Transcript Details
This is a transcript of an educational program. Details about the program and additional media formats for the program are accessible by visiting: https://reachmd.com/programs/medical-industry-feature/biosimilar-access-addressing-barriers-to-build-a-sustainable-marketplace/29769/

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Biosimilar Access: Addressing Barriers to Build a Sustainable Marketplace

Announcer:
Welcome to ReachMD. This medical industry feature, titled “Biosimilar Access: Addressing Barriers to Build a Sustainable Marketplace” is sponsored by Fresenius Kabi. This program is intended for US healthcare professionals. Here’s Dr. Andre Harvin.

Chapter 1: Biosimilar Access: Addressing Barriers to Build a Sustainable Marketplace

Dr. Harvin:
Exciting topic, in my opinion, so I'm going to make it exciting for you, is talking about Biosimilars at the Crossroads. So what's great for us in oncology is that biosimilars is not new to us. I remember when we first started ATAP 4 years ago, topics around biosimilars were very different than the conversations that we're having today. But regardless of our success, when we look at the broader biosimilar platform and market space, so not just in oncology, where to crossroads that we were going to talk about today.

So in terms of disclosures, Fresenius Kabi did help support this program and put together some of the programming that you're going to see. This is not an accredited CE, and I am being compensated for my time here today.

We are going to talk about three objectives. So first and foremost, we're going to make sure that we understand the landscape as it relates to US biosimilar guidelines and adoption versus other countries, really focusing on the regulatory environment that makes this somewhat challenging of what we're seeing here in the US, and compare and contrast that to our neighbors across the pond in the EU. We're also going to discuss how that then relates to that delayed access that we're seeing right now in certain segments of the biosimilar marketplace and all the different stakeholders that play a role in that, right, so we have providers, we have payers, we have our pharmaceutical companies, and at the very center of that, we have patients as well. And last but not least, we're going to talk about some strategies that we could walk away with today of how do we go to the table and say things have to change. We have to make sure that this becomes a sustainable marketplace for all patients that may benefit from biosimilars in the long run.

And that's what brings us to this topic. So this is really about, so what is the true state of biosimilars as it relates to 2024? And again, this is talking about biosimilars as a whole, not just oncology, but as a whole. And Craig Burton actually had a really good quote. He said, ‘Although some biosimilars have seen significant adoption and the use of biosimilars has risen, not all biosimilars have been able to achieve sustainable market use. There remain significant challenges to achieving a biosimilars market that can deliver low prices for patients over the long term. And it's a great quote. And actually, where I look at the emphasis is over the long term, because that's what we're looking for right now, right? We need this marketplace to be sustainable so that we have additional competition. Competition helps with prices, and it also makes us and our manufacturers more confident that additional markers in the future, or different molecules in the future, can be targets of biosimilars. If we don't have this competitive long-term market, then we risk having a potential black slide of whether or not biosimilars will be viable for the long term. He goes on to say that ultimately, ensuring that every patient benefits from biosimilars means ensuring that all biosimilar markets achieve rapid patient access to an adoption of multiple biosimilar competitors. So again, it really brings that concept together of what we're looking for.

Chapter 2: Biosimilars in the US

Dr. Harvin:
And so we start to see it with the numbers, right? Like, the numbers are really important, is that even when we start just looking at how many potential molecules we could have biosimilars for, the EU is just flat out beating us right now. So they have 22 molecules that are now commercially available for their providers and for their patients, and they are creating the sustainable, competitive market dynamic.

Conversely, in the US, we have 15 that have been approved, but only 10 have been launched. So only 2/3 of what's available to us are actually able to be purchased in the market right now, which means we're substantially behind.

And we can actually see that through the other numbers. So in the EU, they have 79 competitors, right, in this biosimilar space, which means that it's an active market. We can pick and choose, we can contract, we can do a lot of different things. Comparatively, within the US, we're at about 38. And that's great. It's much higher than what we were again, when ATAP started about 4 years ago, but we are significantly lagging behind the EU.

Biosimilars have really lived up to their overall promise, right? I remember one of my first things I tried to work on publishing back when I was at OSU, was that biosimilars were going to be great, and they were going to drive a bunch of cost savings into the system, and overwhelmingly they have done that. So we only have data up to 2022, but we can see from 2015 is which we had the first true by a similar launch, all the way through 2022, that has resulted in over $20 billion in cost savings being driven into the US healthcare system, $20 billion in savings with a very limited number of molecules overall. And we see that those savings are accelerating over time, which the last year that we have data for in 2022 alone was almost $10 billion of that. So almost 50% of those savings was realized just within the last full year on record that we have.

And it's an incredible thing that we all should take a lot of pride in, of how we've partnered and worked together to make sure that we create a sustainable market here in the US, especially within oncology. And there's a lot more promise here too. So they are predicting that by 2027, as a health system, we should realize over $180 billion in savings just because of biosimilars into the US health system. But again, there's a level of threat there that we have to ensure that this market is sustainable and can be long-lasting.

Also, we know that access has been substantially expanded by the utilization of biosimilars. Again, 4 years ago, when we were here talking about biosimilars at the very first ATAP conversation, a lot of it was about questions around efficacy and safety and whether or not we could do things like clinically interchange the medications. We're not really talking about that anymore. We're confident, right? We know that they're safe and efficacious. Now we can focus on things like how they've increased overall patient access. They've been used almost 700 million times, and half of those days are additional patient therapy days that without a competitive biosimilar market, patients would not have access to those medications.

Chapter 3: Barriers to Biosimilar Adoption: Payer and PBM Tactics

Dr. Harvin:
One of the last concepts I wanted to talk about are patient out-of-pocket responsibilities. When I first started down the pathway at biosimilars, the person that my boss reported to was the Chief Clinical Officer, and he said, 'Will this strategy reduce patients' out-of-pocket responsibilities?' And with full bass in my voice, I said, 'Absolutely.' Now, luckily he retired, so we never actually had to have this conversation. But what we're seeing is that that's not always the truth.

So what this is showing are patients' out-of-pockets that are $10 or less, whether they are on the originator or biosimilar, and depending on their coverage. And what we're seeing is that there's not a big difference. In the pegfilgrastim class you're actually seeing that commercial patients are actually having to pay more out of pocket for the biosimilar than what they would pay for the originator medication. Now, a lot of that is based on actual insurance design, right? And we're going to talk about that later, and some of the tactics that are being created to drive this.

So let's look at a timely example. And I know we've talked about this a lot at my institution at Cone Health, which is an insulin glargine area. So there are three products on the market. We have Lantus, which is the branded drug. Semglee, which is the biosimilar. It's also interchangeable, which is just interesting because now that designation is just going to go away. I think it really talks about how much we've advanced the conversation on biosimilars in a very short period of time. And then there's also an unbranded insulin glargine. So the unbranded insulin glargine is the cheapest of the three options. The Lantus is the most expensive.

This is looking at claims data that, by and large, you see a lot of providers are writing the initial prescriptions for their patients to go on insulin glargine. When we think about diabetes management and its impact on the overall healthcare system, especially uncontrolled diabetes, this is one of the greatest medications that's available for patients to help control that. And so it's also expensive, so they're one of the last concepts I wanted to talk about are patient out-of-pocket responsibilities. When I first started down the pathway at biosimilars, the person that my boss reported to was the Chief Clinical Officer, and he said, 'Will this strategy reduce patients' out-of-pocket responsibilities?' And with full bass in my voice, I said, 'Absolutely.' Now, luckily he retired, so we never actually had to have this conversation. But what we're seeing is that that's not always the truth.

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And immediately what happens is that there's an NDC block. So those that deal a lot on the pharmaceutical benefits side, I try to adjudicate this prescription, I automatically get a kickback that says you can't utilize this NDC, sorry. Do not pass go. You've got to start all over at that point in time. Look at insulin glargine, 53% of the time PBMs are just blocking that NDC. It means the patient doesn't even have an opportunity to utilize that medication, even though it's the cheapest possible option for them. Yes, Lantis is having some blocking as well. Same thing with the biosimilar, Semglee.

But we also have other aspects that prevent that patient from getting the medication at the end of the day. So you have prior authorization. You could have step-throughs where it's like, hey, you have to fail the Lantus before you can try Semglee, or before you can try the unbranded product. And then there just may be other rejections that occur.

The unfortunate aspect is then you have abandonment as well, where patients just say either, ‘Hey, I'm not coming back. I can't do this back-and-forth.’ Or sometimes they're being punished by their PBM, where it's like, well, hey, if you really want to use this cheaper product, and that's not what I want you to utilize, I'm going to make you pay a lot more out of pocket. And so those patients just elect to not get it. And so at the end of the day, when you actually look at what is filled on those original volume of prescriptions, one, it's sad because all these patients didn't get access to a critical medication, but most of the prescriptions got driven to the most costly option for patients and for the healthcare system.

And this is what we see going on. So they've learned this tactic with insulin, and in here you see that they're also applying it to adalimumab. This was showing that if we did 100% switch to all adalimumab prescriptions in the US to try to drive cost savings, because remember, Humira is like the number one drug right now in the US, that after you get past all these tactics, at best, 1/3 of patients would actually receive any one of the biosimilars available to them. That is unsustainable. And it's a shame of unfortunately what patients have to go through. But it's because of these tactics that it makes it very difficult for us to challenge the norms that these insurance companies are, unfortunately, creating for us.

Chapter 4: Barriers to Biosimilar Adoption: Patent Thickets

Dr. Harvin:
So let's get into patent thickets. So we've talked a lot about this. We talked about competition that we want in the marketplace, all these interesting things. But why is it so difficult in the US? And so it's this concept called patent thickets. And what it means is that manufacturers are able to put so many patents around a single molecule in all aspects of it to make it difficult from a regulatory perspective for us to actually have competition within the space. So this is the key of why it's so difficult to launch biosimilars into that space. And it's unique to the US, because this is just not allowed in other countries. We all have patent offices, whether it's Canada or Great Britain, but the number of patents on the number of molecules available just are tremendous compared to the rest of the world. So 377 patents around 30 biosimilars, compared to 50 and 24 in Canada and the UK. Just a tremendous difference from a regulatory perspective. And what we have to remember is that these patents require biosimilar manufacturers to litigate against or to find ways around so that they can actually bring their product to the marketplace.

And if you look at it for other countries, for any individual company that wants to come forward from a biosimilar, they typically have about one patent that they have to get past in order to bring it forward. And the US manufacturers have 16 on average, patents that they have to get past in order to bring something to the marketplace. It's just very different. This is not about clinical efficacy. This is not about safety. This is about lawyers, the true evils of the world—no.

And this leads to delays and launches. So again, that number we saw at the very beginning is because of this regulatory environment. How long is it taking you to get past some of those other regulatory hoops in order to launch your product? This is where we see that difference of 5 months versus almost 35 months that we're seeing here in the US. And this delay is directly correlating to savings that we're not able to capture here within the US.

And we also have this concept of, like, double patenting. And it's like, look, I'm not a legal guy whatsoever. I was asking them, like, how do I describe it? It just means that they are putting patents on things, that it's a product that's already created, and then they're saying, I'm going to patent more aspects of something that's already available. And so the good thing is, we think about like the Swiss Army knife, if Swiss came to the table, they created their Swiss Army knife, it's great, I have a patent around that. And then next year, they're like, yeah, it's got a knife, but it's also got this can opener in it, and so we're going to patent that can opener apart. And then next year, they're like, you know what else it has? It has this little thing, if you got something on your suit and the little string is hanging out, and just nick it right off. We got that too. And we've got a nail clipper or pliers. And every single year they put another patent on that original Swiss Army knife to mean more and more litigation for anyone else to bring a similar product to the market. That's essentially what is created. And again, it's very unique to the United States that you do not see this anywhere else in the developed world, and is directly correlated to the difficulty of creating and sustaining our biosimilar market.

So this is a really great example, because we're going to compare the next two slides. What happens in the US versus what's happening in the EU around these patents. So you have a molecule that is introduced in 1996 and they immediately put 10 patents on it. It's one invention, right? It's a new molecule. A couple years later, now they're looking at the primary indications. So we've got 7 more patents put on. Next, we're talking about formulation, 21 additional patents. Forward and forward and forward until at the end, we have 73 patents; 73 patents on one molecule. Only 14 of those patents are, like, real. Like, they're distinct. It's a true invention that was created that, from a legal perspective, in the US, they should be able to patent. But because of that double patent and these thickets that are able to be created, the other 59 patents were granted, even though it's not something they should have been able to have a patent for. So that means 80% of the patents associated with this drug should not have been allowed, like, they're non-patentable, whatever, how do you ever say that? I was like, I know I was going to screw that up.

Conversely, in the UK, this same molecule only has 8. Only has 8. So this is the big difference right here. And none of them are in this kind of, like duplicate BS, kind of patent thing that's going on. They only have 8 patents associated with the same molecule. So we're jumping through additional hoops with no benefit to our patients or the healthcare system as a whole.

So a lot of potential has opened up with this new environment that's going to be created. So it was a bipartisan proposed rule that's going forward. And if this passes, more biosimilars may be able to enter the United States. So therefore, we're going to have that robust competition that we're looking for. We could drive additional cost savings. Again, as we create that more sustainable market, we're going to be able to drive savings to the right people at the right time. Hopefully we'll have greater patient access, as we've seen earlier, that when you have more people in the marketplace, it allows for more flexibility with patient assistance programs, so that way patients can get to those medications and get access as quickly as possible. And hopefully at some point in time, will drive additional cost savings for patients as it relates to their out-of-pocket responsibilities.

And so when I heard a lot about this, I'm very appreciative of the work and the efforts that Fresenius Kabi has done, just from a regulatory perspective, to bring this to light and to create that bipartisan support that what has been a just hallmark of our patent system within the US is only harming patients in the healthcare system. And if we genuinely want to change that and change the conversation around the cost of care, then we have to change the way we approach patents as a whole.

Chapter 5: Future of Biosimilars in the US

Dr. Harvin:
So it's important that, as various stakeholders, that we're here today, that we all come together and make sure that we're educated on things that are occurring within the biosimilar space. And my hope is that I helped do that today, is bring a little bit of education, show you some things that you maybe didn't know. I learned a lot myself by working with Fresenius Kabi and putting this presentation together. We all have a very specific role as it relates to ensuring that patients have access to these medications.

I would say, outside of some just tremendous advances and new targeted therapy, the biosimilars have been one of the most impactful things that have happened in cancer care over the last decade. It has created cost savings. It has increased access for our patients. It has done everything that we wanted it to do, and unfortunately, it's still under threat. And so it requires all of us to make sure that if we get our opportunity to come to the table, if we engage with our government relations teams, within our hospital systems or as manufacturers, you go to the table and work with the federal legislation that is focused on creating a competitive and long-term sustainable biosimilar market. That is what we're looking for, and that's what I hope everyone takes away here today, is that that is what

we're committed to. And I want to thank Fresenius Kabi for allowing me to come up here and present today.

Announcer:
This medical industry feature was sponsored by Fresenius Kabi. If you missed any part of this discussion, visit Industry Features on ReachMD.com, where you can Be Part of the Knowledge.