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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In a year marked by exciting advances in health care, it has been my pleasure to serve as the Chairman of the Board of Directors for the National Pharmaceutical Council (NPC).

And as Chairman, I am proud of our work. NPC leveraged its highly regarded position as a health policy organization to convene health care stakeholders for a critically important effort to dig deeper on health care spending issues.

Our Going Below The Surface (GBTS) initiative is a research-first endeavor dedicated to unearthing and examining the drivers of health care spending in the United States. Through this initiative, NPC assembled a diverse group of stakeholders committed to moving past finger-pointing and negative rhetoric in order to explore health care spending with fresh eyes. With 20 partner organizations (and growing), GBTS offers much-needed discussion and collaboration to address difficult questions. NPC’s broader Health Care Spending and Value initiative also made strides in approaching health spending from a different angle. Jointly supported by NPC and Anthem, Inc., our partnership with Health Affairs facilitated a February 2018 conference, Health Spending: Tackling the Big Issues, and funded research to shed light on this important topic.
In addition, NPC utilized our Evidence, Value, Access and Innovation research to contribute important insights to regulatory rule-making efforts. NPC submitted comments to the Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration (FDA), and the Department of Health and Human Services (HHS) to facilitate research-based consideration of health policy proposals that may impact health care for years to come. NPC’s research and resources on these crucial topics will continue to be important in 2019, as they have been for the last 65 years – a milestone anniversary NPC celebrated in May.

As we shift to a value-based health care system, NPC continues to press health care stakeholders to carefully consider when and how to appropriately use value assessment frameworks. When CVS Health announced it would allow employers to exclude from their formularies medicines launched at a price greater than $100,000 per Quality-Adjusted Life Year (QALY), NPC engaged quickly. In a critique published in the Health Affairs Blog, NPC cautioned CVS and other health care stakeholders that using a single cost-effectiveness threshold misses elements of value important to patients and could hamper patient access to innovative medicines.

I am very pleased with NPC’s accomplishments over the past year and I look forward to our continued leadership in health policy research under the guidance of 2019 Chairman Richard H. Bagger, Executive Vice President, Corporate Affairs and Market Access, Celgene Corporation. Although 2019 will surely be a busy year in health care, I am certain that NPC’s continued work to advance health policy research and convene stakeholders will foster an environment that encourages innovation, improved patient outcomes and better health care delivery.

Mark J. Nagy
Vice President, Global Patient Outcomes & Real World Evidence
Eli Lilly and Company
As the policy debate about health care system and payment reform intensified in 2018, NPC filled an important role in the discussion by supporting and conducting peer-reviewed research focused on evidence, the value of medicines and access for patients, and innovation and health care spending.

After announcing NPC’s Health Care Spending and Value initiative at the end of last year, we kicked off 2018 with a conference, Health Spending: Tackling the Big Issues, as part of our partnership with leading policy journal Health Affairs. The event convened a crowd of more than 450 to ask critical questions about how the United States invests its health dollars – more than $3 trillion in spending a year – and what information needs to be considered as both providers and purchasers of health care services contemplate their investments within the system.

The conference was just an introduction. NPC’s series on “Considering Health Spending” in Health Affairs and the Health Affairs Blog (co-supported by Anthem, Inc.), membership in Health Affairs’ Council on Health Care Spending and Value, and the launch of the Going Below The Surface initiative exploring how we use health care resources in the United States all brought our Health Care Spending and Value initiative to the forefront this year.
NPC continued to use our research to offer incisive comments to governmental agencies seeking policy advice, submitting comments to HHS on the anti-kickback statute and its health care blueprint, as well as comments to CMS on new directions for its Innovation Center.

Our outreach is making a difference: The FDA released two final guidance documents that reflected changes — in some cases verbatim — that NPC raised via our longstanding research, public testimony and comments on asymmetry in communicating comparative effectiveness research.

In 2018, NPC’s research and communication teams authored 10 articles and white papers; wrote nearly 20 pieces of commentary and comment letters; and presented our work on evidence, value, access and innovation at more than 80 conferences, webinars, and other speaking events. NPC also continued to be cited in numerous media outlets as an expert voice on these critical topics.

I was also thrilled to welcome four biopharmaceutical companies to NPC’s growing membership roster: AstraZeneca; Gilead Sciences, Inc.; Horizon Pharma plc.; and Spark Therapeutics, Inc., bringing NPC’s membership up to 24 members composed of the leading research-based biopharmaceutical companies that are working to find innovative treatments to improve patient health.

In 2018, we celebrated our 65th anniversary as a health policy research organization. Looking ahead to 2019, I know NPC is up to the task of leading research and conversations with a broad range of stakeholders that will help move the field forward.

Dan Leonard, MA
President and Chief Executive Officer
National Pharmaceutical Council
NPC in 2018: Shaping a Research-based Conversation in Health Care

As a leader in health policy research, NPC uses research, communications and educational outreach to examine critical issues of Evidence, Value, Access and Innovation. NPC’s goals and supporting objectives continue to focus on four primary areas: the availability and acceptance of high-quality evidence to support decision-making, value assessment that encompasses the balance of benefits and costs experienced by patients and society over time, meaningful access to appropriate treatments for patients, and a health care spending ecosystem that promotes sustainable patient access to innovative care. Read on to learn how NPC’s work in these areas is changing the health care conversation to help patients achieve better health.

NPC shared its research at more than 80 conferences and events in 2018, where NPC staff discussed the latest health policy topics with health care stakeholders.
65 Years of Smarter Health Policy Conversations

From NPC’s earliest work on Medicaid to its most recent work on health care spending, NPC has been a leader in health policy research for 65 years.

NPC’s cutting-edge body of policy research continues to grow and evolve under a pressing imperative. The pace of biopharmaceutical innovation has simply outrun the pace of innovation in health care financing and delivery. This growing gap is not acceptable for those within the health sector who are committed to promoting better outcomes for patients.

NPC’s earlier research on issues like medication adherence, formularies and individual patient differences has served as an important building block for the issues we face in the health care sector today.

NPC’s work will build on its 65-year legacy and continue to tackle difficult issues and inform important conversations about novel approaches to payment and health care delivery.

NPC President and Chief Executive Officer Dan Leonard, left, shares a conversation at NPC’s 65th Anniversary reception with Richard H. Bagger, Executive Vice President, Corporate Affairs and Market Access, Celgene Corporation, who served as Vice Chair and Treasurer on NPC’s 2017-2018 Board of Directors, and former NPC Board Chair Kevin Rigby.
Today, NPC’s research priorities reflect critical shifts that have occurred in the health care landscape over the last decade. NPC’s research has deepened the visibility and understanding of topics like real-world evidence, the value of biopharmaceuticals, overlooked challenges in access to care, and the importance of continued innovation across all sectors of our health care system.

To keep up with innovations in science and health, such as immunotherapies and gene technologies – and future cures for other complex conditions – NPC’s work will build on its 65-year legacy and continue to tackle difficult issues and inform important conversations about novel approaches to payment and health care delivery. With this research, NPC can help ensure patients can take advantage of new therapies and benefit from the biopharmaceutical sector’s deep commitment to improving the lives of patients.

NPC marked its anniversary with a reception held in Washington, D.C.

At a reception honoring NPC’s 65 years of health policy research, attendees shared in celebrating NPC’s deep history in health policy.
Evidence: Advancing a Fuller Picture of Treatments

For clinicians, an incomplete picture of a patient’s history can make the job of treating the patient enormously difficult. Similarly, the decisions made by regulators or payers can miss the mark without robust and complete evidence around treatments. To garner a fuller picture, NPC has worked to advance the dialogue on evidence, focusing on four key areas: using real-world evidence (RWE), standards for generating RWE, accessing data and exchanging evidence.

RWE can provide valuable information that deepens the knowledge gained in clinical trials. Yet, it is not always widely understood and is only useful when it is based on sound methodology and of high quality. Research from the Department of Pharmaceutical Health Services Research at the University of Maryland School of Pharmacy and NPC revealed that RWE is considered valuable by the editors of peer-reviewed journals — if it meets certain criteria for quality. Published in the International Journal of Technology Assessment in Health Care, the study provides insight into how journal editors regard and assess RWE studies, and offers guidance on ways to increase respect for and understanding of RWE.

Understanding how treatments work in the real world is an important and complex task to guide the appropriate use of biopharmaceuticals available for typical patients in real-world clinical practice environments.

During a panel discussion at the International Society for Pharmacoeconomics and Outcomes Research’s Annual Meeting in May 2018, NPC Vice President of Comparative Effectiveness Research Jennifer Graff (second from right) shared NPC’s research on the future of real-world evidence.
The ability of biopharmaceutical companies to exchange evidence remains a vital topic for NPC, and we saw encouraging steps by the FDA to clarify rules around the communication of evidence. The agency issued two final guidance documents on the communication of health care economic information and communication to payers regarding unapproved products or unapproved uses to assist planning and budgeting. These positive changes could pave the way for more value-based contracts, efficient coverage determinations and robust health care decision-making. The FDA also released a framework for evaluating the use of RWE to satisfy the requirements of the 21st Century Cures Act, which marked a critical step in the FDA’s efforts to use RWE in assessing efficacy. In addition to NPC’s research, testimony and comments on these topics, some of which were cited in the FDA’s guidance documents, NPC raised awareness among health policy audiences with blog posts and a members-only webinar, and participated in workshops and conferences on evidence communication, generation and standards.

These highlights, among NPC’s many commentaries, presentations and educational activities surrounding evidence and its communication, mark 2018 as one of NPC’s busiest years yet in emphasizing RWE’s value and utility in health care conversations.

**Published Work:**

Paying for prescription medicines based on their value to patients is increasingly seen as a promising approach to combat health care costs. But who defines value and how is it measured?

In 2018, NPC’s research and education efforts advanced the conversation in both value assessment and value-based agreements. An NPC white paper, *Regulatory Barriers Impair Alignment of Biopharmaceutical Price and Value*, identified four areas hampering biopharmaceutical manufacturers and payers from developing value-based agreements. The white paper was also the subject of a webinar and multiple conference presentations, and was cited in comments submitted to HHS and CMS as the agencies considered regulatory changes impacting barriers identified in the white paper.

In the value assessment space, NPC continued building a robust portfolio of work focused on engaging with framework developers on ways to improve their methodologies, involve patient organizations and use a broad range of evidence-based considerations, as outlined in NPC’s *Guiding Practices for Patient-Centered Value Assessment*.

*NPC Vice President of Health Services Research Kimberly Westrich shares forthcoming NPC research at the Pharmacy Quality Alliance’s Social Determinants of Health Forum in November 2018.*
In a move that ran counter to principles defined in the *Guiding Practices*, CVS Health announced that it would allow employers to exclude from their formularies medicines launched at a price greater than $100,000 per Quality-Adjusted Life Year (QALY), as informed by reports from the Institute for Clinical and Economic Review. NPC Chief Science Officer and Executive Vice President Robert W. Dubois, MD, PhD, penned an article published in the *Health Affairs Blog* that outlined the pitfalls of the policy, highlighting that using just a single cost-effectiveness threshold misses elements of value important to patients and could hamper patient access to innovative medicines.

One size doesn’t fit all in value assessment, and NPC’s work to engage stakeholders and hold decision-makers accountable to patient-centered practices in value assessment is key to ensuring value-based approaches yield positive changes across the health care sector.

**Published Work:**


Access: Keeping Doors Open for Patients

Innovation in health care opens countless doors. Conditions that would have been fatal mere decades ago can now be prevented or cured, and many chronic conditions can now be managed with medication and/or therapeutic treatment to slow disease progression and improve quality of life. However, barriers to access can put those treatments out of reach for patients. Hurdles like high-deductible health plans, which require patients to pay more out of their own pockets; increasingly narrow lists of medications that insurers will pay for; and complex approval processes, such as prior authorization review or step therapy (requiring a patient to try one medicine before receiving approval to use another), can all limit patients’ ability to access the best treatment for their condition.

Providing pre-deductible coverage for medicines used to treat common chronic conditions may provide an opportunity to improve access to medications for patients. An issue brief developed with VBID Health outlined how doing so could lower out-of-pocket costs and increase medication adherence for patients – which could impact more than 40 percent of Americans enrolled in high-deductible health plans.

As the volume on the health spending conversation continued to rise, NPC’s research and activities in 2018 offered evidence-based considerations for decision-makers to help ensure patients encounter open doors to the treatments they need.

NPC Chief Science Officer and Executive Vice President Robert W. Dubois shared NPC’s key messages on Evidence, Value, Access and Innovation at events around the country throughout 2018.
NPC’s work in 2018 also explored how these barriers to access and care impact patients by looking at how health plan coverage choices affect them — and how a lack of continuity between plans can be harmful. A study published in *Health Affairs* from the Center for the Evaluation of Value and Risk in Health at Tufts Medical Center and NPC found that coverage of specialty medicines by major U.S. commercial health plans varies widely, which can disrupt patient care if they change plans or jobs. Given the wide variation among plans, these findings reveal the need for greater transparency in the evidence used to determine plan coverage decisions.

Important takeaways from NPC’s research were recognized throughout the year by other health care stakeholders engaging in conversations focused on access. In March, the Integrated Benefits Institute hosted a webinar on the challenges facing employers in working with their pharmacy benefit managers and what steps employers can take to better manage those relationships, a presentation based on NPC’s 2017 publication *Toward Better Value*. NPC’s work also was cited in the President’s Cancer Panel report, *Promoting Value, Affordability, and Innovation in Cancer Drug Treatment*, along with the numerous other publications and educational resources that referenced NPC’s work.
As the volume on the health spending conversation continued to rise, NPC’s research and activities in 2018 offered evidence-based considerations for decision-makers to help ensure patients encounter open doors to the treatments they need.

**Published Work:**


Innovation: Fostering Progress That Improves the Lives of Patients

Fostering an environment that nurtures continued discovery and development of new medicines that improve patients’ health and their quality of life requires research-based policymaking. Poorly considered efforts to re-tool health care delivery risks stifling the discovery driven by biopharmaceutical companies and access to life-changing treatments for patients.

NPC’s research has built an important evidence base to help health policymakers ensure that innovation in the health care delivery system can keep pace with innovation generated in the lab.

NPC/Duke-Margolis Center for Health Policy Research Postdoctoral Health Policy Fellow Taruja Karmarkar and NPC Vice President of Research Michael Carametaro share a conversation about innovation in health care in NPC’s office.
Research from RTI Health Solutions and NPC, “The Effect of Medical Technology Innovations on Patient Outcomes, 1990-2015: Results of a Physician Survey,” published in the Journal of Managed Care & Specialty Pharmacy, surveyed physicians about their perceptions on which areas of innovation have impacted patient outcomes the most over the past 25 years. More than half of physicians attributed the greatest shifts to pharmaceuticals/biopharmaceuticals, suggesting we may be under-investing in the most valuable facet of health technology.

Exploring creative approaches to understanding health care spending, and exploring the role that medical innovation should play in our health care dollars going forward, dominated all areas of health care this year, particularly when HHS issued a request for information on its Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. NPC submitted comments suggesting the department address the barriers to effective value-based contracting, improve transparency with pharmacy benefit management agreements, consider how and by whom value should be determined, explore alternate financing models, improve data access, and consider the long-term value of pharmaceuticals, among other recommendations – all of which offer room for thoughtful conversation on health care spending while still recognizing the value of cutting-edge treatments and revolutionary new medical tools.

NPC also worked to broaden the dialogue on novel approaches to payment and financing that adapt to significant leaps in biopharmaceutical innovation. In an article for Pharmaceutical Executive, NPC and Massachusetts Institute of Technology (MIT) researchers discussed the needs of patients with very rare diseases who require specific cell and gene therapies, and the growing imperative to develop novel financing approaches that manage the disconnect between short-term treatments and extended/uncertain periods of benefit.

Beyond research, NPC also participated in conversations addressing these important questions, such as the Academy of Managed Care Pharmacy (AMCP) Partnership Forum on Designing Benefits and Payment Models for Innovative High-Investment Medications. NPC continued its involvement with the MIT New Drug Development Paradigms (NEWDIGS) initiative that seeks creative ways to think about all aspects of health care and will cosponsor NEWDIGS’ conference on innovative payment systems in February 2019.
The challenges in balancing the many needs of a successful health care system are intimidating, but not insurmountable. Through its research, commentaries, presentations and webinars, NPC has furthered the dialogue on how to balance the complexities of modern health care with preserving the proven impact of biopharmaceutical innovation.

Published Work:


Digging Deeper on Health Care Spending and Value

The growing din of debate on health care costs has yet to translate into sustainable solutions. To help shape a more meaningful dialogue, NPC launched its multipronged Health Care Spending and Value initiative at the end of 2017 to start a serious conversation designed to favor research over finger-pointing and holistic perspectives on spending drivers over simplistic talking points. As part of this research-first initiative, NPC authored work exploring key topics in the health care conversation, including peer-reviewed research on the long-term impact of biopharmaceuticals on patient outcomes over time, a Health Affairs Blog post on the limitations of data commonly used in international comparisons of health spending, and projects exploring health care trade-offs.
NPC also partnered with *Health Affairs* to facilitate research, education and conversation on health spending issues. The partnership kicked off with a conference in February, *Health Spending: Tackling the Big Issues*, convening a crowd of more than 450 to explore the tough questions that need to be addressed. NPC is also co-sponsoring with Anthem, Inc., the ongoing *Health Affairs* “Considering Health Spending” series in its journal and on the *Health Affairs Blog*. The endeavor has yielded more than 50 articles and blog posts since its inception in December 2017.

Timed with the conference, NPC launched a new signature initiative, *Going Below The Surface* (GBTS), to broaden and improve the conversation around how we use health care resources in the United States. The GBTS website created as part of this initiative serves as a platform for dialogue where complex topics have been explored through research, including how to address low-value care, willingness to pay for health care services among various stakeholders, health care allocation and international comparisons of health care spending.

The GBTS Forum, an extension of the initiative’s research and education work, brings together an expert group of 20 partner stakeholders from all segments of health care, creating a forum to look for areas of shared interest and agreement without shying away from asking tough “third rail” questions.
The *Health Affairs* Council on Health Care Spending and Value (also supported in partnership with Anthem, Inc.) was announced this year. The Council, made up of a group of diverse health care thought leaders including NPC’s Dr. Dubois, will examine the different drivers of health care spending. Over the next three years, the Council will provide actionable recommendations for how legal, regulatory and policy changes can be used to tackle our nation’s health spending crisis.

Another important component is NPC’s partnership with AcademyHealth to bring a different perspective to the health care spending discussion. The partnership includes a series of invite-only salons aimed at executives willing to have a high-level dialogue about health care spending and value. AcademyHealth and NPC are also hosting a webinar series to promote serious evidence-based discussions related to costs, value and allocation of health care spending, and how those expenditures can best generate improved health outcomes.

NPC will continue to build on the momentum created in 2018 to foster solutions to health spending that recognize the interconnectedness of health care services and the need for sustainable, patient-centric approaches.
NPC News, Programs and Outreach: Fostering Discussion Around Research

NPC’s body of research was brought to life through a robust array of outreach and education activities in 2018.

NPC’s experts brought research and analysis to more than 80 conferences and events through presentations and moderation of panel discussions on topics including real-world evidence, value-based contracting and value assessment frameworks. NPC’s research staff also contributed to cooperative committees and forums, such as the Academy of Managed Care Pharmacy’s (AMCP) Format Executive Committee. NPC’s expertise was also in demand at conferences and trainings, such as NPC’s nine panels and poster presentations at the International Society for Pharmacoeconomics and Outcomes Research’s (ISPOR) Annual Meeting, further broadening NPC’s reach.

NPC Vice President of Comparative Effectiveness Research Jennifer Graff received AMCP’s Spirit of Volunteerism Award, and was accompanied by several NPC colleagues. From left to right: Kathryn A. Gleason, Lisabeth Buelt, Jennifer Graff, Dan Leonard, Virginia Sweeter and Tanya Bailey.
NPC hosted or co-sponsored with partner organizations five public-facing webinars that offered deeper dives into NPC’s latest research and opportunities to directly interact with study authors and subject matter experts. NPC wrapped up a long-term effort – the CER Collaborative – to train health care decision-makers in assessing and synthesizing comparative effectiveness research for use in making health care and coverage decisions. More than 400 professionals have been trained through this continuing education certificate program since its inception. In 2018, AMCP incorporated content from the CER Collaborative’s program and tools to manage evidence in its online Managed Care 101 program.

NPC also welcomed 2018-2020 NPC/Duke-Margolis Center for Health Policy Research Postdoctoral Health Policy Fellow Taruja Karmarkar, PhD, MHS, as she begins a two-year fellowship seeking to bridge the gap between health research and health policy development and analysis. Dr. Karmarkar’s research seeks to ensure timely access to appropriate medicines for patients using both existing and novel payment approaches. This includes developing best practices for step therapy policies used by health plans as well as modeling alternative payment mechanisms for curative therapies.

As NPC welcomed Dr. Karmarkar, the staff said goodbye to University of Southern California Schaeffer Center for Health Policy and Economics-NPC Postdoctoral Health Policy Fellow Ilene Hollin, PhD, MPH. In Dr. Hollin’s two years with NPC, she authored two forthcoming articles and presented research at numerous national conferences, including the ISPOR Annual Meeting and the AcademyHealth Annual Research Meeting. Dr. Hollin is now an assistant professor in the Department of Health Services Administration and Policy within the College of Public Health at Temple University in Philadelphia.

NPC’s research and activities were bolstered through a broad array of communications efforts. We remained active on social media channels like Twitter, Facebook and LinkedIn; created infographic versions of NPC research; and provided archived footage of webinars and other video content via the NPC 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, and E.V.I.dently®, a monthly e-newsletter, as well as daily topic alerts when new content is posted on the NPC blog. All these resources contain a wealth of information about how the biopharmaceutical industry’s most pressing issues impact patient health.
Membership and Board of Directors

NPC is unique among organizations based in the Washington, D.C., area. Like a trade association, it is supported by the membership of most of the world’s leading biopharmaceutical companies; like a think tank, NPC conducts health policy research that is frequently published in respected peer-reviewed journals. NPC also stands apart from other organizations in that it does not engage in political advocacy but collaborates with stakeholders across the health care sector to understand, consider and develop potential policy solutions.

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, as well as on the Research Work Group and Strategic Communications Work Group.

NPC’s member companies help shape its research agenda through participation in its committees and its Board of Directors. NPC frequently hosts high-level speakers as part of its Board of Directors meetings, such as U.S. Treasury Secretary Steven Mnuchin (pictured above in the center of the bottom row).
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, and access to educational resources, practical tools, analytical papers and other information in the members-only section of the NPC website.

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George Keefe  
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Teva Pharmaceuticals
NPC Staff

Standing: Kimberly Westrich, Emily T. Gerston, Robert W. Dubois, Kathryn A. Gleason, Tanya Bailey, Dan Leonard, Lisabeth Buelt, Jennifer Graff and Michael Ciarametaro

Seated: Sue Grimes, Maria Clemencia Pacheco and Andrea Hofelich

Not pictured: Taruja Karmarkar

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