Overview

On April 17, 2018, the Institute for Patient Access convened the third annual National Policy and Advocacy Summit on Biologics and Biosimilars in Washington, DC. Patients, government representatives, physicians and advocates came together for the day-long event, which celebrated innovation, highlighted the power of biologic and biosimilar treatments, and examined the barriers to patient access.

The event was co-sponsored by the Alliance for Patient Access and the Biologics Prescribers Collaborative.

A series of panels, onstage interviews and featured speakers touched on biosimilar uptake, education efforts, health plan barriers, therapeutic switching and the importance of the physician-patient relationship.

“We celebrate innovation. We invite more research. And we encourage policies that get physicians the information they need to make informed choices about their patients’ health care.”

- David Charles, M.D.
Chairman, Alliance for Patient Access
In a discussion on innovation, moderator and Alliance for Patient Access Chairman David Charles, M.D., marveled at "breakthrough treatments," "new diagnostics," and "wearable devices that weave health care into people’s busy everyday lives." The panelists provided their own insights:

**Allen Meadows, M.D.,** an allergist from Montgomery, Alabama and chair of the Alliance for Patient Access’ Respiratory Therapy Access Physicians Working Group, described how biological treatments have transformed health care. “Each generation, the biologic that comes is better than the last, and I can’t tell you how exciting it is for some of my patients who have severe asthma,” Dr. Meadows explained.

**Steven Grossman, J.D.,** highlighted the importance of more competition to improve the pricing and uptake of biosimilars. Alluding to the health care system’s experience with the first generic versions of traditional medications, Grossman explained, “Until you get about three players, you don’t get competition.”

**Janet Marchibroda** of the Bipartisan Policy Center explored how patent policy impacts innovation and patients’ ability to benefit from an array of treatment options. “What is that balance between innovation, competition and access?” Marchibroda asked, adding, “I think therein lies the challenge.”
The power of innovation also emerged as a theme in U.S. Representative Buddy Carter’s (R-Ga.) address to summit attendees. “Over my years of practice in pharmacy, I’ve seen nothing short of miracles,” explained Rep. Carter, the only pharmacist currently serving in the United States Congress. “I’m a big fan of R&D,” he added.

Rep. Carter also commented on the impact of policies that impede patients’ access to treatment. Gag clauses are “absurd” for blocking pharmacists from telling patients they could pay less for prescription medicines, Rep. Carter explained. He also voiced concerns about the federal 340B drug pricing program, emphasizing that policymakers should put "guardrails" on the program.

In an onstage interview with AfPA Executive Director Brian Kennedy, the Food and Drug Administration’s Leah Christl, Ph.D., addressed the challenges of biosimilar uptake. A key step in encouraging uptake, Dr. Christl explained, is education.

“It’s so important we do this outreach and education about [biosimilars] because it is a new paradigm,” Dr. Christl said. “It’s not just enough to say, ‘Trust us, we got this, [biosimilars are] different, and you don’t need to understand why,’” Dr. Christl added, explaining, “It’s really important to explain what we’re doing, how we’re doing it, and what we’re looking for in our scientific standards.”
Even when innovative treatment options exist, health plan policies determine whether they are accessible. A panel discussion on health plan payment models brought several challenges to light.

Economist Wayne Winegarden, Ph.D., of the Pacific Research Institute walked the audience through the 340B drug pricing program, explaining how it’s diverged from its original intent. He also remarked on the impact of the Institute for Clinical and Economic Review, arguing, “We can’t come up with one price that’s representative of all patients.”

Rheumatologist Madelaine Feldman, M.D., described the potential impact of co-pay accumulator adjustment programs – or “deductible double dipping,” as Dr. Feldman coined the approach. She also examined the role of the pharmacy benefit manager, saying, “They obfuscate. I think that’s a really good word to describe PBMs. ‘Obfuscation.’”

Washington, DC-based advocate and rheumatologist Angus Worthing, M.D., explained policymakers’ proposal to shift Medicare Part B medications to the Medicare Part D program. “Not only are the drugs potentially doing to be delayed from my prescription to the patient getting them,” Dr. Worthing noted, “but they’ll also be more expensive for the patients.”
PATIENT EXPERIENCE

Olympic medalist and lifelong asthmatic Jackie Joyner-Kersee gave the summit’s keynote address. “I thought maybe I wasn’t very good athletically,” Joyner-Kersee explained, recalling her first experience with asthma attacks.

Joyner-Kersee fought to reconcile her identity as an athlete with the limitations of her condition. Working with both her physicians and her coach, she managed to treat her asthma while pushing forward in her career.

Her address highlighted the importance of coming to terms with one’s illness and sticking with a physician-prescribed medication regimen. Despite her struggle with asthma, Joyner-Kersee went on to earn six Olympic medals and four World Championship titles. Sports Illustrated named her the greatest female athlete of the 20th century.
ADVOCACY

The power of the patient experience also resonated in a panel discussion on state advocacy efforts.

*Keep My Rx* Director **Derek Flowers** described multi-state efforts to educate policymakers on the impact of non-medical switching. The Keep My Rx campaign champions policies that prevent health plans from discontinuing or reducing coverage for ongoing medications needed by their beneficiaries with chronic diseases.

**Patrick Stone** of the *National Psoriasis Foundation* reflected on the progress made after several years of patient advocacy on issues such as step therapy, prior authorization and non-medical switching.

**Donnette Smith** of *Mended Hearts* detailed her struggle with utilization management barriers, underscoring how health plans’ attempts at cost cutting can handicap patients’ treatment plans. "How can this guy who has never met me say 'you don't need this drug'?," Smith asked, recalling repeated denials for her PCSK9 inhibitor prescription.

**Jeff Hitchcock** of *Children with Diabetes* shared the organization’s recent research on how diabetes patients experience the impact of non-medical switching. Hitchcock, whose daughter has Type 1 diabetes, explained that, "The importance of sharing your story cannot be underestimated."