VIRTUAL

2021

NATIONAL POLICY & ADVOCACY

SUMMIT ON BIOLOGICS

AfPA Alliance for Patient Access

IfPA Institute for Patient Access

bpc BiologicsPrescribers COLLABORATIVE
A PROJECT OF AfPA

OVERVIEW

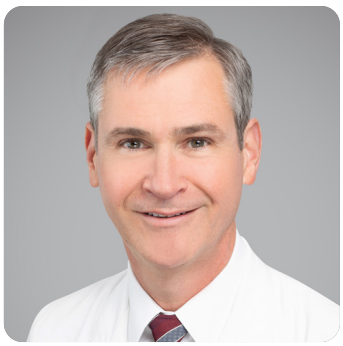
The sixth annual National Policy & Advocacy Summit on Biologics brought together health care providers, policy experts, patient advocates and other stakeholders. The event explored how sound public policies can facilitate the expanded use of biologics in patient-centered care. This year's event, held virtually, examined issues such as:

- Innovation and rare disease
- Current federal and state policy considerations
- The role of biosimilars in expanding treatment options
- Insulin affordability and interchangeable biosimilars.

David Charles, MD, founder of the *Alliance for Patient Access* and co-convener of the *Biologics Prescribers Collaborative*, kicked off the summit with an optimistic message about how patients, providers, advocates and the health care system have all benefitted from the Biologics Price Competition and Innovation Act of 2009.

"It's been just over a decade since the new regulatory pathway opened the door for follow-on biologics, the drugs we call biosimilars," Dr. Charles began, noting, "We find ourselves at an important moment of inflection."

Dr. Charles explained that the pathway contributed to an influx of new treatment options, calling this moment in time "a golden age of medical innovation."



Every day, more patients and clinicians can target and even beat debilitating diseases rather than having to be satisfied with just treating the symptoms.

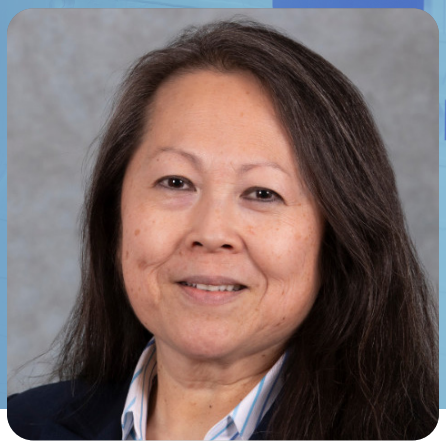
DAVID CHARLES, MD
Alliance for Patient Access

The summit, which included a series of panel discussions, individual stories and interviews, was convened by the Biologics Prescribers Collaborative and hosted by the Alliance for Patient Access and the Institute for Patient Access.

KEYNOTE ADDRESS

Sarah Yam, MD

FDA's Center for Drug Evaluation and Research



The summit's keynote address featured **Sarah Yam, MD**, director of the Office of Therapeutic Biologics and Biosimilars in *FDA's Center for Drug Evaluation and Research*.

Dr. Yim began with an overview of the FDA's current biosimilar approval landscape, noting that regulators have now approved 31 biosimilars, 21 of which are marketed, as well as two interchangeable products. FDA's Biosimilar Product Development Program continues to grow, Dr. Yim reported, spanning 94 development programs for 47 different reference products.

Dr. Yim said FDA's methods for approving biosimilars have evolved significantly over the past decade as the agency has applied lessons learned from experience. The process was very cautious and conservative at first, employing a stepwise approach, Dr. Yim explained. The European Union had an approval process in place for follow-on biologics in 2003, with its first approval coming in 2006. In contrast, the U.S. law wasn't passed until 2010, and the FDA did not approve its first biosimilar drug until 2015.

Dr. Yim also reflected on the Biologics Price Competition and Innovation Act of 2009. The legislation established two distinct categories — biologics and interchangeable biosimilars. She explained that the law requires the FDA to consider two criteria for each, ensuring they are both highly similar to the reference product and have no clinically meaningful differences. Operationalizing these specific requirements is a rigorous process, Dr. Yim noted, that takes several years and hundreds of millions of dollars.

The work of carefully constructing the pathway in the United States took time but was important. Dr. Yim noted that the FDA has benefitted from observing the E.U.'s experience. She said the United States is now catching up and perhaps even moving ahead.

"We're on an accelerating part of the curve," Dr. Yim reflected, "maybe we're over the hump and starting to pick up speed." She predicted that, in 10 years, the U.S. might see a biosimilars marketplace that is more like the generics marketplace.

"I think there are some fundamental differences between biologics and small molecules that will probably make that market slightly different," Dr. Yim noted, "but my hope is that they'll be so common that people will feel much more comfortable using biosimilar and interchangeable products."

The conversation was moderated by **Gavin Clingham** of the *Alliance for Patient Access.*

INNOVATION & RARE DISEASE

Innovative biologic medicines are revolutionizing treatment decisions, especially for the more than 6,800 known rare diseases that affect as many as 30 million Americans.

David Charles, MD, shared his experience as a neurologist using innovative medicines to fight conditions like multiple sclerosis. He noted that new medications are key because patients respond to medications differently. Having innovative biologics available means having more options to tailor care. Alternatives can also help drive affordability and access, he explained.

Rare disease advocate **Layla Lohmann, DDS**, described her personal experience suffering from thyroid eye disease as a child, well before any targeted treatment options were available. As a teenager in the 1990s, she took 13 pills a day to suppress the amount of thyroid stimulation on her eyes, but these medications stopped working two years later. She had her thyroid removed, but her condition resurfaced when she became pregnant as an adult. Fortunately, she said, the FDA fast-tracked a biologic that changed her life after more than 20 years.

The *National Organization for Rare Disorders'* **Richard White** also applauded the innovative progress in recent years but emphasized that unmet need is still tremendous. More than 90% of rare diseases still have no FDA-approved treatment, he noted.

"We're seeing trends in the right direction," he noted. "FDA is seeing more and more applications for rare diseases, and as things like precision medicine and gene therapies keep advancing, there's more progress to be made." White suggested that drug development could be accelerated by overcoming simple obstacles in clinical trial design like reducing travel burdens for patient participants by creating smaller, decentralized trials.

The panelists emphasized that maintaining a favorable policy environment is important for fostering the development of innovative medications and encouraging more funding for research. They also explained that cutting through bureaucratic red tape is critical to providing rare disease patients access to life-changing medications.

The panel was moderated by **Josie Cooper** of the *Alliance for Patient Access*.

FEDERAL & STATE LEGISLATIVE UPDATE

Keeping up the momentum of the recent success of biosimilars in the marketplace will depend on strong state and federal policies.

Angus Worthing, MD, on behalf of the *American College of Rheumatology*, began the legislative discussion by addressing the issue of drug pricing. He expressed concerned with the everyday access and affordability of medications for his patients. Dr. Worthing also, however, urged caution about new policies and negotiations that might end up increasing step therapy or other utilization management tactics, which delay patients from getting the medications they need.

Dr. Worthing noted that the Build Back Better reconciliation bill currently before Congress may include language that risks patient access for medication administered in specialty clinics. Lawmakers must be careful that the mechanics of the bill don't make it financially untenable for clinics to administer biologics, he emphasized. Dr. Worthing explained that this issue could undermine the clinics' own viability or their ability to serve Medicare patients.

Brian Henderson of the *Coalition of State Rheumatology Organizations* talked about a trend emerging in state legislatures: drug affordability review boards. He expressed concern that, if such boards are actually implemented, they could unintentionally steer patients toward higher-cost health care settings.

Both panelists conveyed concerns about increased reliance on a strictly economic approach to value rather than a patient-centered approach, alluding to the criteria used by the Institute for Clinical and Economic Review.

Another challenge is the rise of co-pay accumulator programs, which are now used by more than 20% of large employers. These programs are harmful, the panelists explained, because they prevent manufacturer co-pay cards from applying toward a patient's deductible or maximum out-of-pocket spending. Patients can find themselves facing unexpected and unmanageable expenses to get their medication. Some states have begun prohibiting this strategy, and federal legislation has also been introduced (H.R. 5801).

ADVOCATES' PERSPECTIVE

Melodie Narain-Blackwell, founder of *Color of Crohn's & Chronic Illness, Inc.*, is a patient suffering from a chronic and often debilitating condition, Crohn's disease.

After being diagnosed in 2018, she reached out for support on social media and soon received a flood of responses from other people of color who were suffering from digestive diseases and inflammatory bowel disease. Narain-Blackwell created a Facebook group, and Color of Crohn's & Chronic Illness, Inc. took shape soon after. She discovered huge disparities for communities of color in terms of disease state awareness and health care access, so she began creating programming and materials to meet that need.

Narain-Blackwell reflected on the reported rise of Crohn's, saying, "I really believe that the opportunity to be diagnosed is on the rise — not the actual disease." She noted that people of color "have been disqualified and disregarded for so many years."

"They're finally finding a voice," Narain-Blackwell explained, "and not feeling like what they've gone through is an isolated incident."

The interview was conducted by the *Biologics Prescibers Collaborative's* **Dennis Cryer, MD.**

Rob Goldsmith of the *Endocrine Society* described his organization's recent position statement on increasing insulin access and affordability. "It includes a series of policy recommendations to lower the cost of insulin," said Mr. Goldsmith. "The statement calls for the expedited approval of biosimilar insulins in order to create more competition in the marketplace. Our members strongly support bringing more biosimilar insulins to the market, and we see the recent approval of an interchangeable insulin as a key step forward toward lowering costs."

Goldsmith explained that the society also supports limiting co-pays to $35 a month, as well as rebate reform to ensure any rebate savings are passed along to the consumer at the point of sale. The current draft of the Build Back Better reconciliation bill contains a proposal for capping co-pays on insulin, but Goldsmith was concerned that it could be taken out of the final bill.

Goldsmith called the introduction of the first interchangeable biosimilar insulin "a really important step in the right direction." The move could lower costs for people with diabetes, Goldsmith noted, explaining that continued education was critical to ensuring that patients understood all of their options, including biosimilars and interchangeable biosimilars.

The interview was conducted by **Susan Hepworth** of the *Alliance for Patient Access*.

EXPANDING OPTIONS

Biosimilar can expand treatment options, but only if there is awareness, education, access and, ultimately, uptake.

On that topic, **Chad Pettit** of *Amgen* shared the findings of his company's 2021 Biosimilars Trend Report. "The marketplace with biosimilars is really advancing well in the U.S.," he explained. "As competition has grown, prices have fallen, and we're seeing some really robust biosimilars market share."

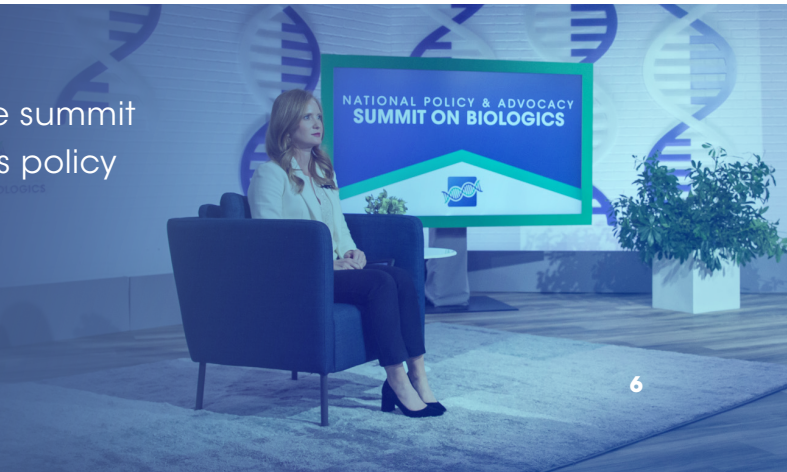
Karen McKerihan, MSN, NP-C, of the *Rheumatology Nurses Society* shed light on how patients are adjusting to biosimilars. "People who are being started on an originator product, and then moving over to a biosimilar have a lot of questions," she explained, whereas "if they're being started directly on a biosimilar, that nuance doesn't seem to be quite as important to them."

Pam Traxel of the *American Cancer Society Cancer Action Network* said patients with serious illnesses like cancer often aren't focused on what medication they're taking at first, other than efficacy. "As a cancer patient goes through their journey, they definitely have a lot more questions. They became a lot more informed about their treatments," she said. "But in the very beginning, I'd say most cancer patients aren't thinking so much about the drug being infused into them. They're really thinking about what it means for them at that moment."

The panelists shared concerns about non-medical switching, when insurers compel stable patients to switch from their current medication to an alternative that's more financially advantageous to the insurer. Panelists agreed that providers and patients, not insurance companies, should make decisions about which medications to take.

To learn more about topics discussed at the summit and the Biologics Prescribers Collaborative's policy priorities and advocacy initiatives,

visit www.biologicsprescribers.org



biologicsprescribers.org

instituteforpatientaccess.org

allianceforpatientaccess.org