VIRTUAL

2020

NATIONAL POLICY & ADVOCACY

SUMMIT ON BIOLOGICS REPORT

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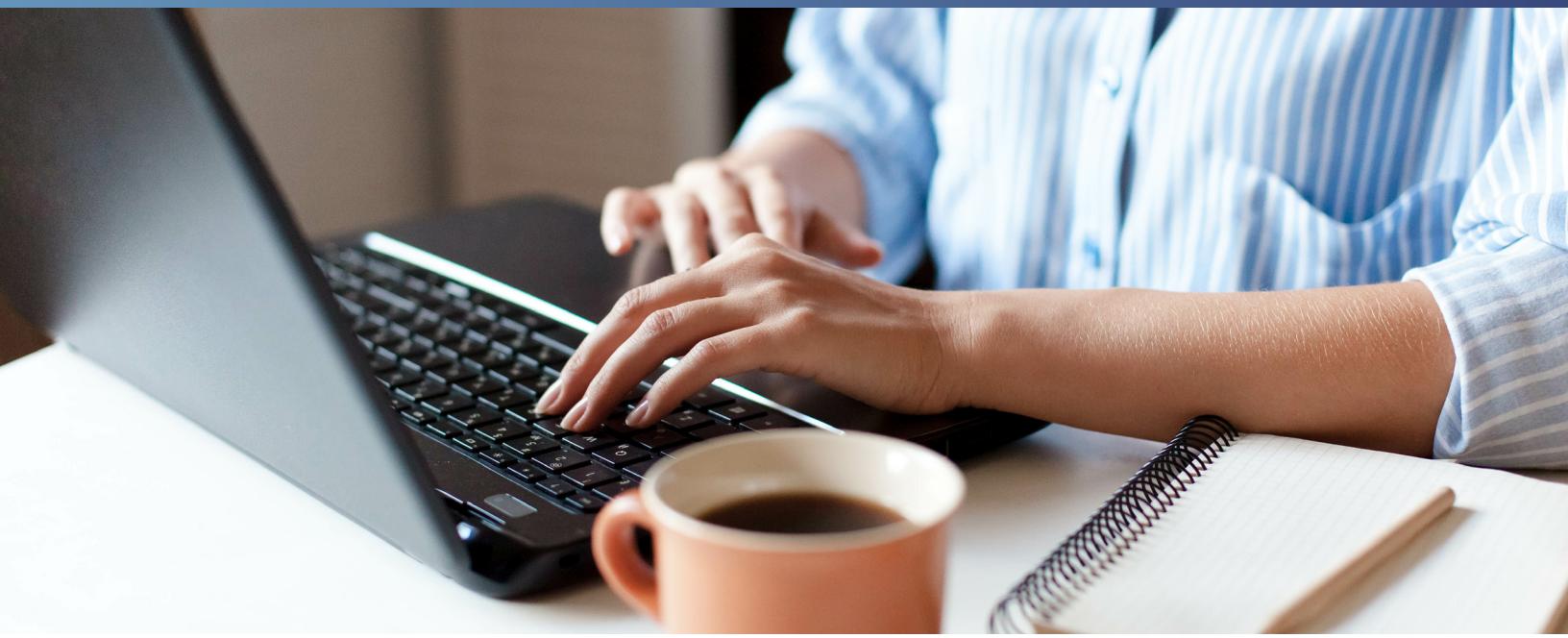

OVERVIEW

The fifth annual National Policy & Advocacy Summit on Biologics brought together health care providers, policy experts, patient advocates and other stakeholders. The event explored how sound public policies can facilitate the safe use of biologics in patient-centered care.

This year's event, held virtually, examined issues such as:

- What the 2020 election means for health care policy
- Biologics' role in treating cancer and migraine disease
- The lasting impact of COVID-19 health policy flexibilities
- Mental health and chronic disease
- Biosimilars' market uptake

David Charles, MD, founder of the *Alliance for Patient Access* and co-convener of the *Biologics Prescribers Collaborative* welcomed panelists and viewers. "While our dialogue today focuses on policy, this summit is more precisely about the people those policies impact – the patients and health care providers who rely upon biologic medicines," Dr. Charles noted.

The summit, which included a series of panel discussions, individual stories and interviews, was convened by the Biologics Prescribers Collaborative and hosted by the Alliance for Patient Access and the Institute for Patient Access.

DAVID CHARLES, MD
Alliance for Patient Access

2020 ELECTION & HEALTH CARE POLICIES

The highly anticipated presidential election laid the groundwork for a panel discussion of how health policy may evolve over the next four years.

Panelist **Alexander Ruoff** of *Bloomberg Government* outlined the potential impact of the Affordable Care Act case under review by the Supreme Court. The case revolves around Obamacare's individual mandate, Ruoff explained, but the larger protections and coverage that the Affordable Care Act provides are at stake.

The future of the Affordable Care Act could also impact biosimilar treatment options, because the legislation established the approval pathway for biosimilars. Panelist **Jennifer Snow** of *Xcenda* was asked what would happen to patients who use biosimilars if the Affordable Care Act was overturned.

"We would have a whole host of problems, especially during a pandemic," Snow said. She did not, however, foresee biosimilars' future being in jeopardy. "Biosimilars…are really well established," Snow noted, "and have bipartisan support."

Panelists also discussed the "most-favored nation" proposed approach to drug pricing, which seeks to lower U.S. drug costs by tying prices to those in other countries. Panelists agreed it will be interesting to see if President-elect Biden follows the Trump administration's lead on this approach.

Though panelists were skeptical about a divided Congress' ability to make meaningful policy change in 2021, Ruoff noted that lessons learned from the COVID-19 pandemic could encourage policymakers to keep health care issues front and center.

> **"During this pandemic, we have to make sure people have coverage. Right now, patients who need prescriptions drugs are not necessarily the priority, and we have to keep pushing to make them the priority."**
>
> **-Jennifer Snow**

Physician Perspective

BIOLOGICS & CANCER CARE

Biologic treatment options have benefited a range of disease states and patients. One important example is the field of oncology.

As **Jeffrey VanDeusen, MD, PhD**, of *AfPA's Oncology Therapy Access Working Group* explained, biologics allow oncologists to control or even halt cancer progression. In the past, patients could only delay cancer progression and buy themselves more time.

Biosimilars in particular have played a useful role by providing options among biologic treatments. Dr. VanDeusen gave the example of a patient developing an allergy to a biologic. Before the advent of biosimilars, the patient would have had to stop taking the effective medication. Because of biosimilar options, however, the patient may be able to continue treatment.

Dr. VanDeusen recalled first pursuing the field of oncology because he wanted to help patients and their families in difficult times. He credited biologic medications with allowing him to do so more effectively than ever before.

Patient Perspective

BIOLOGICS & MIGRAINE DISEASE

People living with migraine disease have also benefitted from biologic treatments.

Shirley Kessel of *Miles for Migraine* underscored the importance of biologic medication by sharing her family's inter-generational experience with migraine disease. Kessel reflected on her mother's debilitating struggle with the disease, which now affects Kessel and her daughters.

Kessel recalled being diagnosed at age 25, when treatment for migraine disease was limited to medications indicated for other diseases. Years later, Kessel's daughter was diagnosed with migraine disease and received the same off-label medication Kessel had 25 years prior. "This isn't fair," Kessel remembered saying to her doctors.

With the advent of biologic medication, Kessel's life with migraine disease improved. She also saw the treatment benefit her daughter, who previously could not go to school, work, prom or graduation because of migraine attacks. The introduction of the new medication, Kessel explained, allowed them to resume their lives.

COVID-19 & HEALTH CARE POLICY

COVID-19 spurred several policy changes designed to protect patients' access to care during the public health emergency. A panel of experts explored the value of these changes and considered which might remain intact even after the pandemic.

Kirsten Sloan of the *American Cancer Society Cancer Action Network* described the toll of COVID-19 on cancer care, reporting that fear of contracting the coronavirus has kept two-thirds of surveyed cancer patients from leaving their homes for treatment. Furthermore, Sloan reported, 50% of cancer patients said the office or clinic where they receive treatment was closing due to COVID-19 safety concerns.

Health plans have recognized the gaps in care and made some effort to help patients continue their treatment. **Patrick Stone** of the *National Psoriasis Foundation* specifically referenced how the expansion of telehealth has allowed continuity of care for patients. "In February, primary care visits averaged around 2,000 telehealth visits per month," Stone noted, "and by April that was up to 1.28 million."

Stone applauded the nimbleness of policymakers for making policy changes quickly in a time of need, but said there was still much to do to protect patient access. He highlighted co-pay accumulator adjustment programs as a particularly troubling barrier.

Dharmesh Patel, MD, of the *Partnership to Advance Cardiovascular Health* reiterated telehealth's role in ensuring that patients' conditions are not worsening. Dr. Patel emphasized that telehealth visits are not meant to replace in-person visits, but are there for patients to use as needed. Regarding patient anxiety about COVID-19 exposure, Dr. Patel made clear: forgoing treatment is much riskier. Some patients are dealing with diseases like heart failure, diabetes, cancer and psoriasis, Dr. Patel explained, and these conditions can aggressively progress without medical attention.

Addressing the patients in the virtual audience, Dr. Patel pleaded: Please don't wait for unfortunate things to happen. He urged people to continue treatment that could help prevent heart attacks, strokes or other dangerous outcomes.

Physician Perspective

MAINTAINING MENTAL HEALTH DURING A PANDEMIC

The COVID-19 pandemic has impacted the quality of mental health across the country. For patients with chronic disease, such as those frequently treated by biologics, the added strain can be a serious burden.

As psychiatrist **Rimal Bera, MD**, of the *University of California Irvine School of Medicine* observed, many people are experiencing abnormal levels of stress and anxiety during the pandemic. Uncertainty, he explained, is often the cause. People are unsure about their finances, health coverage, work, school or their family's health. Dr. Bera characterized the situation as a mental health pandemic within the larger COVID-19 pandemic.

Effects on mental health can contribute to other dangerous extremes like sleeplessness, eating disorders, domestic violence and suicide. But humans can conjure hope and resilience very well, Dr. Bera emphasized, and that is key to keeping a healthy mind.

Dr. Bera reminded people struggling with mental health challenges that they are not alone. "The best way we can take care of ourselves is by making sure we stay connected to others," he concluded.

Physician Perspective

SUCCESS OF BIOSIMILARS

Ensuring accessible treatment options requires a continually growing range of biologics, including biosimilars.

Madelaine Feldman, MD, of the *Alliance for Safe Biologic Medicines* outlined the issue of biosimilar uptake in the United States, the topic of a research study she recently co-authored. On the difference between biosimilar uptake in Europe as compared to the United States, Dr. Feldman emphasized that Europe had a full 10 years' jumpstart on the first biosimilar approval. Adjusting for the difference in timelines, Dr. Feldman explained, the United States keeps pace.

Dr. Feldman noted that, in the same number of years that Europe had approved 13 biosimilars, the U.S. surpassed them, approving 28 biosimilars. She emphasized the importance of innovation and a robust marketplace for biosimilars, which will create competition and ultimately bring down patients' cost sharing. "And that's the most important part," Dr. Feldman concluded.

BIOLOGICS & PATIENT-CENTERED CARE

By expanding options and offering more targeted treatments, biologics plays a critical role in personalized medicine and patient-centered care.

Some patient groups, however, are still waiting, hopeful for even one targeted treatment for their disease. **Annie Kennedy** of the *EveryLife Foundation for Rare Diseases* explained that an estimated 30 million Americans are living with rare disease, and of those, more than 93% lack any FDA-approved therapy. Lack of treatment options can be devastating for patients and their families.

Even if a treatment does become available, patients may still face access barriers because the drugs are difficult to develop and therefore expensive. Some rare disease patients think the fight is over when a drug finally becomes available, but cost sharing and coverage issues can prolong their struggle.

Chad Pettit from the *Amgen Biosimilars Policy Unit* noted that, over time, a robust market for biosimilars would help drive costs down for patients. This would especially help those rare disease patients access expensive therapies. He also emphasized how current regulations ensure the quality of biosimilars. Biosimilars are providing necessary treatment options, lower costs and hope for patients who might otherwise feel defeated, Pettit explained.

Cynthia Bens from the *Personalized Medicine Coalition* highlighted how having different treatment options can empower patients and their provider to tailor treatment plans. Bens emphasized that one medicine does not fit all. Rather, patients, like their conditions, are unique and should have treatment that reflects that fact.

Bens expressed concerns about organizations like the Institute for Clinical and Economic Review using value assessments that look only at population-level decision making from payers' and policymakers' perspectives. Those types of models only have negative consequences for patient access, she said.

To learn more about topics discussed at the summit and the Biologics Prescribers Collaborative's policy priorities and advocacy initiatives, visit www.biologicsprescribers.org.

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