PRESCRIBER PERSPECTIVES

POLICIES IMPACTING BIOSIMILAR ACCESS

As the U.S. shifts from the Trump administration to the Biden administration, at least one policy issue has remained a focus – health care access and the cost of prescription drugs. Access to biologics and biosimilars is an important facet of this conversation, and the issue has prompted a number of policy proposals in recent years.

To discuss those proposals, a March 2021 panel discussion of the Biologics Prescribers Collaborative brought together co-conveners David Charles, MD, and Dennis R. Cryer, MD, as well as rheumatologist and American College of Rheumatology member Angus Worthing, MD.

Held virtually, "Prescriber Perspectives: Policies Impacting Biosimilar Access" explored cost proposals, value assessments and the current role of biosimilars in the marketplace. The panel discussion was moderated by Gavin Clingham of the Alliance for Patient Access.

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MOST FAVORED NATION

Most Favored Nation would tie the price paid for Medicare Part B medications to prices paid in other countries.

Perhaps one of the most controversial drug pricing proposals under consideration is the Most Favored Nation policy. Introduced by the Trump administration last year, this policy would tie the price paid for Medicare Part B medicines – including biologics and biosimilars – to prices paid in certain international countries.

If enacted, Most Favored Nation will surely impact physician practices and patients' ability to access these treatments. When reimbursement for a biologic is less than the cost to purchase, store and administer the medication, it can become financially unfeasible for clinics to provide them. As Dr. Worthing explained, physicians and hospital systems "wouldn't be able to afford the price of the included drugs because of the low reimbursement rate it would bring."

Resulting disruptions to access could be problematic or even dangerous for patients who depend upon biologics to manage chronic diseases. In particular, older patients and those whose immune systems are compromised could be at risk if they faced treatment gaps.

Currently, the Most Favored Nation proposal has been delayed by court decisions, and the Biden administration has frozen all pending regulations for review. Dr. Worthing predicted that the proposal will not be implemented in its current form. He did, however, express concerns about potential action by Congress. He urged providers and advocates to "speak out" to make sure members of Congress were aware of concerns about patient access and the continued viability of medical clinics who serve those patients.

"We wouldn't be able to afford the drugs because of the low reimbursement rates."

-Angus Worthing, MD

VALUE ASSESSMENTS

Meanwhile, other proposals in play would tie patient access to third-party assessments of medications' value. These value calculations are performed by health technology assessment organizations.

> "My patients want access to more therapies - **NOT RESTRICTIONS."**
>
> *-David Charles, MD*

Perhaps the most prominent assessment organization is the Institute for Clinical and Economic Review, better known as ICER. Dr. Charles outlined several concerns with policymakers' using ICER calculations to dictate patients' treatment options:

- **NARROW ECONOMICS PERSPECTIVE.** Assessments are performed by health economists with varying levels of input from the people who are impacted – physicians and patients.
- **RELIANCE ON CLINICAL TRIALS DATA.** ICER performs its cost-effectiveness analyses using data from clinical trials, which are narrow studies that do not fully reflect the real world.
- **TIMING.** ICER sometimes undertakes assessments of drugs that are not yet approved by the Food and Drug Administration. A drug that is still in the process of securing FDA approval, Dr. Charles emphasized, should not yet be assigned a value since the approved uses of the drug are not yet known.

"If, as some assert, the methods that ICER is employing have flaws and those results are then used by payers to restrict patient access to new and innovative therapies," Dr. Charles said, "that's where I as a clinician really have a problem."

Dr. Cryer emphasized the importance of assessments taking patients and their experiences into consideration because they, above all, are the ones affected by assessment outcomes.

PRESCRIBING INCENTIVES

The panel also discussed the implications of policy proposals that would incentivize physicians to prescribe more biosimilars. One proposal would pay physicians a higher reimbursement rate, the average sales price plus 8%, for prescribing the biosimilar rather than an innovator medicine. The reimbursement for the innovator product would remain the average sales price plus 6%.

"I don't think doctors prescribe medications for financial incentives," Dr. Worthing emphasized. "We prescribe medications because they are the best treatment option for the patient."

Incentives could undermine personalized care.

But when a particular drug is costly and threatens a clinic's financial viability, Dr. Worthing reflected, prescribing the drug that offers an incentive instead could become necessary. The chain of events could undermine personalized care and strain the physician-patient relationship, which is built upon trust and shared decision-making.

BIOSIMILARS IN THE MARKETPLACE

Biologic medicines are "extremely complicated and complex molecules," emphasized Dr. Cryer, and they take time, resources and expertise to develop. Their cost often reflects that complexity. As more biosimilars become available, however, patients and physicians should expect to continue seeing cost savings increase as competition improves.

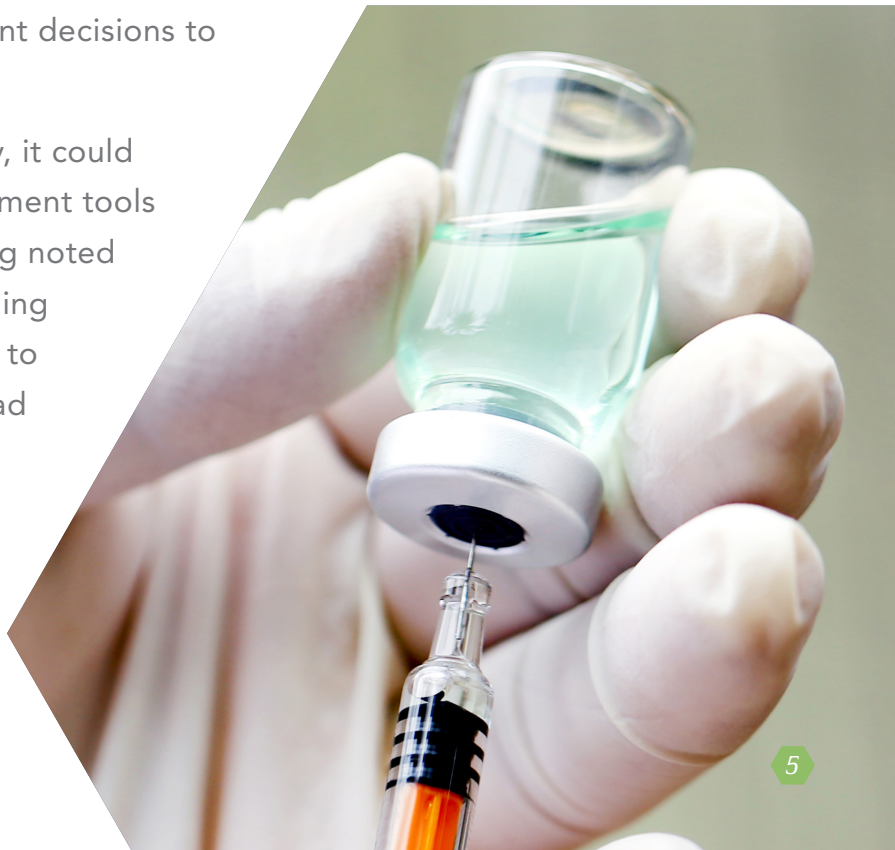
To date, there are 29 FDA-approved biosimilars, 20 of which are cleared for marketing. According to economic predictions, Dr. Worthing noted, costs will decrease by about 30% as more biosimilars become available.

An increase in biosimilars will also expand treatment options for patients with cancer and other serious diseases.

BILLING CODE POLICY

But with more biosimilars comes the possibility of policy implications. Several years ago, the Centers for Medicare and Medicaid Services proposed a single billing code, or J-code, for all biosimilars of the same innovator biologic. The proposal could have unintentionally pushed all patients toward the lowest-cost biosimilar rather than allowing the greater number of biosimilars to expand patients' treatment options, leaving final treatment decisions to individual patients and clinicians.

If a similar policy were introduced today, it could result in more use of utilization management tools and non-medical switching. Dr. Worthing noted how the approach of having a single billing code could cause patients to be moved to another drug for financial reasons instead of health reasons. The panel agreed this practice can have serious clinical implications, especially for patients with cancer or chronic disease.



MOVING FORWARD

The panel closed by highlighting an issue to which the Biologics Prescribers Collaborative has devoted much attention: education about the safety and efficacy of biosimilars.

Education is the key to building physician, patient and advocate confidence in biosimilars. But not enough information is readily available and accessible, the panelists argued. Dr. Worthing cited the Advancing Education on Biosimilars Act of 2020 and the FDA Purple Book, a public list of approved biologics in the United States, as important steps forward. But they alone are not enough.

Dr. Charles reiterated that fact, saying, "Patients and clinicians need to hear it over and over from multiple sources." He and Dr. Cryer emphasized the need for multiple educational resources such as videos, media and newsletters that are provided iteratively over time to build understanding and confidence in biosimilars.

As education improves and expands, so too will access to the growing number of biosimilars.

"IT'S UP TO US."

-Dennis Cryer, MD

On educating physicians and patients about biosimilars.

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