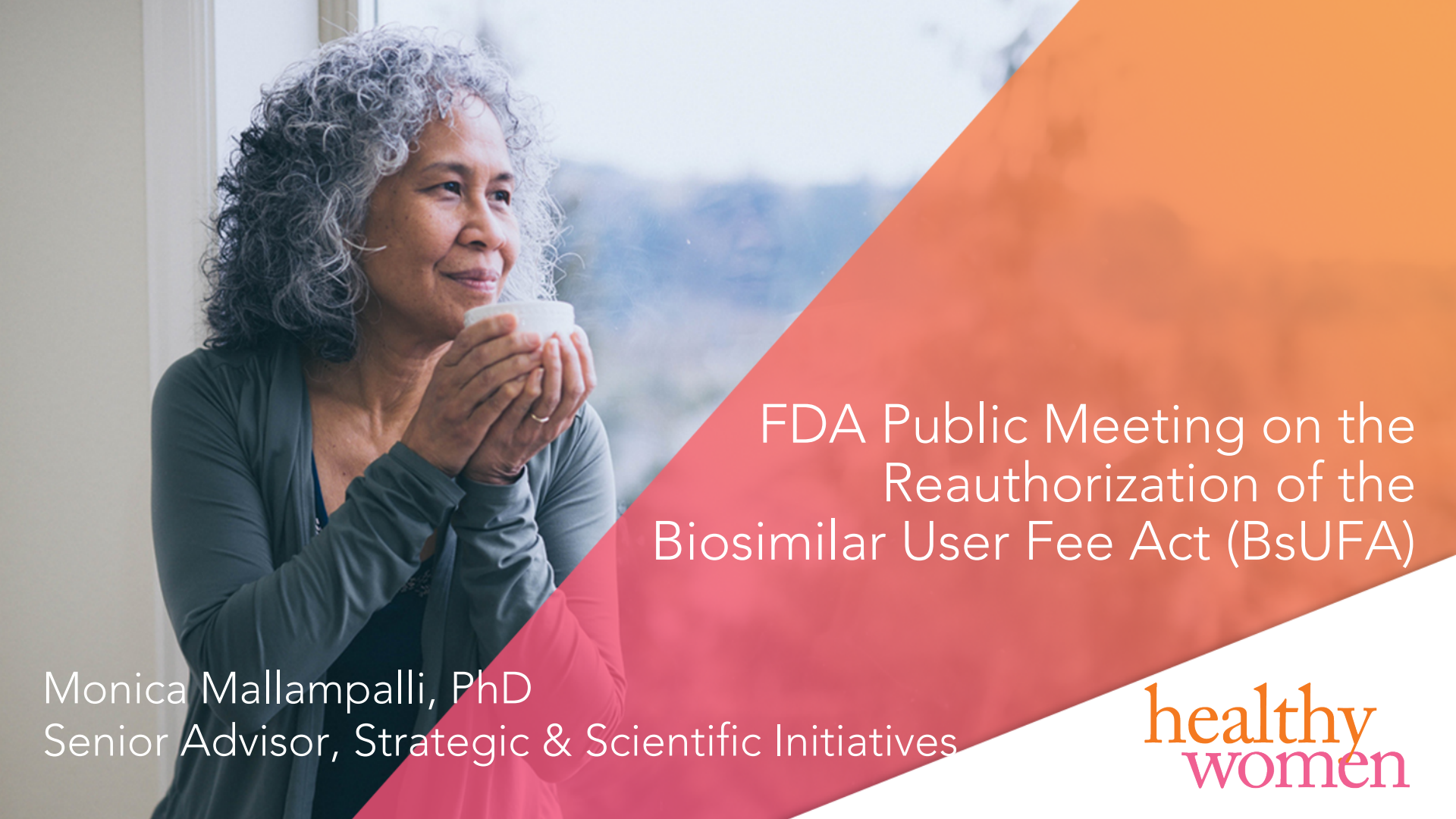

FDA Public Meeting on the Reauthorization of the Biosimilar User Fee Act (BsUFA)

Monica Mallampalli, PhD
Senior Advisor, Strategic & Scientific Initiatives

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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.

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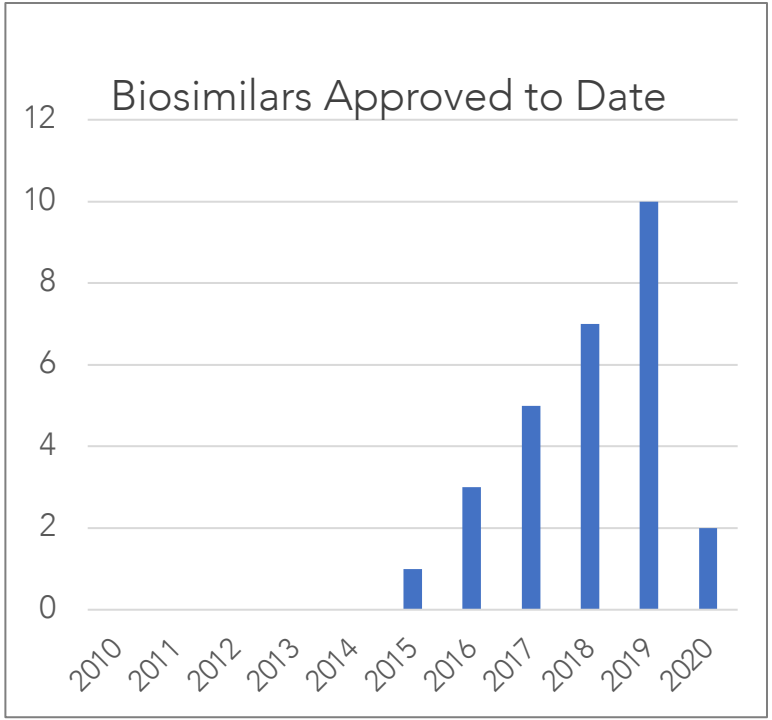
Biosimilars

- Since March 2015 FDA has approved 28 biosimilars in the space of oncology, rheumatology and blood disorders
- According to the FDA.gov:

  Biosimilars have the potential to cause life changing or life altering benefits at reduced cost to the patient.
- FDA has an important role in ensuring that these new innovative medications are safe and effective through robust and efficient regulatory standards



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Biosimilars User Fee Program

HealthyWomen understands that the program plays an important role in FDA's review process and that it:

- Supports FDA's activities to ensure timely and robust review
- Encourages innovation of biosimilars and promotes initiatives that utilizes best science
- Delivers safe and effective treatments efficiently for women who need them

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Re-authorization of BsUFA

FDA can continue to address and improve upon the following:

1. Provide general education on biosimilars
2. Increase confidence on the safety and efficacy of biosimilars
3. Ensure clarity of clinical data on biosimilars as part of the efficient review process

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1. General Education on Biosimilars

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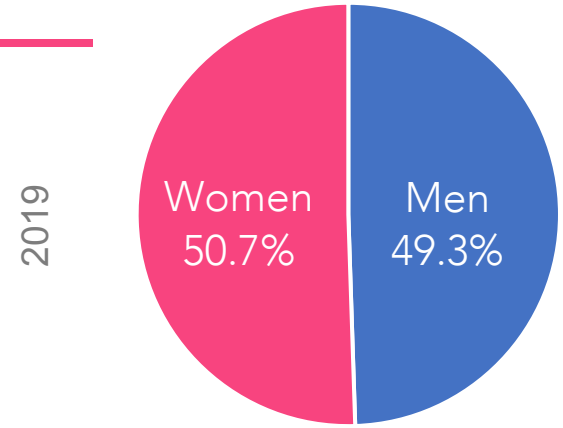
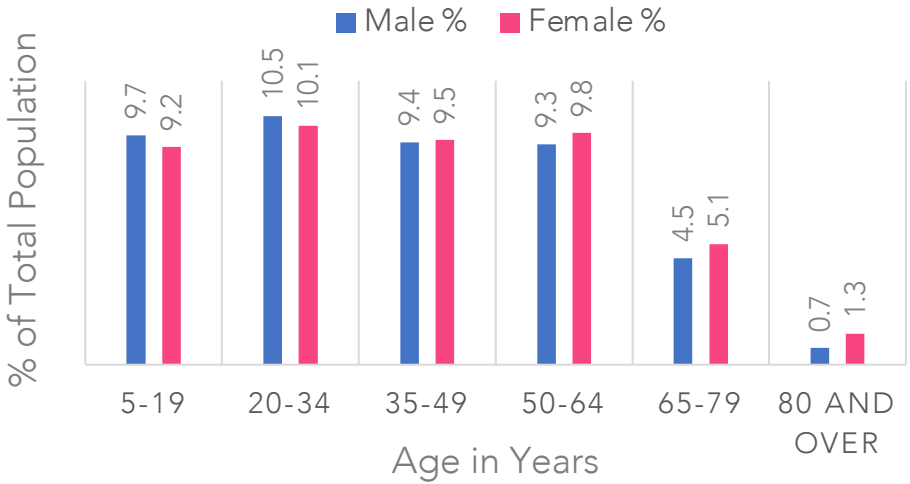
Women as Consumers of Biosimilars



Gender breakdown of US population
www.statista.com



- 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

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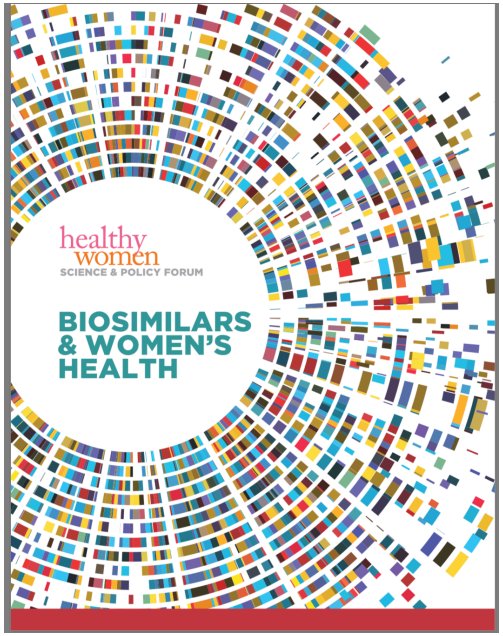
HealthyWomen Consumer Insights:



89% of women have never taken biosimilars

91% have never discussed biosimilars with providers

75% think biosimilars are not generics

1/3rd don't think biosimilars are more affordable compared to biologics

96% women very/somewhat concerned about medication costs

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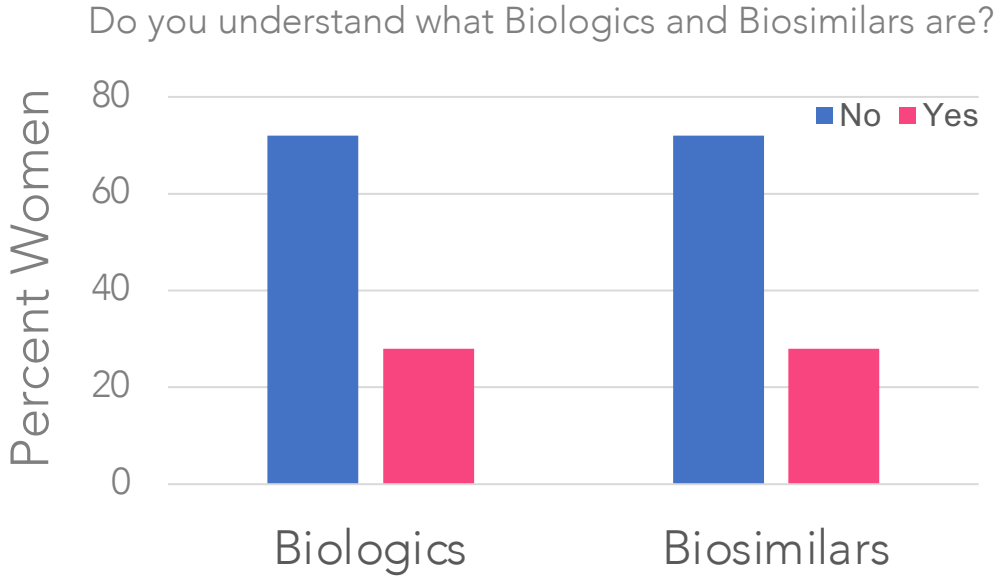
[2019 HealthyWomen Science and Policy Forum Meeting]

HealthyWomen Consumer Insights:

- *Not sure what they are*
- *How closely do they compare with biologics?*
- *This is the first time I've heard of it, despite my interest in health and medicine*



Women Do Not Understand Biologics and Biosimilars

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Healthcare Providers Need Education on Biosimilars

Awareness, Knowledge, and Perceptions of Biosimilars Among Specialty Physicians

Hillel Cohen [1], Donna Beydoun [2], David Chien [3], Tracy Lessor [4], Dorothy McCabe [5], Michael Muenzberg [6], Robert Popovian [7], Jonathan Uy [8]

Conclusions: The results of this survey highlight a significant need for evidence-based education about biosimilars for physicians across specialties. Five major knowledge gaps were identified: defining biologics, biosimilars, and biosimilarity; understanding the approval process and the use of "totality of evidence" to evaluate biosimilars; understanding that the safety and immunogenicity of a biosimilar are comparable to the originator biologic; understanding the rationale for extrapolation of indications; and defining interchangeability and the related rules regarding pharmacy-level substitution.

Adv Ther. 2017 Jan;33(12):2160-2172.

Academic oncology clinicians' understanding of biosimilars and information needed before prescribing

John W Cook [1], Megan K McGrath [1], Margie D Dixon [1], Jeffrey M Switchenko [2], R Donald Harvey [1], Rebecca D Pentz [3]

Conclusion: Understanding of biosimilars is low, and educational needs are high. The information that clinicians deem important to assess, such as safety, efficacy and cost, will need to be provided before they are comfortable prescribing biosimilars.

Adv Med Oncol. 2019 Jan 6;11:1758835918818335.

US rheumatologists' beliefs and knowledge about biosimilars: a survey

Allan Gibofsky, Dorothy McCabe [1]

Conclusions: The results of this survey suggest that US rheumatologists have a good understanding and acceptance of biosimilar products, particularly for the initiation of treatment in biologic-naïve individuals. They were hesitant to switch from a reference product to a biosimilar for a patient doing well on the reference product. Additional education on biosimilars is required to help inform treatment decisions by rheumatologists. A plain language summary of this article has been uploaded as supplementary material, available at Rheumatology online.

Rheumatology (Oxford). 2020 Nov 4:keaa502.

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Education helps Raise Awareness

	US, %		
	General population[a] n=250	Diagnosed[b] n=635	Diagnosed advocacy[c] n=245
Biologic therapy			
Awareness[d,e]			
Has at least a general impression	11	30[A]	47[A,B]
Just know the name	16	19	31[A,B]
Not sure	17	17[C]	12
Never heard of it	57[B,C]	33[C]	10
Currently use	N/A	18	29[B]
Biosimilar therapy			
Awareness[d,e]			
Has at least a general impression	6	9	20[A,B]
Just know the name	10	16[A]	27[A,B]
Not sure	14	21[A]	23[A]
Never heard of it	70[B,C]	54[C]	31
Currently use[f]	N/A	2	9[B]

	US, n			
	Diagnosed[a]	Diagnosed advocacy[b]	Caregiver[c]	General population[d]
Sex, %				
Male	35	37	44	49
Female	65	63	56	51

Patient attitudes and understanding about biosimilars: an international cross-sectional survey. Jacobs I, Singh E, Sewell KL, Al-Sabbagh A, Shane LG. Patient Prefer Adherence. 2016 May 26;10:937-48.

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What can FDA do?

Support education and outreach to women and health care providers with easily accessible and understandable materials

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2. Consumer Confidence on Safety and Efficacy of Biosimilars

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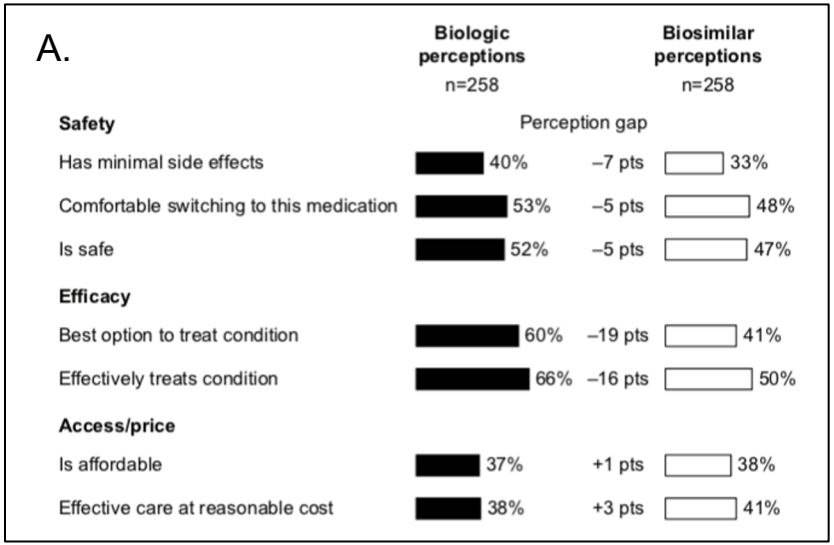
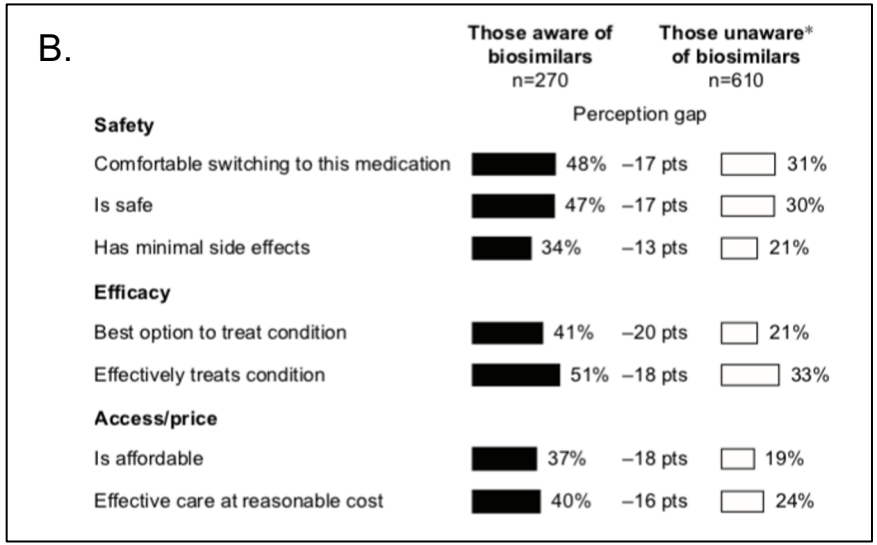
Gaps Exist in Knowledge of Biosimilars Safety and Efficacy





Patient attitudes and understanding about biosimilars: an international cross-sectional survey. Jacobs I, Singh E, Sewell KL, Al-Sabbagh A, Shane LG. Patient Prefer Adherence. 2016 May 26;10:937-48.

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HealthyWomen Consumer Insights:

- *Just like generic drugs, it may have some real components of the real drugs; however, I do not know the long-term benefits or regrets of being forced to take a biosimilar*
- *How do they react in one's body?*
- *I'm concerned biosimilars may not work well*
- *Are they effective?*
- *How are they tested for safety?*

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What can FDA do?

Build confidence in patients and providers on safety and efficacy of biosimilars, especially when switching from a biologic to a biosimilar

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3. Clarity on Clinical Data as Part of the Review Process

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3. Clarity on Clinical data

- Some diseases treated by biosimilars impact women disproportionately
- Women have a 1.5 to1.7-fold greater risk of developing an adverse reaction due to sex-based differences in response to many medications
- Ensure that safety and efficacy data is analyzed and reported by sex when appropriate

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What can FDA do?

Ensure that the there is clarity on data related to safety and efficacy for biosimilars and it is presented to the consumers and healthcare providers on FDA website in a simplified manner

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Conclusion

On behalf of my colleagues and I, we thank the FDA for giving HealthyWomen an opportunity to share our comments today

THANK YOU

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