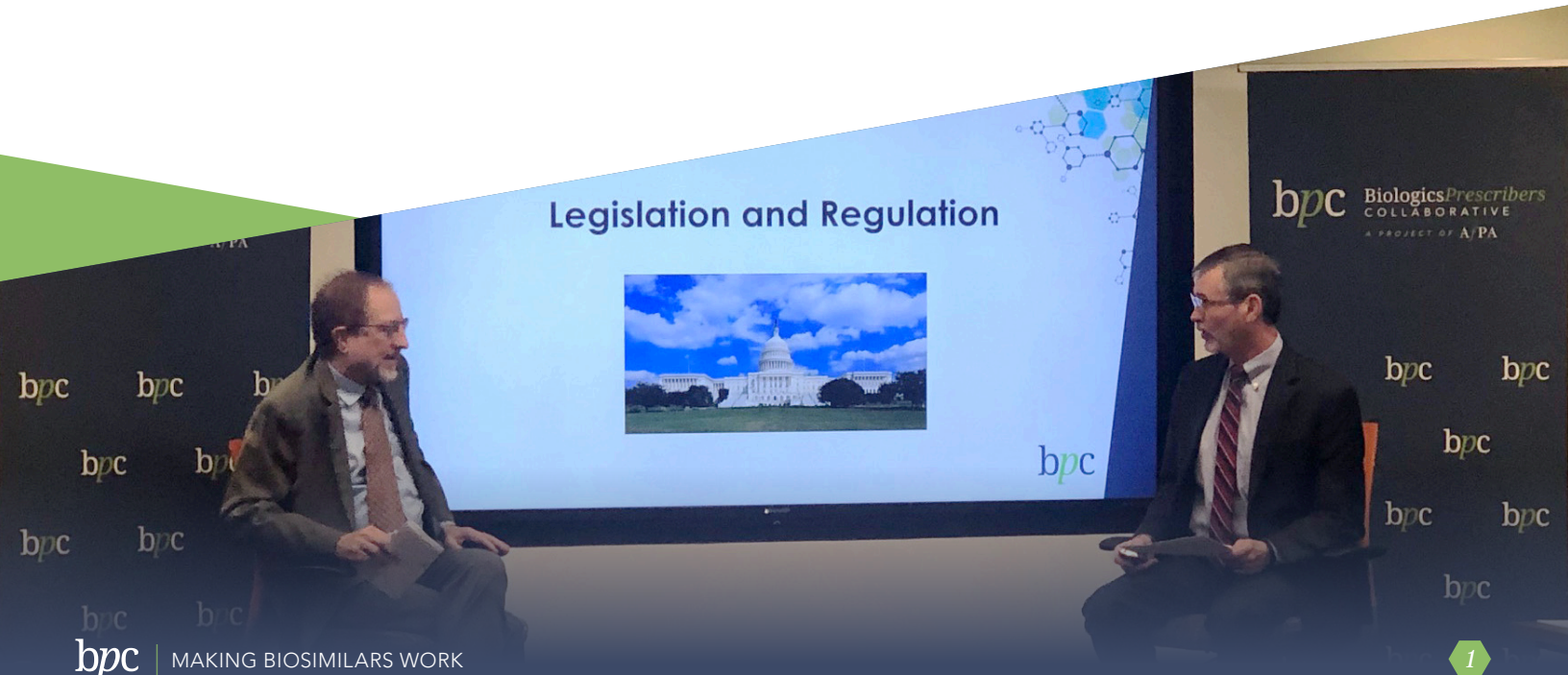
MAKING BIOSIMILARS WORK

Nearly 10 years ago, Congress created a pathway for lower-cost versions of breakthrough biologic drugs. Today, patients with diseases such as cancer, rheumatoid arthritis and Crohn's disease have a growing array of treatment options at their disposal.

So why are some pundits demanding reform?

A November 2019 meeting of the Biologics Prescribers Collaborative explored that very question. Held in Washington, DC, "Making Biosimilars Work" brought together physicians, patient group representatives and other stakeholders. Participants examined whether the existing regulatory structure meets patients' needs – and what educational materials and policies are necessary to make treatment options accessible.



STATE OF AFFAIRS

Biosimilars Today

An interview between regulatory expert Steven Grossman and Biologics Prescribers Collaborative co-convener David Charles, MD, tackled recent criticisms of the biosimilars pathway. "Some people are saying the current regulatory structure is ineffective and that we have to correct it, we have to reform it," Dr. Charles noted, asking, "Are they right?"

In a word, "no," Grossman explained. He noted that criticisms stem largely from impatience and unrealistic expectations. "Developing an approval pathway is an enormous challenge," Grossman emphasized, adding, "The developmental science of biologics is complex, and the FDA took the time it needed to get it right."

"Some people are saying the current regulatory structure is ineffective… ARE THEY RIGHT?"

-David Charles, MD

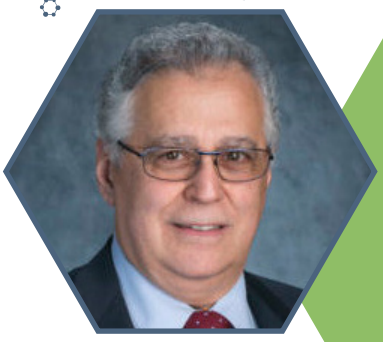
The FDA's years-long process included holding public comment periods on key issues such as:

- How biosimilars would be named
- What details their prescribing information would include
- What would constitute an "interchangeable" biosimilar.

The resulting guidance has shaped a regulatory framework that keeps patients safe and physicians informed, Grossman emphasized. A recent Biologics Prescribers Collaborative infographic reflects that the pathway is also expanding patients' treatment options. Since the biosimilars pathway took shape, more than 25 new biosimilars have been approved by the Food and Drug Administration, with more than 1,000 currently in the pipeline.

The coming years, Grossman noted, will continue the growth in treatment options made possible by the current regulatory structure.

THE PRESCRIBERS' PERSPECTIVE



"I COULDN'T BELIEVE IT."

-Greg Schimizzi, MD

On insurers using fail first to delay patients' access to biosimilars.

For those who worry that uptake lags, that too few patients are taking biosimilars, another factor may be to blame. Input from physicians at the meeting revealed that health plans are using utilization management to block access to biosimilars, just as they do with innovator biologics.

A physician at the Biologics Prescribers Collaborative meeting described his patients with rheumatoid arthritis having to "fail first" before getting insurance coverage for the lower-cost biosimilar. "I couldn't believe it," recalled Gregory Schimizzi, MD, a practicing rheumatologist and co-convener of the Biologics Prescribers Collaborative.

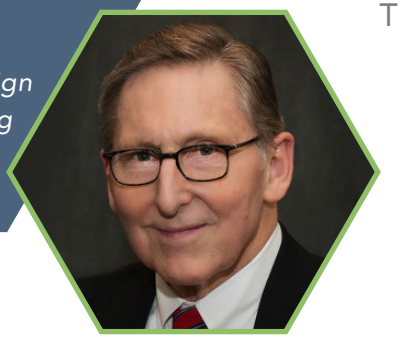
For years, insurers have used prior authorization, step therapy and cost shifting to limit patients' access to innovator biologics. Yet now, as a steadily growing number of biosimilars present other options for patients, insurers may be applying the same tactics.

Physicians at the meeting emphasized sharing the treatment decision-making with their patients. Naïve patients seldom have a strong preference between an original biologic and a biosimilar, the physicians noted, so they often start therapy on the treatment that's least expensive for the patient.

"How do you keep up with which health plans 'prefer' which medications?"

-Dennis Cryer, MD

On how health plan design complicates prescribing decisions.



Switching, however, can create real challenges. Greg Schimizzi, MD and Michael Blaisse, MD, described the frustration of having patients' insurers restructure their formulary on a regular basis, forcing stable patients to move off the medicine that's working for them.

The conversation was moderated by Biologics Prescribers Collaborative Co-Convener Dennis Cryer, MD.

FILLING THE GAPS ON PATIENT EDUCATION

The meeting's final discussion examined what information, materials and outreach patients might need to better understand biological medicine.

Preliminary findings from a Biologics Prescribers Collaborative survey of patients suggested continued confusion about how biosimilars differ from original biologics. It also conveyed that patients:

- Are most interested in biosimilars as an opportunity for potential cost savings
- Are most interested in learning about biosimilar options when circumstances with their insurer may require them to change treatments
- Strongly dislike being forced to switch from an existing treatment because of insurers.

Members from several prominent patient advocacy organizations offered insights from their groups' experiences. Participants agreed that patients are most interested in learning about biosimilars as they relate directly to them and when they present immediate treatment options. Physicians agreed that patients take confidence in hearing about other patients under their physician's care who have responded well to biosimilars.

NEXT STEPS

The meeting highlighted the value of collaboration among patient advocacy organizations and prescribers of biological medicine. Moving forward, the Biologics Prescribers Collaborative will work to synthesize the efforts of these two groups, especially on educational materials that can aid patients and clinicians in navigating the growing range of biological treatment options.

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MEETING ATTENDEES

Alliance for Patient Access | American College of Allergy, Asthma, and Immunology

American College of Rheumatology | American Gastroenterological Association

Amgen | Arthritis Foundation | Cancer Support Community

Coalition of State Rheumatology Organizations | CryerHealth

HPS Group LLC | International Myeloma Foundation

Johnson & Johnson | Lupus and Allied Diseases Association

National Infusion Center Association | Susan G Komen for the Cure

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