

2nd ANNUAL



NATIONAL POLICY & ADVOCACY SUMMIT
BIOLOGICS AND BIOSIMILARS
2017



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OVERVIEW

On April 6, 2017, the Institute for Patient Access convened the second annual National Policy and Advocacy Summit on Biologics and Biosimilars in Washington, DC. Patients, government representatives, physicians and advocates explored throughout the day-long event how more biological options present both new challenges and new possibilities for treatment.

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

The summit examined policies that shape access to biologics and biosimilars -- such as approval, therapeutic switching and health plan barriers -- as well as their impact on patients.

The day's discussions made one point clear: a handful of breakthrough medicines has quickly ballooned into a robust class of powerful treatments, and advocates are hard at work to keep those medicines accessible to the patients who need them.

*“ Physicians and patients are no longer asking **if** a biological medicine is the best choice, but – more likely – **which** biological medicine is the best choice. ”*

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



GLOBAL POLICY ISSUES

An international panel examined Europe and Latin America’s experiences with biologics and biosimilars, including what lessons they might offer the United States.



Patient advocate **Neil Betteridge** of the UK conveyed findings by Professor Michael Kaeding of the University of Duisburg-Essen that patients’ adverse events were underreported.

“Physicians and patients need to be better informed about tracking and monitoring...” he emphasized.



Patient advocate **Eva Maria Ruiz de Castilla** described the patchwork regulatory approval process in Latin America and the complications it poses for patients and providers.

She also described the region’s approach to biosimilar switching as “a matter of budget.”



Oncologist **Arturo Loaiza-Bonilla, M.D.**, pointed to rituximab for cancer patients as an example of why extrapolating approved uses for a biologic that treats multiple conditions

can be problematic. “The impact of a drug on immune systems differs across disease states,” he noted.



U.S. POLICY ISSUES

Questions of switching resurfaced in the “Policy Advocacy in the States” panel, which also examined the problems associated with step therapy.



Kevin Daley of the *Coalition of State Rheumatology Organizations* described patients’ frustrations with non-medical switching after spending “six months to a year” working with their

doctor to pinpoint the right medication. He called it “a farce” for health plans to expect savings when they wind up spending more to address the medical effects of switching.



Kathleen Arntsen of the *Lupus and Allied Diseases Association* described patients’ work to get step therapy protections unanimously passed by the New York legislature.

Kathleen also opened up about her personal experience with step therapy.



Harry Gewanter, M.D., of the *Alliance for Safe Biologic Medicines* offered the physician’s perspective, pointing out the irony of utilization management techniques. Health insurers

are “the only people we pay to give us a hard time, to tell us no,” he explained.



In a morning address to summit attendees, **Sen. Bill Cassidy, M.D.**, (R-LA.) provided a federal legislator’s viewpoint on breakthrough drugs’ value. A patient who benefits from a life-changing therapy such as a biologic is “working, living life, paying taxes, and not in the hospital,” Sen. Cassidy explained, adding that “If there’s a breakthrough therapy, it needs to be quickly approved.”

Sen. Cassidy emphasized that policymakers must determine how to advance access to breakthrough medicine “without bankrupting the country.” He argued, however, that price controls would have the opposite effect, chilling investment and hindering innovation for complex conditions.

FOOD AND DRUG ADMINISTRATION GUIDANCE



Hosted by *Inside Health Policy* Associate Editor **Nicholas Florko**, afternoon panelists considered biosimilar labeling, the impact of distinct naming and what interchangeable biosimilars might mean for patients and policy.

Greg Schimizzi, M.D., of the *Biologics Prescribers Collaborative* commended the FDA's work toward get biologic and biosimilar agents approved. He added that "It would be nice to have statements about what is and is not an appropriate substitution."

Stephen Marmaras of the patient advocacy group *Global Healthy Living Foundation* highlighted patients' concerns that health plans will use biosimilars as "an opportunity...to exploit financial gain."

Steven Grossman, J.D., a regulatory consultant, recalled regulatory mishaps related to generic medications during the Reagan administration. Today's FDA "doesn't want to have that result," he argued, "they want to do it right."



Recent FDA guidance on biosimilar naming and draft guidance on interchangeability made regulatory issues a central topic for the summit. The FDA's **Leah Christl, Ph.D.**, elaborated on interchangeability guidance, explaining that the agency would build upon its totality of evidence approach. She also noted that the agency may require post market data for therapies whose impact carries "residual uncertainty."



PATIENT IMPACT

Olympic medalist and cancer survivor Shannon Miller gave the event's keynote address, a testimony to the power of the physician-patient relationship and how breakthrough medicine saves patients' lives.

Though best known as a seven-time Olympic gold medalist and member of the United States' 1996 "Magnificent Seven" gymnastics team, Miller is now a women's health advocate. In describing her battle with ovarian cancer, Miller encouraged patients, "Keep fighting and take advantage of new, breakthrough therapies!"

She also emphasized the importance of trust between patient and physician. "Patients need every question answered," she explained, "You need to feel your life is a priority." She praised her physicians for providing her with direction, resources and specific, achievable goals.

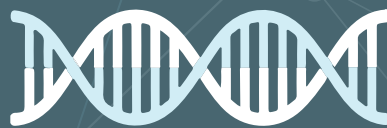


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