Bonus: Access/Health Equity With Biosimilars
(Sponsored by The Biosimilars Forum)
Leon Kircik, MD, interviewed by Macartney Welborn, MD

MACARTNEY WELBORN, MD: Hello, everyone, welcome to another episode of *Dialogues in Dermatology*. My name is Macartney Welborn and I am a dermatology resident from the University of Florida College of Medicine. Today's topic centers around access and health equity in regards to biosimilar medications. In this episode, I am honored to be joined by Dr. Leon Kircik, who will help guide us through this topic. Dr. Kircik is an Associate Clinical Professor of Dermatology at Indiana University Medical Center, as well as a Clinical Professor at Icahn School of Medicine at Mount Sinai in New York City.—

--He is also the Medical Director of Derm Research at Physician Skin Care, Louisville, Kentucky, and is the principal investigator for many clinical trials. Dr. Kircik completed his dermatology residency at State University of New York in Buffalo and completed a Mohs micrographic surgery and cutaneous oncology fellowship under Dr. Frederic Mohs at the University of Wisconsin. Welcome to the podcast, Dr. Kircik. We are honored to have you and thank you so much for taking the time to sit down and talk with us.

LEON KIRCIK, MD: Thank you, Macartney. Thank you for inviting me.

MACARTNEY WELBORN, MD: This is our second lecture on biosimilars. And we're very excited to discuss more about them. But do you mind just starting with a brief overview of what biosimilars are and kind of giving us a reminder?

LEON KIRCIK, MD: Actually, if you look at the history of biosimilars, it was part of the Affordable Care Act. And it's known as the abbreviated licensure pathway and it was created by the Biologics Price Competition and Innovation Act of 2009 as a part of the Affordable Care Act.

And the interesting part is in the community, usually when we hear biosimilars, we think it's the generic version of the biologics.—

--But actually, it is much, much different than the generics. So the generics are for small molecules and the active matters, the pure active that we have in the generics compared to the branded products. When it comes to biosimilars, it is different. So originally, actually we're a little bit behind Europe. It started in Europe and the EMEA, the regulating agency in Europe, they want the biosimilars not only to be similar and identical but also to the original biologic but also they want the quality assessment, along with the nonclinical and clinical standards.—

--Now, FDA's requirement and definition is a little bit different. So they want the biological product that's highly similar to the reference product, notwithstanding minor differences in clinically inactive components and, not or but and, there are no clinically meaningful differences from the reference product in terms of the safety, purity, and potency. So there are more restrictions on the FDA definition, even though things are not very clear.—

--What does highly similar mean? It can be a lot of different criteria for highly similar. But the important part here is that the approval process is different for generics versus the biosimilars. And the biosimilars are basically biopolymers of organic molecule that are manufactured in living systems. And so there are in the manufacturing system, it's the important criteria for the biosimilars rather than the generics.—

--So for example, cloning technology, selection of the host cell, the growth media, bioreactive conditions, filtration, centrifugation, chromatography, the stabilizers, the constitution of the final product, those are all important factors that goes into the biosimilar approval.

MACARTNEY WELBORN, MD: Thank you for that overview, that's very helpful. What is your personal experience with biosimilars? Have you prescribed them or worked with them, either in your patients or in clinical trials?

LEON KIRCIK, MD: Actually, in real life we still don't have any biosimilars in the market for dermatology. We have a bunch of approved biosimilars for dermatology but they are not in the market, due to litigation. So still, lawyers are sort of figuring it out but I think some will be coming soon, probably next year or maybe two years time, because of the agreements between the biologic companies and the biosimilar companies legal understandings. Even though we have a bunch of approved ones.—

--Now, I have participated in many different clinical trials for biosimilars. I believe there are at least six, seven adalimumab biosimilars being studied in one way or another, and some are already approved. So I was involved in some of those. I was involved with the Etanercept, one or two Etanercept biosimilar studies. So yes, I was involved. My experience is limited to the clinical trials but just like anybody else, because again I think it's important to know we don't have any biosimilars in dermatology.—

--In Europe, they are ahead of us. They already have infliximab biosimilars that they are using, I believe also other ones.

MACARTNEY WELBORN, MD: When you were using them in clinical trials, was there anything you noticed that was better or worse, or was it largely a very similar process?

LEON KIRCIK, MD: It is largely I should say a similar process. Now, one thing concerns me and this is absolutely totally legal. For example, you can have a biosimilar that has been studied only in Crohn's disease. Let's take adalimumab, for example. Adalimumab is one of the

biologics that has several indications, including rheumatoid arthritis, psoriasis, psoriatic arthritis, Crohn's, you name it, there is a bunch of them.—

--Now, legally if you have a biosimilar that has been studied just let's say in Crohn's disease and approved and it's in the market, you can actually use it for psoriasis and it can be used for psoriasis. And that concerns me a little bit, that we have no track record of that particular biosimilar being studied in what I am using it for.—

--But, of course, the studies that I was involved with was psoriasis, so at least I would feel comfortable using those that I know they have been studied in the disease state that I'm going to be using it, rather than another disease state unrelated to what I am doing.

MACARTNEY WELBORN, MD: That's a great point. Logistically, do you know yet when biosimilars are available to be prescribed by us, will we be able to choose which one? Or is it more going to come from the insurance end or the pharmacy end, which one they distribute to the patient?

LEON KIRCIK, MD: That is the million dollar question. Right now when we write a generic, you don't know which generic the patients are getting. Let's say triamcinolone cream, when you write a triamcinolone cream there are probably 11 generics of that. And when the patient goes to the pharmacies and they get the generic du jour, whatever the company's generic they have a deal with the pharmacy, that's what they're going to get.—

--Now, it's very interesting what's going to happen for the biosimilar ones. The biosimilars, when they come to the market and the ones that are approved now, for example, they have some kind of a suffix at the end which shows which companies a biosimilar is, right?, and they actually do have names that you can prescribe that particular biosimilar for a particular company.--

--So we already have names. We have, for example, Zarxio, this is the first biosimilar approved in the U.S. for Neupogen. That was the first one. It's nothing to do with us but they do have a name. And also when you write adalimumab, then there is a suffix at the end which is going to show which company's biosimilar is. Now, the question is, for example, the biosimilar that got approved by Amgen for adalimumab is called Amgevita. And at the end of the adalimumab generic name, there is a "dash, a-t-t-o," which shows that that is basically the biosimilar from Amgen.—

--Now, I don't know when we get these drugs in the market, are you going to be able to write Amgevita and are you going to get Amgen's particular adalimumab or they can also even substitute that? And that's going to be on the state level. So every state has a different legislator. And every state is going to have a different rule. For example, in some states they have 72 hours to notify the doctor that the patient is going to get a biosimilar.—

--In some states, they have to notify the patient, as well. In some states, a patient is going to have the option to say, "You know what? I don't want the biosimilar, I want the original one," and then they might end up paying the difference. The patient may actually pay the difference or end up paying the difference. For example, in Hawaii, the state legislators said you have to let the doctor know in 24 hours.—

--In Colorado, the state legislators say you have to let the doctor know in reasonable time. Go figure out what the reasonable time is, right? So a lot of those things that you're asking, probably it's going to happen in the state level rather than the federal level. So it's going to be very, very interesting. I was just reading this the other day, in Delaware, you have to have a written consent from the patient that you can substitute and give a biosimilar.—

--Twenty-two states allow the physician to prevent substitution if you write "brand medically necessary," just like we have it for the generics versus branded product. So it's going to be a

mess. It's going to be in every state different. Unfortunately, it's going to be state by state and it's going to be very difficult to figure those things out.

MACARTNEY WELBORN, MD: Thank you for making us all aware of that. I didn't know that it was going to be state by state, which is unfortunate. And obviously, it's going to create a lot of onus on the physicians themselves to know their state rules and keep up with that. So one of the large benefits of biosimilars is cost. That's what we're all hoping, is that they're going to be cheaper and more accessible to our patients. Do you have any examples of the cost comparison of a brand name drug versus a biosimilar at this point?

LEON KIRCIK, MD: As you know, unfortunately in this country, drug prices are not transparent. So it all depends on the discounting that the drug company is going to give to the third party payers and the PBMs, the pharmacy benefit managers. Now, of course and logically, if you have a free marketplace and when you have six, seven biosimilars of the same drug, you expect and you hope that there is going to be competition and that should push the prices down as much as possible.—

--But on the other hand, if they all decide that they're going to give a ten percent discount, now you go and figure out what's going to happen. The other thing that might be happening, which does happen in the generic versus the branded products, I remember one of the cholesterol pills that my mom was getting, the original. When the generics came to the market, the original company, the branded product, they said, "We're going to match every price that the generics have."—

--Then why would you write the generic? You would get the branded product. So the same thing may happen. What if AbbVie says, "For all Humira, adalimumab biosimilars, we'll match the price." So now, why would I write the biosimilar? I'd rather give a branded product. So it's going to be very interesting how that marketplace is going to turn into.—

--Ironically when we go to Europe, really the advance of the biosimilars did not decrease the prices as much in Europe. But granted, they have a totally different system. They have a nationalized healthcare system. Over there, you're dealing with one payer, the government. Versus here, we have who knows how many different payers, different insurance companies. So it's going to be really very interesting to see.—

--But overall, hope. And hopefully, it will decrease the prices and it will create more access to our patients. And that's what we really want from our perspective, prescriber perspective. We want more access and we want it easier on us to prescribe.

MACARTNEY WELBORN, MD: Absolutely. All those prior auths and appeals that take up all that time, trying to get it approved for your patients.

LEON KIRCIK, MD: Absolutely. Who wants to do prior authorization, right? It will be like heaven if we can get away with that.

MACARTNEY WELBORN, MD: That would be wonderful. So speaking of access, do you think there are any specific patient populations that would benefit the most from biosimilars, and if we are able to reduce the cost with them?

LEON KIRCIK, MD: Now, with the recent legislation that passed the Congress a couple of days ago, now the government actually can negotiate drug prices with pharma, I think that will be very helpful, now that we know certain populations are just insured by the government insurances: Medicare, Medicaid. Hopefully, those patients will have better access to all drugs, but maybe more with biosimilars if the prices are significantly different and when those government entities can deal and wheel hopefully and bargain for prices.

MACARTNEY WELBORN, MD: Based on our conversation, do you have any few key takeaways that you want our listeners to think about in regards to biosimilars?

LEON KIRCIK, MD: I don't think so. But I hope, and I look forward to more access for our patients to biosimilars and biologics, hopefully.

MACARTNEY WELBORN, MD: That would be wonderful. Well, thank you so much everybody for joining us today and listening to this episode of *Dialogues in Dermatology* podcast. And again, a huge thank you to Dr. Kircik for all this wonderful information for our listeners.

LEON KIRCIK, MD: Thank you for including me.