Transcript Details

This is a transcript of a continuing medical education (CME) activity. Additional media formats for the activity and full activity details (including sponsor and supporter, disclosures, and instructions for claiming credit) are available by visiting:
https://reachmd.com/programs/cme/winding-road-biosimilar-adoption-united-states/10682/

Released: 03/05/2019

Time needed to complete: 15 minutes

ReachMD
www.reachmd.com
info@reachmd.com
(866) 423-7849

The Winding Road to Biosimilar Adoption in the United States

Announcer:
Welcome to CME on ReachMD. This activity, titled The Winding Road to Biosimilar Adoption in the United States, is provided in partnership with Prova Education and supported by an educational grant from Merck. Before you begin this activity, be sure to review the disclosure statements and learning objectives. Here's your host, Dr. Jennifer Caudle.

Dr. Caudle:
Despite the excitement surrounding biosimilar adoption in the United States, uptake into the healthcare system has been surprisingly slow. Biosimilars are expected to provide patients increased and cost-effective access to promising and often lifesaving medications while simultaneously lowering healthcare system costs. However, there are still complex barriers to achieving this goal. We'll explore these and other issues surrounding biosimilar adoption today.

This the CME on ReachMD, and I'm your host, Dr. Jennifer Caudle, and I'd like to welcome Dr. Cate Lockhart, Executive Director for the Biologics and Biosimilars Collective Intelligence Consortium.

Dr. Lockhart, it's great to have you with us.

Dr. Lockhart:
Thank you very much. It's my pleasure to be here.

Dr. Caudle:
So, can you start by giving us an overview of biosimilars and how they differ from originator products and generic drugs respectively?

Dr. Lockhart:
Sure. The official definition of biosimilar provided by the USFDA is "a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product." So this means that the biosimilar product has the same amino acid sequence, structure, function, as the reference product other than minor differences that fall within an acceptable tolerance in clinically inactive components of molecule. The biosimilar must also show that it's the same in terms of purity, potency and bioactivity as the reference product.

And people are sometimes uncomfortable with the fact that these are similar and not identical, but I think a really important point to remember is that biologic products—and this includes the originator or the reference product—are usually large proteins with a very large, very complex manufacturing process that involves living cells, and all biologic products have inherent variability from lot to lot. This means you could take a dose from one lot of the originator product and another dose from a different lot of the same originator product and they will be a little bit different, but the difference will not have any effect on the clinical effectiveness of the product. The same is true with biosimilars. Although, some may argue that the tolerances are even tighter with biosimilars because they must prove analytically that the variability is at least equivalent to the reference product, and often it falls even within that tolerance range. Now, generic drugs are copies of branded small molecule drugs, but biosimilar is to biologic as generic is to brand, so scientifically, biosimilars are totally different than generics, but philosophically, it's exactly the same thing.

Dr. Caudle:
Thank you. And now that we know the difference, what role do biosimilars play in the current healthcare environment and best practice paradigms?

Dr. Lockhart:
Well, biosimilars are simply another alternative product to use instead of the originator product. There is really no impact on providing best-of-care medicine to patients because it doesn't change your protocols or guidelines or clinical practices at all. What it does is influence the economics of providing care by having the option of choosing a less expensive product in the biosimilar. Biosimilars are approved in the FDA under an abbreviated pathway called the Biologics Price Competition and Innovation Act of 2009—the BPCIA because that's too many words—which was enacted in 2010. It's kind of like the Hatch-Waxman Act of 1984 that was enacted for supporting innovation in generics. So the goal of the BPCIA is also to provide incentives to companies to bring biosimilars to the market, thus providing market competition in an effort to reduce prices and improve patient access to these otherwise very expensive medications. Through this abbreviated pathway, the emphasis is on the analytical evidence and less emphasis on clinical trials to demonstrate similarity, compared to the reference product at least. And this may sound easy, but the analyses required are actually quite extensive. And then they have to show safety, immunogenicity, pharmacokinetics, pharmacodynamics, all within the FDA-accepted tolerance range compared to the reference product. And then, finally, the product is tested in patients in an indication for which the originator product is FDA-approved to show no clinically meaningful difference in this patient population with the biosimilar.

And because of this abbreviated pathway, some people are uncertain about whether or not the biosimilar is, in fact, safe and effective in real practice, and there are concerns about immunogenicity, as most of these products are antibodies. There is concern about whether or not switching from the reference product to the biosimilar will result in any change in patient stability or outcomes. There is also some confusion around terminology.

First of all, the term "interchangeability" is confusing. In the US, it's actually a statutory term. The US is the only country in the world that has a separate designation for interchangeability over biosimilarity. It requires an additional clinical study in humans to show that switching from a reference product to a biosimilar does, in fact, result in no clinical difference. Another part of the misconception is that an interchangeability status, interchangeability status for biosimilar, is somehow a better biosimilar than one that doesn't have interchangeability status, and that's not true. It really just means the company spent the extra time and money to do an additional study that was not required for the biosimilar approval. And at the end of the day, if a product is granted interchangeability, all that means is that a pharmacist can substitute that product without first checking with the physician.

So this brings us to the idea of switching. In Europe, the first biosimilar was approved in 2006, compared with 2015 in the US, so they have over a decade of experience and now have over 50 biosimilars on the market. Now, to date, there have been 90—nine zero—studies in Europe showing the safety and effectiveness of biosimilars. There has been no evidence of immunogenicity, no risk in terms of safety or effectiveness switching from the biosimilar—or from an originator to a biosimilar—and there is at least one study even showing that there is no risk in switching from a biosimilar back to the originator product.

Dr. Caudle:
So let's stay on that theme of point of contention for a moment because we know there are some misconceptions and awareness gaps around biosimilars. So, can you speak to some of these barriers?

Dr. Lockhart:
Sure. It's true there is still a lot of uncertainty or discomfort among both prescribers and patients around biosimilars. In one recent survey of over 1,200 physicians in the US—and these are physicians that were in specialties that are most commonly prescribing biologic drugs—they found that 75% of those survey respondents trust the FDA approval decisions; but when they were asked if they thought biosimilars, which are FDA approved, were safe and effective for naive and existing patients, fewer than half overall believed that that was true. So they trust the FDA but are still uncomfortable with biosimilars. And this comfort level ranged between 35% to 57% across the specialties, so there are clearly some opportunities for education in the physician population. Similarly, a survey of patients with inflammatory diseases or cancer that could be treated with available biosimilars, most had no knowledge of what a biosimilar was. And of those who were aware of biosimilars, half or fewer of them felt that they were effective, safe, affordable, and only 48% were comfortable with switching.

So, part of the barriers are based on lack of knowledge or understanding across stakeholder groups representing many opportunities for education, but then there is also the promise of reduced price, which is also sometimes muddy. The reduced price is sometimes obscured through contracting and rebates through payers, PBMs, health systems, and there is a lot of moving parts in these agreements. The presence of biosimilars is reducing the cost of these expensive treatments overall, but it's often difficult to follow the dollar, and the complexity of the US healthcare system does not do us any favors in that respect. For the healthcare system, for health

care overall, it's not an immediate return on investment necessarily, but it's such an important one for the healthcare system overall.

Dr. Caudle:
For those of you who are just joining us, this is CME on ReachMD. I'm your host, Dr. Jennifer Caudle, and I have the pleasure of speaking with Dr. Cate Lockhart about biosimilars.

So we were just talking about some misconceptions surrounding these drugs, but let's focus for a minute on the various parties invested in their adoption, such as Pharma, payers, government agencies and, of course, both clinicians and patients. What kind of obstacles do these connected groups face?

Dr. Lockhart:
So I think the key statement in your question is connected groups. One barrier that we've seen emerge in the US is the so-called pay-to-delay arrangements in which an originator company pays a biosimilar company to delay the market launch of their FDA-approved biosimilar product, and this results in retained market share for the originator product for a few extra years, but the result in the US is that FDA approval is no longer synonymous with market availability. Another barrier that I alluded to before as well is there is a presence of contracts between manufacturers, payers, PBMs, health systems and those types of entities which, as I said, can obscure the price reduction that may be offered by biosimilars. And again, the key is that we often consider all of these entities in our healthcare system as silos with individual agendas, but I think it would do us all well to remember that all stakeholders are ultimately connected.

Dr. Caudle:
And are there partnerships that can ease the path of biosimilar adoption?

Dr. Lockhart:
I think partnerships are a very powerful and productive way to initiate change in general or at least come to an understanding of the varying perspectives that we all have depending on your stakeholder group. And healthcare is by nature a partnership between patient, clinician, insurance payer, pharmaceutical manufacturer, and I think it's important for each of these perspectives to be heard and understood by all of the other parties. And I'd like to highlight my organization if I could: the Biologics and Biosimilars Collective Intelligence Consortium, or BBCIC, which is by definition a multi-stakeholder collaborative. We're a nonprofit research organization that conducts rigorous postmarketing observational research in an effort to build the base—the evidence base around biosimilars. This is real-world evidence that we're talking about. People are looking for information to support their clinical and coverage or reimbursement decisions, and our aim is to provide just that, an evidence base for them to base their decisions on.

One of the strengths of the BBCIC is this collaborative partnership under which we operate. We have participant organizations across the stakeholder groups including manufacturers, payers, healthcare systems, other nonprofit organizations, patient representatives, and we also have an FDA-appointed liaison that serves on our planning board, and each of these organizations has a seat on all of our committees and can participate in any of the research teams, any of the research projects that are of interest to them. The scientific agenda of the organization is approved and prioritized by the whole group, so everyone has a voice. It's very much research by committee. And everyone can benefit from a front-row seat on the research teams. The result is rigorous research without some of the perceived bias that may emerge with sponsorship from a single entity, and we benefit from the wealth of knowledge and experience that each party brings and the perspectives of the diverse group.

Dr. Caudle:
Now we know that the uptake of biosimilars in the United States has been very slow, even in the face of increasing approvals by the FDA, especially when compared to Europe. So, is there anything we can learn from the European biosimilar experience?

Dr. Lockhart:
There is very little that we can really compare between the US healthcare system and those systems in Europe as we have so many more nuances and so many more layers and moving parts and complexity compared to what in Europe are mostly single-payer systems, but there is a wealth of experience with biosimilar products in Europe that we can certainly learn from.

Dr. Caudle:
Well, you've certainly given us a lot of information on biosimilars today. And just to wrap all of this up, what are your key takeaways for our audience?

Dr. Lockhart:
Biosimilars really are essential for the health of our healthcare system, and it's important to be informed with a long view of the undeniable benefit that market competition can have, and we need more champions of biosimilars in the US.

Dr. Caudle:

Well, those are some great insights that we can take with us as today's program comes to a close, and I'd like to thank Dr. Cate Lockhart for joining me to discuss the emerging roles and challenges for biosimilars in patient care.

Dr. Lockhart, it was a pleasure speaking with you.

Dr. Lockhart:
Thank you so much for having me.

Announcer:
This activity has been provided in partnership with Prova Education. To receive your free CME credit, be sure to complete the post-test and evaluation by visiting ReachMD.com/Prova. Thank you for joining us.