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Biosimilars: Unanswered Questions

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Debate continues about how **biosimilars** that are emerging to treat rheumatic diseases will be named and monitored, said panelists at a recent meeting in Washington, D.C. —Biosimilars in the United States: Next Steps.

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Angus Worthing, MD, FACR, FACP, a member of the ACR's Government Affairs Committee, shared rheumatologists' concerns as these new therapies come to market. And it's an urgent debate: a biosimilar to Remicade (infliximab), called **Inflectra (infliximab-dyyb), was approved** by the Food and Drug Administration (FDA) on April 5. And two more are on the horizon: The FDA's Arthritis Advisory Committee will meet and review proposed biosimilars for **etanercept** and **adalimumab** in July.

"Right now, we have a lot of confidence that the FDA will give us good information on these products' safety and efficacy," said Dr. Worthing. "Full transparency about biosimilars is [needed in order] for everyone to be confident about using

Compared, Plus Naming Guidance for Biosimilars

these therapies to treat rheumatic diseases. Patients need to know what they're taking, and physicians need to know what they're prescribing. This can be accomplished by using distinct names for biosimilars, having clear information on FDA drug labels and implementing consumer-oriented pharmacy dispensing practices."

Drug Naming & Substitution Concerns

Prescribers still control drug substitution at this point, because no manufacturers have applied for interchangeable status yet. There's a higher standard of proof involved when the drug is so similar to the reference product that it could be substituted by the pharmacy like generic drugs are, something that concerns rheumatologists, according to Dr. Worthing. Pharmacy notification of biosimilar substitution to prescribers is something rheumatologists strongly support, he said.

"We currently do not know what may happen when switching a patient back and forth between a biosimilar drug and its original reference product," he continued. Some patients could become immune to the new biosimilar, as well as the original biologic drug, he said. "This may cause the drugs not to work or even cause allergic reactions, which is why it's incredibly important that we protect patients against forced switching between **biologics** and biosimilars by insurance companies and pharmacy benefit management companies."

When a patient's condition is well controlled or in remission on one agent, changing products may not be in the patient's best interest.

The FDA Steps In

The FDA has issued draft guidance documents on **naming** and labeling to gather opinions on future regulations, said panelist Leah Christl, PhD, the FDA's associate director for therapeutic biologics. It is also investing in professional and patient education campaigns, and has created the **Purple Book**, an online biosimilars resource for prescribers.

"With biosimilars, we're talking about demonstrating similarity to a reference product that [has already proved] to be safe and effective," said Dr. Christl. "When we talk about switching drugs in the U.S., that's interchangeability, which is [held to] a different standard. But biosimilarity is not [held to] a lesser standard of safety and efficacy. The impact of switching and alternating drugs—the data must address that."

Distinct names will promote pharmacovigilance, making it easier to monitor, track, and report adverse events for biosimilars, Dr. Christl added. The Academy of Managed Care Pharmacists has launched a program, **the Biologics and Biosimilars Collective Intelligence Consortium**, to help pharmacists report and track these data.

Cost Creates Urgency

Surging costs of biologics make solving these issues a pressing matter, because many patients can't access life-changing therapies, said Barbara Finck, MD, chief medical officer of Coherus Biosciences and a rheumatologist. Biosimilars will create competition that could save patients money while still meeting the same high standards, she said.

"Biosimilarity is really about variability. It's about how close we can match that innovator drug. If it matches closely enough, you may not even need a clinical trial," said Dr. Finck.

Biosimilars could cost as much as 20% less than biologics, improving patient access, said Leigh Purvis, director of health services research for AARP. Cost sharing for patients has risen dramatically, so even with insurance, they can't afford biologics.

"We don't think there's anything to be afraid of," Ms. Purvis said. "The FDA has safety and efficacy covered. We want the competition. The competition will only happen if you allow substitution."

Work Together

The debate around biosimilars is complex, but if stakeholders work together, the obstacles can be overcome to the benefit of everyone, said Dr. Worthing.

"It's easy to get lost in the weeds of regulatory issues, but biosimilar naming, labeling and interchangeability issues have real and profound safety and health consequences for patients," he said. "Rheumatologists are looking forward to prescribing biosimilars."

Susan Bernstein is a freelance medical journalist based in Atlanta.

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