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 pharmaceutical 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.
TABLE OF CONTENTS

Chairman’s Message ........................................................................................................ 4

President’s Message ........................................................................................................ 5

Leading the Dialogue on Evidence,
Value, Access and Innovation .......................................................................................... 6
  Real-world Evidence ..................................................................................................... 6
  Value .............................................................................................................................. 9
  Access .......................................................................................................................... 11
  Innovation .................................................................................................................... 13

NPC Programs and Outreach .......................................................................................... 15

Membership and Board of Directors .............................................................................. 16
  Other Members of the Board ....................................................................................... 17

NPC Staff ......................................................................................................................... 18
CHAIRMAN’S MESSAGE

It’s been an honor to serve as NPC’s chairman this past year. As I reflect on all of NPC’s accomplishments during the last 12 months, the number and quality of its activities are important and impressive. NPC’s impact in shaping the evolving health care environment continues to develop.

NPC’s staff is known for its work in conducting credible peer-reviewed research to inform policymakers and other stakeholders related to some of health care’s most pressing challenges. Collaborating with other health care organizations and educating about important health care policy issues are key reasons why NPC is an organization that is sought out not only by the biopharmaceutical industry, but by other health care stakeholders for its insights on value assessment frameworks, quality measures and real-word evidence (RWE), to name a few issues.

In 2017, NPC especially made its mark on health care value assessment frameworks, providing constructive feedback to organizations such as the Institute for Clinical and Economic Review (ICER) and the Innovation and Value Initiative (IVI). NPC’s thoughtful approach has been instrumental in improving frameworks’ underlying methodologies. As an emerging field, there is still more work to be done on frameworks in 2018, and I am confident that NPC is up to the task. Importantly, in 2017, NPC increased its focus on clearly communicating its findings and amplifying its voice in the ongoing health care debates.

NPC continued to weigh in on RWE and its use by the Food and Drug Administration (FDA) and payers, how to increase patient access to treatments through health benefit design and how to address barriers to outcomes-based contracts, among other issues. In addition, NPC raised its profile through its published research and commentaries, as well as via numerous speaking roles at conferences.

I am proud of all that NPC has accomplished in the last year, and I am looking forward to seeing the organization further build on this year’s success under the leadership of the 2018 chairman, Mark J. Nagy, Vice President, Global Patient Outcomes & Real World Evidence, Eli Lilly and Company, Inc.

Josh Ofman
Senior Vice President, Global Value, Access & Policy, Amgen, Inc
NPC 2017 Chairman of the Board of Directors
PRESIDENT’S MESSAGE

Today, we are seeing significant scientific breakthroughs that are revolutionizing health care treatments, especially in oncology and rare diseases. At the same time, we’re also engaged in a significant debate about the value of those treatments, patient access to needed care and how we are spending our health care dollars. In 2017, NPC research, communications and educational initiatives were particularly relevant in addressing this important discussion.

We got off to a strong start, building off of the success of our 2016 conference, Assessing Value: Promise & Pitfalls, as we released several peer-reviewed studies and commentaries on value assessment frameworks. The topic of how to assess the value of a treatment remained front and center, and NPC played a critical role in holding framework developers accountable when they fell short on important patient-focused elements, but also commended developers when they evolved their methods to better incorporate patient input.

Critical access and evidence issues also continued to be on our radar in 2017, as NPC tackled topics such as patient out-of-pocket costs, benefits management and quality measurement. Our ongoing work in the area of RWE also resonated with stakeholders as the FDA issued draft and final guidances on important reforms related to communicating and utilizing this key information.

Overall, we published nearly 20 peer-reviewed studies and white papers, along with commentaries, blog posts and infographics to supplement our research. NPC staff presented at more than 40 conferences and meetings this year, discussing our work in the areas of evidence, value, access and innovation. NPC also continued to be cited in numerous media outlets as an expert voice on these critical topics.

I also was pleased to welcome two new biopharmaceutical companies to NPC’s growing membership: Ipsen Biopharmaceuticals, Inc., and Spark Therapeutics.

Looking ahead to 2018, NPC is already gearing up to kick off a serious conversation about health care spending, bringing together stakeholders from all corners of health care. It’s time for all health care stakeholders to stop the finger-pointing, roll up our sleeves and work together to get to the root of the health care spending debate and seek solutions. I hope everyone will join us in this dialogue.

Dan Leonard
NPC President
LEADING THE DIALOGUE ON EVIDENCE, VALUE, ACCESS AND INNOVATION

In 2017, NPC maintained our focus on four main issue areas that impact patient health outcomes: evidence, value, access and innovation. NPC’s research, communications and education activities explored how evidence is conducted, used and communicated; how biopharmaceuticals and other medical treatments are valued; how health care is delivered, paid for and accessed; and how we ensure that our health care delivery and payment systems can keep pace with rapid medical innovations.

Real-world Evidence

Understanding how treatments work in the real world, or under everyday circumstances, has great benefit for health care decision-makers. This kind of RWE, gleaned from electronic health records, administrative claims, mobile health devices and other sources, helps patients and their physicians make better treatment choices, provides payers with additional information for making coverage decisions and enables researchers to better understand how a treatment works in more diverse populations. In 2017, NPC continued to play a leading role on RWE through our peer-reviewed research and related activities that explored how decision-makers are using RWE, and under what circumstances, as well as how it can be communicated by various stakeholders.

NPC’s existing body of research and 2017 publications dovetailed with a number of events related to RWE. The subject was a major focus for the FDA, which released draft guidance documents regarding communications and considered how to enact the RWE provisions of the 21st Century Cures Act. In January, the agency released a series of draft guidance documents that clarify how and when different types of studies that include clinical and economic information may be communicated. In the guidance on “Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities,” the FDA highlighted several case examples from NPC’s work that stress the importance of high-quality evidence, the role of that evidence in decision-making and the ability of all stakeholders to communicate that evidence to improve our health care system and patient outcomes.

NPC submitted comments on this draft guidance and in response to FDA’s request for information on Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products about improving how the exchange of clinical and economic information between biopharmaceutical manufacturers, payers and population health decision-makers is regulated. The comments cited an NPC white paper, “Information Wanted: Finding the Balance in Pharmaceutical Evidence Exchange With Payers and Providers,” illustrating how health communication is currently used and how it can be more useful in the future. Led by NPC and Xcenda/Amerisource Bergen, this white paper asked payers and providers what types of evidence are most important to them when it comes to making population coverage decisions for formularies and care pathways. The study further illuminated the gaps between what payers and providers want and need, and what information can be shared with them under current regulations.

According to two separate studies published by NPC and the University of Arizona College of Pharmacy in 2017, payers use RWE infrequently. Although payers, particularly those in managed care organizations, recognize the value of using RWE, it was not often used in pharmacy and therapeutics committee reviews. “Is Real-World Evidence Used in P&T Monographs and Therapeutic Class Reviews?”, published in the June issue of the Journal of Managed Care & Specialty Pharmacy (JMCP), showed that even among therapeutic
In 2017, NPC continued to play a leading role on RWE through our peer-reviewed research and related activities that explored how decision-makers are using RWE, and under what circumstances, as well as how it can be communicated by various stakeholders.

class reviews where RWE is more readily available, payers most commonly utilized clinical studies and product label information. Although the research offers a strong understanding as to how payers are currently using RWE, additional research is needed to understand when and what types of RWE can inform coverage and reimbursement decisions in a more consistent manner.

The second study, “Real-World Evidence: Useful in the Real World of US Payer Decision Making? How? When? And What Studies?” found that instead, payer organizations were more likely to use RWE for utilization management, financial analyses and safety evaluations. The study was published in *Value in Health*.

While payers may use RWE infrequently, they are collecting the type of data that is essential for RWE. An assessment led by Avalere and NPC, “Health Plan Use of Patient Data: From the Routine to the Transformational,” found health plans are using data to shape care delivery, improve system efficiency and achieve better health outcomes, and identified seven ways health plans use that data.

Recognizing what “good” RWE looks like can be challenging, which is why NPC, the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), and the Academy of Managed Care Pharmacy (AMCP) have continued their joint effort, the CER Collaborative. The CER Collaborative, now in its eighth year, has assisted hundreds of health care stakeholders in assessing and synthesizing comparative effectiveness research for use in making health care and coverage decisions. In 2017, the Collaborative hosted several continuing education and certificate sessions to train decision-makers in the use of its online tool, and it is a key component in the AMCP Foundation Annual Pharmacy & Therapeutics Competition. Both the CER Collaborative and the online tool were highlighted in ISPOR’s *Value and Outcomes Spotlight* and in a keynote address at the March AMCP Student Chapter Leadership Academy.
NPC also assisted other organizations with an interest in RWE. As part of the Green Park Collaborative, a multi-stakeholder forum, NPC contributed to the development of the RWE Decoder, a tool designed to help decision-makers assess the rigor and relevance of RWE studies in a simple and practical way. As part of the Massachusetts Institute of Technology’s New Drug Development Paradigms Initiative (NEWDIGS) Next Wave, an effort focused on evidence needs to support innovation, NPC is providing insights on ways to better integrate RWE in pre- and post-market drug development.

Given the broader stakeholder interest in RWE and the need for broader evidence to be communicated, it was a popular topic at health care conferences as well. NPC Vice President of Comparative Effectiveness Research Jennifer Graff, PharmD, and other staff and researchers spoke at a number of conferences, including the AMCP Annual Meeting, the ISPOR Annual International Meeting, Asembia Specialty Pharmacy Summit, Health Technology Assessment international (HTAi) Annual Meeting, the Drug Information Association Global Annual Meeting and the ICER Annual Policy Summit, and participated in several RWE meetings hosted by the Duke-Robert J. Margolis, MD, Center for Health Policy and other organizations. In addition, NPC co-sponsored a roundtable on RWE and real-world data with the National Health Council, at which participants from the patient community discussed what RWE is and what patients’ needs are when it comes to understanding and using this evidence.
NPC’s ongoing work in this area was more important than ever as we continued to examine and provide constructive feedback to organizations developing frameworks.

Value

This year saw the approval of several groundbreaking treatments, including a gene therapy for blindness and a targeted therapy for leukemia, among others. Yet how these innovations are valued by health care stakeholders remains a complex topic, and one that several organizations attempted to address through value assessment frameworks. NPC’s ongoing work in this area was more important than ever as we continued to examine and provide constructive feedback to organizations developing frameworks, such as ICER, the National Comprehensive Cancer Network and IVI. Our feedback was grounded in our Guiding Practices for Patient-Centered Value Assessment, outlining ways to help ensure that value assessment frameworks are effective tools for advancing patient care and achieving better clinical, economic and humanistic outcomes, rather than well-intentioned but flawed tools that impede such progress.

Engagement with ICER remained an important focus of NPC’s work in this area. During the year, NPC submitted public comments and had ongoing conversations with ICER about its revised value assessment framework, particularly its reliance on affordability and quality-adjusted life year (QALY) thresholds and lack of full model transparency. Although ICER’s latest revision reflected a number of NPC’s recommendations, the framework remains flawed.

Given these existing flaws, NPC expressed concern via the Health Affairs Blog about a partnership between ICER and the U.S. Department of Veterans Affairs (VA) Pharmacy Benefits Management Services office to integrate ICER’s value assessment framework in the VA’s formulary management process. While NPC supports efforts to improve veterans’ health care, enhance the use of value as the underpinning for health care decision-making in the VA and improve transparency in the VA process, the issues with ICER’s underlying framework methodology and uncertainty about how the VA would use the framework raised red flags. NPC’s article prompted a response from the VA, which offered clarity for the first time on how the agency makes certain decisions and how it envisions using the ICER framework.

The Health Affairs Blog was the site of another conversation among health care stakeholders. A March post by NPC Chief Science Officer and Executive Vice President Robert W. Dubois, MD, PhD, and NPC Vice President of Health Services Research Kimberly Westrich, MA, “Value Assessment Frameworks: Are They Up To The Challenge?”, emphasized NPC’s guiding practices and examined the limitations of existing frameworks, particularly in considering what’s important to patients. Avalere Health and FasterCures responded to NPC’s article, both affirming and calling attention to NPC’s work to date to evaluate and improve existing frameworks.

Another study, published in the June issue of JMCP, compared multiple myeloma assessments from four different value frameworks. The study underscored how assessments that arrive at different conclusions can create confusion among end users; this can be mitigated through frameworks that are transparent, reproducible and relevant for their respective target audiences. This study builds off of a white paper on the same topic that NPC conducted with the Lewin Group.

NPC also weighed in on a draft report, “A Health Economics Approach to US Value Assessment Frameworks,” issued by
ISPOR’s Special Task Force Initiative on US Value Assessment Frameworks. In keeping with NPC’s guiding practices, NPC encouraged ISPOR to incorporate a broad range of stakeholder input, reconsider use of the cost-per-QALY decision rule, and incorporate recommendations related to evidence selection and evaluation, including the use of RWE, among other suggestions.

Value assessment frameworks were a key issue at a number of events that NPC participated in throughout the year. NPC jointly hosted a workshop with Pharmaceutical Research and Manufacturers of America (PhRMA) and Tufts Medical Center, “Understanding the Strengths and Weaknesses of Value Assessment Frameworks: An Interactive Workshop,” to give health care stakeholders a hands-on chance to explore several frameworks and their assessment outputs. NPC staff moderated and joined an issue panel debate at both the ISPOR Annual International Meeting and the ACMP Foundation Symposium on the need for a plurality of frameworks versus a one-size-fits-all approach; and presented at the Personalized Medicine Coalition’s 13th Annual Personalized Medicine Conference, among other events. NPC’s 2016 participation in the AMCP Partnership Forum, “Driving Value and Outcomes in Oncology,” resulted in the publication of the proceedings in JMCP in May.

NPC worked to broaden this conversation and involve a wider group of health care stakeholders in a dialogue about value in health. As part of this effort, NPC engaged with patient organizations to share their perspectives on value assessments through a question-and-answer series that appeared on our blog. Additional NPC commentaries on value assessment frameworks appeared in the Health Affairs Blog, the American Journal of Pharmacy Benefits (AJPB) and Chain Drug Review, as well as on our blog.

NPC President Dan Leonard, seen here at an Atlantic Live event hosted by a member company, speaks regularly with health care stakeholders about NPC’s important research and activities.
NPC’s research in 2017 looked at what factors can impede access and examined how to address the rising financial burden on patients and the health care system.

**Access**

Patients today may have greater access to health insurance, but many patients still lack meaningful access to medicines — and barriers to access can cause delays in patients starting a treatment regimen or switching to a more effective treatment if the first one is not working. NPC’s research in 2017 looked at what factors can impede access and examined how to address the rising financial burden on patients and the health care system.

As our health care system continues to shift from a focus on volume- to value-based payments, accountable care programs can help health care stakeholders drive toward more effective treatment plans. Quality measurement, tied to financial incentives, is one of many approaches accountable care programs are using to promote system-wide improvement. Measures can help payers to reward better care, providers to take action to improve care and patients to make informed decisions about their care.

According to a study conducted by NPC in partnership with Discern Health, the Duke-Margolis Center for Health Policy and the American Society of Clinical Oncology, gaps in the quality measures used by accountable care programs to assess cancer care may create obstacles in delivering the best care for patients, leading to missed opportunities to improve patient outcomes. The study, “Improving Oncology Quality Measurement in Accountable Care,” outlined recommendations for improving accountable care measure sets, in particular by shifting the emphasis from condition-specific processes of care, such as stage-specific therapies, and instead prioritizing the development and use of more meaningful cross-cutting measures. The study was broadly disseminated at the National Quality Forum’s Annual Conference in April, discussed during a webinar hosted by NPC and Discern Health, and supported by a companion paper that was published in *JMCP*.

As part of an ongoing portfolio of research to better understand how accountable care organizations (ACOs) are optimizing the use of medications, NPC worked with Leavitt Partners on research that was published in the June issue of *JMCP*. The study found that medication use practices may be easier to implement if ACOs provide access to data to both pharmacists and physicians, focus on removing technological barriers, gather buy-in from frontline physicians and integrate pharmacists into care teams.

NPC research also examined benefit design, another important area that has a tremendous impact on health care access and costs.

In particular, patients who have the same condition sometimes pay different out-of-pocket costs for their medications. NPC research, “Does a One-Size-Fits-All Cost-Sharing Approach Incentivize Appropriate Medication Use? A Roundtable on the Fairness and Ethics Associated with Variable Cost Sharing,” explored when this cost differential is more appropriate. To support the research, which appeared in *JMCP*, NPC developed an infographic, hosted a webinar and published related commentaries in *AJPB* and *Chain Drug Review*.

Many employers rely on pharmacy benefit managers (PBMs) to handle their employees’ health care benefits. However, according to a study conducted by Benfield, a division of Gallagher Benefit Services, on behalf of NPC, there is a disconnect between the important role employers believe their
PBMs play in helping to manage prescription drug benefits and employers’ perceptions of the overall value they are getting from their PBMs. Findings indicate that this disconnect is rooted in employer concerns about transparency, contract complexity, rebates and focus on value.

In conjunction with the study “Toward Better Value: Employer Perspectives on What’s Wrong With the Management of Prescription Drug Benefits and How to Fix It,” Benfield developed tools to assist employers with the PBM assessment process. The “PBM Relationship Segmentation” tool provides employers with the ability to quickly assess where they stand with their PBM on satisfaction and trust vs. engagement; the “Improving Prescription Drug Benefit Support” tool helps employers assess the value they are receiving from their consultants and how engaged an organization is with their consultants. NPC also partnered with the National Alliance of Healthcare Purchaser Coalitions on a webinar that highlighted key points from the study and featured a discussion with a purchaser coalition reactor panel, and to distribute the research at the National Alliance’s annual conference.

In addition to our own research, NPC supported the Turning the Tide Against Cancer initiative (T3), which hosted a webinar with Ms. Westrich and published a report outlining “the best practices and recommendations to ensure oncology clinical pathways fulfill their promise of delivering patient-centered, high-value care.”

NPC also spoke at events such as the AcademyHealth Annual Research Meeting and the AMCP Partnership Forum on advancing value-based contracting, at which participants examined successes, opportunities and challenges facing these models; sought to reach consensus on a definition of value-based contracting; and developed action plans to mitigate current and future legal and regulatory barriers.
Innovation

It is important to foster an environment that sustains and enhances innovation to ensure the continued discovery and development of new medicines that improve patients’ health and their quality of life. Yet we recognize that there is an inherent struggle among the various health care sectors and stakeholders about how we can balance access and innovation, as well as ensure that our health care dollars are being spent on high-value treatments that are most effective for patients.

Several NPC studies published in 2017 and related activities focused on this struggle. One study, “Insurance Switching and the Mismatch Between the Costs and Benefits of New Technologies,” examined the disconnect between the short-term budget impact of a treatment and its downstream effects on payers and society. For example, new therapies that cure hepatitis C require significant upfront investment, but are curative and reduce long-term costs significantly compared with years of living with the disease and its complications. Immediate budget implications have led many insurers, including state Medicaid programs, to limit access. The study, published in the American Journal of Managed Care (AJMC), noted that addressing this disconnect will require creative approaches to health care financing models to assure appropriate access to cost-effective therapies, incentivize future innovation and provide sustainable economics for payers.

Innovative payment models to address some of these concerns are being tested by the Centers for Medicare and Medicaid Services (CMS), whose Information Center launched a request for information on its proposed new direction.

NPC submitted comments to CMS in November, noting that the Information Center’s various pilot payment programs and quality measures with hospitals and physicians could prove successful if they emphasize the appropriate utilization of services and minimize unintended consequences. NPC pointed out that focusing on market choice and competition, incentivizing value, aiming for patient centricity, ensuring transparency in design and evaluation, making models voluntary and utilizing small-scale testing are important attributes that should be codified via rulemaking.

Programs like the MIT NEWDIGS Financing and reimbursement of Cures in the US (FoCUS) initiative, with which NPC is engaged, are also examining new payment mechanisms. FoCUS activities “center around the design, rapid cycle prototyping, and piloting of financing and reimbursement models for curative therapies in the US, with targeted pilot launches occurring throughout the life of the project.”

Another NPC study, “Concerns Around Budget Impact Thresholds: Not All Drugs Are the Same,” published in Value in Health, explored the potential impact of setting spending caps based on budget thresholds for individual drugs. The study found that spending caps at the product level have the potential to reduce market efficiency due to their independence from value and the presence of important operational challenges.

An NPC study on pharmaceutical costs conducted with Precision Health Economics, “What Do Pharmaceuticals Really Cost in the Long Run?”, was published in AJMC. The long-run average cost of a pharmaceutical includes not only the initial branded drug price, but also subsequent price changes. Those that occur after a treatment’s patent has expired and generics

“NPC is undertaking further research on health care spending as part of a broader initiative to foster a serious conversation among all stakeholders.”
enter the market are especially impactful in lowering the long-run average cost. The study found that to ensure all drugs providing long-run value end up entering the marketplace, market access and other policy decisions should consider the full range of long-term costs, not just prices at a particular point in time.

NPC spoke on these topics at several events in 2017, including a panel on "Managing the Health Care Affordability Crisis: Approaches that Benefit Both the Payer and Patient" featuring NPC Vice President of Research Michael Ciarametaro, MBA, at the AMCP Annual Meeting and, separately, at the AMCP Partnership Forum on precision medicine.

NPC is undertaking further research on health care spending as part of a broader initiative to foster a serious conversation among all stakeholders. In July, NPC launched a request for proposals, resulting in the selection of six projects that explore questions about the level and growth rate of health spending, both in the U.S. and abroad; the distribution of spending; efforts to improve the value of care; and options for constraining health care costs.

An initial partnership with Health Affairs will focus on health systems research and engage in web-based and in-person dialogue, including public conferences, as a way of ensuring broad exploration into these questions. In December, Health Affairs and NPC announced the partnership via a series of posts on the Health Affairs Blog, including one authored by Dr. Dubois.

Dr. Dubois speaks about challenges in understanding and addressing health care spending at a general session of the AMCP Nexus 2017 conference. Dr. Dubois was a featured speaker at many conferences and events due to his expertise in health policy research.
NPC Programs and Outreach

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 our research for easy sharing; and provided archived footage of our 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, and E.V.I.dently®, our monthly e-newsletter, as well as daily topic alerts when new content is posted on our blog. All of these resources contain a wealth of information about how the biopharmaceutical industry’s most pressing issues impact patient health.

In addition, Mr. Leonard wrote a regular column for AJPB, and several commentaries were published in Morning Consult and in the Health Affairs Blog. NPC experts were also quoted in numerous news articles.

Along with our outreach efforts, NPC’s work has also been strengthened by University of Southern California Schaeffer Center for Health Policy and Economics-NPC Postdoctoral Health Policy Fellow Ilene Hollin, PhD, MPH. In Dr. Hollin’s second year of her fellowship, she spoke at a number of conferences, including AMCP Nexus, the AcademyHealth Annual Research Meeting and ISPOR’s Annual International Meeting, in addition to continuing her research about unintended consequences for families with children with medical complexities who are enrolled in high-deductible health plans, and evaluating the way various stakeholders define value.
NPC is unique among organizations based in the Washington, D.C., area. Similar to 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 our Board of Directors and helps to shape our research agenda through participation on various board-level committees, as well as on our Research Work Group and Strategic Communications Work Group.

In addition to NPC’s public resources, such as our website, social media channels and signature e-newsletters (CER Daily Newsfeed® and Evidently®), resources 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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