The National Pharmaceutical Council is a health policy research organization dedicated to the advancement of good evidence and science, and to fostering an environment in the United States that supports medical innovation. Founded in 1953 and supported by the nation’s major research-based biopharmaceutical companies, NPC focuses on research development, information dissemination and education on the critical issues of evidence, innovation and the value of medicines for patients. For more information, visit www.npcnow.org and follow NPC on Twitter @npcnow.
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CHAIRMAN’S MESSAGE

It’s been an honor to serve as Board Chair for the National Pharmaceutical Council, an organization that plays a unique role in health care policy. Through evidence-based, peer-reviewed research and collaborative educational activities, NPC’s work provides a thoughtful approach to understanding our most pressing health care challenges.

During the last year, this approach was especially evident in discussions about the value of biopharmaceuticals and how to invest health care spending most effectively to improve patient outcomes. NPC’s work in analyzing value assessment frameworks provides a robust understanding of how a range of organizations are considering value, and how much more work is still required in this area. Health care stakeholders regularly look to NPC’s research and leadership in value assessment as they seek to develop comments and participate in conversations about value.

NPC also has led efforts to broaden the dialogue on health care spending through the Going Below The Surface Forum, support for Health Affairs’ “Considering Health Spending” series of articles and blogs, a conference, as well as roundtables and webinars hosted in partnership with

NPC’s work sets the tone for all stakeholders working to craft solutions for health care’s greatest challenges, and doing so in a way that is research-driven, collaborative, and with a steady eye on patient needs.
other organizations. By digging deeper into not just how we are spending our health dollars, but also examining how well we are doing so, NPC is bringing a new level of understanding to a complex policy area. In fact, the Going Below The Surface Forum is proof of NPC’s ability to bring together diverse stakeholders for constructive dialogue about difficult topics. There has been real progress during the past year, with Forum partners hosting regional town hall meetings and now undertaking projects to address low-value health care.

Additionally, NPC’s noted work to strengthen the use of real-world evidence (RWE) and modernize our payment and delivery systems continues. NPC is working closely with groups including the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) and Tufts University to move the field of RWE forward and provide input to the U.S. Food and Drug Administration (FDA) as the agency considers how to utilize RWE in decision-making. NPC’s engagement with MIT is aimed at finding workable solutions to vexing, system-wide financing problems.

I am excited to see NPC’s ongoing efforts to foster a constructive health policy conversation under the leadership of NPC’s 2020 Board Chair, Blasine Penkowski, Chief Strategic Customer Officer of Johnson & Johnson Health Care Systems Inc. NPC’s work sets the tone for all stakeholders working to craft solutions for health care’s greatest challenges, and doing so in a way that is research-driven, collaborative, and with a steady eye on patient needs.

Richard H. Bagger
Executive Vice President
Corporate Affairs and Market Access
Celgene Corporation (through December 2019)
Over the last several years, we’ve seen a steady flow of headlines reporting on innovative, life-changing therapies developed by biopharmaceutical companies, and 2019 was no different. For the NPC team, each leap forward has underscored the growing impact of innovation on the lives of patients and the imperative behind our organization’s efforts to generate high-quality health policy research and analysis.

Though 2019 brought noisy and intense debate over health spending and other pressing health policy issues, we were heartened to see stakeholders from across the landscape engage in and come together for a different kind of conversation – one rooted in thoughtful discussion informed by evidence.

Through our continued support of the Going Below The Surface initiative, patient groups, payers, providers, employers and life science organizations have all convened around a research-first discussion on health spending, driving meaningful conversations and rigorous health policy research that can help inform good decisions.

We were also proud to see NPC research put to good use. Our research was used to inform discussions at
conferences, cited by stakeholder groups, leveraged in collaborative working groups, and even used to support a discussion that culminated in an update to Internal Revenue Service (IRS) guidelines that will lower barriers to medication access for patients with chronic disease and potentially lower costs.

By the numbers, NPC had an incredibly fruitful year. Taken together, the team authored 14 new peer-reviewed studies and self-published reports, published numerous commentaries, submitted comment letters to regulatory agencies and decision-making bodies, and attended or presented at more than 48 conferences, webinars and other events.

We also welcomed new member companies this year, including Intercept Pharmaceuticals, Sarepta Therapeutics and UCB. They, and all of our member companies, are leaders in driving the kind of innovation needed to improve the lives of patients.

Reflecting on 2019, the most striking shift for me is seeing an appetite for a deeper, more thoughtful health policy conversation take hold, driven by a growing recognition that pithy talking points and clickable headlines simply can’t move us in the right direction to address the complex challenges we face in health care.

To achieve meaningful progress, stakeholders must equip themselves with evidence that can help them differentiate between solutions that appear as though they ought to work and solutions that are geared to truly deliver the improved outcomes, better value and lower spending that we all seek. That makes NPC’s mission to explore, demonstrate and communicate – through research, education and partnerships – the role and value of innovative biopharmaceuticals to achieve better patient health as vital today as ever.

Dan Leonard
President and Chief Executive Officer
National Pharmaceutical Council
NPC IN 2019: DRIVING RESEARCH, CONVENING STAKEHOLDERS TO TAKE ON HEALTH CARE’S GREATEST CHALLENGES

The National Pharmaceutical Council’s research and educational activities are focused on addressing four key areas in health care: evidence, value, access, and innovation and health spending.

We’re committed to tackling some of the most complex topics in health care, including questions such as: How can we address the rising costs faced by patients, especially those who are covered under high-deductible health plans? How can health system decision-makers, including payers, employers and pharmacy benefit managers, reliably make decisions informed by good quality evidence? As we seek to reduce the use of low-value care and better drive use of high-value health care services, are we appropriately weighing what’s important to patients when we try to define “value?”

Within this report, we capture how NPC’s health policy research, analysis and education efforts are contributing to critically important discussions around some of the thorniest issues in health care.

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NPC Chief Science Officer Robert Dubois speaks at the AcademyHealth National Health Policy Conference.
To accelerate biopharmaceutical innovation, improve the quality of health care delivered, and make health care delivery more efficient requires high-quality evidence about what works for whom. Too often, there is limited information. That is why there is growing interest in learning from real-world data from everyday patient interactions with the health system found in electronic health records, clinical laboratories, diagnostic testing, claims and pharmacy dispensing records. Studies and analyses gleaned from this data, known as real-world evidence (RWE), can help determine how treatments work in typical patients in everyday care settings.

But RWE can only be useful if it rigorously adheres to sound and widely accepted methodologies, the underlying data is high-quality, and it is recognized and used by decision-makers. That’s why NPC is advancing the dialogue on evidence, focusing on improving the quality of evidence developed and breaking down barriers to its use.

Among our efforts, NPC has actively engaged in the ongoing development of the framework for how the FDA may use RWE to inform drug labeling and approvals. To aid in those efforts, NPC is partnering with the RWE Transparency Initiative, led by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), to provide practical tools to enhance research methods transparency and raise the credibility and trust of RWE results.

Studies and analyses gleaned from this data, known as real-world evidence, can help determine how treatments work in typical patients in everyday care settings.
Despite improvements in RWE methodological standards, NPC research found significant variation in the consistency, volume and types of evidence used to guide health plan coverage policies that impact patient access to treatment. To overcome barriers to more routine use of high-quality evidence, NPC staff have actively participated in multi-stakeholder groups to update best practices in developing coverage policies at health plans, and in the development of the Academy of Managed Care Pharmacy’s (AMCP) updated *Format for Formulary Submissions*. The Format is a system that has enabled the biopharmaceutical industry to share information more easily with health plans in compliance with FDA regulations.

And NPC’s body of work on high-quality evidence standards has served as a resource for stakeholders, cited and used by the FDA and the National Academies of Science. Our peer-reviewed studies on evidence topics published in 2019 served as catalysts for discussion with partners on important RWE initiatives, and at conferences and educational forums.

**Additional Research**


- **Academy of Managed Care Pharmacy (AMCP) Partnership Forum: Managing Total Cost of Care Through Medical and Pharmacy Data Integration**, *Journal of Managed Care & Specialty Pharmacy*, March 25, 2019.


*NPC Vice President for Comparative Effectiveness Research Jennifer Graff was a frequent speaker on real-world evidence topics at conferences and meetings in 2019.*
VALUE

Value measurement and assessment should encompass the balance of benefits and costs experienced by patients and society over time.

Many organizations look to NPC’s work on value assessment for guidance as they consider how to respond to the Institute for Clinical and Economic Review’s (ICER) reports, provide resources to their own members and educate others about this topic. In fact, NPC’s studies are frequently cited by other organizations in comments submitted to ICER and in their newsletters, helping to broaden conversations about how to measure the value of all treatments, not just medicines. Although we remain concerned about its overall process, ICER has made changes to its framework based on NPC’s recommendations, including issuing a call for non-drug assessment topics in 2020. NPC’s experts also are frequently quoted in the media and asked to present at public forums on value assessment.

In October, we released Current Landscape: Value Assessment Frameworks, which calls attention to a variety of value assessment methods. The new analysis was widely shared over social media, downloaded by thousands of key stakeholders and distributed at meetings, including the STAT Summit, which NPC supported as a sponsor.

Many organizations look to NPC’s work on value assessment for guidance as they consider how to respond to the Institute for Clinical and Economic Review’s reports, provide resources to their own members and educate others about this topic.
In addition to numerous blog posts and commentaries, NPC’s research team generated two peer-reviewed studies on this topic:

- **Novel Approaches to Value Assessment Beyond the Cost-Effectiveness Framework**, *Value in Health*, June 20, 2019.

- **As Value Assessments Evolve, Are They Ready for Prime Time?*, *Value in Health*, July 31, 2019.

Value assessment is not NPC’s only focus in the value space. We also continued our work addressing barriers to value-based arrangements (*Value-Based Arrangements May Be More Prevalent Than Assumed*, *The American Journal of Managed Care*, February 13, 2019), along with pushing for accountability when data is misused to generate faulty analyses (*Rx Drug Costs: List Prices Versus Net Prices and the Importance of Staying Within the Data*, *Health Affairs Blog*, March 1, 2019).

In October, we released *Current Landscape: Value Assessment Frameworks*, which calls attention to a variety of value assessment methods.
For patients, accessing the right care can require navigating a maze of challenges – prior authorization, step therapy, high deductibles – instituted by employers and payers seeking to manage drug utilization and costs. While health coverage is a critical gateway to access, patients with health insurance can find that these challenges become real barriers that delay or bar access to appropriate treatments. In turn, blunt measures designed to manage drug utilization can compromise patient care and health, and ultimately lead to higher overall spending to manage the downstream consequences of poorer health or hospitalizations.

NPC’s research is aimed at equipping decision-makers with evidence and analysis needed to craft effective payment and delivery models that recognize this potential for unintended consequences, individual patient differences and the need to ensure meaningful access to appropriate medicines.

In the case of high-deductible health plans (HDHPs), NPC-supported research was a catalyst in 2019 for an executive order and IRS guidance that allowed health savings account-eligible HDHPs the flexibility to cover essential medicines and services used to treat chronic diseases prior to meeting the deductible.

While health coverage is a critical gateway to access, patients with health insurance can find that these challenges become real barriers that delay or bar access to appropriate treatments.
In addition to focusing on benefit design, NPC has highlighted the challenges associated with formulary restrictions such as step therapy. NPC has responded via public comment to the Centers for Medicare and Medicaid Services’ (CMS) proposals to increase the use of step therapy in Medicare Advantage and Medicaid Fee-for-Service programs and convened a multi-stakeholder roundtable to develop key principles for step therapy. These principles have been shared at forums hosted by payer and policy groups.

**Additional Research**

- **U.S. Care Pathways: Continued Focus on Oncology and Outstanding Challenges**, *The American Journal of Managed Care*, June 18, 2019.


- **Access to Care: Development of a Medication Access Framework for Quality Measurement**, Pharmacy Quality Alliance (PQA)/NPC White Paper, March 14, 2019; on November 19, 2019, NPC and PQA announced an RFP for research that builds off this report.

In 2019, the rapid pace of development and approval of gene therapies and other innovative new treatments continued to outstrip the ability of our health care delivery and payment system to keep pace.

New treatments highlight the challenges and complexities of our health care delivery system and the need for research-based policies that can maintain an ecosystem that encourages further discovery and progress.

NPC partnered with MIT’s NEW Drug Development ParadIGmS (NEWDIGS) Initiative to host a day-long conference in Washington D.C., “Paying for Cures: Ensuring Patient Access and Sustainability,” to spur meaningful dialogue on ways to develop precision financing solutions for durable and potentially curative therapies. Beyond the conference, NPC staff has been active participants in NEWDIGS programs to develop and test financing concepts.

NPC also spearheaded and published a peer-reviewed study in the January issue of Health Affairs, What’s Been the Bang for the Buck? Cost-Effectiveness of Health Care Spending Across Selected Conditions in the U.S. The research put into perspective the value of innovative treatments over time, adjusting health spending figures for top diseases for inflation and prevalence, and evaluating spending against improvements in patient health. The study was cited in the New York Times, Chain Drug Review, and in a Health Affairs commentary, while the supporting resource materials developed by NPC have been used by member companies in presentations and briefing documents.

The research put into perspective the value of innovative treatments over time, adjusting health spending figures for top diseases for inflation and prevalence, and evaluating spending against improvements in patient health.
Additional Research


- **Reconciling the Seemingly Irreconcilable: How Much Are We Spending on Drugs?**, *Value in Health*, January 11, 2019.


Dr. Dubois (right) discusses value assessment with Institute for Clinical and Economic Review COO Sarah Emond and Financial Times Correspondent Hannah Kuchler at the FT Pharma Pricing and Value Summit in New York City.
Health Care Spending and Value Initiative

NPC’s focus on health spending also includes a partnership with *Health Affairs*, a multifaceted collaboration aimed at driving discussion through the *Health Affairs* Council on Health Care Spending and Value, and support, in conjunction with Anthem, Inc., for the “Considering Health Spending” article and blog series. In September, NPC partnered with *Health Affairs* to host a conference at the National Press Club in Washington, D.C., “Health Spending: Moving From Theory to Action.”

In 2019, NPC fostered discussions on health spending that reflect the complexities that need to be addressed and the thoughtful, research-first solutions required for real progress. NPC brought together a group of 20 diverse stakeholder organizations as part of the *Going Below The Surface* Forum, to get to the root of what is driving health care spending in the United States, seek solutions and take actionable steps. The Forum and its partners hosted a

NPC President and CEO Dan Leonard (center) participates in a panel discussion with CMS Administrator Seema Verma and POLITICO reporter Dan Diamond at the Milken Institute’s Future of Health Summit.

In 2019, NPC fostered discussions on health spending that reflect the complexities that need to be addressed and the thoughtful, research-first solutions required for real progress.
NPC hosts webinars on a variety of topics, including one on quality measures featuring experts from Discern Health (pictured here with NPC’s Kimberly Westrich, left).

NPC Vice President of Research Michael Ciarometaro has focused on health care financing reforms and works closely with MIT’s NEWDIGS Initiative.
Some of NPC’s research and program initiatives cut across all four of our goal areas, such as continuing our health policy fellowship, responding to federal agencies’ requests for comment and communicating our research via e-newsletters, commentaries and presentations.

In addition to presenting at or sponsoring more than 80 conferences and meetings in 2019, NPC was pleased to continue ongoing programs to advance health care policy research. Foremost among these is our fellowship program in partnership with the Duke Robert J. Margolis, MD, Center for Health Policy. Our current fellow, Taruja Karmarkar, PhD, MHS, is in the second half of this two-year program, studying step therapy practices used by health plans and modeling alternative payment mechanisms for curative therapies. A new fellow, the fourth since NPC began the program, will begin in July 2020.

NPC expanded efforts to take an evidence-based approach in responding to federal agencies’ requests for comment or information.
requests for comment or information. When NPC’s research has been able to inform on relevant policy issues put forth by the U.S. Department of Health and Human Services, CMS and others, NPC has submitted responses.

NPC shared research and activities via a broad array of communications efforts. We remained active on social media channels like Twitter, Facebook and LinkedIn; created graphic versions of our research for easy sharing; and provided archived footage of our many webinars and other video content via our YouTube channel. In addition, NPC continued to offer the CER Daily Newsfeed®, a daily summary of RWE and health policy research activities and news from around the world, E.V.I.dently®, our monthly e-newsletter, as well as daily topic alerts when new content is posted on our blog. NPC executives penned columns published in news outlets such as Specialty Pharmacy Times, Chain Drug Review, STAT and Morning Consult, among others. All these resources contain a wealth of information about how the biopharmaceutical industry’s most pressing issues impact patient health.
NPC is a member-based non-profit organization supported by leading biopharmaceutical companies committed to facilitating research that is rigorous, timely and gets to the heart of pressing health policy issues. NPC does not engage in political advocacy. Rather, like a think tank, NPC conducts health policy research frequently published in respected peer-reviewed journals, and regularly engages in multi-stakeholder initiatives, conferences and other industry dialogues.

Each member company is represented on NPC’s Board of Directors and helps to shape the research agenda through participation on various board-level committees, and on the Research Work Group and Strategic Communications Work Group.

In addition to NPC’s public resources, materials developed solely for NPC members include executive briefs detailing the impact of developments in the health care landscape on the biopharmaceutical industry. Educational resources, practical tools, analytical papers and other information are housed in the members-only section of the NPC website.

CMS Administrator Seema Verma and former FDA Administrator Scott Gottlieb were among health policy experts who addressed NPC’s Board of Directors in 2019.
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