Biosimilars: Supporting Equity and Access to Healthcare

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Biosimilars: Supporting Equity and Access to Healthcare
Mission & Values

**MISSION**
Educate women ages 35 to 64 to make informed health choices.

**VALUES**

**Trusted Partner:** We educate and engage women by providing them with scientifically-reviewed, evidence-based information that allows them to make informed health choices to live well and age well.

**Independent Voice:** Our reputational value to our stakeholders is in serving as the leading source of women’s health information, which we execute on through transparency in all relationships and collaborations.

**Digital Excellence:** Every day, we work to serve women by providing access to timely, inspiring and enduring online content.

**Thought Leadership:** Our ability to grow, innovate and shape the future of women’s health is in our ability to identify and set the agenda around topics before they become critical and to share our knowledge with stakeholders.
Our Reach

For more than 30 years, HealthyWomen.org has remained true to its founding mission. From the start, we’ve been committed to creating and broadly disseminating evidence-based and clinically sound health resources tailored for the unique, and often overlooked, health experiences of women aged 35 to 64.

~1.5K unique monthly visitors to HealthyWomen.org
~64K subscribers to bi-weekly consumer e-newsletters
~28K Facebook likes
~17K Twitter followers
Areas of Focus

**Education & Awareness**
We provide scientifically reviewed, evidence-based information that allows women to take a proactive role in their health and the health of their families.

**Science & Innovation**
We convene information exchanges that aim to advance and elevate conversations around unmet needs in women’s health — and inform our areas of focus.

**Policy & Advocacy**
We support and promote policy issues that are of importance to women’s health with a focus on access, affordability, safety and the inclusion of women in science and research.
Biological Products

- Produced in a living system such as a microorganism (yeast, bacteria), or plant or animal cells.
- Large complex molecule or mixtures of molecules
- Different than chemical drugs – prepared from combining specific chemicals in an ordered process
- Commonly known as Biologics

Kozlowski, S et. al, NEJM 2011, 385
The Basics of Biosimilars

• Biological product that is highly similar to a biologic (reference/originator) already approved by the FDA
• No clinically meaningful differences from the reference product in terms safety, purity and potency
• Same mechanism(s) of action for the proposed condition(s)
• Condition(s) of use previously approved for the reference
• Same route of administration, dosage form and strength
The Basics of Biosimilars: Interchangeable Product

- Biosimilar product substituted for the reference without the intervention of the prescribing health care provider
- Gives same clinical result in any given patient

FDA has an important role in ensuring that these new innovative medications are safe and effective through robust and efficient regulatory standards.
The Basics of Biosimilars

- FDA has approved 30 biosimilars since 2015
- Conditions: oncology, rheumatology and blood disorders
- According to fda.gov: 
  Biosimilars have the potential to cause life changing or life altering benefits at reduced cost to the patient.

Biosimilars Approved to Date

- 2010: 0
- 2011: 2
- 2012: 4
- 2013: 8
- 2014: 10
- 2015: 12
- 2016: 6
- 2017: 8
- 2018: 12
- 2019: 12
- 2020: 2

healthy women
KEY FINDING: Biosimilars Access will benefit women

- Women will have access to a broader set of treatment options at lower prices than now available
- Applies to Seniors and low-income patients
- Utilization demographics:
  - 2 out of 3 treated are women
  - 86% above age 40
  - 42% are low income

Patient Population for Selected Biologics and Biosimilars by Gender, 2014

Women as Consumers of Biosimilars

- Ages 35-64 years (mid-life) – Women 19.3% versus Men 18.7% in 2019
- Mid-life women bear the biggest burden of chronic health conditions
HealthyWomen Consumer Insights: Key Takeaways

89% of women have never taken biosimilars
91% have never discussed biosimilars with providers
75% think biosimilars are not generics
1/3 don’t think biosimilars are more affordable compared to biologics
96% women very/somewhat concerned about medication costs
Value of Biosimilars in Women’s Health

ROUNDTABLE SERIES

March 2021
www.healthywomen.org

• What Women Need To Know About Biosimilars as the Latest Treatment Options
• What Providers Need To Know To Use Biosimilars As Treatment Options
• Innovations in Treatment through Biosimilars
Value of Biosimilars in Women’s Health: Key Themes

- Education is needed and is key to raising awareness and understanding among patients, advocates and healthcare providers
- More biosimilars are coming as more biologics come off patent in the US (compared to Europe)
- Communication is key especially about biosimilars as a treatment options
- Biosimilars hold enormous promise of lower costs and improved access, especially in women – innovation will increase competition
Thank You

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The Next Generation of Generics: Biosimilars

Biosimilars can close equity gaps and provide cost-savings throughout the country
Our Members Represent the Majority of Biosimilars Makers in the United States
What are Biosimilars?

- No difference in safety & efficacy
- Biosimilars are created using living cells
- Typically administered via injection or infusion
- Became available in Europe in 2006
- Introduced in the U.S. in 2009
- The first biosimilar launched in the U.S. in 2015

Conditions treated:
- Cancer
- Arthritis
- Crohn’s Disease
- Psoriasis
- IBS
- Kidney conditions
- More…
Women are the majority of caregivers. It is estimated by the Family Caregiver Alliance that more than two-thirds of caregivers are women.

Women are more likely to be impacted by conditions biosimilars treat -- two out of three patients being treated with biologic medicines are women according to a Medical Expenditure Panel Survey.

Biologics are the single biggest driver of rising drug prices in the United States -- representing 2 percent of all U.S. prescriptions -- mostly women -- but 37 percent of net drug spending.

The Biosimilars – Women’s Health Connection

Biosimilars have the potential to bridge women’s health inequities.
Biosimilar Access will Benefit Women, Seniors and Low-Income Patients

Women, seniors, and low-income individuals are expected to benefit most from increased access to biosimilars

These groups are predominantly impacted by the conditions currently treated by higher cost biologics for which biosimilar competition can reduce costs

• 66% patients being treated with biologics are women
• 86% of the total patients are above the age of 40
• 42% are either poor or low-income patients

Data based on Biosimilars in the United States: Providing More Patients Greater Access to Lifesaving Medicines by The Biosimilars Council
Education is critical to increase access and adoption of biosimilars

54% of participants in an international autoimmune disorder study had never heard of biosimilars (65% of participants were women)

70% of women in a 2019 Center for Biosimilars survey did not understand biologics or biosimilars
Increasing Access is Important to Reach Women and Address Inequities

• By improving informational and educational resources on biosimilars, women’s health publications, physicians, nurses, and pharmacists can better inform their patients with valuable information on these treatments and therefore allowing women patients to access more affordable medicines.

• Legislation can also be a powerful tool on this front:
  • The Advancing Education On Biosimilars Act, signed by President Biden in April 2021, is a strong start to educating and informing key health care providers about biosimilars to unlock savings.
Federal Pro-Biosimilars Legislation to Generate Access, Equity, and Lower Prices

### Reducing Out-of-Pocket Costs for Biosimilars in Medicare Part B

**Eliminates out-of-pocket costs** for a biosimilar under Medicare Part B

### Promoting Competition Executive Order

**Directs HHS** “to increase support for generic and biosimilar drugs.”

### H.R. 2815, the BIOSIM ACT

**Increase the add-on payment for a biosimilar from ASP+6% to ASP+8%**

### Star Rating for Biosimilars Act (H.R. 2855)

**Establishes a new quality measure** in the Medicare Advantage and Part D Star Rating system.


**Directs CMS to implement a “shared savings” program**, which would share biosimilar savings with physicians.
National Lieutenant Governors Association Resolution

- NLGA recently passed a resolution supporting equity and access to healthcare and affordable treatment options, including biosimilars
- The resolution states:
  
  “data demonstrates that increased access to affordable generic and biosimilar medicines can be a major part of the solution to help break down some barriers and support patients in maintaining their health”

  “biosimilars are FDA-approved biologic medicines that are as safe and effective as the reference biologic and provide an opportunity to expand access and generate savings for patients in the U.S.”
Because When Biosimilars are Introduced, They’re More Affordable and Force Competition

- Filgrastim
- Infliximab
- Pegfilgrastim
- Epoetin Alfa
- Bevacizumab
- Trastuzumab
- Rituximab

Brand biologic pre-biosimilar
Biosimilar average
Biosimilar Substitution Sunset States

**Virginia**
Prescriber/pharmacy communication provision sunset was July 1, 2015
Bill: S 1285/ H 1422 (2013)

**North Carolina**
Prescriber/pharmacy communication provision sunset was October 1, 2020
Bill: HB 195 (2015)

**Oregon**
Prescriber/pharmacy communication provision sunset is January 2, 2022.
Initial Bill: S. 460 (2013) with a sunset of January 1, 2016. The sunset was extended to 2022 in the 2016 session in H 4105.

**New York**
Entire statute sunsets on October 23, 2022
Bill: AB 7509 (2018)
RESEARCH SNEAK PEAK: State Savings Potential

With 75% market share, biosimilars would save U.S. states $14.08 Billion per year, including:

- $8.39 Billion in commercial savings
- $3.19 Billion in Medicare savings
- $2.49 Billion in Medicaid Savings

The top five states would save $3.63 Billion per year

Florida: $960.63 Million
California: $1.028 Billion
Texas: $820.16 Million
New York: $820.72 Million
Pennsylvania: $802.85 Million

Data based on Q2, 2021 savings calculations conducted by the Pacific Research Institute.
Key Takeaways for Women’s Health Advocates & Legislators

**Educate**
Educating physicians, constituents and providers

**Advocate**
Advocating for pro-biosimilars policy at your state capitols to support women’s equity

**Act**
Ask your doctors about biosimilars for applicable conditions

**Prescribe**
Talk to pharmacists about acquiring biosimilars prescriptions
Discussion