

The Value Proposition 2019

National Policy & Advocacy Summit on Biologics and Biosimilars















OVERVIEW

On April 10, 2019, the *Institute for Patient Access* convened the fourth annual National Policy & Advocacy Summit on Biologics and Biosimilars in Washington, DC.

Dubbed "The Value Proposition," the event was co-hosted by the Alliance for Patient Access and the Biologics Prescribers Collaborative. It welcomed health care providers, patients, advocates and policymakers for a day-long exploration of innovation, access and value. A series of panels, onstage interviews and featured speakers touched on range of issues – including biosimilar uptake, non-medical switching, advocacy successes, innovative payment models and policy reform efforts.

The day's discussion illuminated AfPA's vision of a patient-centered health care system that reveres the physician-patient relationship and holds access as the highest aim. The result is better health outcomes, AfPA Chairman David Charles, MD explained, in his opening remarks, and eliminating avoidable costs to patients and the health care system.

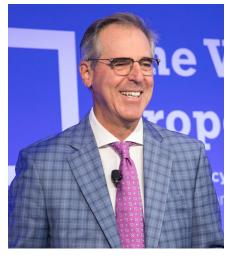


We move fearlessly toward a system that empowers health care providers, respects patients and gives credence to personalized care.



 David Charles, M.D.
 Chairman, Alliance for Patient Access







PATIENT EXPERIENCE

Languishing in a hospital bed after surgery for life-threatening Crohn's disease, San Diego Chargers' **Rolf Benirschke**, dangerously underweight and saddled with ostomy bags at only 24 years old, couldn't see the value of going on.

"From my perspective," Benirschke recalled, "my life was over."

But with top-notch medical care and the support of his family and teammates, Benirschke rallied. He ultimately returned to the NFL, where he played seven more seasons and was named NFL Man of the Year.

During his remarks at the summit, Benirschke marveled at the progress of modern medicine, pointing to the existence of biologics to treat Crohn's and IBD, where steroids had once been one of the only treatment options. His recovery story inspired attendees and reinforced for the audience the importance of access to innovative medicine.

Benirschke encouraged advocates and physicians in the room to continue their work, allowing advocacy to "fuel you like it fuels me."

BIOSIMILAR UPTAKE & EDUCATION

The value of innovative medicine and choice among therapies emerged as a central summit theme.





In a panel discussion of biosimilar uptake, IQVIA's Murray Aitken noted that the European Union has moved biosimilars to market more quickly than the United States has, resulting in more

approved therapies. But approval doesn't equate to availability. Europe's tender system, a winner-take-all approach to contracting between health care systems and drug manufacturers, can result in "forced switching issues" for patients, Aitken explained.



And forced switching doesn't sit well with patients and health care providers. As panelist Aline Charabaty, MD, of the American Gastroenterological Association noted, "Patients

don't want to change anything once they find the drug that works for them." Dr. Charabaty expressed physicians' collective concern that patients could be switched without their physician's knowledge or consent, and emphasized that biosimilar options were welcome as long as physicians retain control of treatment decisions



Part of that control means having comprehensive data on biosimilars, a fact of which the *Food* and *Drug Administration's*Sarah Ikenberry is keenly aware. Recent FDA research

revealed that physicians are focused on "what is the data, what are the approval standards, what is FDA looking at," Ikenberry explained.



The panel, moderated by The Pink Sheet's Nielsen
Hobbs, agreed that the combination of education efforts, additional biosimilar approvals and a steady influx of peer-reviewed data

would continue to build physician and patient confidence and to increase treatment options.

ACCESS & ADVOCACY



The impact of non-medical switching loomed large during AfPA Executive Director **Brian Kennedy's** presentation of a recent AfPA study on the issue. Describing switching as "pennywise, pound foolish," Kennedy explained how

disruptions in treatment can drive up costs through hospitalizations, doctors visits and extra labs tests. He also noted the far-reaching impact of switching on the lives of patients, who reported emotional stress, lagging productivity at work and the inability to handle caregiving responsibilities at home.

The study also highlighted concerning rates of medication abandonment among patients who were switched. "I'm really angry about that 40% who just give up," David Charles, MD, noted, referring to the rate at which non-medical switching leads frustrated patients to quit their medicine.

Non-medical switching isn't the only access barrier facing patients and providers. Insurers often hamper high-cost, high-value therapies like biologics with utilization management tools, seeking to curb costs by limiting patient access.

In a panel discussion on talking with health plans, **Ryan Gough** of the *Partnership to Advance Cardiovascular Health* and **Stacey Worthy** of the *Aimed Alliance* conveyed their organizations' efforts to improve patient access. Gough described coupling data with patient testimonials to pressure insurers with high rates of rejection for cholesterol-lowering PCSK9 inhibitors.

Worthy outlined her organization's efforts at educating employers, the largest purchaser of health insurance, about the benefits of comprehensive coverage. By outlining the benefits of access in terms of how employers can "increase productivity, decrease absenteeism, decrease medical expenses under health plan," Worthy explained, employers are more willing to improve patient access.

The panel was moderated by the Global Alliance for Patient Access' Chase Martin.



COST-SAVINGS PROPOSALS

Access issues also dominated the day's final panel discussion, which explored proposals for reducing health care costs.



The Trump administration's idea of shifting Medicare Part B drugs to Part D, the prescription drug plan, for instance, is "one of those ideas people hoped has died on the vine," explained **Kevin Kirby** of *The Moran Company*, "but is still in the president's most recent budget proposal." As **Madelaine Feldman**, **MD**, president of the *Coalition of State Rheumatology Organizations* noted, some patients "can't afford Part D" because it's excluded from the supplemental Medicare coverage that patients use to access Part B medications.

The group also examined the Trump administration's proposal for an international pricing index, which AfPA's **Gavin Clingham** described as "one of the larger and more controversial" ideas put forth by the

administration. Panelists expressed concern with the scope of the project, which would affect 50 percent of Medicare providers and impact patient access.

The cost-savings concept that most resonated with panelists and audience members was the administration's recent proposal to end secretive rebate negotiations between pharmacy benefit managers and manufacturers—replacing them with direct-to-patient drug discounts. "This would disrupt the entire system for Part D," Dr. Feldman predicted, adding, "In three-to-five years this could trickle down to the commercial [health plans]. Competition could bring prices down."

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