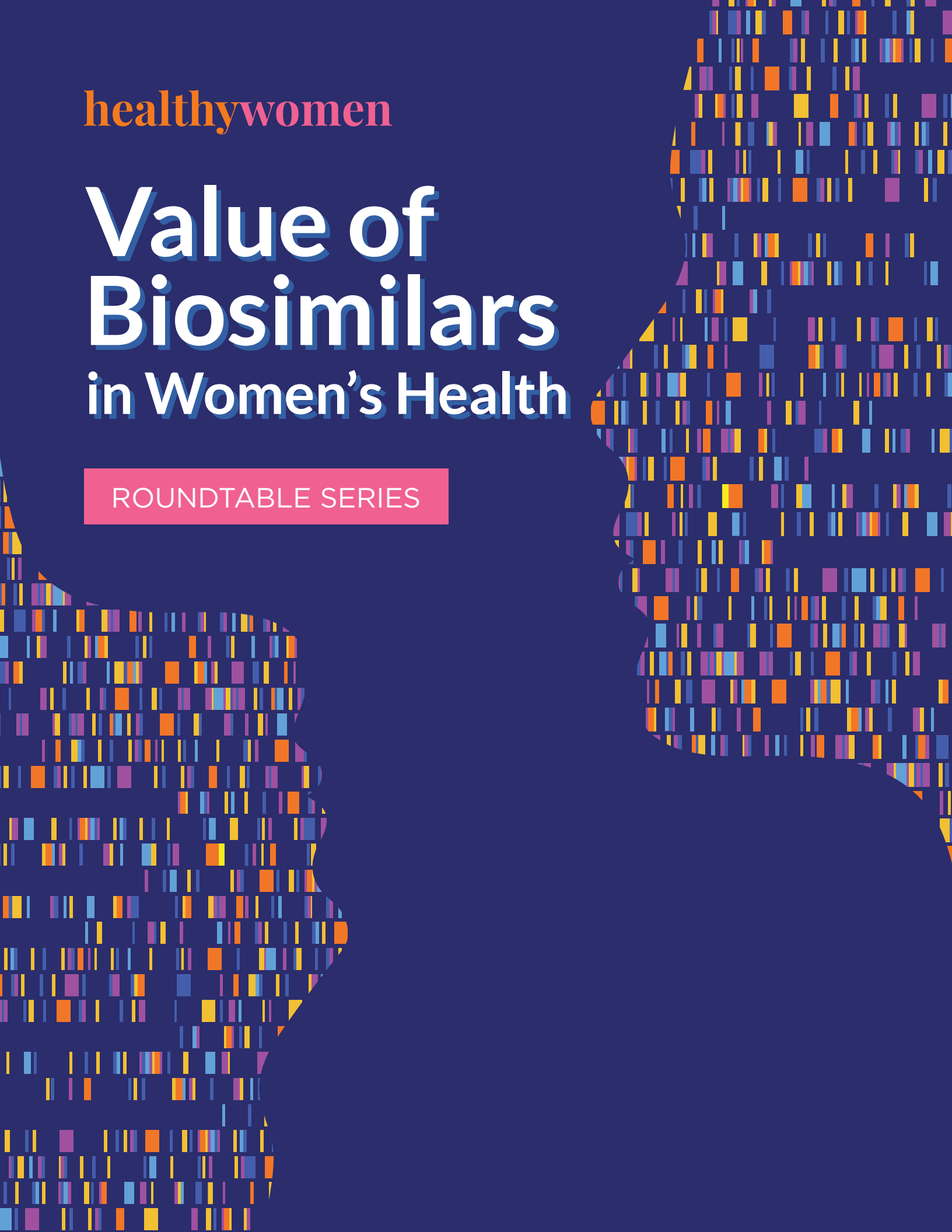


healthywomen

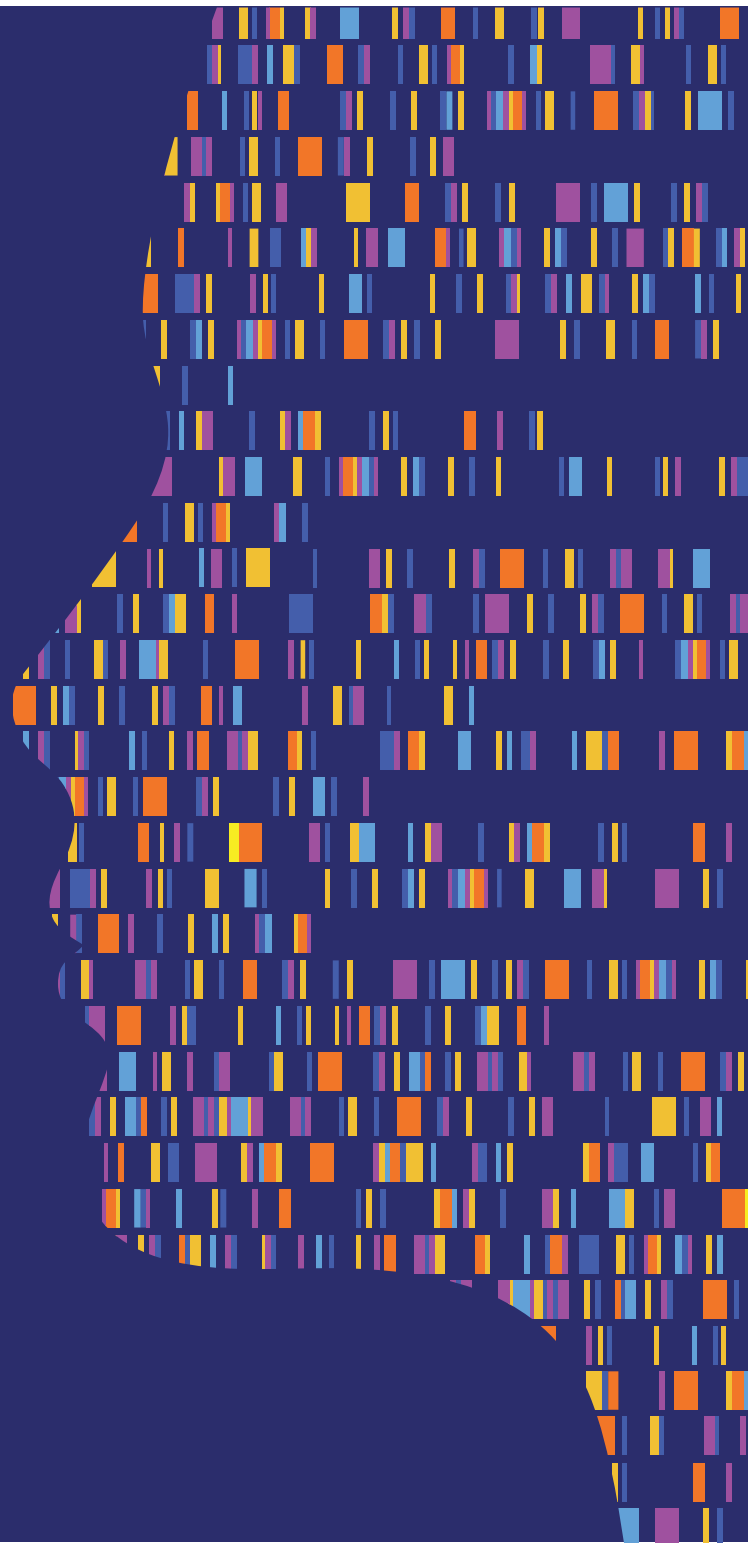
# Value of Biosimilars in Women's Health

ROUNDTABLE SERIES



# Table of Contents

Executive Summary.....	3
Biosimilars Defined.....	5
Roundtable One: What Women Need to Know About Biosimilars as the Latest Treatment Options .....	6
Roundtable Two: What Providers Need to Know to Use Biosimilars as Treatment Options.....	7
Roundtable Three: Innovations in Treatment Through Biosimilars .....	8
The Future of Biosimilars.....	9
About HealthyWomen .....	9






# Executive Summary

Medical advances in the United States can save lives — if you can afford them. Yet, as many as one in four Americans cannot afford their medications. Even for people who can afford some medicines, the best medication for them might still be out of reach because of cost.

Biosimilars, a class of biologics, or biologically based drugs, have enormous promise to lower costs and improve access to innovative, lifesaving treatments. But these drugs are not well understood by patients and some healthcare providers. Though 67% of the patient population for most biosimilars is female, a 2019 HealthyWomen survey showed that 70% of women did not understand biologics or biosimilars.



**Biosimilars have enormous promise to lower costs and improve access to innovative, lifesaving treatments.**

Between March 4 and 18, 2021, HealthyWomen conducted "Value of Biosimilars in Women's Health," a series of three roundtable forums to explore how biosimilars can improve women's health. This series brought together a wide range of healthcare experts — from patients and advocates to physicians, researchers and drug company leaders. The experts shed light on key topics and painted an inspiring picture of the potential for biosimilars to improve women's access to affordable care. Across the series, several key themes emerged:

■ **Education on biosimilars is needed.**

- Most people don't know what biosimilars are. Biosimilars closely resemble biologic drugs that have been approved by the U.S. Food and Drug Administration (FDA). Both are made from living sources and treat diseases such as cancer and autoimmune disorders.

- Education is key to raising awareness and understanding of these treatments among patients, patient advocates and even healthcare providers.

■ **We're still in the early days of biosimilars in the United States, and more biosimilars are coming.**

- The first biosimilar in the United States launched in 2015, but biosimilars have been available in Europe since 2006.
- As more biologics come off patent in the United States, more biosimilars will become available. Many new biosimilars are in the pipeline and drug companies are invested in bringing new drugs to the U.S. market.

■ **Biosimilars hold the promise of lower costs and better access, especially for women.**

- Innovation in biosimilars will increase competition, which will bring costs down and may result in substantial cost savings for patients and the healthcare system as a whole. Lowering costs will help more women access care.
- Not only do biosimilars cost less than biological reference products, the mere presence of lower-cost biosimilars can force down drug prices overall.

■ **Communication about treatment options that include biosimilars is key.**

- The FDA is considered the gold standard on communication about biosimilars and provides communication tools for patients and providers.
- Many healthcare organizations and advocacy groups have partnered to create consistent messaging to speak with one voice and limit confusion for patients.
- Patients with questions or interest in biosimilars should talk to their healthcare providers and seek out other patients to learn from their experiences.




# Introduction

For more than 30 years, HealthyWomen has provided education and information about treatment options to empower women to be proactive in managing their health. On the cutting edge of medicine, biosimilars warrant more education.

In 2019, HealthyWomen held a [one-day forum](#) to explore what biosimilars mean to women's health. The key takeaway was that biosimilars have potential to increase access to affordable, lifesaving drugs but that barriers still existed. A 2019 HealthyWomen survey found that 70% of women didn't understand biosimilars and uptake has been relatively low.

To raise awareness about biosimilars, HealthyWomen held three roundtables in March 2021, hosted by Monica Mallampalli, Ph.D., HealthyWomen's senior scientific advisor. These discussions included experts with a wide range of backgrounds and perspectives. Each session focused on an important aspect of biosimilars, including:

- What women need to know about biosimilars as the latest treatment options
- What providers need to know to utilize biosimilars as treatment options
- Innovations in treatment through biosimilars



For biosimilars to achieve their potential, patients and healthcare providers need to better understand and trust the products.

Across the series, experts reinforced several key messages:

**Biosimilars are safe and effective.** They work as well as the biologics they're based on and are as safe as the approved biologic reference products.

**Biosimilars are good for women's health.** Two-thirds of patients who can benefit from biosimilars are women. Biosimilars can expand access to care by offering affordable options that are just as effective as other treatments. "We should be supporting women to make choices for their own health," said Erika Satterwhite, head of global policy at Viatrix. "Part of that is improving access to affordable medicines like biosimilars."

**The FDA has approved 29 biosimilars, 20 of which are currently available to patients.** These drugs treat chronic conditions, such as autoimmune diseases (e.g., rheumatoid arthritis) and cancer, including cancers that disproportionately affect women (e.g., breast cancer).

**More biosimilars are coming.** Many biologics are still protected by patents, but patents expire each year, opening up opportunities for competition in the biosimilars market. By 2023, [nearly 20](#) cancer biologics will come off patent. There are [17 oncology biosimilars](#) already making their way through the approval process and seven to 10 rheumatology drugs could reach the market by 2023, according to panelists. "It's really going to give women a lot of choices," said Pam Traxel, senior vice president of ACS CAN, the American Cancer Society's advocacy affiliate. "While you might not have the opportunity to take a biosimilar now, in future years you will."

**For biosimilars to achieve their potential, patients and healthcare providers need to better understand and trust the products.** Improving awareness will help increase adoption and prepare patients and providers to take advantage of biosimilars when they become available.

# Biosimilars Defined

A biosimilar is defined by the FDA as “a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product.” Biosimilars are near copies — though not exactly the same — as biologics. Both biologics and biosimilars are made from living organisms or natural sources, such as plant, animal or human cells. The biologic that a biosimilar is based on or compared to is often called a reference, originator or innovator product.

A good analogy for biosimilars is generic drugs, which are chemical copies of brand-name drugs and have the same active ingredients and dosing. Biosimilars are not exact copies of biologics because variation exists in the natural materials and production, making each batch unique. But just as generics can replace brand-name drugs, biosimilars can be used in place of biologics.





## Roundtable One: What Women Need to Know About Biosimilars as the Latest Treatment Options

On March 4, 2021, HealthyWomen hosted the first of three roundtable discussions on biosimilars. The session focused on the need for education about biosimilars and how to raise awareness among diverse healthcare consumers. The panel was composed of a diverse group of experts, including:

- Alisa Vidulich (moderator), Policy Director, Arthritis Foundation
- Brooke Abbott, Patient Thought Leader and Founder, crazycreolemommy.com
- Sarah Ikenberry, Senior Communications Advisor, FDA Office of Therapeutic Biologics and Biosimilars in the Center for Evaluation and Research
- Pam Traxel, Senior Vice President, ACS CAN


The panel discussed several important topics:

**Biosimilars in Women's Health:** Biosimilars are important for women's health because many of them treat conditions that disproportionately affect women, such as breast cancer, rheumatoid arthritis and irritable bowel syndrome. Not only are two-thirds of the patients who can benefit from biosimilars women, but women also make the majority of healthcare decisions for their loved ones as well as themselves, and they serve as caregivers more often than men. To make informed healthcare decisions, women must understand all of their options, including biosimilars.

**The Value of Biosimilars:** Biologic drugs can be so costly that women may struggle to afford them or go without treatment altogether, and biosimilars can reduce some of these cost barriers. The American Cancer Society's [2020 Cost of Cancer report](#) showed that biosimilars can reduce treatment costs by 21%. Traxel said, "When we think about health equity, what we want to make sure is that cost doesn't create an additional disparity in outcomes for patients."

**The Importance of Education:** Comprehensive yet digestible information about biosimilars can help patients make educated decisions about their care. The FDA has taken a lead role in providing that education in collaboration with healthcare providers and advocacy groups. The goal is to speak with one voice and reduce confusion for patients, especially those with multiple conditions.

**Communities Communicating:** Brooke Abbott, who is both a patient and a patient advocate, encouraged healthcare providers to engage with their patients and help them connect with a diverse community. Abbott applauded social media use by providers and drug manufacturers as a way to reach patients. "I feel like there are some bridges that have been fortified during this time and the education is really getting to the patients through a funnel of advocates."



To make informed healthcare decisions, women must understand all of their options, including biosimilars.

**What Patients Can Do:** Panelists encouraged women to ask their doctors if a biosimilar is available for their condition. Patients should also talk with other patients, including those with different experiences, to get new ideas about possible treatment approaches. "When you're thinking about creating a treatment plan for yourself, you want to make sure that you're covering all your bases," she said, urging women to be proactive about future options, even if their current treatment is working. "I can't stress enough how important it is to have open communication with your healthcare team constantly."

## Roundtable Two: What Providers Need to Know to Use Biosimilars as Treatment Options

On March 11, 2021, HealthyWomen held the second in the three-part roundtable series on biosimilars. The session focused on the need to improve provider education about biosimilars. The panel discussed barriers to the use of biosimilars, such as perceptions that biosimilars do not always save patients money or lack of familiarity with biosimilars or the data behind them.

The expert panel members, all with deep biosimilars experience, included:

- Sameer Awsare, M.D., FACP, (moderator)  
Associate Executive Director, Permanente Medical Group
- Dennis Cryer, M.D., Biologics Prescribers Collaborative
- Angus Worthing, M.D., Arthritis and Rheumatism Associates and Clinical Assistant Professor of Medicine (Rheumatology), Georgetown University Medical Center
- Stacy Elder Dalpoas, Pharm.D., MPH, Clinical Pharmacy Manager, Novant Health

Education efforts need to focus not only on prescribers but on the whole care team, including nurses, pharmacists and others.

**Knowledge Gaps:** Because biosimilars are relatively new in the United States, education gaps exist among healthcare providers, according to Cryer of the Biologics Prescribers Collaborative. "Although it's somewhat variable from specialty to specialty, I think there is still a great deal of ignorance or lack of understanding of biosimilars."

Healthcare providers typically learn about new drugs through clinical trial data published in peer-reviewed journals, through FDA labeling, and through their professional specialty societies' educational materials. Studies from countries where biosimilars have been in use for longer show that biosimilars are as safe and

effective as biologics. Still, more research may be needed to build comfort among prescribers, especially as some providers dismiss overseas studies, according to panelists.

Providers must also make an effort to stay up to date with current research on their own. "For the most part, we are relying upon continuing our education as it is pertinent to our practice settings," said Dalpoas, clinical pharmacy manager at Novant Health.

In this rapidly evolving field, new research is also necessary to understand providers' current perceptions of biosimilars and tailoring provider education to current realities. "The entire face of the biosimilar market has changed in the last three years," said Dalpoas.

**The Growing Market:** As prescribers become more accustomed to biosimilars, some biosimilars have become the go-to drug in their category. For example, a biosimilar that promotes white blood cell production after cancer treatment has a 72% utilization rate. However, a [biosimilar for autoimmune disorders](#), represented just 17% of the market.

Sameer Awsare of the Permanente Medical Group noted that 71 biologics will come off patent by 2023, which will open the door to new biosimilars. The challenge may be getting providers comfortable with biosimilars and trusting that they are therapeutically equivalent to the biologic version. Education efforts need to focus not only on prescribers but on the whole care team, including nurses, pharmacists and others.

**The Impact on Patients:** The real impact of biosimilars became clear to Angus Worthing, a rheumatologist at the Georgetown University Medical Center, when he saw patients on biologics or biosimilars finally find relief after months or years of disabling pain. "Getting on these drugs not only helps pain but prevents disability from joint damage and improves people's health and lifespan."

## Roundtable Three: Innovations in Treatment Through Biosimilars

On March 18, 2021, HealthyWomen hosted our third roundtable, composed of pharmaceutical industry leaders who came together to discuss the current state and future outlook for biosimilars. This panel of experts represented leading biosimilar producers who work on the front lines of biosimilar innovation, including:

- Meaghan Rose Smith (moderator), Executive Director, Biosimilars Forum
- Erika Satterwhite, Head of Global Policy, Viatrix
- Chad Pettit, Executive Director, Marketing, Global Biosimilars Commercial Lead, Amgen
- Juliana Reed, Vice President, Global Corporate Affairs Biosimilars, Pfizer
- James Carey, Assistant Vice President, Health Policy, Merck

Panelists discussed the young history of biosimilars in the United States; factors that support innovation; the impact of biosimilars; and the future outlook for the field, including the fact that there are many companies investing in the future of biosimilars across a range of therapeutic areas, including oncology, immunology, diabetes, ophthalmology, rheumatology and inflammatory diseases.

Meaghan Rose Smith, executive director of the Biosimilars Forum, summed up the promise and challenge. "Biologic drugs, including biosimilars, represent the cutting edge of medical research. But [biologics] have also been the biggest driver of drug spending in the U.S." Though [biologics](#) represented 37% of net drug spending in 2017, they accounted for 93% of the increase in spending.

The biosimilar must be proven to be just as safe and effective as the biologic reference product.


James Carey, assistant vice president for health policy at Merck, noted the potential of biosimilars to change that dynamic by making these innovative new treatments more affordable. "It is the competition among biologics, including biosimilars, that has the potential to reduce healthcare costs for everyone."

**The Path to Innovation:** The [Biologics Price Competition and Innovation Act of 2009](#), part of the Affordable Care Act, created an abbreviated approval path for biosimilars. Still, the approval standards are the most robust in the world and should give patients and providers confidence in the products, according to Chad Pettit, executive director of marketing, global biosimilars commercial lead at Amgen. The development process can take seven or eight years, according to the panel. The law set the standard that there can be "no clinically meaningful differences in safety, purity and potency between a biosimilar and the originator product." This means that the biosimilar must be proven to be just as safe and effective as the biologic reference product before the FDA can approve it.

**Barriers to Adoption:** Some panelists pointed to regulatory challenges and certain financial incentives that make biosimilars less attractive to prescribers as the cause of the relatively low adoption of biosimilars in the United States. "Incentives really need to align across the system to ensure that the availability of lower-cost options like biosimilars really do translate into savings for the entire system, including all of the stakeholders — providers and patients included." Panelists also noted that biosimilar adoption has been held back by misinformation and pointed to the FDA as the trusted authority to help overcome mistrust.

**The Impact of Biosimilars:** Despite barriers, biosimilars have already positively affected costs. According to Pettit, the biosimilar with the fastest uptake leads its segment with 50% market share and caused the reference product market share to drop by half in 24 months. He





referenced recent industry research showing that \$4 billion was spent on biosimilars — and that spending resulted in \$7.4 billion in public savings over what would have been spent on biologics. But the impact goes beyond direct savings. Competition from biosimilars has also led to 10%-15% price declines in originator products, even where biosimilars have a relatively small share of the market.

According to Juliana Reed, vice president of global corporate affairs, Biosimilars at Pfizer, these savings translate into financial benefits for patients. Pfizer's analysis of one of its biosimilars showed at least 45% savings in out-of-pocket costs for patients, Reed said.

Beyond individual savings, though, Carey said there are broader benefits in markets with more uptake of biosimilars. "It's broadened the ability for patients to receive these types of treatments because they are more cost effective for that system, and that's a win-win across the board."

**The Goal:** According to Reed, biosimilars still have a long way to reach their full potential. "[When] 90% of American consumers have access to a lower-cost biosimilar, we'll be able to say the market is working. Forty, 50, 20% is not enough, not for consumers and not for the savings that our healthcare system needs and our families need."



## The Future of Biosimilars

Healthcare costs create significant barriers to millions of patients in the United States. Biosimilars have potential to ease financial strain from medication costs, but only if people know about them and trust them. The scientific data show that biosimilars are on par with their biologic counterparts. The big opportunity for savings will come as more biologic drugs' patents expire and as more biosimilars become available. As competition hopefully floods the drug market, prices should come down and lifesaving treatments should become more accessible to more people.

"Investing in healthcare is really investing in the future of society," Pettit said. "Biosimilar medicines offer the best hope to effectively manage diseases like cancer and chronic inflammation and also contain long-term healthcare costs."

Raising awareness of biosimilars as viable treatments options is part of HealthyWomen's commitment to educating people about novel treatment options and ways to access more affordable, vital treatments so they can make informed decisions about their health care.

# About HealthyWomen

HealthyWomen is an established and trusted not-for-profit organization that has inspired and empowered millions of women to take a proactive role in their health and the health of their families for 30 years. Over the years, HealthyWomen has developed an extensive library of information on topics ranging from heart disease and breast cancer to sexuality and wellness — with hundreds of lifestyle and condition-oriented topics in between. With clinical information that is reviewed by leading health experts to ensure that it is accurate and reflects the latest scientific advances, HealthyWomen is a proven and reliable resource for consumers. Notably, HealthyWomen prides itself on its 24/7 multichannel media platform with award-winning educational content as well as advocacy and awareness campaigns. HealthyWomen delivers information that women can learn from and act upon via informative, motivating and shareable content. HealthyWomen continues to be a rich resource with a broad reach among a highly engaged community, reaching over 1.5 million women each month; engaging over 60,000 healthcare providers (60% RNs and NPs, 40% OB-GYNs, general practitioners and MDs); and proudly partnering with dozens of local and national organizations.

*This report was created with support from  
Amgen and Viatrix.*

