8th ANNUAL
NATIONAL POLICY & ADVOCACY SUMMIT ON BIOLOGICS

November 2023
The eighth annual National Policy & Advocacy Summit on Biologics convened health care providers, policy experts, patient advocates and other stakeholders in Washington, DC.

Following a year of significant change in the field of biologics, speakers and participants discussed how these innovative treatments can benefit patients and how the health care community can support patient-centered care.

This year’s summit focused on:

- The evolving biologics and biosimilars landscape
- The influence of third parties on treatment access
- Data’s value as an advocacy tool
- Federal regulators’ new authority

David Charles, MD, chief medical officer of the Alliance for Patient Access and co-convener of the Biologics Prescribers Collaborative, welcomed participants to the event. He acknowledged the many health care advances over the past year, especially in the field of biologics.

As treatment options have expanded, however, health plans and third parties have found new ways to hinder patient access and obstruct timely, personalized treatment.
U.S. Representative Carol Miller, a member of the House Ways and Means Committee’s Subcommittee on Health, offered opening remarks for the summit.

“Innovations like biologics and telehealth have made it so much easier for Americans to access health care.”

Health care should be affordable and accessible, she said, and innovative treatments and services have had a positive impact on patients across the country. While there have been great wins in health policy, significant challenges remain. Pharmacy benefit managers, for example, are a serious concern for the congresswoman.

“PBMs are keeping drug prices high for patients, and they are stifling innovation,” she said.

Rep. Miller reiterated her commitment to solutions that increase patient care and improve access, especially for rural communities. She applauded the work of advocates fighting for patient access and affordability.

Rep. Miller set the stage for the day’s discussions of the challenges patients face and opportunities for stakeholders to advocate for patient-centered care.
Leah Christl, PhD  
Executive Director of Global Regulatory and R&D Policy, Amgen  

Leah Christl discussed how the field of biologics has rapidly grown thanks to biosimilars. “There’s a good level of interest in continuing in the biosimilars space and investing in development of those products and expanding therapeutic areas,” Christl explained.

There still will be knowledge gaps, even as these treatments become more common. The nuanced differences between biosimilars and interchangeable biosimilars, for example, may prove confusing initially. But pharmacist education can help ensure that interchangeability regulations and consistent policies are implemented effectively to benefit patients.

Angus Worthing, MD  
Board of Directors, American College of Rheumatology  

Angus Worthing, MD, described how increasing biosimilar and interchangeable biosimilar options can increase affordability and improve access for patients. “My goal is to get people on the right drug as quickly as possible,” Dr. Worthing said, “and also increasingly to try and prevent financial toxicity.”

Phil Schneider, FASHP, FFIP  
Chair of International Advisory Committee, Alliance for Safe Biologic Medicines  

Phil Schneider emphasized the need for pharmacists to stay up to date on policies related to biologic treatments, especially on the topic of substituting interchangeable biosimilars.

But third parties may limit patient access. Pharmacy benefit managers, for example, create formularies that maximize their profits, with rebates often directly benefiting shareholders rather than patients. “Physicians and pharmacists have accountability and responsibility for the care of patients,” Schneider explained. “And that’s beginning to erode away based on the model that PBMs have.”

This panel was moderated by Gavin Clingham, director of public policy for the Alliance for Patient Access.
Brian Henderson
State Government Affairs, Coalition of State Rheumatology Organizations

Brian Henderson kicked off the panel by explaining that advocacy efforts on pharmacy benefit managers have made a significant difference.

“As recent as probably six years ago,” Henderson reflected, “I think if you talked to a congressperson or a state legislator, a lot of them wouldn’t have known what a pharmacy benefit manager is, and now all of them do.”

Advocacy efforts at the state level matter as well, Henderson explained. Prescription drug affordability boards are being implemented across the country, and patient advocates must engage with policymakers to ensure that these boards prioritize patients. A single person’s advocacy can make an impact, Henderson emphasized.

Ashira Vantrees
Staff Attorney, Aimed Alliance

Ashira Vantrees highlighted non-medical switching reforms across the country, including policies that would prevent stable patients from having their medication switched mid-year.

As solutions take shape, however, other barriers arise. Vantrees pointed to alternative funding programs, where third-party vendors divert insured patients to charitable assistance programs to get their prescription medication.

“That exploitation of [patient assistance programs] is really concerning, and the inherent nature of these programs is really coercive toward patients,” Vantrees said.

Sarah Buchanan
Director of Federal Government Relations & Health Policy, National Psoriasis Foundation

Sarah Buchanan reflected on how advocacy efforts have led to significant victories. Step therapy reform, for example, has been passed in states across the country, putting treatment decisions back in patients and providers’ hands. Advocacy efforts have also led to exciting developments with federal legislation. And earlier this year, a federal court ruled that copay accumulator programs violate the law.

“Right now, accumulators should be banned for most drugs.”

She encouraged advocates to keep pushing for reforms that improve patient access.

This panel was moderated by David Charles, MD, co-founder of the Alliance for Patient Access.
The Inflation Reduction Act gives the Centers for Medicare and Medicaid Services the unprecedented responsibility of negotiating prices for some of the most commonly administered drugs, Joel White explained. The negotiation process, however, isn’t visible to the public.

Who is CMS negotiating these prices for? Taxpayers? Patients? Plans?

Transparency is a concern among patient advocates, White noted. It’s unclear how these conversations will go, or the extent to which the public will have an opportunity to provide input. The negotiated prices may also have consequences for patient access and innovation in both the short and long term.

National coverage determinations and recent decisions about treatments approved through the Accelerated Approval Pathway have demonstrated the impact of federal regulators, Michael Ward noted.

Though the Accelerated Approval Pathway has been used for years to expedite patients’ access to breakthrough treatments, the Centers for Medicare and Medicaid Services recently imposed restrictions on some drugs approved through the pathway.

“There’s been a lot of pressure on thinking about how we pay for these drugs,” Ward noted.

Meanwhile, in the case of innovative Alzheimer’s treatments, the agency eliminated its national coverage determination, leaving pivotal decisions about patient access up to regional Medicare administrative contractors.

Anna Hyde highlighted the role of patients in the implementation of the Inflation Reduction Act.

While patients can benefit from the out-of-pocket cap and the Medicare Prescription Payment Plan provided for by the Inflation Reduction Act, Hyde explained, CMS must be prepared to provide clear, concise and consistent education to make these programs useful and usable for patients.

Getting the patient perspective during drug pricing negotiation is also important to consider. “If you’re going to determine maximum fair price,” Hyde asked, “are you doing that in a patient-centered way?”

This panel was moderated by Amanda Conschafter, director of strategic communications for the Alliance for Patient Access.
DATA: A KEY ADVOCACY TOOL

Rachel Klein
Deputy Executive Director, The AIDS Institute

Rachel Klein described how data can be a valuable advocacy tool if it’s distilled and presented in a way that resonates with policymakers.

Advocates and health care providers, who are best positioned to explain the frustrations and barriers they face on a regular basis, can use data to reinforce the impacts of insurer and pharmacy benefit manager interference. Data can also underscore the financial burden placed on patients and caregivers, highlighting for policymakers why reform is necessary.

Advocates should also convey the cost of the status quo. Asking policymakers to consider, “What is the cost of inaction?” Klein noted, can be powerful.

Donna Cryer
Founder & CEO, Global Liver Institute

Donna Cryer explained that access to data can help drive policy change. But data often has blind spots, Cryer explained. Large segments of certain populations, such as Black Americans, are often missing. Researchers are actively working to be more inclusive. With more comprehensive data, the health care community can reduce disparities and improve treatment for all patients.

Jared Willis
President, Catalyst Strategies

Policymakers want to know more about the fiscal impact of any proposed policy, Jared Willis explained. Hard numbers can support the stories told by providers, patients and caregivers, encouraging decision makers to embrace policies that put patients first.

But patient advocates often take on the burden of quantifying and describing important data. They must pinpoint key data points and reiterate those points consistently to drive their message home. If delivered effectively, their message can lead to significant change.

Successful advocacy, Willis noted, is how topics like pharmacy benefit managers and copay accumulators have grown to capture the attention of policymakers and the media.

This panel was moderated by Derek Flowers, grassroots advocacy director for the Alliance for Patient Access.
Third-Party Health Care Players

J. Allen Meadows, MD  
Executive Director of Advocacy and Governmental Affairs, American College of Allergy, Asthma and Immunology

J. Allen Meadows, MD, explained that pharmacy benefit managers’ practices now have the attention of federal policymakers, who are taking a closer look.

Health care providers played an important role in educating policymakers on this topic, Dr. Meadows noted, as they offer unique insight into the challenges that pharmacy benefit managers pose to patient care. “If we don’t take the big role as the advocate,” Dr. Meadows said of health care providers, “I don’t think other people will.”

Elizabeth Johnson noted that the inner workings of the health care system are sometimes unknown to patients, putting them at a disadvantage. She pointed to Medicare administrative contractors, regional third parties who help administer Medicare benefits and make coverage decisions.

Last summer, for example, Medicare administrative contractors placed an asthma treatment on the self-administered drug list, even though the treatment was approved only for clinician administration. Johnson explained that advocacy efforts helped reverse the decision before it could harm patients.

“It was physicians writing letters,” she explained, noting that concerted advocacy has a lasting positive impact for patients.

Casey McPherson  
Manager of Clinician Advocacy, Alliance for Patient Access

Casey McPherson described the influence of the Institute for Clinical and Economic Review, the Boston-based health economics organization that assesses medical treatment’s value and price. The organization uses a metric known as the QALY, or quality-adjusted life year, which can discriminate against certain patient populations. ICER has also begun preemptively assessing drugs before they’re even available to patients.

“ICER is reviewing this drug, trying to determine the value of the treatment, months before they’ve even submitted it to the FDA.”

Advocacy efforts have raised awareness of ICER and the QALY, he pointed out, ultimately leading to the introduction of legislation that would institute a federal ban.
To learn more about topics discussed at the summit and the Biologics Prescribers Collaborative’s policy priorities and advocacy initiatives,

Visit www.biologicsprescribers.org