



Podcast Transcript

"Biosimilars and Cost-Savings"

Recorded: October 16, 2020

Moderator: North Carolina State Senator Natalie Murdock

Panelists:

Carol Lynch, Sandoz US President, Head Sandoz North America

Pam Traxel, Senior Vice President, American Cancer Society Cancer Action Network

Cheryl Larson, President & CEO of the non-profit Midwest Business Group on Health (MBGH)

Voiceover: Welcome to the [Women In Government Podcast](#). Whether discussing important issues or policies of the day, this is the place where lawmakers and decision-makers unite to get the conversation started.

Senator Natalie Murdock: Science is forever evolving, particularly when it comes to cutting-edge medicines aimed at improving the quality of life for millions of people. It has been a decade since one innovation entered the picture which has helped save lives, while being an affordable option for those living with cancer, arthritis, and autoimmune diseases.

Hello, I'm [North Carolina State Senator Natalie Murdock](#). Thank you for listening to the latest [Women In Government podcast](#). On this episode, we're celebrating the 10-year anniversary of biosimilars. For those of you who don't know what they are, or how they're developed and regulated, this episode is a must-listen.

Joining the conversation is [Carol Lynch](#), President of [Sandoz US](#) and head of North America. Carol has more than 25 years of global pharmaceutical and generic industry experience.

Carol Lynch: Thank you for the invitation. I'm really happy to be here joining you today.

Senator Natalie Murdock We also have [Pam Traxel](#), Senior Vice President of the [American Cancer Society Cancer Action Network](#).

Pam Traxel: Thank you so much, I'm so excited to be here today to talk about this really important topic.

Senator Natalie Murdock: Thank you Pam, and finally [Cheryl Larson](#) is joining in on the conversation. She is President and CEO of the nonprofit [Midwest Business Group on Health \(MBGH\)](#).

Cheryl Larson: Happy to be here, very important topic, going to impact the healthcare industry in the near future. Thank you.

Senator Natalie Murdock: Before we get started, I'd like to thank everyone for listening and don't forget to subscribe to, like, or share our [podcast](#). You can also email us by visiting [womeningovernment.org](#).



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Senator Natalie Murdock: Biosimilars are available in almost 100 countries around the world, including those in Europe, as well as Australia, Canada, Japan, and the US. Carol, one key focus of your organization is the development, manufacturing, and commercialization of biosimilars. For those who are unfamiliar, can you explain what they are and what diseases they target?

Carol Lynch: Yes, of course, thank you for the question. And it's amazing, isn't it, that [ten years](#) since the [pathway to approve biosimilars](#) was first introduced, and five years since the launch of the first biosimilar, we're still explaining to people what biosimilars are -- but I'm happy to take that on.

So biosimilars are FDA-approved versions of existing biologic medicines. In essence, biosimilars are to biologics, what generics are to brand small-molecule medicines. And in terms of the patients that they're used to treat, are really those patients who are suffering from the complex chronic conditions just like you mentioned; so, patients who have cancer, rheumatoid arthritis, and other complex autoimmune conditions.

Now with the introduction of biosimilars, these patients no longer have to choose between quality, efficacy, and safety, or savings; and when you think about that patient population this is particularly relevant. Patients who are taking their meds long term no longer have to make that choice, where in the past, they may have either forgone treatment or even settled sometimes for less effective therapies. So, I think this has been a major step forward for US patients.

Senator Natalie Murdock: Thank you. Biosimilars typically sell at a discounted rate due to their lower costs. Those medicines have the potential to substantially reduce out-of-pocket costs, which is great for all Americans across the board. Can you provide a little bit more detail regarding savings and some of the other benefits of prescribing and taking a biosimilar?

Carol Lynch: Absolutely, and as you mentioned, you know because of the cost savings, they really do play an important role in creating sustainability for the healthcare system, which especially during times of COVID, is really overburdened. And the way that they do this is through introducing competition, and through competition you therefore create savings. And [it's been estimated](#) that biosimilars can actually save the US healthcare system up to \$100 billion for the five-year period between 2020 and 2025, whilst at the same time, offering patients an alternative product which is safe, effective, and obviously high quality.

Now we've got some early proof points which is really great because the availability of the biosimilar Filgrastim has already been shown to demonstrate to have [saved \\$1.2 billion](#) in savings to the US healthcare system from 2016 through to 2020. So, you can imagine the savings that the system could make if this was applied across all biosimilars that are in the market today and those that are still to come.



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So, what can we do with their savings? And how do they benefit patients? So, the one way that these savings can be used is to make sure that more patients can get access to these biologic medicines, because the access has been restricted in the past because they're quite expensive.

The other way that the patients can benefit as well is when the savings are generated, they can also be reallocated to put towards innovative therapies that are coming through. So, when we get breakthrough medications being launched, if you're saving on the older products, then you can put the savings toward making sure that patients have access to the newer products as they come through. So, two great benefits for patients: either expanding access to healthcare or making sure that more patients can get access to those breakthrough medicines when they're launched.

Senator Natalie Murdock: According to the Pacific Research Institute publication [Promoting Biosimilar Competition to Reduce Patients' Out-of-Pocket Costs](#), it was determined that depending upon the drug, and based on treatment assumptions, biosimilars can reduce the amount of money spent by patients by up to 47%. A great example is a biosimilar that competes with Humira and Enbrel and sells at the expected discount of 50%. I see there are nine classes where biosimilar competitors have been approved. What are some of the biosimilar success stories here in the US?

Carol Lynch: There are a number of successes, but maybe I'll focus on just three. First of all, I think getting the [first launch](#) felt like a major success and even though it's five years ago now, we still celebrate it. And with the fifth birthday of Zarxio (Filgrastim), which was launched in 2015, one of the great success stories was that it [actually overtook the originator brand within three years](#) from a market adoption perspective. So, it shows you that the potential for biosimilars really is there in the US market and obviously US patients therefore benefit from having the biosimilar available.

Because Zarxio was the earliest launch product, it's the one for which we have the most data. And we've now been able to collect real-world evidence, and the cost effectiveness data through real life usage has shown the savings that I mentioned earlier, the \$1.2 billion in savings to the US healthcare system. And as a consequence of this cost effectiveness being demonstrated, we've recently seen [a change in the National Cancer Care Network Guidelines](#) to expand the use of Filgrastim in a prophylactic setting to a broader patient population. In other words, more patients and now considered to be eligible to receive this product compared to previously, because the cost-effectiveness has actually been demonstrated in real world evidence; so, I think that is a second major success.

And then the third one is a bit of a combination one. So, I think what we've seen in the US, that we've seen a [massive acceleration](#) in the number of biosimilars that have been approved. So were catching up with other countries around the world; we now have 28 products which have been approved. And the launches that have happened in the last 12 months, we've actually seen market adoption in a much more rapid vein compared to the earlier launches. So, I think we're starting to see a step change in the adoption of biosimilars, which means that the American patients get to benefit.



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Senator Natalie Murdock: Thank you. For those who know this landscape well, they say there are three ways that Europe is ahead of us here in the US: maturity of market, the number of competitors, and biosimilar market share. Many of us are pretty new to the topic and are not economists. Can you explain how our system differs from the EU, and are there still barriers to uptake?

Carol Lynch: Yeah absolutely, and while it's easy for us all to think about Europe as one body, actually there are a number of obviously different country regulations as well. But across the board, there are significant differences in the policy approaches to biosimilar pricing for example, and reimbursement, as well as the level of education around the product. And then importantly there are incentives in place to encourage biosimilar uptake -- can you see that in different countries across Europe? And whilst biosimilars definitely continue to build momentum in the US, they're still facing a number of challenges that are ultimately affecting patient access to these lifesaving biologic medicines.

Now according to a [Biosimilars Forum report](#), between 2018 and 2020, the estimated lost savings to the healthcare system, because of this poor adoption of biosimilars, is greater than \$19 billion; so those are lost savings for the healthcare system. Now as I mentioned, I think we're still at 28 -- I have to keep an eye every day on the number of approvals -- but the last time I looked we were definitely at [28 FDA approved biosimilars](#), but only 18 commercially available to patients. And in order to realize the full promise of biosimilars for the US, we really need to support policies that increase their adoption, to talk to the total market share that you mentioned, to help to create a more balanced and competitive marketplace. These include a number of different areas, but two that I would focus on are a lack of payment policy incentives that really would try biosimilar adoption, but then also we need to continue with the education to make sure that we're really addressing the misinformation campaigns that still exist about biosimilars.

Senator Natalie Murdock: Every batch of every biologic medicine, including biosimilars, has to stay within precise ranges to ensure that any variations do not lead to a different medicine in terms of safety and efficacy. Can you explain the process to ensure that biosimilars are safe and effective?

Carol Lynch: Sure, so firstly, [biosimilars are FDA-approved](#) and because of that, they go through a rigorous testing process and are subject to [the same quality manufacturing standards](#) that are applied to the brand medicine in terms of safety, efficacy, and quality. Now as you mentioned, because of the inherent variability of the biologic system in the manufacturing process. Any biologic drug will display a certain degree of molecular variability, but this is tightly controlled. Because of this, no two batches of any biologic, whether it's the brand biologic or the biosimilar at the same and biologics can be considered, in a way, biosimilars of themselves. Now this range of variability is allowed for clinically important aspects of the biosimilar medicine, and it's the same that's allowed between batches of the reference biologic medicine too. So, these are tightly controlled and regulated by FDA. And in fact, in our manufacturing sites within Sandoz you can be absolutely reassured around quality. All of our products, whether they are the generics, the biosimilars, or the brands are manufactured in the same site and they're manufactured under the same quality management standards.



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Senator Natalie Murdock: Biosimilars were introduced with the goal of reducing healthcare costs related to biologics. As we already established, many patients facing high out-of-pocket costs are prescribed biologic medicines that treat cancer. According to the [Kaiser Family Foundation](#), of the people covered by employer-sponsored health insurance, 70% of those with coinsurance have a maximum dollar limit on the amount of coinsurance they must pay. For patients that are meeting full maximum dollar limit on their coinsurance payment, the annual cost will likely reflect their out-of-pocket limit. For the 30% of patients without a coinsurance limit, the cost differences between the original medication and the lower cost biosimilar can be substantial.

I know this is a lot to take in for the average listener. That's why I'd like to have Pam Traxel enter the conversation. As Senior Vice President of the [American Cancer Society Cancer Action Network](#), how do you see biosimilars impacting care for patients with cancer? And how are they impacting patient access to biologics for treatment and support patients with cancer?

Pam Traxel: Thanks so much for asking that. We are really in a golden age of biosimilars, especially when it comes to the [treatment of cancer care](#). In 2019, we saw three biosimilars launched to market that are really the backbone of treating cancer; and those biosimilars have had extraordinary uptake, with some studies showing, including the [latest study by IQVIA](#), that they're tracking towards nearly 50% of the overall market. This is a huge game change for cancer patients. Really what this means is that more patients are able to access these therapies at a lower cost and be able to do more to fight and survive their cancer.

Senator Natalie Murdock: Pam, I know the American Cancer Society is [fighting healthcare disparities](#). What role do biosimilars play in this fight?

Pam Traxel: Really when we think about healthcare cost, we really have to think about how we're allocating our dollars towards healthcare spend. If we are going to resolve disparities in healthcare and make sure that everyone has the resources they need to battle their cancer, we need to do everything we can to provide effective therapies to patients at the best cost that we can. Biosimilars really represent a really great opportunity for that.

As we discussed earlier in this panel, and I think that actually Carol raised some really good points. Biosimilars represent an opportunity for patients to receive high-quality medicines at a reduced cost to them and that can really make a big difference in resolving health inequities when it comes to cancer care.

Senator Natalie Murdock: Thank you Pam. The [oncology care model 'OPM'](#) is a reimbursement system developed by the [Center for Medicare and Medicaid Innovation](#) and was designed to improve health outcomes and produce higher quality care at the same cost or lower costs to Medicare. Have you heard that biosimilars have played an important role in the multi payer model? Can you tell us how they're helping achieve the intended objective?



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Pam Traxel: Absolutely, you know when we look at the [Oncology Care Model](#), really the purpose of that and any other kind of model that's set up in this way, really the goal of the model is to ask physicians to generate savings for the Medicare system and that they're rewarded, really, for generating those savings. And they're a bunch of different models and there are more things that [CMS](#) is considering going forward, but it's really an opportunity for physicians to be on the front lines to reduce healthcare cost.

And so, what we're really excited about is with biosimilars, a physician has an opportunity to prescribe a biologic to a patient to fight their cancer with a lower cost to the patient and a lower cost to Medicare. And that's really exactly what the Oncology Care Model was intended to do, so really biosimilars fit very squarely within the Oncology Care Model and we're really excited to see the uptake in oncology. It's really been quite amazing.

Senator Natalie Murdock: The large potential reduction in out-of-pocket spending provides justification for policymakers--like myself--to address the market and regulatory inefficiencies that are inhibiting a more robust biosimilars market from developing. Pam, what biosimilar policy will provide the most impact to patients with cancer?

Pam Traxel: For me, and honestly for legislators like yourself, I think the most important thing we need to think about is what we can do to reduce the patient out-of-pocket costs. We're seeing an alarming rise in the amount of money that individual cancer patients have to pay out-of-pocket for their cancer care. So, we at ACSCAN would [advocate](#) for any policy that either reduces or eliminates cost sharing for patients taking a biosimilar. There are many policy proposals in place, including one that would [waive patient cost sharing for biosimilars](#), which would really be a great step forward to helping people battle their cancer.

Senator Natalie Murdock: It's estimated that [biosimilars will reduce direct spending](#) on biologic drugs by \$54 billion between now and 2026, with a range of \$24 - \$150 billion. Pricing competition has the potential to force out competition altogether. We're seeing that employers are getting intrigued by how biosimilars might offer a lower cost option for those who need expensive biologic drugs. In fact, the [Willis Towers Watson 24 Best Practices and Healthcare Employer](#) survey found that 30% of employers have formed strategies to leverage available biosimilars. Cheryl Larson is President and CEO of the nonprofit [Midwest Business Group on Health](#), MBGH. I'd like to welcome her to the discussion.

Cheryl, biosimilars getting more and more attention these days. Are individual private companies and state employers' retirement systems all aware of the potential savings they can provide? For example, in the state of Illinois where MBGH is located?

Cheryl Larson: Thank you Senator Murdock. Although the vast majority of employers know about biosimilars, most of them are not integrating them into their pharmacy benefit strategy. Yet we know there are significant cost savings with biosimilars; in fact, [one source](#) indicated that in the state of Illinois alone, where in MBGH is headquartered, the current savings is about \$6 million annually with an



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opportunity to increase the savings to about \$37 million a year to \$105 million a year, if the market share increases 25% to 75% -- and I think these numbers are very conservative. Our larger and jumbo employers are paying attention to biosimilars, but for most employers, especially the small to mid-sized employer, we know adoption has been slow and there are many reasons for this.

I did appreciate Carol Lynch's comments about lack of payment policy incentives and misinformation campaign. Then I'll add to that list, that price negotiation that employers have with players like PBMs (Pharmaceutical Benefit Managers) that rely heavily on rebates and discounts to get a drug on formulary, often favor the use of a biologic originator drug over a biosimilar and it's mostly because biosimilars don't pay them rebate. So, one of our key goals in talking to our members as employers about biosimilars, is to be transparent about what's really going on in the pharmacy benefit space in general to help our employer plan sponsors.

Senator Natalie Murdock: Are individual private companies and state employers' retirement systems all equipped with the knowledge on actionable steps that they can take to help realize potential biosimilar savings?

Cheryl Larson: Great question. About 11 years ago, the Midwest Business Group on Health launched the [National Employer Initiative on Specialty Drugs](#), which is an employer-led research project that helps employers make critical informed decisions to help them better manage the high cost of specialty and biologic drugs. This summer, we launched a new report called [Transforming the Pharmacy Benefit: the Role of Biosimilars](#), and this report includes action steps for employers to take. I'm going to share a few key highlights; for example, ensuring that employers make sure their PBM has the FDA list of approved biosimilars available and add them to the PBM formulary on both the medical benefits and the pharmacy benefits side. And also defining biosimilars in PBM contracts, and these contracts are usually written in such a way that benefits the PBM and not the employer -- they are not transparent. And also making sure that the PBM contracts include 100% pass-through language, so that all rebates are passed back to the employer, that is not happening. And it also enables the employer to have the ability to audit the PBM, not all PBM contracts allow for that.

Employers also need to avoid conflicts of interest. For example, many PBMs put drugs on formulary based on rebate and not on clinical efficacy and safety, and this continues to be a big problem. Employers also need to ask their PBMs for the clinical criteria and coverage for health conditions that a biologic is approved for, but the biosimilar is not. They need to make that change, so that the biosimilar can also be prescribed.

And then there's pharmacogenomics testing that should be used prior to filling certain biologic and biosimilar prescriptions to make sure the drug prescribed will actually work with the patient's DNA. We also recommend that for new prescriptions, the plan should require utilization of a biosimilar first, and they should use a value-based plan design method to either waive or reduce the copay or coinsurance. And finally, we know it's important that carriers and other stakeholders need to work with us to educate our employees and family members, and also educate physicians and incent them to prescribe the most efficacious lowest-cost drug first.



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Senator Natalie Murdock: When we look at the amount of savings applied to total out-of-pocket costs in the non-biologic drug classes, where biosimilar competitors have been approved, [use of biosimilars can reduce the total spending by \\$238 million](#). What can private companies and state employers' retirement systems do to help realize the potential biosimilar savings available to each of them?

Cheryl Larson: In our world of self-insured employers, and that includes the government, we are the real payers of healthcare. It's not the carriers, or the PBMs. We're the ones actually paying the bills and these vendors are paying the bills on our behalf, so the risks and the costs fall on us and so does our role as fiduciary, which makes us responsible to provide the best benefits at the best price for our employees and family members.

So, getting the right drug, at the right price, for the right patient is key. Yet, we are paying, as an employer community, for a lot of waste, misuse, and low and no-value care. And biosimilars are a cost-savings tool for an employer's health benefit toolbox. We know that employers need more [education](#) on biosimilars, we've been providing it to them for many years. We've seen a lot of surveys and information out there. One survey recently indicated that the average employer does need more education and awareness. When we're working with our members, were not relying on their health plans, or carriers, or PBMs, or their consultants and brokers to provide them with information in this space. As an employer coalition, we are doing it and we're being very transparent about waste and costs in the system and the importance of biosimilars in the future.

Senator Natalie Murdock: The government created the [Biologics Price Competition and Innovation Act](#) and abbreviated licensure pathway for biologic products that are demonstrated to be biosimilar, with a biologic product that is no longer protected by a patent. With this in mind, is there anything state legislators can do to help raise the awareness of the potential biosimilar savings to state employers' retirement systems?

Cheryl Larson: To the extent that state legislators can impact state systems and coverage, they should do so. Again, the challenge will be how the PBMs accept biosimilars into their formulary. There is a lot still broken in the drug industry with certain stakeholders, and in order for biosimilars to be adopted, all of the barriers need to be removed. We talked about some of those barriers in our report, and I only shared a few of them today; there are others.

Senator Natalie Murdock: When we talk about patient care, how do biosimilars impact states?

Cheryl Larson: There are three key patient groups: Medicare, state employees, and retirees. And as more and more biosimilars come to market and get covered by the health plans, this will positively impact cost, just as it will on the public employer or commercial side.

Senator Natalie Murdock: Outside of the [Biologics Price Competition and Innovation Act](#), which was introduced through the [Affordable Care Act](#), what can be done to influence biosimilar uptake at the federal level?



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Cheryl Larson: Well outside of federal legislation for possible price controls, self-insured employers are not usually impacted. This could prompt some changes in the space, but to directly impact self-insured employers from that federal level is challenging.

Senator Natalie Murdock: Thank you for giving us more information about that. As we wrap up, I want to ask all of you one last question: what do you think the future of biosimilars will be in the next five years? Carol, we can start with you.

Carol Lynch: I have to say that I am optimistic. With the number of launches of more biosimilars that we're anticipating over the next five years, I think this is really going to expand treatment options for patients. By making these biologics more affordable, and potentially equalizing access to patients to these medicines, maybe, just maybe, we can achieve the same level of market maturity as we see today in Europe.

Senator Natalie Murdock: Pam?

Pam Traxel: Carol, I think the points that you raised were really strong. I think for me, from a patient perspective, I'm hoping that the future of biosimilars in five years is a really different experience than we have now. Most patients don't know what a biosimilar is, and they aren't being prescribed it. Five years from now, I hope that there are a robust set of patients who are living stronger, healthier lives because of biosimilars and are experiencing less out-of-pocket costs because that is what they have been prescribed. So, hopefully, if we all work together, that could potentially be the future of biosimilars.

Senator Natalie Murdock: And Cheryl, do you have any thoughts?

Cheryl Larson: Today we learned that there are about [20 biosimilars](#) in the US, and we know [Europe](#) has more than double that number. And there are about 70 in development in the US with more scheduled for approval this year, so there will continue to be advances in pharmacogenomic testing. And this will be an even bigger deal in the future and something that employers need to pay attention to, because the last thing we want is that a patient is not tested to determine if the drug will work in someone, and the physician has prescribed a medication that is not going to be effective in them.

There will also be more advancements in the FDA approval process, with more rigor surrounding the similarity of biosimilars and biologics and improved approval process. Employer strategies to move access to biosimilars from the medical to the pharmacy benefit will also drive improvements in this process. And finally, efforts in addressing how rebates are used and cost transparency demand will continue to drive movement towards more biosimilars.

Senator Natalie Murdock: In any closing comments? Carol, we can start with you.



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Carol Lynch: Yeah, I think we've had a great conversation today, but I think what comes through very strongly to me is that it's very clear that we all need to do our part, which includes policy fixes to ensure that patients and providers in the U.S. can benefit from biosimilars

Senator Natalie Murdock: Thank you so much Carol. Pam, how about you?

Pam Traxel: This really has been a great conversation. I think I would really encourage folks to really take this podcast and think about, what is your role? What could you be doing more? Perhaps this is your first time becoming acquainted with the issue of biosimilars. As you can see from this discussion, there are ample ways for people to get involved to make sure that we have a robust and healthy biosimilars market here in the United States and so I would really encourage people to think about what's that next step that you can take to learn more and become engaged.

Senator Natalie Murdock: And Cheryl?

Cheryl Larson: I very much agree with both of my colleagues today. With employers becoming more educated, and the need for more cost-management efforts, especially in today's situation. Biosimilars, like generics, will become an integral part of an employer pharmacy benefits strategy, as long as we can get other stakeholders to remove the roadblocks that sometimes prevent this. And I'll share two quotes that really summarized this. This [first quote](#) is from a large employer, they say:

"Don't accept the status quo, there is a lack of willingness for vendors to change and employers need disruption and transformation. The easiest way to do this is through pharmacy benefits. If one PBM doesn't want to play, there are others waiting."

And I was quoted in our biosimilars report and this summarizes, kind of, our perspective and its:

"Transparency, truth, and collaboration is what's needed to fix pharmacy benefits today. MBGH and other coalitions across the country want to help employers get there by giving them more control and confidence to ensure each patient gets the right drug at the right price. This is our stake in the ground."

Senator Natalie Murdock: Thank you so much to Carol, Pam, and Cheryl. Over the past 10 years, innovation has led to the creation of cutting-edge medicines that treat cancer, arthritis, and auto-immune diseases, just to name a few. Biosimilars medicines that have the same quality, safety, and efficacy as the originator biologic, are akin to the generic medicines or the biologics market. These medicines expand treatment options that can potentially improve patient outcomes by increasing or providing earlier access to therapies. They increase market competition, incentivizing manufacturers to lower prices, and results in increased cost savings to patients. It's important to note that these savings did not fully alleviate the problem of out-of-pocket costs posed for many at risk patients. An effective out-of-pocket cap on spending it's still necessary.



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Today biosimilar’s entry into the US market has been slow, minimally effective at lowering prices, and has failed to overcome discounts to middlemen. That’s why it’s important for policymakers to evaluate additional changes that can help increase availability and accessibility of biosimilars.

Once again, I’d like to thank our panel for sharing such great insights. I also like to thank all the listeners for taking the time to hear this important discussion. Don’t forget to subscribe to, like, or share our podcast. You can also email us by visiting womeningovernment.org. You’ve been listening to the [Women In Government podcast](#), a resource made available for those interested in discussing important issues and policies of the day. For more information please visit our website at womeningovernment.org.



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