

8<sup>th</sup> ANNUAL

# NATIONAL POLICY & ADVOCACY SUMMIT ON BIOLOGICS



Alliance for  
Patient Access



BiologicsPrescribers  
COLLABORATIVE  
A PROJECT OF AfPA



Institute for  
Patient Access

# OVERVIEW

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-convenor 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.



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**Good policies  
can protect  
patients.**

”  
**DAVID CHARLES, MD**  
*Alliance for Patient Access*



# CONGRESSIONAL REMARKS

U.S. Representative  
**Carol Miller**

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.

# THE BIOLOGICS LANDSCAPE



**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."

Getting patients on the right track and ensuring they're informed about their treatment can be challenging, and instances of switching can complicate patients' understanding of their treatment regimen. As more biosimilars become available, providers will need to continue educating patients on treatment options and switching.



**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*.

# POLICYMAKER ENGAGEMENT



**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*.

# FEDERAL REGULATORS



**Joel White**  
*Founder & President,  
Horizon Government  
Affairs*

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.



**Michael Ward**  
*Vice President of Public  
Policy and Government  
Relations, Alliance for  
Aging Research*

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**  
*Vice President of  
Advocacy and Access,  
Arthritis Foundation*

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 Conschaffer**, 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.

"Having the right type of data – accurate data, comprehensive data – is really essential to making an effective argument," Cryer emphasized. Advocates also need to understand how to use that data effectively.

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*.

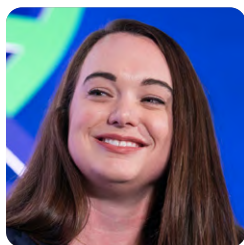
# THIRD-PARTY HEALTH CARE PLAYERS



**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, LPN**  
*President, National Association of Medication Access & Patient Advocacy*

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](http://www.biologicsprescribers.org)



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