



AfPA's National Policy & Advocacy Summit



Overview

The ninth annual National Policy & Advocacy Summit convened health care providers, policy experts, patients, advocates and other stakeholders in Washington, D.C. on September 24, 2024.

Presenters and participants highlighted the importance of partnership and advocacy to shape policies that prioritize patients and encourage timely access to treatment.

This year's summit explored:

- The key decision makers who influence health policy and treatment access
- The changing treatment landscape and innovation's ability to improve patient choice
- The critical role of advocacy in shaping patient-centered health policy
- The intersection of physical and mental health throughout the health care system.

Josie Cooper, executive director of the *Alliance for Patient Access*, welcomed the event's participants. She noted that the summit fell on an important access milestone – the 40th anniversary of the Drug Price Competition and Patent Term Restoration Act. Also known as Hatch-Waxman, this legislation first established an approval pathway for generic medications.

These treatments have since saved the U.S. health care system almost \$3 trillion. Policy decisions like these can and do play a major role in Americans' day-to-day lives, and encouraging policy that reflects patient-centered care is crucial.



“ With effective advocacy, we can create a better health care system and better outcomes for patients. ”

Josie Cooper
Executive Director,
Alliance for Patient Access



Congressional Remarks

U.S. Representative Michelle Steel

U.S. Representative Michelle Steel (R-CA), a member of the Committee on Ways and Means' Subcommittee on Health, delivered a virtual address to open the summit.

Rep. Steel is a passionate advocate for patient-centered health care and described her experience working on critical legislative efforts, including The Lower Costs, More Transparency Act. The legislation would mandate that insurers disclose information about medical costs so patients can make informed care decisions. It would also require health insurers and pharmacy benefit managers to disclose negotiated drug rebates and discounts, increasing transparency around the costs of prescription drugs. These reforms would help return patients to the center of the focus of health care.

Engaging lawmakers is an important piece of the puzzle for advocates, she said, highlighting the need for engagement in policy efforts to drive meaningful reform in the U.S. health care system.

Rep. Steel set the table for a day of in-depth discussions with experts across health care fields focused on the challenges patients face and opportunities for stakeholders to advocate for patient-centered care.

“ By working together, we can make progress for the patients at the heart of the health care system. ”

U.S. Representative
Michelle Steel



Keynote Address

Damon Tweedy, MD

Damon Tweedy, MD, author of *Black Man in a White Coat* and *Facing the Unseen*, delivered the keynote address.

Dr. Tweedy reflected on his experience as a medical student and how his psychiatry rotation revealed the role that mental health care plays across the health care system. During residency, he had the opportunity to work in a hospital and clinic setting for most of his rotations. His psychiatry rotation, however, took place in a psychiatric hospital miles away and cordoned off near the state jail.

He described how mental health care often occurs apart from physical health care. That divide, he noted, can lead to stigma and make patients reluctant to pursue care. He recalled from his earlier years of practice how law enforcement officers were sometimes the ones to transfer a mental health patient from a hospital to a psychiatric facility.

Mental health challenges can and do arise across many areas of medicine. But siloed care often poses problems. Psychiatric units and clinics are often completely separated, despite the value of holistic care. The current system's separation doesn't work, Dr. Tweedy emphasized.

Integrated care for both mental and physical health would make a difference. If hospitals and clinics provided both kinds of care at initial intake sites, patients might be able to have all their needs met.

At his current practice, Dr. Tweedy co-leads an effort to integrate primary and mental health care. While acknowledging progress, Dr. Tweedy also noted that the health care system has a long way to go.

Dr. Tweedy described wanting to prepare the next generation of health care providers to recognize and address mental health challenges. Future practitioners who don't specialize in psychiatry – which is the vast majority – should still be equipped with psychiatric training, he explained. They will encounter mental health conditions and complications, and they need to be prepared.

“ Every area of medicine needs a layer of mental health care support. ”

Damon Tweedy, MD

Pressure on Patients



Kollet Barkhouse
*Alternative Funding
Program Task Force*

Kollet Barkhouse spoke about a patient barrier known as alternative funding programs. These programs occur at the employer level, where specialty medications are removed from the health plan formulary, forcing insured patients into alternate means like charitable patient assistance programs to get their medication.

“This is the kind of stress that is being put on patients,” Barkhouse said. “We have patients who have been waiting for 18 months for their medication.”

These programs come on the heels of other cost barriers, such as copay accumulator programs and copay maximizer programs. Barkhouse explained that these programs place immense burden on patients and can lead to dangerous treatment delays.



**Mariana Socal,
MD, PhD**
Johns Hopkins University

Dr. Mariana Socal explained that pharmacy benefit managers have a significant influence on which treatments a patient can access. They negotiate the plan’s formulary and determine utilization management restrictions. In many cases, pharmacy benefit managers are developing formularies not with patients in mind, but with their own profits prioritized.

Dr. Socal also highlighted that vertical integration has become commonplace.

“We see insurance plans merging with PBMs,” Dr. Socal said, “with PBMs and pharmacies being owned by the same parent company.”

As a result, pharmacies may be limited in what they can dispense, patients may face more onerous paperwork barriers, or patients may not have coverage because their medication isn’t profitable for the insurer.



Ashira Vantrees
Aimed Alliance

Ashira Vantrees outlined the nuances of how pharmacy benefit managers negotiate formularies and pricing. With such a large information gap, it is challenging to figure out how to best regulate these massive entities.

“There’s such a lack of transparency surrounding PBM practices,” Vantrees noted.

She explained that patients need policies where they experience immediate cost savings benefits. Delinking drug rebate profits and having pharmacy benefit managers receive a flat fee for their services may help.

At the state level, Vantrees noted, there has been significant reform to provide relief to patients, which bodes well for future federal legislation.

This panel was moderated by **David Charles, MD**, co-founder of the *Alliance for Patient Access*.

The Changing Landscape of Biologics



Ralph McKibbin, MD
Alliance for Safe Biologic Medicines

Ralph McKibbin provided a clinician's perspective on the future of biosimilars. He emphasized the need for personalized treatment and raised concerns about the unintended consequences of easing requirements for biosimilars to achieve interchangeability. "Patients are not widgets," Dr. McKibbin emphasized. "You can't switch them around and consider them all the same."

Individual patients need a treatment approach targeted to them. He stressed the importance of clinician input, and shared concerns that, without the proper oversight from the FDA, all biosimilars could be deemed interchangeable. Dr. McKibbin called for policies that ensure biosimilar switching continues to ensure efficacy and patient safety.



Chad Pettit
Amgen

Chad Pettit also explored the topic of biosimilar interchangeability. This regulatory designation allows pharmacists to substitute biosimilars for other biologics without prior approval from the prescribing health care provider. To achieve "interchangeable" status, a biosimilar must undergo further testing and meet additional requirements, a matter that's best left to the FDA.

One of the major benefits of biosimilars, Pettit pointed out, is their cost savings for the health care system.

"There have been over \$30 billion in savings in the United States stemming from the use of biosimilar medications," Pettit noted.

Pettit explained that the first biosimilars led to competition-driven price reductions, underscoring the potential cost savings for patients as well as the value of innovation.



Jennifer Snow
Apteka Policy

Jennifer Snow stressed the critical role of policy in shaping the future of biologics and biosimilars.

"A strong policy platform is key," Snow said. "We need biosimilars to thrive for costs to lower over time."

Snow has led the development of a comprehensive report on the biologics marketplace. The research examines whether biosimilars have truly provided cost savings to both patients and companies since their release, and what policymakers should consider moving forward.

One key finding is a greater uptake of clinician-administered biosimilars compared to pharmacy benefit biosimilars, a trend driven by clinicians' clearer understanding of biosimilars.

This panel was moderated by **Gavin Clingham**, director of public policy for the *Alliance for Patient Access*.



Spotlight

Prescription Drug Affordability Boards



Thayer Roberts

Partnership to Improve Patient Care

Thayer Roberts discussed how state legislatures across the country are beginning to establish prescription drug affordability boards. These boards are intended to address rising prescription drug costs, but they often fail to do so in a patient-centered way.

Roberts described uncertainty about who the ultimate recipient of cost savings typically is: patients, or health plans?

“We should be looking at value and affordability to the patient,” Roberts said. “In reality, a lot of these systems are set up to determine value to the payer.”

The way that prescription drug affordability boards determine value also may be problematic, Roberts explained. They may use metrics like the quality-adjusted life year, a population-health metric that has been widely criticized for discriminating against chronically ill and older patients.

Value and affordability are important to consider, Roberts pointed out, but evaluations must consider the real-world perspectives of patients, family members, caregivers and clinicians.

Advocates have an important role to play across the country, she explained. In states where prescription drug affordability boards exist, advocates can engage directly with the board to submit comments and offer public testimony. In states that are considering a prescription drug affordability board, advocates have an opportunity to speak up about the potential harm these organizations can cause.

This discussion was moderated by **Casey McPherson**, director of clinician advocacy for the *Alliance for Patient Access*.

The Critical Role of CMS



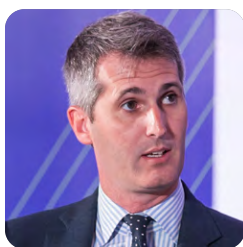
Bonnie Duffy

MAPRx

Bonnie Duffy gave an in-depth overview of the Medicare Part D benefit restructuring, including the \$2,000 out-of-pocket cap and the Medicare Prescription Payment Plan. She emphasized the importance of preparing for potential unintended consequences for Medicare beneficiaries, such as increased premiums and more restricted formularies.

“When the Part D program was first implemented, a similar conversation was held to help seniors address any unintended consequences.”

At another pivotal moment for the program, she stressed that CMS needs to use all available tools to establish clear guidelines for the best possible outcomes for beneficiaries.



Ryan Gough

Partnership to Advance Cardiovascular Health

Ryan Gough reflected on his experience working with CMS as a representative of the Partnership to Advance Cardiovascular Health. During the drug negotiation process, patients, providers and advocates had an opportunity to provide comments and testimony to CMS. Gough, however, noted that the process could have been smoother.

Gough discussed how the negotiations specifically impact cardiovascular drugs, expressing concern that the high costs of

development, coupled with the negotiations, may deter manufacturers from producing innovative treatments in this space.

“We have a cardiovascular crisis in the U.S. but need continued investment to address it. I’m afraid the IRA has disincentivized discovery in cardiovascular care at a very unfortunate time.”

He pointed out that there are efforts being made to rectify these unintended consequences, ensuring seniors continue to benefit from innovative treatment options.



Adina Lasser

Alliance for Aging Research

Adina Lasser gave an overview of the upcoming changes to the Inflation

Reduction Act, or IRA. She explained that one of the IRA’s primary goals is to lower drug costs, particularly through the restructuring of the Medicare Part D program and the introduction of drug price negotiations.

But with these upcoming changes, Lasser highlighted patients must stay informed.

“Beneficiaries should keep a close eye and make sure their current plan is the best option for them.”

By 2026, the redesign will be in full effect, and the negotiated prices will be implemented. Even though long-term consequences remain uncertain, Lasser urged beneficiaries to stay up to date as reforms take place.

This panel was moderated by **Amanda Conschafter**, chief executive officer of *Woodberry Associates*.



Spotlight

The Patient Perspective



Julie Owens

Vision Health Advocacy Coalition

Julie Owens, a patient and advocate, shared her personal story about living with a rare disease.

Julie's experience living with a rare disease – and the lessons she has learned navigating the diagnostic process, insurance hurdles, and finding support for both physical and mental health support – had led her to advocacy work.

Despite the challenges she faced, and because of them, Owens embraced this new role as an advocate, speaking with legislators and working on behalf of other rare disease patients like herself.

She encouraged others to share their experiences.

“You're the best to tell your story.”

Julie Owens
Patient Advocate

“You are the research,” Owens emphasized. “You know what you have gone through. You're the best to tell your story.”

Owens urged patients with similar stories to lean into advocacy, highlighting the importance of patient voices in policy discussions that drive meaningful change to the health care system.

This discussion was moderated by **Olivia Perry**, coalition director for the *Alliance for Patient Access*.

Advocacy in Action



Josie Cooper

Alliance for Patient Access

Josie Cooper described how advocacy groups are constantly learning and improving how they engage with policymakers. An advocacy win in one disease state may provide guidance for a different disease state experiencing a similar challenge, she noted.

Cooper also highlighted several policy wins, emphasizing the value of ground support and local advocacy partners.

“We have a really developed community of advocates - patients, providers, advocacy partners,” Cooper said.

She also alluded to looming policy challenges, such as alternative funding programs and prescription drug affordability boards, and the need for advocates to be planning ahead to tackle these and other emerging threats.



Carl Schmid

HIV+Hepatitis Policy Institute

Carl Schmid talked about the wealth of treatments and cures across disease states like HIV and hepatitis. Patients and providers have more treatment paths than ever before, Schmid noted, but they need access to them.

Sometimes poorly conceived policies give health plans too much leverage in individual treatment decisions. Schmid emphasized the

importance of being creative and hitting the problem from all angles.

“Bringing the patient community together,” Schmid said, “and working with the media is important.”

Amplifying the voice of patients can demonstrate the real impact and harm caused by these policies, Schmid concluded, ultimately persuading policymakers to enact more patient-centered policies.



Ava Zebrick

Obesity Action Coalition

Ava Zebrick described her journey addressing her medical condition, facing medical debt and then ultimately being inspired to take on the role of patient advocate. Hearing others talk about her condition and the need for greater advocacy and awareness inspired her to pursue it as a career.

And Zebrick has seen the impact of patient voices.

“Infusing the patient voice,” Zebrick said, “is making a difference in these legislative visits.”

Patient advocacy plays an important role in shaping sound policy. From spreading awareness to engaging directly with legislators to fight for a bill, patient advocates are a crucial voice in their communities.

This panel was moderated by **Brian Kennedy**, executive director of the *Global Alliance for Patient Access*.



To learn more about topics discussed at the summit and the Alliance for Patient Access' policy priorities and advocacy initiatives, visit

AllianceforPatientAccess.org



Alliance for Patient Access

ABOUT THE ALLIANCE FOR PATIENT ACCESS

The Alliance for Patient Access is a national network of policy-minded health care providers advocating for patient-centered care.

AllianceforPatientAccess.org

