Bevacizumab-awwb (Mvasi)
- **Herceptin**
  - Trastuzumab-dkst (Ogivri)

Patent for branded bevacizumab expires in 2020

- Bevacizumab biosimilar: bevacizumab-awwb (ABP-215) FDA approved 2017

Patent for branded trastuzumab expires in 2019

- Trastuzumab biosimilar: trastuzumab-dkst (MYL-14010) FDA approved 2017

FDA. Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations. FDA.gov Website. Updated 19 Sep 2018. Available at: https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/ucm411418.htm.

Pegfilgrastim Biosimilars

	Statutory Requirement	Pegfilgrastim-jmdb (Fulphila)	Pegfilgrastim-cbqv (Udenyca)
Demonstrate High Similarity	Analytical Data • Physiochemical and functional analytical data demonstrated that biosimilar is highly similar to Neulasta®(pegfilgrastim)	✔	✔
	Animal Studies • Confirmed that the pharmacologic & toxicological profiles of Neulasta® and biosimilar are similar	✔	✔
	Clinical Studies • Study to evaluate PK/PD, and safety	Healthy Subjects	Healthy Subjects
Same as Reference Biologic	Mechanism of Action • Mediated by selective binding to the G-CSF receptor and is similar across all labeled indications	✔	✔
	Route of administration • Same route of administration dosage form, and strengths as Neulasta®	✔	✔
	Interchangeable Product	✘	✘

https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/761075Orig1s000SumR.pdf https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/761039s000lbl.pdf

Bevacizumab-awwb (MVASI)

Objective Endpoint	Outcome
Analytical & Functional Assessment	
VEGF binding affinity & inhibition of activity	• Comparable equilibrium binding to VEGF as reference products bevacizumab • Displayed similar potency in inhibition of proliferation in HUVEC and inhibition of VEGFR2 receptor tyrosine kinase autophosphorylation
Comparative binding to FcRn and FcγRIIIa	• Similar in vitro binding to FcRn to originator bevacizumab • In vitro binding to FcγRIIIa was moderately higher for biosimilar vs originator, difference not statistically significant • Bev-aawb and bev have been shown to lack ADCC activity
Antitumor activity in xenograft models	• Displayed similar tumor growth inhibition in colon and epidermoid xenograft models • Inhibited VEGF-induced vascular permeability in mouse skin vascularity
Toxicology	• Similar toxicokinetic parameters in animals studies

Seo N et al. *Mabs*. 2018;10(4):678-91.
Markus R, et al. Gastrointestinal Cancers Symposium. San Francisco, CA; Conference Jan 15-17s.

Bevacizumab-awwb (MVASI)

Objective Endpoint	Outcome
Phase 1 Trial in Health Subjects	
Primary endpoint: AUC_{inf}, C_{max}	• Similar serum concentration-time profiles • Peak concentrations were observed 1.5 -3 hr after of infusion
Secondary endpoint: Safety	• Most Aes were mold to moderate, no AES, SAEs, or deaths led to study discontinuation • AEs possibly or probably related to study drug occurred in 27.3%, 17.1%, and 22.4% of patients who received Bev-awwb, Bev US, & Bev EU • No clinically relevant changes in laboratory tests, ECG, vital signs, or physical examinations

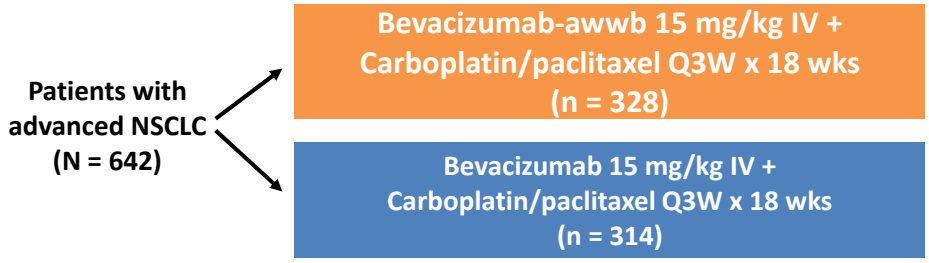
Markus R, et al. *Cancer Chemother Pharmcol*. 2017;80(4):755-63.

Bevacizumab-awwb vs Bevacizumab in Normal Volunteers: Pharmacokinetics

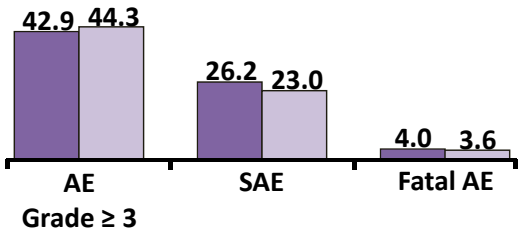
Agent	Mean C_{max} µg/mL (n)	Mean AUC_{last}µg h/mL (n)	Mean AUC_{inf} µg h/mL (n)	Median t_{max}(h) (n) (range)	Mean $t_{1/2}$ (days) (n) (SD)
Bev-awwb	87.2 (67)	28,200 (62)	29,400 (66)	1.50 (67) (1.47-24.0)	17.77 (66) (3.68)
Bev (US)	89.1 (66)	28,500 (62)	29,600 (66)	1.50 (66) (1.48-24.0)	17.5 (66) (3.39)
Bev (EU)	84.7 (64)	29,400 (64)	30,600 (66)	3.94 (64) (1.47-8.00)	18.5 (66) (3.28)

Markus R, et al. *Cancer Chemother Pharmacol*. 2017;80:755-763.

Phase III Trial: Bevacizumab-awwb vs Bevacizumab in Advanced NSCLC



Agent	ORR, %	Median DoR, Mos
Bevacizumab-awwb (n = 324)	39	5.8
Bevacizumab (n = 314)	41.7	5.6



FDA Advisory Committee document. ABP 215 – Bevacizumab biosimilar candidate.

Bevacizumab-awwb: Secondary endpoints

Phase III trial in nonsquamous NSCLC	
PFS	• PFS was comparable in the Bev-awwb 60.1% vs bevacizumab 60.2% • Estimated HR for Bev-awwb realtive to bevacizumab was 1.03 (90% CI, 0.83, 1.29)
OS	• Fatal AEs occurred in 4.0% with Bev-awwb vs Bev 3.6% • OS comparable Bev-awwb 86.7% vs Bev 88.3%
Incidence of ADAs	• Immunogenicity was similar, Bev-awwb 1.4% vs Bev 2.5% • No patient developed neutralizing antibodies

ADA = Antidrug Antibody

Thatcher et al. 17th world conference on lung cancer. Vienna Austria Dec4-7s., ESMO conference 2018 Copenhage, Denkmark October.

Bevacizumab-awwb: Extrapolated Indications

- Metastatic colorectal cancer
  - First- or second-line treatment combined with IV 5-FU-based chemotherapy
  - Second-line treatment with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy after progression with first-line bevacizumab regimen
  - Not indicated for the adjuvant treatment of surgically resected colorectal cancer
  - Non-squamous NSCLC
  - First-line treatment of unresectable, locally advanced, recurrent, or metastatic NSCLC in combination with carboplatin/paclitaxel
  - Glioblastoma
  - Second-line treatment in progressive disease following prior therapy, based on improvement in ORR
- Metastatic renal cell carcinoma
  - In combination with interferon alfa
- Cervical cancer
  - In patients with recurrent, persistent, or metastatic disease, in combination with paclitaxel/cisplatin or paclitaxel/topotecan

FDA. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm576112.htm

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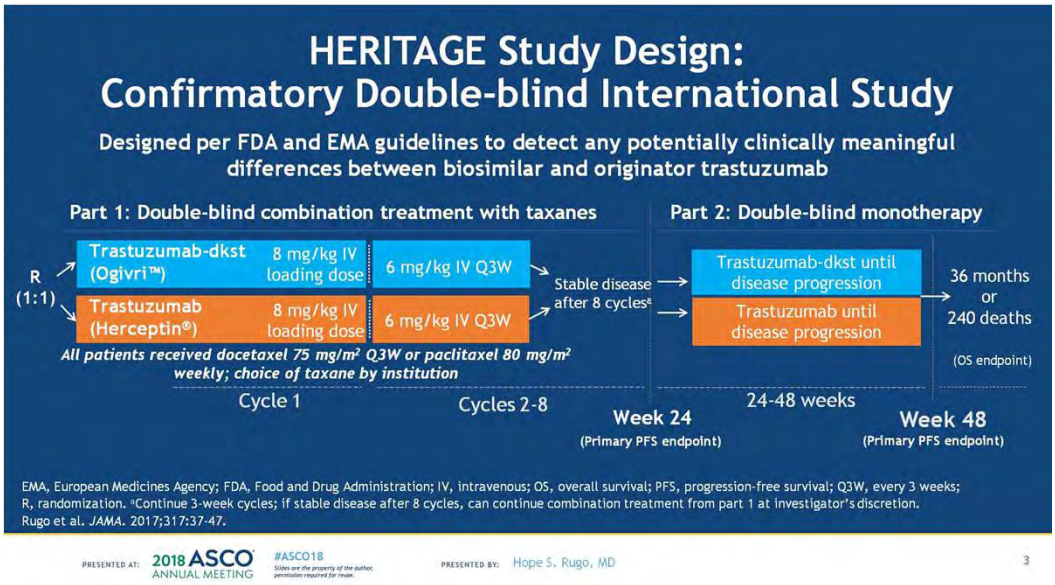

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Similar Efficacy Between Trastuzumab-dkst and Trastuzumab Observed Through 48 Weeks

	Progression-free survival		Overall survival[b]	
	Trastuzumab-dkst	Trastuzumab	Trastuzumab-dkst	Trastuzumab
Median (95% CI)	11.1 (8.81-11.20)	11.1 (8.60-11.20)	NE	NE
Log-rank *P* value	0.842 + censored		0.131 + censored	
Stratified hazard ratio (95% CI)[a]	0.95 (0.714-1.251)		0.61 (0.360-1.039)	
P value	0.694		—	

[a]Stratified by assigned taxane, tumor progression, and tumor endocrine status. [b]Assessments are ongoing and OS will be calculated after 240 deaths or 36 months.

NE, not estimable; OS, overall survival.

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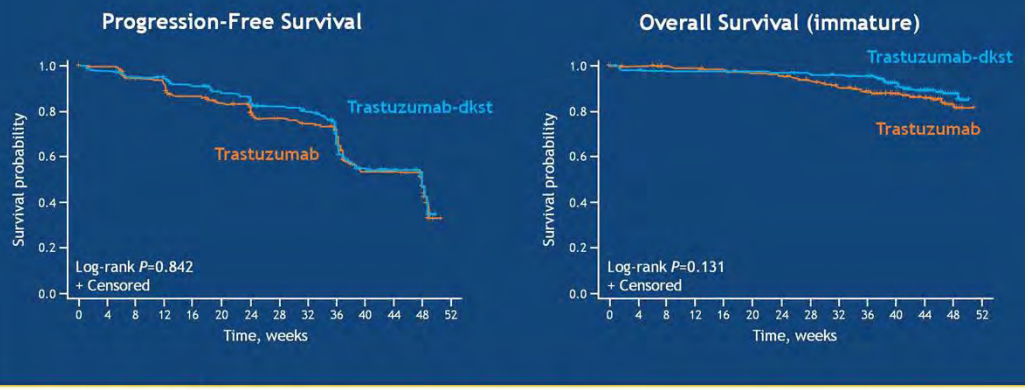
Similar Efficacy Between Trastuzumab-dkst and Trastuzumab Observed Through 48 Weeks



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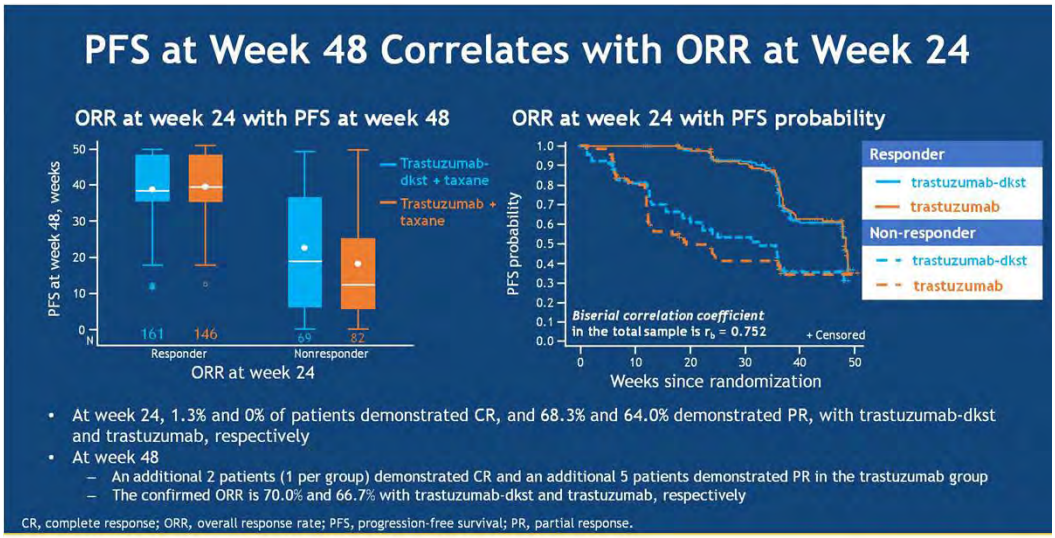

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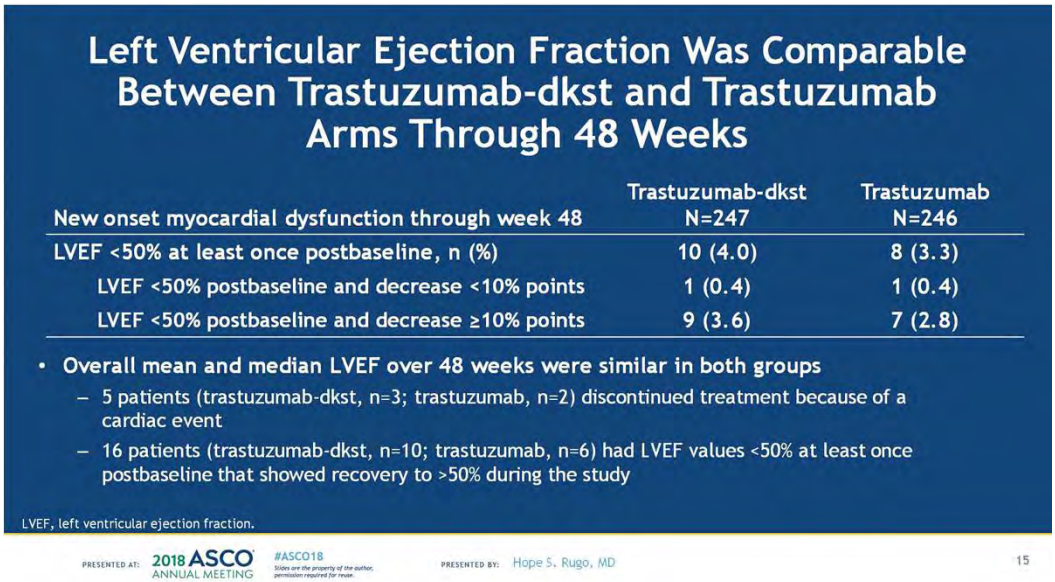

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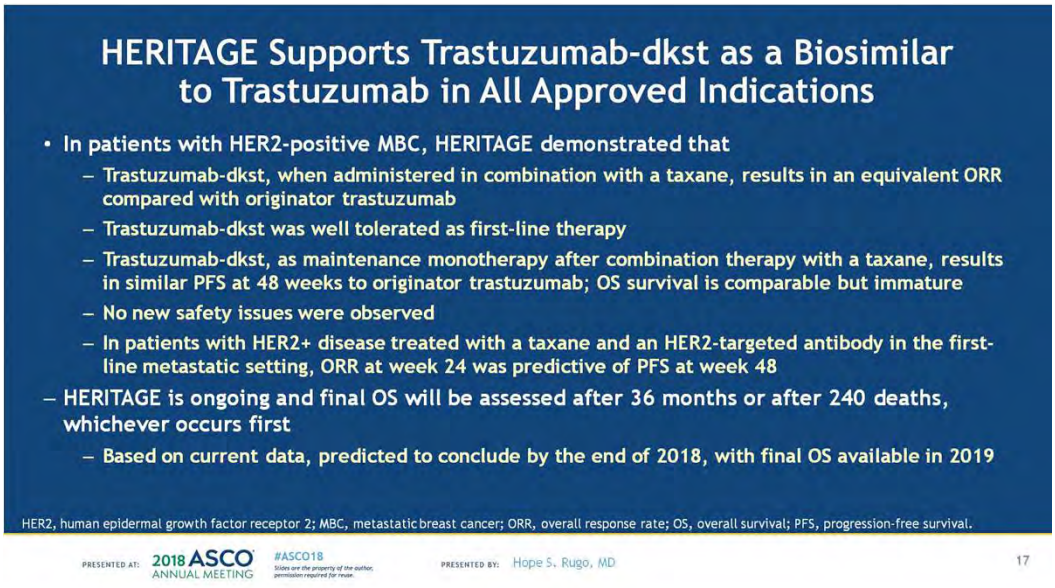

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Selected Trastuzumab Biosimilars in 1:1 Randomized Phase III Trials

Agent	Study Design	Endpoints	Results	Researcher Conclusions
ABP 980 (LILAC)	ABP 980 vs OriT (both + paclitaxel q3w x 4 cycles neoadjuvant, then w/out paclitaxel q3w to 1 yr adjuvant) on pCR in patients with HER2+ EBC (N=725; n = 696 in pCR evaluable pop.).	1st: RD, RR of pCR in breast tissue + axillary lymph nodes. 2nd: safety	pCR in ABP 980 vs OriT: 48.0% vs 40.5%; RD: 7.3%; RR: 1.19%. Grade ≥3 TEAEs: 14.8% vs 14.1%.	ABP 980 and OriT clinically equivalent in neoadjuvant setting for these patients.
PF-05280014 (REFLECTIONS B327-04)	PF-05280014 vs T-EU (8 mg/kg→6 mg/kg q3w x 6 cycles w/docetaxel + carboplatin) in patients with HER2+ EBC (N=226), stratified by hormone receptor status, primary tumor size.	1st: steady state drug concentration C_{trough} >20 µg/mL at Cycle 5; 2nd: ORR, pCR	C_{trough} >20 µg/mL in PF-05280014 vs T-EU: 92.1% vs 93.3%. pCR, 47% vs 50%; ORR, 88.1% vs 82.0%.	PF-05280014 showed similarity to T-EU in safety and immunogenicity, and noninferiority in PK

bpCR, breast pathologic complete response; EBC, early breast cancer; HER2, human epidermal growth factor receptor 2; LVEF, left ventricular ejection fraction; MBC, metastatic breast cancer; OriT, originator trastuzumab; pCR, pathologic complete response; PK, pharmacokinetics; T-EU, European Union-sourced reference trastuzumab.

Von Minkwitz G, et al. ESMO 2017. Abstract 151PD. Lammers P, et al. ESMO 2017. Abstract 154PD. Pegram M, et al. ESMO 2017. Abstract 238PD. Pivot X, et al. *J Clin Oncol*. 2018; 36:968-74.

Selected Trastuzumab Biosimilars in 1:1 Randomized Phase III Trials (cont'd)

Agent	Study Design	Endpoints	Results	Researcher Conclusions
PF-05280014 (REFLECTIONS B327-02)	First-line PF-05280014 vs T-EU (first dose 4 mg/kg; then 2 mg/kg weekly until at least week 33 (both + paclitaxel) in patients with HER2+ MBC (N=707).	1st: ORR. 2nd: safety, tumor control, PK, immunogenicity	PF-05280014 vs T-EU: ORR = 0.940; Safety, PK, immunogenicity equivalent.	PF-05280014 similar to T-EU for efficacy, immunogenicity, safety, and PK.
SB3	SB3 vs OriT (8→6 mg/kg q3w x 8 cycles) + DOC and FEC (4 cycles) neoadjuvant in pts w/HER2+ EBC or LABC, LVEF ≥ 55% (N = 875)*, then 10 cycles adjuvant SB3 vs OriT.	1st: pCR in breast tumor. 2nd: safety, immunogenicity, EFS, OS	bpCR in SB3 vs OriT: 51.7% vs 42.0%.PK, safety, immunogenicity equivalent.	SB3 comparable to OriT for safety, PK, immunogenicity, and efficacy.

*Stratified by hormone receptor status, disease stage.

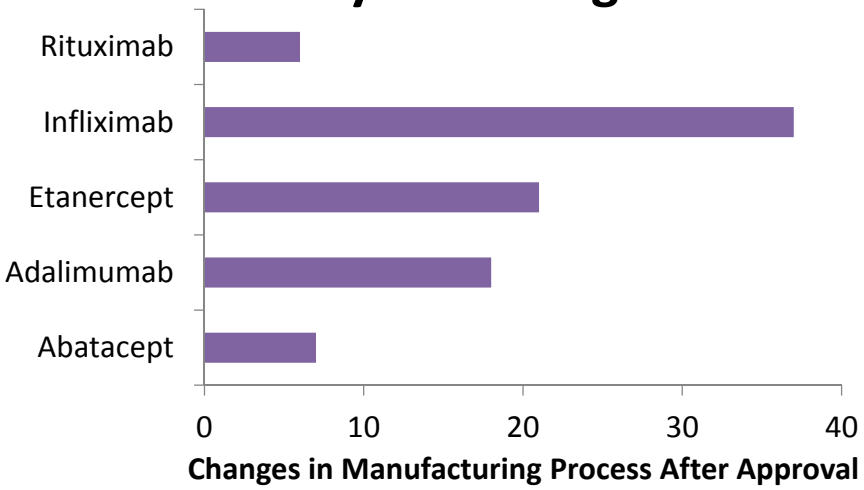
bpCR, breast pathologic complete response; EBC, early breast cancer; HER2, human epidermal growth factor receptor 2; LVEF, left ventricular ejection fraction; MBC, metastatic breast cancer; OriT, originator trastuzumab; pCR, pathologic complete response; PK, pharmacokinetics; T-EU, European Union-sourced reference trastuzumab.

Von Minkwitz G, et al. ESMO 2017. Abstract 151PD. Lammers P, et al. ESMO 2017. Abstract 154PD. Pegram M, et al. ESMO 2017. Abstract 238PD. Pivot X, et al. *J Clin Oncol*. 2018; 36:968-74.

Therapeutic Oncology Biosimilars: Perspectives

- Many oncologist regard supportive care biosimilars is easier compared to therapeutic biosimilars
  - Suboptimal drug performance would have fewer ramifications in this setting
- Extrapolation
  - Metastatic settings to curable settings
  - Metastatic to neoadjuvant setting
  - Combination with other agents (ie pertuzumab)
- Long-term outcomes
- Effect on cost
  - Impact on practice
  - Impact on patient

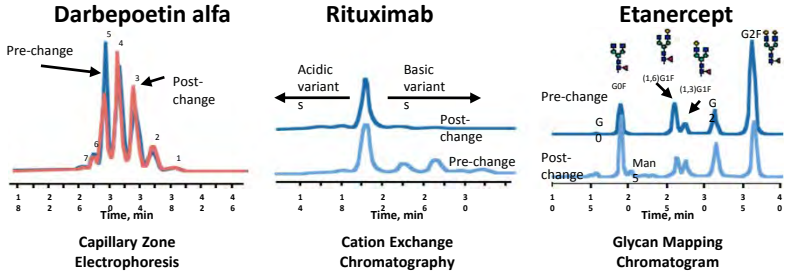
Reference Biologics and Post-Approval 'Life Cycle' Changes



Schneider CK. *Ann Rheum Dis*. 2013; 72:315-318.

Originator Manufacturing Process Changes

- Small modifications may result in gradual changes



- Despite these differences, when the products are within a prespecified acceptable range, the products are marketed with no change in label
- If large alterations occur, analytical studies (and possibly additional clinical studies) are required to compare post-change product with existing pre-change product

Schiestl M, et al. *Nature Biotechnology*. 2011;29(4):310-312.

Interchangeability of Biosimilars

- An "interchangeable" biologic product must demonstrate that it can be expected to produce the same clinical result as the reference product in any given patient
- In addition, if the biologic product is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biologic product and the reference product is not greater than the risk of using the reference product without such alternation or switch

Federal Register. 2010. 24853.

Interchangeability

- Safety standards for determining interchangeability
  - Major risk is immunogenicity
  - Residual questions about diminished efficacy or increased immune-related reactions
- Will be "difficult" in the initial 351(k) application due to the sequential nature of the assessment
  - Immune reactions are highly variable and sensitive to many different factors
  - Data package to be submitted will generally not be sufficiently sensitive to detect rare/serious adverse events

H.R.3590 Patient Protection and Affordable Care Act (Enrolled Bill [Final as Passed Both House and Senate] - ENR. Food and Drug Administration. 10 Oct. 2016. http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/ucm216146.pdf.

Biosimilar Switch Considerations

- Decisions should be evidence-based (including real-world data)
- Decisions by treating M.D. made on case-by-case basis
- Switching data should not be extrapolated
- Automatic substitution not recommended at this time
- Close monitoring post-switch (enrolled in registries)

Moots R et al. *Curr Rheumatol Rep*. 2017; 19:37.

Biosimilar Switch Considerations

- Previous adverse reactions
- Utility of anti-drug antibodies (ADAs)/serum drug level testing
- Benefits investigation
- Pharmacovigilance:
  - Enroll patients in national registries
  - MedWatch reporting

Moots R et al. *Curr Rheumatol Rep*. 2017; 19:37.

Interchangeability

- 351(k) required conditions for interchangeability designation:
  - Biosimilarity established
  - Produces same clinical result in any given patient
  - Risk in terms of safety or efficacy of alternating or switching is not greater than risk of using innovator product without alternation or switch
- 351(i) interchangeability actionable definition:
  - "Product that may be substituted for the reference product without the intervention of the healthcare provider who prescribed the reference product"
  - Substitution depends on state law

FDA. Considerations in Demonstrating Interchangeability with a Reference Product: DRAFT Guidance. September 20, 2017.

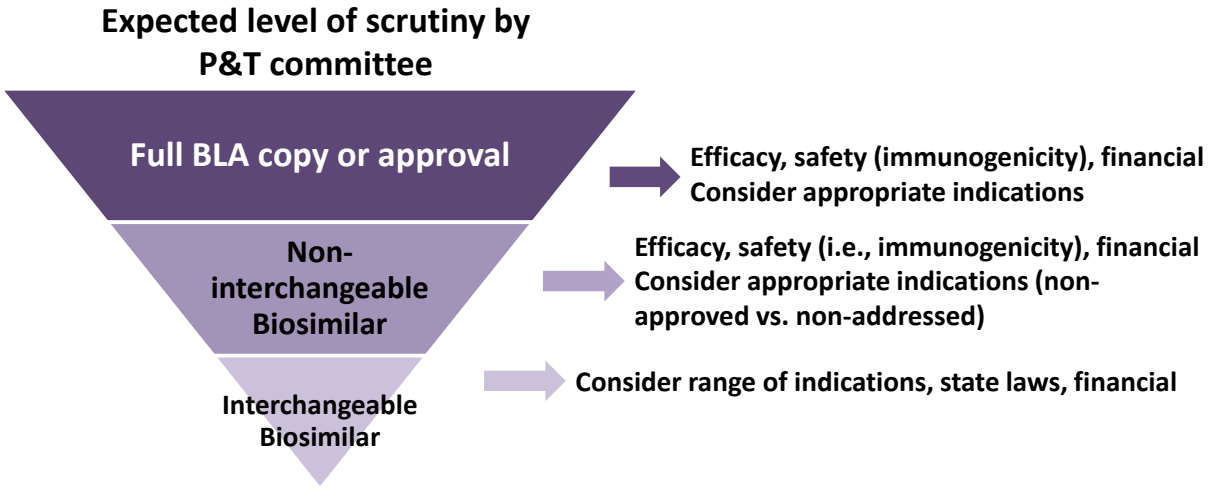
Interchangeability Guidance

- Draft guidance released by FDA in January 2017
- Scope:
  - Data/information needed to demonstrate interchangeability
  - Key design and analysis requirements of a switching study or studies to support interchangeability
  - Recommendations regarding use of innovator product in a switching study or studies
  - Considerations for presentations, devices, closure systems for proposed interchangeable products

FDA. Considerations in Demonstrating Interchangeability with a Reference Product. Guidance for Industry. September 20, 2017.

Therapeutic Interchange for Biosimilars

Explicit review of similarity data by the FDA will make interchange decisions easier for these indications



Therapeutic Interchange for Biosimilars

- FDA categorization as “interchangeable biosimilar” or “biosimilar”
  - Potential impact of state laws on implementation
- Prepare a monograph for the biosimilar and policy for review by the P&T committee
  - Describe the data comparing the biosimilar with reference product
  - Expected outcomes
    - Clinical: efficacy, safety, immunogenicity
    - Economic
- Many examples:
  - Non-biologics: analgesic, anti-infective, cardiovascular, CNS, GI
  - Biologics: Insulins, IVIG, erythropoiesis-stimulating proteins

Tyler LS et al. *Am J Health-Syst Pharm*. 2008; 65:1272-83.

Therapeutic Interchange Challenges

- Biosimilarity (and interchangeability) data may not be available for all indications
  - May need to extrapolate or
  - Limit use to specific indications
- Transitions of care
  - Risk of immunogenicity
  - Patient cost burden/preference
  - Prescriber preference

Tyler LS et al. *Am J Health-Syst Pharm*. 2008; 65:1272-83.

The Purple Book

- Simple PDF; not a searchable database like the Orange Book
- Go-to list for biologic and biosimilar products approved by the FDA
- Information provided:
  - Date of approval
  - Approval pathway [351(a), 351(k)]
  - Interchangeability status (I)
  - Biosimilar status (B)
  - Exclusivity expiration date
- Updated “as resources permit”

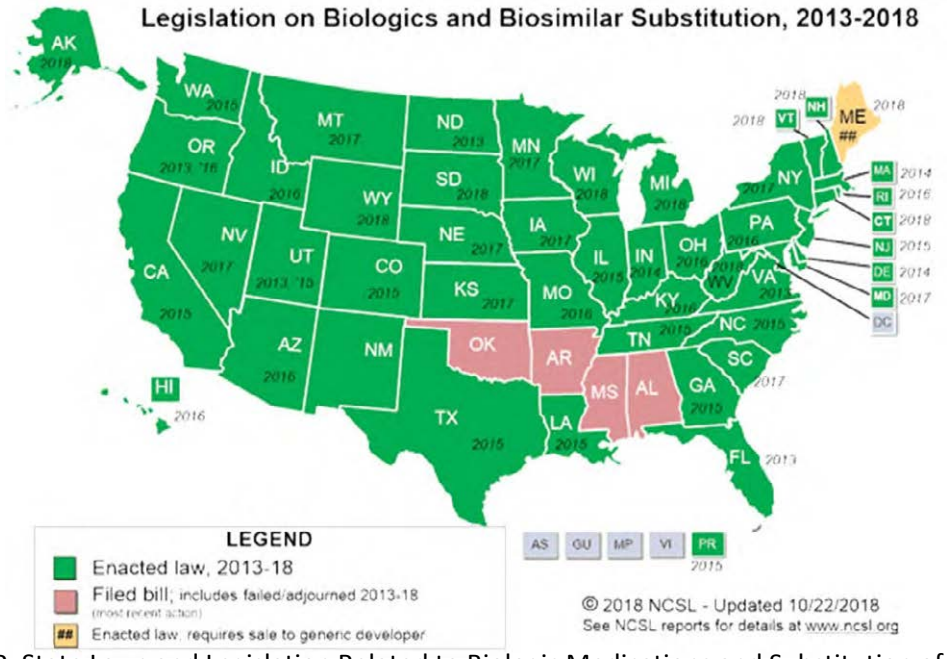
FDA. The Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations. September 20, 2017.

Example Purple Book Listing

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)	WITHDRAWN
125118	abatacept	Orencia	12/23/05				
103575	abciximab	ReoPro	12/22/94	NA	NA		
125274	abobotulinumtoxinA	Dysport	04/29/09				
125057	adalimumab	Humira	12/31/02	NA	NA		
761058	adalimumab-adbm	Cyltezo	08/25/17			B	

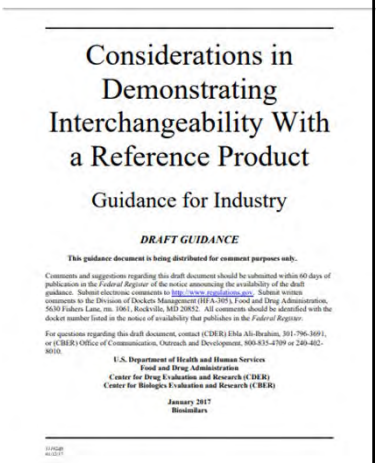
FDA. The Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations. September 20, 2017.



Cauchi R. State Laws and Legislation Related to Biologic Medications and Substitution of Biosimilars. National Conference of State Legislatures; 2018.

Interchangeability

- Interchangeable is an FDA designation
  - Requires higher standards than 'biosimilarity' alone
- A product with an interchangeable designation may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product
- HOWEVER
  - FDA approval requirements for interchangeable designation and trial design for testing are not finalized
  - State substitution laws will impact practice
  - Any biological product under consideration for substitution must first be approved as "interchangeable" by the FDA



Considerations in Demonstrating Interchangeability With a Reference Product

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

January 2017
Biosimilars

http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm290967.htm
http://www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx.

Therapeutic Interchange

- Therapeutic interchange "provides pharmacists with the authorization to use a formulary therapeutic alternative in place of a non-formulary medication or a non-preferred formulary medication"
  - Automatic or with prescriber pre-notification
  - Notification is done in a systematic manner
- Appropriate for drugs with different chemical structures and similar safety/efficacy profile
- Endorsed by PhRMA and AMA
- Guidelines available from the American College of Clinical Pharmacy

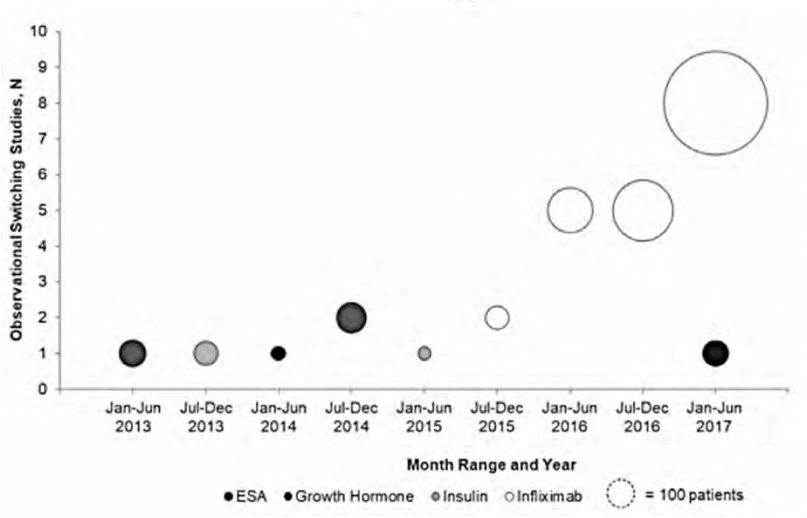
Tyler LS et al. *Am J Health-Syst Pharm*. 2008; 65:1272–83; Gray T, et al. *Pharmacotherapy*. 2005; 25:1666–80; Gray T et al for the American College of Clinical Pharmacy. *Pharmacotherapy*. 2005; 25:1666-80.

Generic or Therapeutic Substitution Policy

- ASHP guideline definitions:
  - Generic equivalents: drugs considered to be bioequivalent by FDA
  - Therapeutic equivalents: products differing in composition or drug entity considered to have similar therapeutic profile
- Best Practices:
  - Pharmacist is responsible for product selection (pursuant to the order)
  - Prescriber opt-out (justification must be scientifically and clinically sound)
- Address interchangeable biosimilar requirements (if state law allows) or utilize therapeutic equivalence

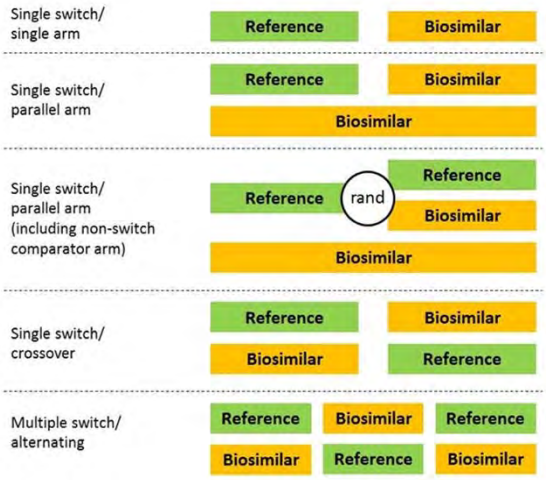
Tyler LS et al. *Am J Health-Syst Pharm*. 2008; 65:1272–83.

Publication Trends in Biosimilar Switching



McKinnon RA et al. *BioDrugs*. 2018; 32:27-52.

Interchangeability Studies



www.gabionline.net/Guidelines/FDA-issues-draft-guidance-on-biosimilar-interchangeability

Considerations for pharmacists evaluating biosimilars for formulary inclusion

Considerations for P&T Committee Members Evaluating Biosimilars for Formulary Inclusion

Clinical Considerations

- **Indications**
- **Evaluation of efficacy and safety using available data**
- **Immunogenicity**

Product Considerations

- **Nomenclature**
- **Manufacturing and supply chain considerations**
- **Packaging, labeling, and storage**

Institutional Considerations

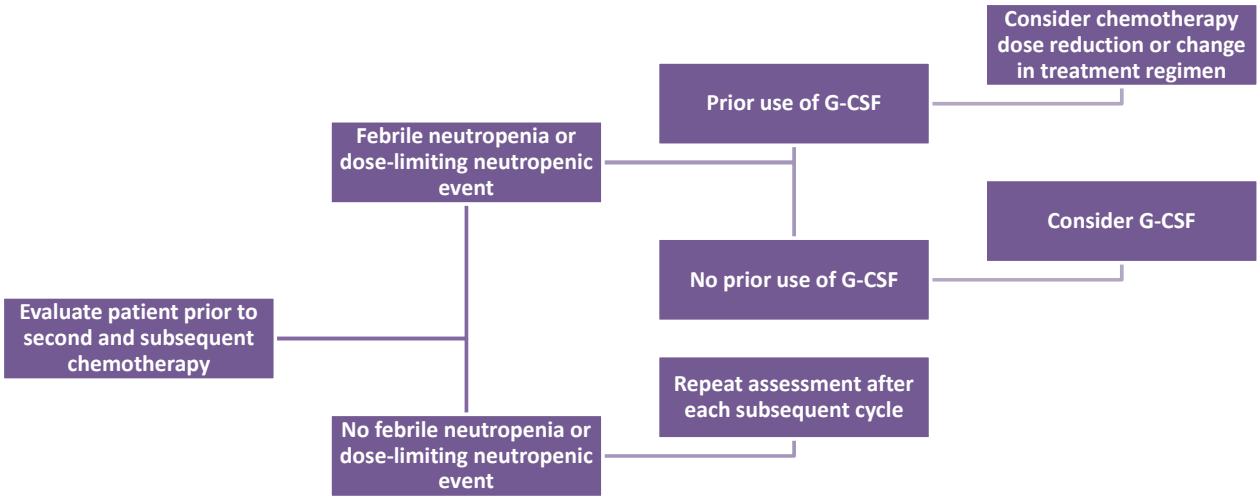
- **Substitutions and interchangeability**
- **Therapeutic interchange**
- **Transitions of care**
- **Pharmacovigilance**
- **Cost**
- **Reimbursement**
- **Provider and patient education**
- **Information technology**

Ventola CL.*P&T*. 2015:40;680-689.

P&T Conversations at the Coffee Table

Product characteristics	Are there any differences in formulation or excipients between the biosimilar under consideration versus the reference product?
	Are there any differences in compatibility (e.g., injection pain, interference with laboratory assays) between the biosimilar under consideration and the reference product?
Medication availability	Are there any differences in clinic administration and/or retail availability between the biosimilar under consideration and reference product that may affect the overall availability of the products?
	Does the manufacturer have a process to ensure a reliable and uninterrupted supply of the product? Does the manufacturer maintain adequate levels of reserve product in stock?
Reimbursement	Will the biosimilar have all of the same indications as the originator?
Information technology support	Does the hospital have a robust information technology infrastructure to support the biosimilar? – Differentiating the biosimilar under consideration from the reference product during order entry? – Tracking which product was administered (biosimilar under consideration versus the reference product)?

Guideline Recommendations



National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology : Myeloid growth factors, version 2. 2018.

Guideline Recommendations

- Febrile neutropenia is defined as a single temperature ≥38.3° C or ≥38° C for over 1 hour.
- Neutropenia: <500 neutrophils/mcL or <1000 neutrophils/mcL and a predicted decline to ≤500 neutrophils/mcL over the next 48 hours
- G-CSF refers to the following approved agents: filgrastim, filgrastim-sndz, tbo-filgrastim, and pegfilgrastim.
- Dose-limiting neutropenic event could be a nadir count or day of treatment count that could otherwise impact planned dose of chemotherapy.

National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology : Myeloid growth factors, version 2. 2018.

Clinical Guideline Incorporating Biosimilars

Indication	Recommendation
G-CSF for prophylaxis of febrile neutropenia and maintenance of scheduled dose delivery	Filgrastim (Category 1); tbo-filgrastim (Category 1); filgrastim-sndz (Category 1); pegfilgrastim (Category 1)
MGFs for therapeutic use and maintenance of scheduled dose delivery	Filgrastim; filgrastim-sndz; sargramostim
Mobilization of hematopoietic progenitor cells in autologous setting	1. Single-agent growth factor – Filgrastim; filgrastim-sndz; tbo-filgrastim 2. Combination chemotherapy followed by MGF – Filgrastim; filgrastim-sndz; tbo-filgrastim 3. Concurrent MGF – Filgrastim/filgrastim-sndz + sargramostim 4. MGF + plerixafor – Filgrastim; filgrastim-sndz; tbo-filgrastim

G-CSF = granulocyte colony-stimulating factor; MGF = myeloid growth factor.

Adapted from: National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Myeloid growth factors, version February 2018. Please note: NCCN lacked sufficient data to consider pegfilgrastim-jmdb and filgrastim-aafi, which had been recently approved by FDA when the guidelines were released. Pegfilgrastim-cbqv was not yet approved when the NCCN guidelines were released.

Education of providers

- Physicians, patients, and employers lack awareness about the safety of and savings opportunity from biosimilars
- Biosimilar manufacturer
  - Provide patient and physician education
- Payers: Incentivize stakeholders to gain experience
- Employers: Share biosimilar savings with employees
- Policymakers: Promote biosimilars as safe and effective

Physician Familiarity with Biosimilars

- Survey Evaluation of NCCN Participants on Biosimilars
- Rate their familiarity with developments for biosimilars, including recent legislation that provides an approval pathway for non-innovator (e.g., "generic")
- Address an understanding of manufacturers to introduce copies of biologics through an abbreviated review process

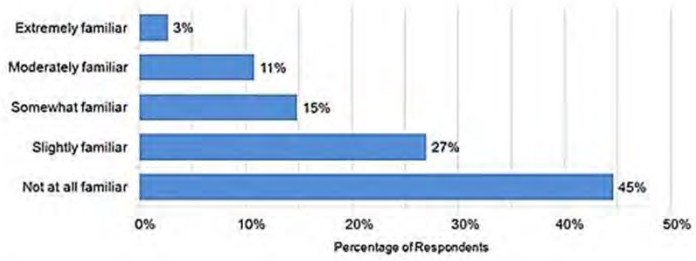
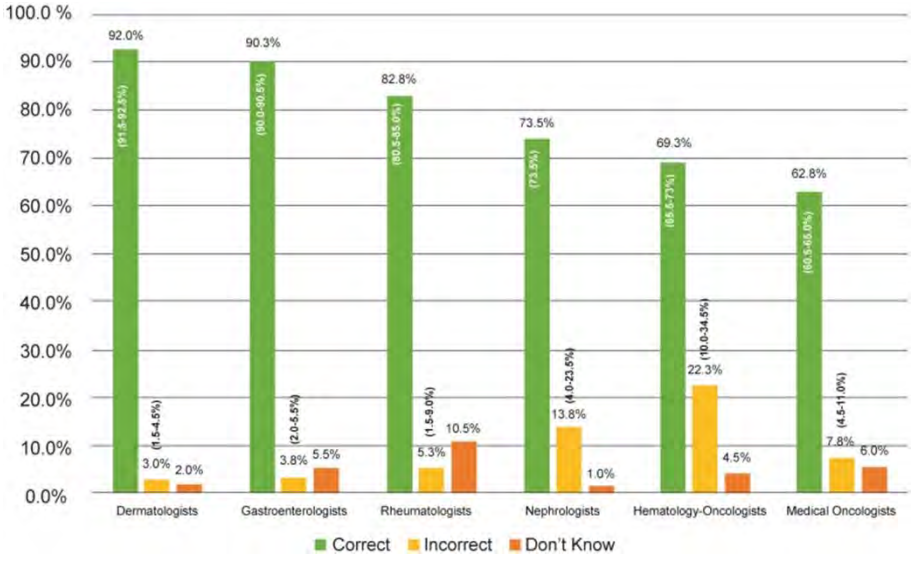


Figure 1. Familiarity with developments for biosimilars. Respondents were asked their level of overall familiarity with the developments for biosimilars, including recent legislation that provides an approval pathway for manufacturers to introduce biosimilars through an abbreviated review process (n=74).

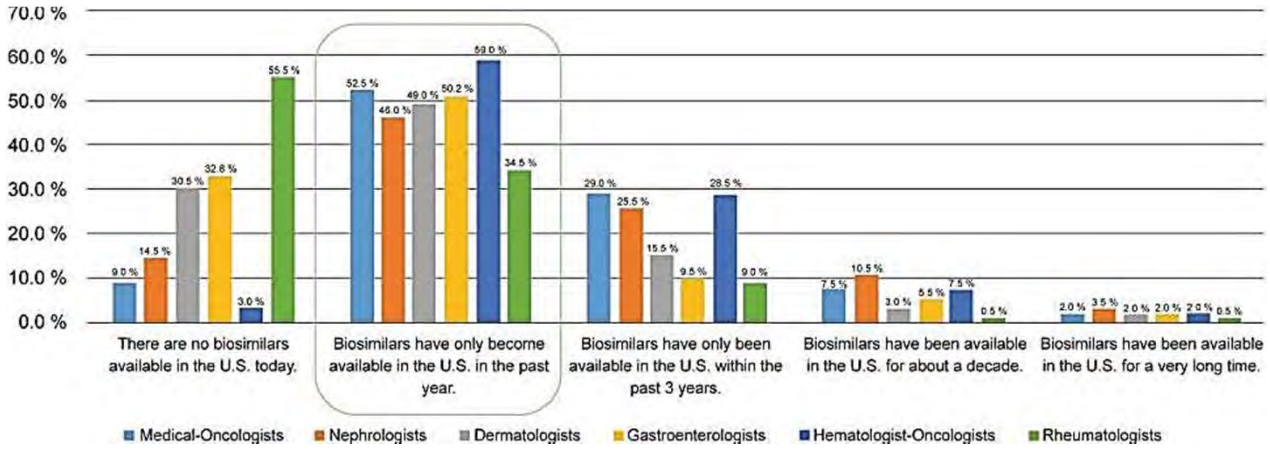
Biosimilars: More Education is Needed, NCCN eBulletin, April 18, 2011

Physician Ability to Identify Biologics



Cohen H et al. *Adv Ther*. 2016; 33:2160-72.

Physician Awareness of Biologics and Biosimilars

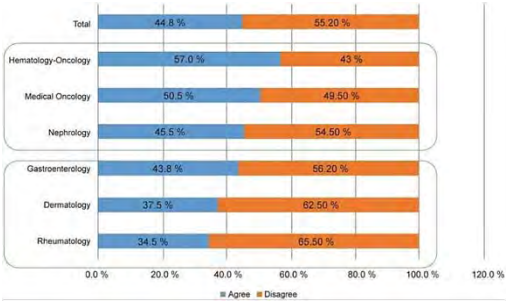


Cohen H et al. *Adv Ther*. 2016; 33:2160-72.

Physician Understanding of Biosimilars

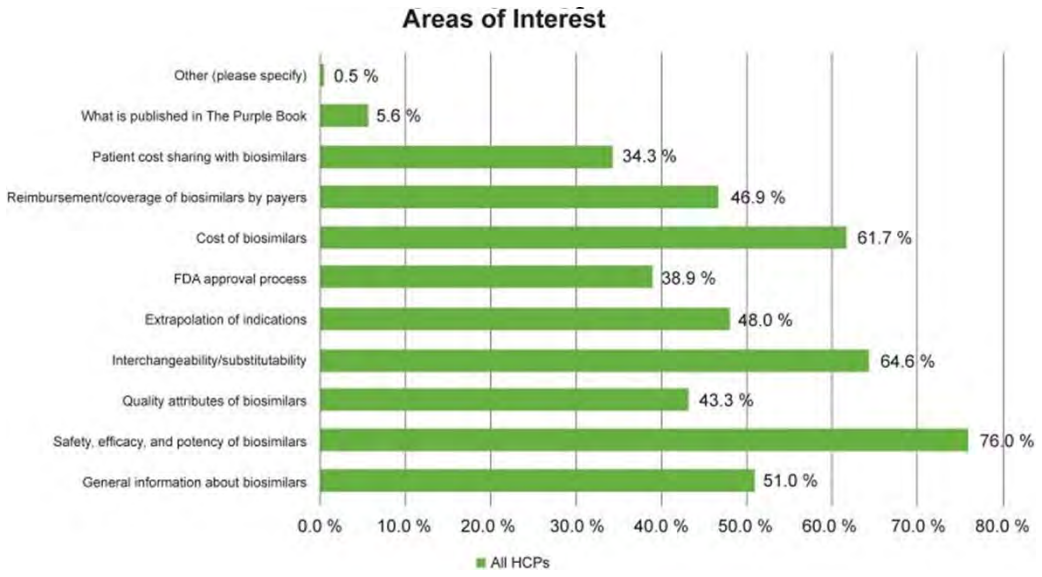
	Medical-Oncologists	Nephrologists	Dermatologists	Gastroenterologists	Hematologist-Oncologists	Rheumatologists	Total
A. The biosimilar will have equivalent efficacy as its originator brand counterpart.	67.5 %	67.5 %	52.0 %	59.2 %	69.0 %	58.5 %	62.3 %
B. The biosimilar will be at least as safe as its originator brand counterpart.	66.5 %	53.5 %	48.0 %	56.7 %	62.5 %	56.0 %	57.2 %
C. A pharmacist will be allowed to substitute a biosimilar for the originator brand counterpart without asking the prescriber.	18.5 %	22.0 %	28.0 %	14.9 %	17.5 %	22.0 %	20.5 %
D. The biosimilar will always be approved for all of the indications of use of the originator brand counterpart.	28.5 %	27.5 %	25.5 %	24.9 %	37.0 %	29.0 %	28.7 %
E. None of the above.	3.0 %	5.0 %	9.5 %	9.5 %	2.5 %	7.0 %	6.1 %
F. I don't know	7.0 %	7.0 %	9.5 %	6.0 %	7.5 %	8.0 %	7.5 %

Expectation that biosimilar use will be safe and appropriate in naïve and existing patients



Cohen H et al. *Adv Ther*. 2016; 33:2160-72.

Physician Interest in Understanding



Cohen H et al. *Adv Ther*. 2016; 33:2160-72.

Physician Education Tips From Pharmacists

- Provide physicians with easy access to current clinical information on biologic therapies, including therapeutic guidelines, clinical trial results, and adverse effects
  - Address during grand rounds
    - Development of biologics and biosimilars
  - Address during P&T committee meetings
    - During formulary review
      - Efficacy
      - Outcomes
      - Safety
      - Extrapolation of data
      - Cost
  - Address during one-on-one discussions
    - Biosimilar basics
    - Clinical studies
    - Current outcomes data
- Reinforce this information with advanced practitioners and nurses

Patient Knowledge

- A 2015 American Autoimmune-Related Diseases Association survey of 362 of its members, 96% of whom have an autoimmune disease, found that more than 80% did not know what biosimilar medicines were
- In 2015, 67% of consumers did not know what a biosimilar was, while only 17% chose the correct definition from several choices
- Payers may target patients directly with information about lower costs for biosimilars compared with the reference biologic medication

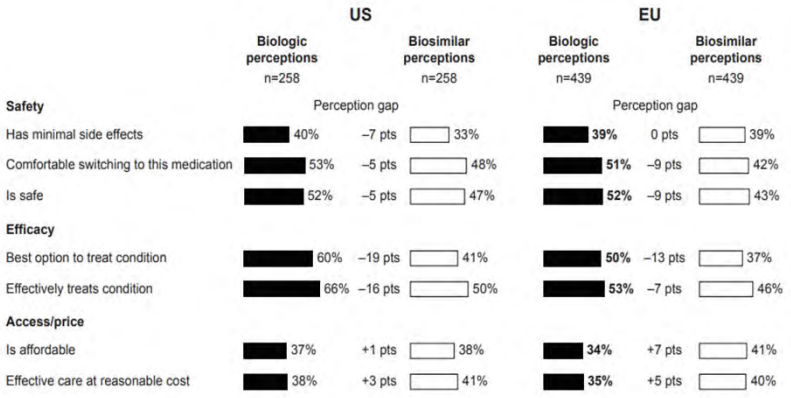
aarda.org/wp-content/uploads/2017/03/BiosimilarsWhitePaperPressRelease.pdf. Accessed October 22, 2018.
pwchk.com/en/people-and-organisation/hc-top-issues-10-jun2016.pdf. Published June 2016. Accessed October 14, 2018

Patient Awareness of Biosimilars

	US, %			European Union, %		
	General population n=250	Diagnosed n=635	Diagnosed advocacy n=245	General population n=499	Diagnosed n=1009	Diagnosed advocacy n=245
BIOLOGIC THERAPY (AWARENESS)						
Has at least a general impression	11	30	47	10	19	43
Just know the name	16	19	31	17	26	29
Not sure	17	17	12	22	18	15
Never heard of it	57	33	10	50	37	12
Currently use	N/A	18	29	N/A	9	31
BIOSIMILAR THERAPY (AWARENESS)						
Has at least a general impression	6	9	20	6	11	30
Just know the name	10	16	27	10	19	31
Not sure	14	21	23	19	22	19
Never heard of it	70	54	31	66	49	20
Currently use	N/A	2	9	N/A	5	22

Jacobs I et al. *Patient Prefer Adherence*. 2016; 10:937-48.

Patient Biosimilar Understanding



Jacobs I et al. *Patient Prefer Adherence*. 2016; 10:937-48.

Pharmacists Tips for Educating Patients

- Use of biologic therapies in the specific disease
- Definition of a biosimilar
- Totality of evidence required for a biosimilar
- Efficacy similar to innovator (reference) biologic
- Safety similar to innovator biologic
- Delivery/administration of the agent
- Device use (if applicable)
- Access to treatment, insurance coverage, and out-of-pocket cost
- Services available to support the patient
- Clinical trials, including standard biosimilar trial design (active innovator comparator; no placebo arm)
- Manufacturer identity

The American Society of Clinical Oncology recommendations

- Call for healthcare professionals to educate patients
- Need for medical societies, government sources, and patient advocacy organizations to provide public awareness
- Develop education programs
- Establish as well as use standardized, publicly available materials

Lyman GH et al. *J Clin Oncol.* 2018;36:1260-5.

FDA Regulation on Biosimilars

Biosimilar Action Plan

1. Improving the efficiency of the biosimilar and interchangeable product development and approval process
2. Maximizing scientific and regulatory clarity for the biosimilar product development community
3. Developing effective communications to improve understanding of biosimilars among patients, providers, and payers
4. Supporting market competition by reducing gaming of FDA requirements or other attempts to unfairly delay market competition to follow-on products

https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/UCM613761.pdf. July 2018

FDA Regulation on Biosimilars

Key Agenda Goals

1. Exploring whether data-sharing agreements with other regulatory systems could provide insight into biosimilars' real-world safety and efficacy, as well as facilitate the increased use of non-US licensed comparator products in similarity studies
2. Updating The Purple Book and evaluating how to incorporate additional information to provide developers with more transparency
3. Releasing finalized biosimilar labeling guidance
4. Developing new FDA review tools, such as standardized review templates, that are tailored to biosimilar and interchangeable applications
5. Taking new steps to challenge gaming tactics by partnering with the Federal Trade Commission to address anticompetitive behavior

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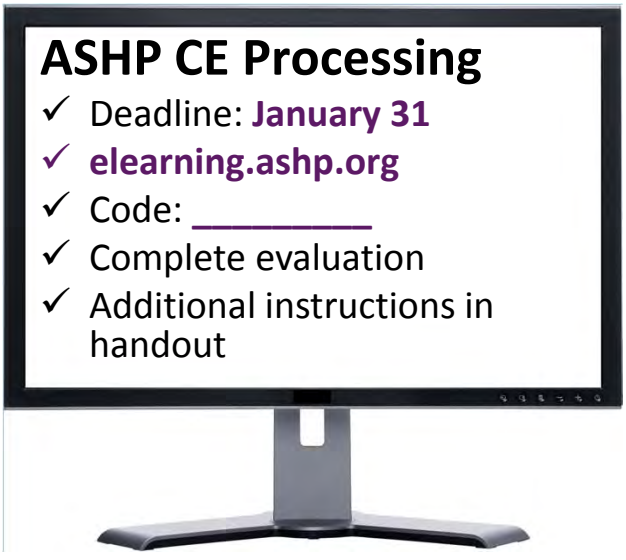
Key Takeaways

- Biosimilars continue to move forward into the mainstream of rheumatology, supportive care, and oncology
- Oncology biosimilars provide similar efficacy to the originator product
- Interchangeability will continue to become a larger discussion as new trials and guidance become available
- Continued education with healthcare providers and patients will be essential in transitioning patients to biosimilar use

Thank you for coming!



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1.5 hr CE

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Questions? Contact **EducServ@ashp.org**!

ABOUT THE FACULTY

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Ali McBride, Pharm.D., M.S., BCPS, BCOP, FASHP, is the Clinical Coordinator of Hematology/Oncology at The University of Arizona Cancer Center. He currently serves as Secretary of the Association of Community Cancer Centers (ACCC) and he has been actively involved with the American Society of Health-System Pharmacy (ASHP) currently serving as the Chair for the SAG on Emerging Sciences.

Dr. McBride has been working on oncology drug shortages and has testified on behalf of HOPA at FDA Drug Shortage Workshop, presented on behalf of ACCC at the Washington DC Congressional Session and was an invited member of the ASHP Drug Shortage Stakeholders Meeting. Dr. McBride is also actively involved with Biosimilar regulation and the pharmacoecomic impact of biosimilars into the US Marketplace. He currently serves as a working group member for HOPA on its biosimilar committee. In addition, he currently serves on the National Quality Forum Cancer Standing Committee. He has published numerous articles focussing on drug shortages, oral chemotherapy adherence, stem cell transplant and biosimilar implementation into the US health care market.

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Sandra Cuellar, Pharm.D., BCOP, is Clinical Assistant Professor in the Department of Pharmacy Practice at the University of Illinois at Chicago (UIC) College of Pharmacy. Dr. Cuellar has been active in the field of hematology/oncology for 13 years. She is the coordinator and clinical assistant professor for oncology therapeutics.

Dr. Cuellar received her Bachelor of Liberal Arts from Augustana College in Rock Island, Illinois, followed by her Doctor of Pharmacy from the University of Illinois at Chicago College of Pharmacy. She then completed a Pharmacy Practice Residency at University of Kentucky Chandler Medical Center. Following her residency, she completed a specialty oncology residency at MD Anderson Cancer Center in Houston, Texas. She currently is the clinical pharmacist in the Out-Patient Cancer Center and is also the director of the oncology specialty residency program at UIC. Dr. Cuellar is an editor at large for the Journal of Hematology Oncology Pharmacy and is involved in research, consulting, and publications in the field of hematology/oncology. Dr. Cuellar has served as a member of the American Society of Health-System Pharmacists (ASHP) Educational Steering Committee and Chair of the 2016-2017 Hematology/Oncology Pharmacy Association-Board Certification in Oncology Pharmacy recertification committee. In addition, she serves as an ASHP oncology residency surveyor.

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