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Biosimilars Forum Calls For Further Action On Biden's Competition Order

Impending Humira Launches Would Benefit From Increased Competition

by Chloe Kent

Generics Bulletin sits down with Biosimilars Forum executive director Julie Reed to discuss preparing the HHS for Humira biosimilars, what more the agency could do for the industry and the Forum's priorities over the next year.

In July 2021, US president Joe Biden signed an executive order to promote competition in the American economy, including proposals to tackle a lack of competition in healthcare by increasing support for generic and biosimilar drugs. Nearly a year on, Biosimilars Forum executive director Julie Reed has called for further action from the US Department of Health and Human Services regarding this order, ahead of the launch of numerous Humira (adalimumab) biosimilars in the US market over 2023.

"We encourage the secretary and all of his staff in the administration to do more," Reed told *Generics Bulletin*. "We'd like to see more action on the president's executive order from last year. Their own inspector general's office has told them they could do more, and we want HHS to prepare for the launches next year." (Also see "*Drug Pricing Reform: Now It Is HHS Secretary Becerra's Turn*" - Pink Sheet, 11 Jul, 2021.)

She continued: "They need to be hand in hand with the US Food and Drug Administration in combating misinformation, and make sure that their policies reflect the entire biosimilar landscape and they don't favor one biosimilar over the other."

A recent study conducted by the HHS-OIG found that increasing use of biosimilars would lead to a "significant spending reduction" for Medicare Part D and its beneficiaries, but that the drugs

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Julie Reed

were ultimately being underutilized *(see sidebar)*. Many plans did not cover biosimilars at all, and those that did rarely designed their formularies in a way that would encourage their use.

In 2019 alone, the report found, Medicare could have saved between $84m and $143m, or 18%-31% of the program's gross spending on biosimilars and branded biologics, had it implemented better biosimilars policies.

The OIG has now recommended that the Centers for Medicare & Medicaid Services encourage Part D plans to increase access to biosimilars and monitor the situation going forward.

Reed said: "If you compare Europe to the US, we do not have policies that are increasing access, we have barriers. We need policymakers to remove those barriers, such as by creating policies that remove incentives for doctors to choose to use a higher cost product versus a lower cost biosimilar, or policies that we know the UK National Health Service and other countries have done such as shared savings."

HHS Study Finds Medicare Part D Underutilizing Biosimilars

By Chloe Kent

13 Apr 2022

Research from the US HHS has found that millions of dollars could be saved by Medicare by increasing the biosimilar coverage of Part D plans.

Read the full article here

Increasing access to biosimilars has never been more crucial now that numerous Humira biosimilars are set to launch in the US over 2023. (Also see "*Humira One Year Out: The Largest LOE Event In US Pharma History*" - Generics Bulletin, 31 Jan, 2022.) Humira has spent nine years in a row as the world's top selling drug and was only recently unseated by Pfizer/BioNTech's Comirnaty mRNA vaccine for COVID-19, so competition in the US adalimumab space is likely to be fierce. (Also see "*How Humira Finally Lost The Top Spot In Drug Sales*" - Scrip, 29 Dec, 2021.)

"Those Humira biosimilars need access," says Reed. "You'll see the greatest cost savings the more biosimilars are on formularies, which is huge for the US."

2023 Budget Mentions Little Of Biosimilars

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Reed's comments came shortly after HHS secretary Xavier Becerra's announcement of the department's *2023 budget*, where she remarked that "not enough was said about biosimilars."

She did note, however, that the biosimilars space could stand to benefit from the establishment of the Advanced Research Projects Agency for Health. ARPA-H is a new unit within the HHS outlined during Becerra's testimony, which will support transformative high-risk, high-reward research to drive biomedical and health breakthroughs. Its establishment was authorized on 15 March.

The biosimilars industry may also benefit from various proposed funds the HHS has set out in its budget to support medical innovation, including: a $5.0bn commitment to the prevention, treatment and possible cure of conditions such as cancer, infectious diseases and Alzheimer's disease; as well as $6.8bn for the FDA to continue to work with developers, researchers, manufacturers and other partners to expedite the development and availability of therapeutic drugs and biological products.

The Biosimilars Forum, Reed said, "will work with the agency identifying opportunities and ways that biosimilars program and the Office of Therapeutic Biologics and Biosimilars can take advantage of those opportunities."

She continued: "Allowing manufacturers working with the agency and regulator to innovate is really important, within the confines of the Biologics Price Competition and Innovation Act and the reference product. I think the agency recognizes that – it's always important, because the science is changing."

Reed Outlines Key Priorities For 2022

With the impact of biosimilars about to exceed that of small molecule generics for the first time, the Biosimilars Forum has its work cut out in ensuring that the market is able to thrive. (Also see "*US Biosimilar Impact Set To Overtake Small-Molecule Generics*" - Generics Bulletin, 26 Apr, 2022.)

Reed said: "We are educating constantly, trying to get policymakers to see what other countries have done to be successful, because we know there's greater cost savings that the US could achieve. Especially today with the economy and inflation, it's the opportune time."

She continued: "What we are seeing is when biosimilars have access to formularies – and more than one biosimilar needs to have access – the competition is working, the prices go down. Competition works, when there is access, and the more biosimilars have access to a formulary the faster prices go down across the board."

Alongside ensuring wider formulary access for biosimilar products, the Forum is also focused on passing the third iteration of the Biosimilars User Fee Amendments program, which will run from

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2023 to 2027. BsUFA authorizes the FDA to access and collect fees for biosimilars, which are then dedicated to expediting the review process for other biosimilar products.

Streamlining the review system for biosimilar supplements and creating more certainty for sponsors were high among goals outlined in the BsUFA III commitment letter, which was released following months of negotiations in September last year. (Also see "*FDA Publishes BsUFA III Commitment Letter Ahead Of 2022 Renewal*" - Generics Bulletin, 22 Sep, 2021.)

Reed said: "We're excited about it. We pay the user fees to help support the FDA and resource it. This will provide greater resources for the FDA biosimilars program, provide greater clarity and shorten timeframes in getting decisions for developers."

Reed Sets Out Priorities For US Biosimilars Forum

By David Wallace

16 Feb 2022
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.

Read the full article here

She added: "We hear from Congress pretty much every day about the user fees, and every night we're getting some other piece of legislation for us to evaluate and weigh in on. That's great, because that's what the Forum is, it's the voice of the industry."

The Forum's third key priority, Reed said, was combating misinformation about biosimilars – particularly when it comes to interchangeability. The interchangeable designation is unique to the US, and allows biosimilars to be substituted for biologic reference products by a pharmacist without requiring prescriber oversight, saving money for patients and payers.

Only products which take the time to carry out the necessary interchangeability studies and apply to the FDA for the classification can be substituted in this way, which Reed explained can lead to the misconception that a biosimilar with an interchangeable designation is superior to a non-interchangeable biosimilar.

Reed elaborated: "Interchangeability has only to do with pharmacy substitution, allowing a retail pharmacist to substitute in the biosimilar without the authorization of a doctor. Whether a biosimilar is interchangeable or non-interchangeable, both are approved and have the same safety, quality and efficacy."

She added: "One of the things HHS does need to do is correct its formulary language to be sure

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that it does not limit any formulary changes to an interchangeable biosimilar only. That's misinformation, it's misleading, and it skips all the formularies that deal with physician-administered biosimilars that do not come through the retail pharmacy."

Tackling this misinformation, she concludes, is of extra importance given the landmark year the industry will soon embark on.

"If you want to achieve the greatest cost savings," Reed remarked, "give access to every biosimilar out on the marketplace next year. Every Humira biosimilar should have access and let the competition begin. Next year, we'll see what biosimilars are really, really about."

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