



healthy  
women  
SCIENCE & POLICY FORUM

# BIOSIMILARS & WOMEN'S HEALTH

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# EXECUTIVE SUMMARY

The unsustainable cost of specialty drugs in the United States is increasingly making these lifesaving drugs unavailable or unaffordable for a widening group of Americans. No one is hit harder than women, who are more likely to be diagnosed with autoimmune conditions, osteoporosis and certain cancers for which the majority of these medications are used. Indeed, women make up 67 percent of patients who require high-cost biologics to manage their disease.

The complexity of biologics, however, including their manufacturing processes, makes it impossible to develop an identical molecule to the reference product, as with generics. Instead, the competition must come from biosimilars, biologic products produced in the same manner as biologics, but not considered bioequivalent or interchangeable with the reference product.

While biosimilars have been available for nearly 15 years in Europe and other countries, the first one was not approved in the U.S. until 2015. Although the FDA has since approved 25 biosimilars, just a handful are on the market and the potential cost savings has not been realized.

To explore the issue of biosimilars and their implications for women's health, HealthyWomen convened the *Biosimilars & Women's Health Science & Policy Forum* on October 25, 2019, in Washington, DC. The forum brought together more than 60 women's health advocates, policy makers, clinicians and government agency representatives to discuss where we are today with the biosimilar landscape in the U.S., including current challenges and health implications for women. This forum exemplifies HealthyWomen's commitment to convene forums with varied expert perspectives on issues important to women's health and to instill women's voices and insights into scientific topics and areas of innovation.

The forum featured panel presentations and discussion with scientific experts and advocacy leadership, ending with robust discussions among panelists and participants.

The key takeaway from the forum is that biosimilars have great potential to increase women's access to affordable lifesaving drugs, but that there are numerous challenges and barriers to overcome before biosimilars are widely and more easily accessible to the patients who most need them.

HealthyWomen hopes this report from our forum provides a roadmap that health care providers, policymakers, educators and advocates can use to address these barriers and actualize biosimilars as a more affordable option for the millions of patients who rely on these important medications.

# KEY DEFINITIONS<sup>1,2</sup>

## **Biobetter.**

A new molecular entity that may be similar to an approved biologic from the same manufacturer but that differs in terms of the dosing regimen, safety, efficacy and immunogenicity.<sup>3</sup>

## **Biologic.**

Complex, large molecule mixtures that are not easily identified or characterized. They are manufactured in a living system such as a micro-organism, or plant or animal cells, often using recombinant DNA technology. Biologics include vaccines, certain hormones, monoclonal antibodies, gene therapies and recombinant proteins.

## **Biosimilars.**

Biologic products produced in the same manner as biologics but because the manufacturing process is, by nature of the molecule, unique with every batch, cannot be considered bioequivalent or interchangeable. Thus, manufacturers must conduct clinical trials to demonstrate that the drug has similar efficacy and safety to the reference drug, i.e., showing biosimilarity.

## **Extrapolation.**

Allowing the biosimilar to be used for all the indications of the originator product even if clinical trials for that condition have not been conducted.

## **Generic.**

Drugs with the same active ingredient, strength, dosage form, route of administration and bioequivalence as a brand-name drug. They are considered “therapeutically equivalent” to the brand-name drug, enabling interchangeability. No clinical trials are required for approval although manufacturers must demonstrate bioequivalence in humans.

## **Interchangeable.**

The FDA has regulations that would allow a biosimilar to be automatically substituted for the biologic without provider intervention (subject to state laws) if it is “expected to produce the same clinical result as the reference product in any given patient” with no greater risk of side effects.<sup>4</sup> However, biosimilar manufacturers must conduct additional clinical studies to receive interchangeability designation. This is a hard hurdle to meet and, to date, none of the approved biosimilars have received such status.<sup>5</sup>

## **Reference product.**

The FDA-approved biologic against which the biosimilar is compared.

## **Small molecule drugs.**

These drugs are manufactured through chemical synthesis with well-defined chemical structures that can be chemically analyzed.

## THE PROBLEM

Prescription drugs makes up an increasing proportion of overall spending on health care in the U.S. Estimates vary, but a recent *Health Affairs* analysis put the cost at \$480 billion in 2016, about 15 percent of overall health care spending that year.<sup>6</sup> That amount is expected to increase 2 to 5 percent a year over the next five years, far exceeding medical inflation.<sup>7</sup>

Most of that cost and most of that increase comes from specialty drugs, complex large molecules, including biologics, used to treat numerous autoimmune diseases, cancer and other conditions. In 2018, the U.S. spent an estimated \$125 billion on these drugs, an increase of 50 percent since 2014.<sup>8</sup> Today, specialty drugs account for half of all spending on pharmaceuticals in the U.S., even though just 1 to 2 percent of Americans require these medications.<sup>9,10</sup>

The increased spending comes not just from the introduction of new drugs onto the market, but from manufacturers increasing the cost of existing drugs. Last year, spending on specialty drugs grew nearly 12 percent, while spending on traditional drugs grew less than 2 percent.<sup>11</sup>

These drugs cost tens of thousands of dollars a year, often putting them out of reach for many

women. And yet women make up the majority of those who need them, with the Biosimilars Council estimating women make up 67 percent of the patient population for most biologics.<sup>12</sup>

The rise of high-deductible health plans makes these medications even more unaffordable. A HealthyWomen *WomenTALK*<sup>®</sup> survey of more than 1,000 women found that 37 percent have trouble paying for their prescription medications, while nearly half of those with chronic health conditions reported difficulties. Reflecting this reality, 52 percent of women who fall into this category say they received financial help from family and friends to pay for their medicine and 41 percent got help from a pharmaceutical company in the form of a coupon payment or discount card. Additionally, nearly a third (27 percent) received financial assistance from a nonprofit patient-assistance program.

All of which means that these life-saving medications may be out of reach of many women. One analysis found that even high-income women experience delays in breast cancer treatment that may be related to high out-of-pocket costs.<sup>13</sup> Another found that high out-of-pocket costs for the breast cancer drug Herceptin<sup>®</sup> (trastuzumab) posed a barrier to physicians prescribing it.<sup>14</sup>

## THE SOLUTION: BIOSIMILARS

The answer to high-cost specialty drugs is supposed to be biosimilars. Biosimilars are compounds produced in the same manner as branded biologics. However, because the manufacturing process for biologics is so complex, it is impossible for a biosimilar to be chemically identical to its reference product as a generic drug is to its original product. Instead, biosimilars are considered “highly similar” to the reference product.<sup>15</sup>

The first biosimilars were approved in Europe in 2006. Today, the European Medicines Agency has approved more than 50, most of which are on the market.<sup>16</sup> This effort has lowered prices and increased access for millions of patients. For

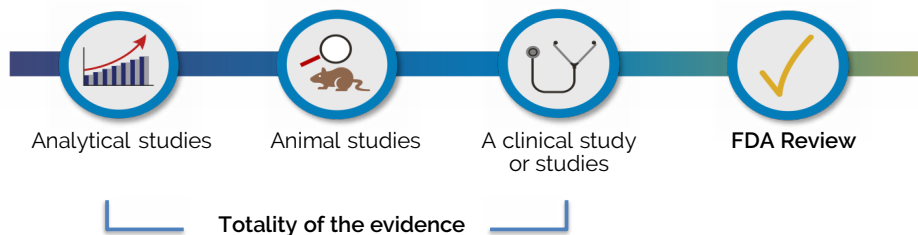
**Although the FDA has since approved 25 biosimilars, just a handful are on the market and the potential cost savings has not been realized.**

instance, the United Kingdom's National Health Service expects to save \$193 million a year now that biosimilars for one of the top-selling drugs in the world, Humira<sup>®</sup> (adalimumab), are available.<sup>17</sup>

The U.S., however, lagged far behind its European counterparts in developing a regulatory roadmap to biosimilars. That didn't come until the Affordable Care Act was signed into law in 2010. It contained the Biologics Price Competition and Innovation Act, which created an abbreviated licensure path-

way for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference product. It requires that the drug be "biosimilar" to the reference product, with no clinically significant differences (Figure 1).<sup>18</sup>

**FIGURE 1: DEMONSTRATING BIOSIMILARITY**



Source: U.S. Food and Drug Administration, Office of Therapeutic Biologics and Biosimilars

Still, the FDA didn't approve the first biosimilar until 2015. As of late November 2019, the agency had approved 25 biosimilars, but less than half were on the market stymied, in part, by continuing litigation from reference drug manufacturers (Table 1).<sup>19,20</sup>

"The U.S. not only has fewer biosimilars available in the marketplace, but the market penetration of those products is also low," said speaker Caleb Alexander, MD, professor of epidemiology and medicine at Johns Hopkins University in Baltimore, "with recent estimates suggesting that some biosimilars may be reaching as little as 4 percent of eligible patients."

However, the FDA has significantly ramped up its review of biosimilar applications in the past year even as the number of applications has increased. As of October 2, 2019, 73 programs for 38 different reference products were enrolled in the Biosimilar Product Development

Program to discuss development of proposed biosimilar products or interchangeable products, said Sarah Yim, MD, acting director of the FDA's Office of Therapeutic Biologics and Biosimilars.

They include insulin, growth hormones and pancreatic enzymes, she said, which are expected to be approved by March 2020.

**THE UNREALIZED SAVINGS OF HERCEPTIN® BIOSIMILARS**

It costs a lot of money when reference drug manufacturers block access to biosimilars. For instance, the first biosimilar to the cancer drug Herceptin (trastuzumab) was approved in 2017, but a trastuzumab biosimilar didn't launch until 2019. The lag in the availability of trastuzumab biosimilars cost the U.S. an estimated \$140 million in lost savings in 2018 alone.<sup>21</sup>

**TABLE 1: BIOSIMILARS LAUNCHED**

Nine biosimilars have entered the U.S. market as of November 2019<sup>22</sup>

Reference Drug	Biosimilar	Therapeutic Area
Avastin® (bevacizumab)	Mvasi® bevacizumab-awwb	Oncology
Herceptin® (trastuzumab)	Kanjinti® (trastuzumab-anns)	Oncology
Neupogen® (filgrastim)	Zarxio® (filgrastim-sndz Injection)	Neutropenia
	Nivety™ (filgrastim-aafi)	
Neulasta® (pegfilgrastim)	Fulphila® (pegfilgrastim-jmdb)	
	Udencya® (pegfilgrastim-cbqv)	
Remicade® (infliximab)	Inflectra® (infliximab-dyyb)	Rheumatology/autoimmune
	Renflexis® (infliximab-abda)	

## THE POTENTIAL OF BIOSIMILARS

Will biosimilars be the Holy Grail to stem rising drug costs? “Possibly,” was the message from presenters.

Certainly, several studies predict cost savings, they noted. For instance, a 2018 RAND report estimated a potential \$54 billion savings from biosimilars between 2017 and 2026, about 3 percent of total biologics spending depending on price, sales, and competition.<sup>23</sup>

Another analysis for IQVIA Institute suggested that, if current expectations hold, by 2023 the part of the biologic market with competition from biosimilars will have grown threefold, resulting in an estimated \$160 billion savings in drug costs, about 10 percent of what would have been spent without biosimilars.<sup>19</sup>

All of which can expand access, as a study from Avalere Health found. It determined that 1.2 million Americans could gain access to treatment by 2025 as the result of biosimilar availability, with women, lower income and elderly individuals disproportionately benefitting from access to biosimilar medicines.<sup>12</sup>

“Given that women are often the prime decision-makers regarding health care spending,

**The key takeaway from the forum is that biosimilars have great potential to increase women’s access and affordability to lifesaving drugs, but that there are numerous challenges and barriers to overcome before biosimilars are widely and more easily accessible to the patients who most need them.**

and may face greater strain from out-of-pocket costs,” said Dr. Alexander, “the prospect of greater savings from a healthier biosimilar marketplace is one that women have a vested interest in seeing.”

## BE REALISTIC ABOUT SAVINGS

Although biosimilars should be to biologics as generics are to drugs, payers, health care providers and patients need to be realistic about what savings may occur, speakers said. That's because biosimilars are far more expensive to produce than generics, given how they are manufactured. Biosimilars are also far more expensive to bring to market. Estimates are that it costs \$40 million or more to bring a biosimilar to market compared to between \$2 and \$5 million for a generic. It also takes 5 to 8 years for FDA approval for a biosimilar compared to 2 or 3 years for a generic.<sup>24,25</sup>

The few biosimilars that have reached the U.S. market so far are generally priced about 15 percent below the wholesale cost of the reference product. The first biosimilar to Rituxan® (rituximab), which launched in November 2019, offered just a 10 percent discount.<sup>26</sup>

While providing some savings, the difference is not large enough to convince payers or clinicians to switch from the reference product. As one U.S. payer said when interviewed on the topic: "Without 'shock and awe' pricing, we won't endorse biosimilars as a country and as a payer community. And then biosimilars will fail and we'll never . . . have made much of an impact on U.S. drug spending."<sup>27</sup>

## BARRIERS TO UPTAKE

As nearly all speakers noted, the potential of biosimilars to increase accessibility and affordability is stymied by numerous challenges and barriers.

"Challenges to biosimilar entry and utilization in the U.S. have proven to be more substantial than initially estimated and price competition much lower than expected," Dr. Alexander said.

Creating a competitive biologics environment is more challenging than developing small-molecule competition, noted Gillian Woollett, MA, DPhil, senior vice president, Avalere, LLC. It involves not just more complex manufacturing, but significant issues in prescribing patterns, interchangeability, physician reimbursement and payer coverage.

These include regulatory roadblocks that slow approvals; manufacturer litigation that delays the launch of approved products; payer policies; and

Indeed, an Avalere report of 18 plans representing 172 million covered lives found that 10 plans, representing half of the covered lives, required doctors to start their patients on Remicade before switching patients to one of two approved infliximab biosimilars. Just one health plan, representing just 1 percent of the 172 million lives covered in the study, supported the use of either infliximab biosimilar over Remicade through step therapy; while one other (representing 2 percent of covered lives) allowed the use of either Remicade or the biosimilar Inflectra.<sup>28</sup>

That could change as more competition enters the market. For instance, three pegfilgrastim biosimilars to the reference drug Neulasta® (pegfilgrastim), used to treat neutropenia in cancer patients, are available in the U.S., all at between a 33 and 37 percent discount compared to Neupogen.<sup>29</sup>

At that discount, health plans have taken notice. Five large plans representing 49 percent of covered lives had policies favoring a Neupogen biosimilar, while just a third of the covered individuals were in plans that favored the reference product. Still, 28 percent of plans representing about a third of the covered lives, had policies that favored Neupogen over the biosimilar.<sup>28</sup>

**“The biggest barriers to biosimilar access for women is lack of patient knowledge, lack of provider knowledge and cost and safety concerns.”**

— **Monica Mallampalli, PhD, MSc, senior advisor, Scientific and Strategic Initiatives, HealthyWomen**

patient and provider suspicions of biosimilar safety and efficacy, speakers said.



"I am getting to the point of believing the U.S. barriers to entry will ultimately — because we're the biggest market in the world — deny the world biosimilars," Dr. Woollett said. "We must seize the opportunity to capture the successful EU experience and optimize efficiency of biosimilar approval in the U.S. to support access worldwide to leverage development costs."

"The biggest barriers to biosimilar access for women," said HealthyWomen's Senior Advisor, Scientific and Strategic Initiatives Monica Mallampalli, PhD, MSc, during her presentation, "is lack of patient knowledge, lack of provider knowledge and cost and safety concerns."

## THE FDA STEPS UP

Presenters all agreed that the pace of biosimilar approval at the FDA has been notoriously slow. "It is my personal belief that the FDA has the information to expedite more efficient development and more approvals of biosimilars," Dr. Woollett said. "We need to speed this up and we need to get more efficient and faster and use current established regulatory science to achieve that."

She suggested that the FDA should accept clinical trials conducted for biosimilar approval in other countries as part of the approval process here in

Plus, there is simply not the competition that exists when small molecule drugs go off patent and generics enter the market. The first approved generic gets six months of exclusivity, explained Alex Brill, a resident fellow at the American Enterprise Institute, during his presentation, and the brand typically doesn't change its price even as it loses market share. Then, when additional generics enter the space, the generic price plummets.

But with biosimilars, he said, the reference biological drops its price when the biosimilar enters the market, making it more difficult for the biosimilar to compete and, thus, gain market share, particularly since most offer just a 15 percent discount.

the U.S. "I would argue that once one biosimilar has been approved in, say, Europe, to a reference product already available in the EU and the U.S., then that's the same biosimilar we need here. So, a bridge for one is a bridge for all."

The FDA has taken notice, issuing more product-specific and clinical trial guidance designed to speed biosimilars to market, including its Biosimilar Action Plan, described below. The agency has also reorganized the Office of New Drugs to have a greater focus on biosimilars.

### FDA BIOSIMILAR ACTION PLAN

The FDA's Biosimilar Action Plan, released in July 2018, is designed to provide greater support to biosimilar sponsors and streamline the development and approval process. Among its components:<sup>30</sup>

- Developing and implementing new FDA review tools, such as standardized review templates that are tailored to marketing applications for biosimilar and interchangeable products.
- Creating information resources and development tools for sponsors of biosimilar applications.
- Enhancing the Purple Book, which lists biological products, including biosimilar (and eventually interchangeable biological products), to include more information about approved biological products.
- Actively exploring the potential for entering into new data-sharing agreements with foreign regulators to facilitate the increased use of non-U.S.-licensed comparator products in certain studies to support a biosimilar application.
- Establishing a new Office of Therapeutic Biologics and Biosimilars to improve the coordination and support of activities and accelerate responses.
- Publishing final or revised draft guidance on biosimilar product labeling
- Providing additional clarity and support on interchangeability, analytical approaches and product quality and manufacturing processes.

## EDUCATING THE PATIENT

*"Gaps exist in knowledge and perceptions about the use of biologic and biosimilar therapies in disease treatment. Patient education programs, developed in partnership with advocacy groups, should provide patients with the necessary information to make informed decisions about the use of these products."*

– Jacobs I, Singh E, Sewell KL, et al. Patient attitudes and understanding about biosimilars: an international cross-sectional survey. *Patient Prefer Adherence*. 2016;10:937-948.

There is a huge need to educate patients and the general public about biosimilars and their potential, speakers said, with numerous surveys and studies demonstrating an enormous knowledge gap, even among those who are already being treated with a biologic. For instance:

- A 2015 survey of 362 members of the American Autoimmune Related Diseases Association, 96 percent of whom were living with an autoimmune disease, found that more than 80 percent did not know what biosimilar medicines were and about 52 percent did not understand how they differed from the reference drugs.<sup>31</sup>
- A study of 635 U.S. patients diagnosed with an autoimmune disease or cancer (65 percent of whom were women) found that 54 percent had never heard of biosimilars and only 9 percent had "at least a general impression."<sup>32</sup> The study also found, however, that the more patients knew about biosimilars, the more comfortable

they were switching to one from a reference product and the more likely they were to believe biosimilars were safe, effective and affordable.<sup>32</sup>

- A 2017 survey from the Arthritis Foundation and a more recent listening tour found that less than half of the patients surveyed knew what biosimilars were, said the Foundation's Vice President of Advocacy and Access Anna Hyde, during the meeting. Although the Foundation has information on its web site, "from a patient perspective, why would you go to the web site specifically searching for biosimilar information if you don't know what biosimilars are in the first place?" she asked.

One thing she heard over and over again on the listening tour, Ms. Hyde said, is that patients want to know how others with their condition reacted to a drug. "They get the clinical rationale for why they should be on this drug, but the first thing they want to know is, 'How did a patient with my disease profile react when they took this medication?' It's that peer-to-peer support that's really going to push them over. It's not so much a clinical thing, it's more of an emotional thing." And that, she said, "represents the future challenge of how we tailor our efforts and resources around biosimilars."

The educational need may differ among patient populations, however. "I'm not seeing a lot of issues in the practice community in terms of explaining biosimilars to patients, especially if they're switching from the reference drug (Neupogen<sup>®</sup>) to (the biosimilar) Zarxio<sup>®</sup>," said Lisa Kennedy Sheldon, PhD, APRN, chief clinical officer, Oncology Nursing Society, during her presentation.

## EDUCATING HEALTH CARE PROVIDERS

Educating the physician is necessary, said panelist Virginia Ladd, founder of the American Autoimmune Related Diseases Association, "because if the patient is educated and the doctor is hesitant, then the patient is going to be hesitant."

However, several speakers highlighted knowledge gaps in physician understanding about

biosimilars as well as health care providers' reluctance to use them, particularly for patients who are doing well on the reference product. This is despite extensive evidence that switching from the reference drug to the biosimilar is safe with no loss of efficacy or increase in immunogenicity.<sup>33</sup>

"Demonstrating biosimilarity is obviously completely different than establishing efficacy," said Dr. Yim. Since the agency just wants to prove that the biosimilar is the same product as the reference product, it relies on analytical rather than clinical studies. "The problem," she said, "is most people are most familiar with clinical studies, including doctors and patients. So, it's a matter of trying to get people more comfortable with analytical data. That's our challenge with education."

#### FOR INSTANCE:

- A survey of 100 physicians released in September 2019 found that while 51 percent said they understood biosimilarity, and while most were confident in their ability to use biosimilars, their reluctance to use them doubled or tripled when asked about switching a patient from a reference drug that is working to a biosimilar. About a quarter were either reluctant or had no confidence at all in switching patients to a biosimilar during an active treatment regimen. In addition, 74 percent said that physician confidence is the main barrier to widespread biosimilar adoption.<sup>34</sup>

Physicians said "It doesn't make sense" to switch a patient who is doing well from a brand-name product to a biosimilar. As one doctor said: "The potential cost savings is very real; however much remains to be seen in terms of data and safety."

- Two surveys released during the 2019 American College of Rheumatology annual meeting also held some interesting data.

One survey of 291 U.S. rheumatologists found that just a third were willing to switch a patient who was doing well on the reference drug to a biosimilar, although 72 percent said they were willing to initiate a biosimilar for a biologic-naïve patient.<sup>35</sup>

Another study of 54 rheumatologists found that just 15 percent were comfortable with current safety and efficacy data for biosimilars and 53 percent would not extrapolate studies to prescribe for a different indication. They also said it would take discounts of 31 to 50 percent to get them to consider a biosimilar rather than the reference drug.<sup>36</sup>

Yet rheumatologists have been able to prescribe biosimilars for Remicade since 2016.

**There is a huge need to educate patients and the general public about biosimilars and their potential, with numerous surveys and studies demonstrating an enormous knowledge gap, even among those who are already being treated with a biologic.**

Ms. Hyde noted that some of the rheumatologists who work with the Arthritis Foundation have switched all their patients to biosimilars because they believe in the value and the long-term promise of lower costs. "But if you press them on why their colleagues may be hesitant to do so as well, you end up coming back to that change factor. Change is hard. It's that emotional response that often supersedes the more scientific or clinical one."

Dr. Kennedy Sheldon recalled a biosimilars panel she participated on during a large women's health meeting. Most participants were health care providers. "They had no clue. They had no understanding about biosimilars, and they were just totally lost," she said.

#### THREE MYTHS ABOUT BIOSIMILARS

Key educational messages are needed to counter the **three main myths** that physicians and patients have about biosimilars, Dr. Alexander said:

1. Cheaper means less safe.
2. Confirmatory trials are too small to detect clinically meaningful differences between the reference drug and the biosimilar.
3. Extrapolation is dangerous without trials for each indication.

# BARRIERS FROM REFERENCE MANUFACTURERS

To maintain market share, reference drug manufacturers are pushing back in several ways, including adding patents to continue protecting their drug; developing “biobetters,” which are similar to the reference product but differ in terms of dosing, safety, efficacy and immunogenicity; offering deep rebates and discounts to payers to offset biosimilar discounts; and citing their risk evaluation and mitigation strategies (REMS) for their refusal to provide samples to biosimilar manufacturers for clinical trials.<sup>3</sup>

The FDA recently approved a subcutaneous version of the breast cancer drug Herceptin (trastuzumab). While trastuzumab is infused over 30 to 90 minutes, the biobetter Herceptin Hylecta<sup>®</sup> (trastuzumab hyaluronidase-osyk) can be administered in five to 10 minutes, offering a significant advantage to patients.<sup>37</sup> Indeed, studies find that women significantly preferred this method of delivery.<sup>38</sup> None of the five approved trastuzumab biosimilars, however, can be delivered subcutaneously.

“The window is closing for biosimilar products to make a dent because by the time they hit the market there will be other products that are more innovative that clinicians and patients will prefer,” said Dr. Alexander.

It’s a fine balance, said Stacey L. Worthy, a partner in the DCBA Law & Policy firm and a policy advisor to HealthyWomen, during her presentation. “There’s a significant need to create the environment that allows biologic reference products and biosimilars to compete,” she said. “At the same time, it has to be balanced by making sure that manufacturers of the reference products are incentivized to continue innovating.”

Nonetheless, she said, “We also want to root out anti-competitive behaviors, such as those by bad actors in the industry that may be abusing certain regulatory means to delay competition.

**“Educating the physician is necessary because if the patient is educated and the doctor is hesitant, then the patient is going to be hesitant.”**

— Virginia Ladd, founder, American Autoimmune Related Diseases Association.

She highlighted several barriers to greater biosimilar uptake for which congressional and regulatory pathways are underway to try and address, including:

- **Incentivizing clinicians to prescribe biosimilars.** Under Medicare, physicians are currently reimbursed the average sales price (ASP) of the infused/injectable drugs plus a 4.5 percent administrative fee. That fee would be lower if the biosimilar costs less than the reference drug, providing a disincentive to prescribe the biosimilar. A bill now making its way through Congress would increase reimbursement for biosimilar drugs to ASP plus 8 percent for five years.
- **Health plan coverage of biosimilars.** The Star Ratings for Biosimilars Act would require Health and Human Services to evaluate Medicare Advantage plans based on whether biosimilars are available to enrollees, including utilization management approaches and the percentage of enrollees prescribed biosimilars rather than reference drug. The results would become part of the formula that determines a plan’s quality rating.

- **Prevent the use of REMS protocols to stymie biosimilar entry.** The Strengthening Health Care and Lower Prescription Drug Costs Act promotes competition for biosimilars by establishing civil actions for license holders of covered reference products that fail to provide sufficient quantities of their product to eligible product developers.
- **High out-of-pocket costs for patients.** The Acting to Cancel Copays and Ensure Substantial Savings for Biosimilars (ACCESS) Act would eliminate a patient's copay for biosimilars if the patient would normally pay the full cost of a biologic drug under Medicare Part B.
- **Pay-for-delay.** The Preserve Access to Affordable Generics and Biosimilars Act prohibits "pay for delay" settlement agreements that occur when the reference product uses patient settlements to delay a potential biosimilar from entering the market.
- **Sham citizen petitions.** The Stop STALLING Act permits the Federal Trade Commission to initiate civil actions against a person who files a sham petition to interfere with the development of a biosimilar product.
- **Educational efforts.** The Advancing Education on Biosimilars Act of 2019 would create federal programs to promote biosimilars, including the development of continuing medical education for prescribers and a public web site to educate patients and providers about biologics and biosimilars.

## CONCLUSION

Speakers and panelists at HealthyWomen's *Biosimilars & Women's Health Science & Policy Forum* identified numerous challenges to the widespread adoption of biosimilars, while highlighting the benefit of biosimilars for women, who are the majority of those who need these treatment options.

The forum ended with an engaging discussion among the panelists and participants, with important reflections on potential solutions with consideration to inherent challenges.

"Biologics are so important to this group of patients and the cost can be so devastating to a family," said Dr. Alexander. "Hopefully, we can bring that cost down. But when we bring the cost down, we have to be careful that we're not also interfering too much between the doctor and the patient relationship."

Ms. Hyde asked: "If you take all the market incentives possible and put them out into practice, what does it matter if a patient and provider don't feel comfortable with the biosimilar?" But the reverse is true, too, she suggested. "If the patients and providers are all gung-ho and 100 percent and want to take biosimilars, but then the market incentives aren't there, what does it matter? I think that the two lanes have to be dealt with concurrently."

"There's an urgency to this," said Dr. Woollett. "U.S. patients are going to be denied these medicines and they are going to die unless we change something."

HealthyWomen is encouraged that learnings from our forum may offer insight for health care providers, policymakers, educators and advocates about the important role biosimilars have for women's health as an affordable treatment option and about the need to remove barriers preventing women from accessing them.

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# HEALTHYWOMEN

HealthyWomen is the nation's leading independent, nonprofit health information source for women. Our mission is to educate women to make informed health choices for themselves and for their families. For 30 years, millions of women have turned to HealthyWomen for answers to their most personal health care questions. HealthyWomen provides objective, research-based health information reviewed by medical experts to ensure its accuracy. Consumers, health care providers, nonprofit and corporate partners and the media trust HealthyWomen as a valued and reliable health information source.

Nothing is more important to our health than access to competent and affordable care and the safety of our medicines and health care delivery practices. HealthyWomen works to educate women about health policy issues on these and other issues. We recognize the importance of clinical trials to improving women's health and we support women's health research, particularly to account for sex differences in research results. HealthyWomen advocates on behalf of women to ensure that women's health is a primary focus of policy makers and advocacy groups. Our investment in developing science-based information and our effort to incorporate perspectives reflected by advances in research and technology will further our mission to provide women with relevant and accurate health resources.

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February 2020





# BIOSIMILARS & WOMEN'S HEALTH

SCIENCE & POLICY FORUM

National Union Building, 918 F St., NW  
October 25, 2019  
8:30 – 2:30 pm

- 8:30-9:00 am: Registration and Breakfast**
- 9:00-9:15 am: Welcome**  
*Beth Battaglino, RN, CEO, HealthyWomen*
- 9:15-9:45 am: Current State of Biosimilars in the US – an overview**  
*Gillian Woollett, MA, DPhil, Senior Vice President, Avalere Health LLC*
- 9:45-10:15 am: Federal Legislative and Regulatory Updates**  
*Stacey L. Worthy, Esq., DCBA Law & Policy LLP*
- 10:15-10:30 am: Break**
- 10:30-Noon: Research to Market: Recent Advances and Challenges**  
Moderator: *Michael Miller, MD, Senior Policy Advisor, HealthyWomen*  
Panelists:
  - *Sarah Yim, MD, Acting Head, Office of Therapeutic Biologics and Biosimilars, FDA*
  - *Alex Brill, Resident Fellow, American Enterprise Institute*
  - *Caleb Alexander, MD, Professor of Epidemiology and Medicine, Johns Hopkins University*
- Noon-1:15 pm Lunch**  
**Women as Consumers of Biosimilars – Survey Results**  
*Monica Mallampalli, PhD, MSc, Senior Advisor, Scientific and Strategic Initiatives, HealthyWomen*
- 1:15-2:15 pm: Biosimilars & Women's Health: Challenges and Opportunities for Women's Access to Treatment**  
Moderator: *Monica Mallampalli, PhD, MSc, Senior Advisor, Scientific and Strategic Initiatives, HealthyWomen*  
Panelists:
  - *Virginia Ladd, Advisor to the President and Founder, American Autoimmune Related Diseases Association, Inc.*
  - *Anna Hyde, Vice President of Advocacy and Access, Arthritis Foundation*
  - *Lisa Kennedy Sheldon, PhD, APRN, AOCNP, FAAN, Chief Clinical Officer, Oncology Nursing Society*
- 2:15-2:30 pm: Wrap Up**



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