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Reed Sets Out Priorities For US Biosimilars Forum

New Executive Director Julie Reed Also Highlights Benefits Of Diverse Membership

by David Wallace

In an exclusive interview with *Generics Bulletin,* the Biosimilars Forum's executive director Julie Reed sets out the group's priorities and explains how its diverse membership is helping to position it as a leading voice for the US biosimilars industry.

With biosimilars taking on an increasingly prominent role in the US, Biosimilars Forum leader Julie Reed believes that they can offer a "ready-made solution" to current healthcare pressures.

However, Reed highlighted in an exclusive interview with *Generics Bulletin* as she moved from being president of the Forum to executive director, a number of key aspects around access, regulation, education and legislation must be addressed if biosimilars are to fulfil their full potential.

Commenting on her appointment to the role of executive director, Reed – an industry veteran who has previously worked in leading roles at firms such as Pfizer, Hospira and Coherus – said the move represented a significant change.

As president – a role in which she served the Biosimilars Forum for more than eight years, having also co-founded the organization – "it was a labor of volunteered love for all those years," she

explained.

But now "I will be representing only the Biosimilars Forum, I am no longer with Pfizer. I will be solely devoted to our members and advancing biosimilars in the US. Which have been a passion and focus of my career globally for almost 20 years."

"So it's a significant change for me but also for the Forum. And it's an honor to have the leading companies in biosimilars choose me as their leader."

Improving Access And Implementing BsUFA III

Asked about the Forum's immediate priorities, Reed said that "first and foremost is improving access to biosimilars in the US." Policy makers in the US were currently looking at ways to lower the cost of medicines, she highlighted, "and what we have in biosimilars already is a ready-made solution on the shelf."

So "rather than limit access to new innovative medicines, or negotiating drug prices, we will continue to work with Congress on positive movement on the policies that we know will improve access to biosimilars."

With biosimilars in the US predicted to lower health costs by "anywhere between $38bn up to over $100bn in the next five years," she emphasized, "that's a ready-made solution." What was needed now, she said was further incentives from Congress to improve access, along with additional action from all industry stakeholders.

"Our experience globally is that it takes all stakeholders to get proactive about biosimilars," she explained. "It's not just going to happen because industry does this. So private payers, we need parity access, we need payers to put biosimilars on the formularies – not one biosimilar, but all the biosimilars."

The Forum would be active at both the national and individual state level to drive the uptake of biosimilars, she described. "People are leaving cost savings on the table," Reed suggested, "and our goal is to educate that those are available."

This included working with employers and labor organizations, she highlighted. "Ford motor company, the Economic Alliance For Michigan; they are already saving billions of dollars by converting to biosimilars. Those are the things that we will continue to lead, as the industry leader, with all stakeholders and be fully engaged."

> *"Everyone wants to have the FDA have the resources to implement its COVID inspection plan."*

Meanwhile, on specific incentives to drive biosimilar use, the Forum was sometimes looking to other regions – including Europe – for inspiration. "I think the lessons and progress Europe has made in uptake of biosimilars is something the US needs to look at and to enact," Reed commented. "We know as the biosimilars industry, our experience is that proactive policies by payers and governments to increase the uptake of biosimilars are necessary."

"So as an example – the [UK] National Health Service, they did a shared savings program. And we know that this would work in the US, if we can get the Centers for Medicare & Medicaid Services to do it. And we're encouraging them to do it. The NHS has been able to fund nurses, countries are using the savings to fund new medicines, which is all good for the ecosystem."

Another high priority for the Forum, Reed said, was following through on the latest iteration of the Biosimilar User Fee Act, BsUFA III.

"We've been spending all year negotiating with the [US Food and Drug Administration] and the other trades. We have a commitment letter. What you'll see, which is very exciting, is that in BsUFA III we will continue our strengthening of the agency's biosimilars program. We'll see the evolution of the pathway – less data requirements, faster timelines, more communication." (Also see "*FDA Publishes BsUFA III Commitment Letter Ahead Of 2022 Renewal*" - Generics Bulletin, 22 Sep, 2021.)

"What we also want is, I think with the learnings of COVID, is we need the agency to do inspections. So that will be a big piece for us and I think everyone wants to have the agency have the resources to implement its COVID inspection plan." (Also see "*FDA Will Take Action On Biosimilars Delayed By Inspection Lag*" - Generics Bulletin, 21 Oct, 2021.)

Misinformation 'Continues To Be An Issue'

Another priority for the Biosimilars Forum would be to "continue to work on misinformation," Reed said.

Misinformation, she confirmed, "continues to be an issue, and the Forum and our members are very diligent about watching for misinformation; when we see it, we work directly with the FDA and the Federal Trade Commission on that, and we are pleased with how quickly they respond."

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Meanwhile, she added, "there is ongoing education by the Forum. The FDA is a great partner with that, as are the patient groups and the physician groups. And the more we do, the less misinformation we have out there."

Interchangeability Does Not Imply Superiority

Asked about the growing significance of interchangeability for US biosimilars – with Viatris having launched its interchangeable insulin glargine biosimilar, Semglee, last year (Also see "*First Interchangeable Biosimilar Launched In US*" - Generics Bulletin, 16 Nov, 2021.) and a Humira (adalimumab) biosimilar having also received the designation (Also see "*First Interchangeable Humira Biosimilar Approved In US*" - Generics Bulletin, 18 Oct, 2021.) – Reed was careful to highlight that interchangeability was not a sign of a product's superiority to a non-interchangeable biosimilar.

"I think one of the key things – and this is part of the misinformation – is that interchangeability is really not about building confidence," she commented. "Every patient and doctor should feel confident about a biosimilar whether it's interchangeable or not."

"Interchangeability gets confusing," she acknowledged; "people think that if it's interchangeable then it must be better, or have a higher standard of safety – it's not."

"The mechanism for interchangeability is substitution at the pharmacy level. It's an automatic substitution classification versus a safety or efficacy or any type of quality classification."

And "what it will do is increase access, at the pharmacy level, allowing pharmacists to substitute the biosimilars that are dispensed at the pharmacy."

Biosimilar Interchangeability: A Blessing Or A Curse?

By David Wallace

09 Jul 2021

Biosimilar interchangeability is a hot topic in the US, with the first FDA decision on a formal interchangeability designation expected this month. But across the industry, views differ dramatically on the desirability and likely impact of this additional standard to biosimilarity.

Read the full article here

"Now that doesn't take away from any of the payers being able to include all biosimilars, whether they are interchangeable or not, on their formularies. Because most of the biosimilars in the marketplace today are dispensed and prescribed by physicians." "Physicians want choice. Patients want choice. So we're hopeful that payers will provide that access across all biosimilars."

Humira Set To Be 'A Tipping Point' For Biosimilars

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Turning to the imminent onset of biosimilar competition to Humira – with US rivals expected to launch from January 2023 (*see sidebar*) – Reed acknowledged the significance of the moment for the biosimilars industry.

"It's huge – it's the largest drug in the US," she highlighted. "And significant cost savings will come from just that launch alone. So it will be a tipping point."

"We've got seven biosimilars in the queue, lining up and approved and ready to go, with their different settlement dates, one after the other."

Emphasizing the importance of ensuring access to all of the competing biosimilars in the Humira space, Reed acknowledged that "some of the adalimumab biosimilars will be interchangeable, some not. Again, physicians want choice, patients want choice, and access to all of them is going to be important. And part of the whole ecosystem of sustainability."

"So why not go after all the savings we can get, and that means lots of competition."

With Humira biosimilars now so close to launching, Reed said, "we're excited. But we're [also] excited about the [biosimilars] we already have, and the ones that are coming. It's fun to develop something brand new that brings cost savings."

Humira One Year Out: The Largest LOE Event In US Pharma History

By Dean Rudge

31 Jan 2022
Ahead of the first biosimilar Humira product set to launch in 365 days, *Generics Bulletin* provides a comprehensive run-down of where biosimilar sponsors stand and the key issues ahead of market formation.

Read the full article here

Diverse Membership Offers Credibility On Intellectual Property

While well-known for its gargantuan sales figures, Humira is also notorious in the biosimilars world for the vast array of intellectual property that AbbVie has built up around the brand in the US.

Asked about IP obstacles for biosimilars – including so-called "patent thickets" and legal decisions such as the two rulings last year that blocked Enbrel (etanercept) rivals from the market until 2029 (Also see "*Eight More Years: US Supreme Court Sinks Sandoz' Hopes On Enbrel*" - Generics Bulletin, 18 May, 2021.) (Also see "*Samsung Bioepis Also Faces 2029 Wait For US Etanercept Biosimilar*" - Generics Bulletin, 29 Nov, 2021.) – Reed revealed that "IP is an issue that the Forum is going to tackle," with the organization's position on the topic strengthened by a membership that straddled both the off-patent and originator sides of the industry.

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"This year we'll be starting an IP committee to see where we can come to a consensus about IP and how it affects biosimilars."

"When we came together, if you look at our membership, it is very diverse," Reed pointed out. "You've got Pfizer, you've got Teva – you have what were traditional innovators and traditional generic drug companies, now focused on biosimilars, which is very unique."

"The Forum believes in strong intellectual property – it's important for innovation – but we also believe in access. So this year we'll be starting an IP committee to see where we can come to a consensus about IP and how it affects biosimilars."

"And that goes again to why we're the leaders, because the diversity of our members and the fact that we're focused on biosimilars [means that] stakeholders and policy makers can rely on the Forum to not have a bias one way or the other. We're coming to a consensus about biosimilars. And no-one else can do that."

Asked about the Forum's position compared to other industry groups – such as the Biosimilars Council that is part of the Association for Accessible Medicines – Reed insisted that "I have the highest respect for the Biosimilars Council and the AAM," but maintained that diversity of membership was at the root of "the credibility and integrity of the Forum."

"One of the reasons we have the name of the Forum is that we and our companies are so engaged," Reed indicated. "Everybody shows up to committee meetings. I'm really honored to be one of the first ever employees of the forum, but it's an association of volunteers: passionate member companies in biosimilars."

Biosimilars Forum Members:

- Biogen
- Boehringer Ingelheim
- Coherus BioSciences
- Organon
- Pfizer
- Samsung Bioepis
- Sandoz
- Teva
- Viatris

“We drive for consensus,” Reed summarized. “One of the things that I think is incredible is that we are a culture. Member companies come with open minds, they leave any former biases out; they come to the forum with the biosimilar hat on – not their generic hat, not their innovator hat, but what’s good for the biosimilars industry and marketplace.”

“So we’re the only ones who can do that and represent the industry.”

Ramping Up Education In Ophthalmology Ahead Of Ranibizumab Launch

Looking ahead to immediate milestones on the horizon for biosimilars, Reed commented on the expected launch of US competition to Lucentis (ranibizumab) later this year, after the FDA in 2021 approved the first biosimilar with ophthalmic indications. (Also see "*US Lucentis Competition Expectations Upended By Byooviz*" - Generics Bulletin, 22 Sep, 2021.)

“It’s a focus, we’re excited,” she said. “And we are reaching out to ophthalmology – the patient groups, the physician groups – and with the FDA we plan to educate.”

“We have a list of the upcoming therapeutic areas where biosimilars will be launched,” Reed noted, “and we reach out to get education going. Education is so key, because, you know biosimilars are a whole unique industry, a unique medicine and everything else. So it’s introducing something new.”

“So if there’s misinformation out there, it scares patients, and we combat that,” Reed indicated, conceding that “we expect to see it every time there’s a new therapeutic class of biosimilar introduced.”

“Hopefully over time we’ll start to see that stop, and [we’ll see] biosimilars being launched with patients knowing what they are and with physicians having the confidence that they should have,” Reed said, stating simply that “they’re approved by the FDA, and the FDA is the gold standard.”

“But every single time, we’re going to work ahead of the launches so that the industry and our members are successful.”

‘Build Back Better’ Could Be Back

Finally, touching on the Biden administration’s Build Back Better package of legislation – which contained Medicare price negotiation aspects that it was feared could threaten US biosimilar competition, but which appeared to have been stopped in its tracks early this year (Also see "*Manchin Pushback Bad News For Biden But Good News For Biosimilars*" - Generics Bulletin, 11 Jan, 2022.) – Reed confirmed “it has stalled.”

But, she indicated, “there is a desire, from what we’re seeing and hearing in our conversations, to

break it up. So to do smaller pieces of the bill moving forward."

"We continue to monitor it and talk to the policy makers, members of the Senate and Congress and the House, and we continue to have the concern about if it goes as it was that it will hurt development of biosimilars."

"So we've been really proactive in educating everyone on the Hill about what this does."

Ultimately, Reed concluded, despite so much talk over Build Back Better and Medicare price negotiation, "we've got a readily available solution on the shelf" in the form of biosimilars.

"Let's be proactive and get biosimilar uptake higher," she suggested. "We'd save a lot of money just with that."