



2015

ANNUAL
REPORT

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](https://twitter.com/npcnow).

2015 MARKED AN EXCITING, YET CHALLENGING YEAR

for the biopharmaceutical industry. With the significant discussion about hepatitis C cures, presidential support for precision medicine, the implementation of new payment and delivery models, and continued challenges with Affordable Care Act provisions, debates raged on the best ways to adapt to changes in the environment and enhance patient outcomes.

The National Pharmaceutical Council (NPC) played a unique role in this environment, as it has done for more than 60 years as a leader in health policy research. NPC conducted peer-reviewed research to examine key questions and consider potential answers, engaged stakeholders in meaningful dialogue, and shared the industry's concerns via conference presentations, webinars, commentaries, blog posts, and social media—all while seeking patient-centered solutions to our most pressing challenges.

NPC's research brought together thought leaders and other stakeholders on topics such as real-world evidence, innovation, and the value of and access to biopharmaceuticals for patients. These are areas that NPC will continue to explore in the near future, per a strategic plan approved by the Board of Directors to guide the organization during the next few years. NPC's current research portfolio provides a strong foundation for the work that lies ahead.

My term as chairman ended in November, and I leave the Board of Directors and NPC in good hands with my successor, Patrick Magri of Merck & Co., Inc. I am confident that NPC will continue to lead the way on conducting research, communicating about research findings and critical health policy issues, and pushing for biopharmaceutical innovation—all in support of our ultimate goal of achieving better patient health.



David J. Martin
Senior Vice President, Market Access and Commercial Services
Eisai, Inc.

CHAIRMAN'S MESSAGE



PRESIDENT'S MESSAGE



WE ARE LIVING IN ONE OF THE GREAT MOMENTS IN HISTORY

with regard to the treatment and curing of disease. New, more effective, and individualized treatments are fundamentally changing and improving our ability to manage—and even cure—once untreatable conditions. Conditions like HIV and AIDS have been transformed from life-ending illnesses to chronic, manageable conditions; hepatitis C no longer costs patients their lives and its cures will likely save our health care system millions by eliminating unnecessary hospital care; and we are making more and more progress in defeating cancer every year.

Innovation in the biopharmaceutical industry has never been more essential. And yet the challenges facing the industry have never been greater.

That's why, over the last year, NPC has focused its work on helping policymakers, payers, patients, and providers across the health care system better understand the challenges of looking at the cost of therapies alone—and the importance of fully realizing the lifetime value of biopharmaceuticals to our *entire health care system*. In doing so, NPC has also continued to highlight how the access to, use and communication of both public and private high-quality data and real-world evidence by *all* stakeholders is vital to improving patient outcomes and making health care delivery more effective and efficient. And NPC remains committed to producing research and creating an ongoing dialogue around the importance of innovative payment and delivery models that recognize individual patient differences and that ensure meaningful, timely access to appropriate treatment.

NPC's previous efforts to increase understanding and better communicate to broader audiences were expanded further in 2015. Through peer-reviewed publications, commentaries, events, and other outreach—often in coordination with academic and thought-leader organizations—we used a range of communication tools to enhance general knowledge around access to and value of biopharmaceuticals in health care.

We were honored to have three companies join us as members in 2015—Biogen, Gilead Sciences, Inc. and Takeda Pharmaceuticals USA, Inc. In doing so, they joined with the other leaders in the biopharmaceutical industry who recognize NPC's value in fostering an environment that encourages medical innovation, promotes high-quality care, and puts value and patient access at its center.

In the year ahead, NPC will continue to constructively address the issues that are shaping health policy. We will continue to bring the biopharmaceutical industry together and to sustain innovation that results in enhanced treatments and health outcomes.

We are optimistic about the future of patient health in America. Through a solid research portfolio, strong partnerships, and effective outreach, NPC will continue to explore, demonstrate, and communicate the role and value of biopharmaceuticals in order to achieve better patient health.

A handwritten signature in dark ink, appearing to read "Dan Leonard".

Dan Leonard, MA
President

IN 2015, NPC'S RESEARCH AND ACTIVITIES FOCUSED ON THREE AREAS THAT IMPACT PATIENT OUTCOMES: generating high-quality, real-world **evidence** in health care decision-making; recognizing the **value** of medicines as an integral component of care; and ensuring that patients have meaningful **access** to appropriate medications.

NPC RESEARCH AND ACTIVITIES

EVIDENCE: HIGH-QUALITY, REAL-WORLD EVIDENCE IS GENERATED, ACCEPTED, AND USED TO INFORM DECISION-MAKING

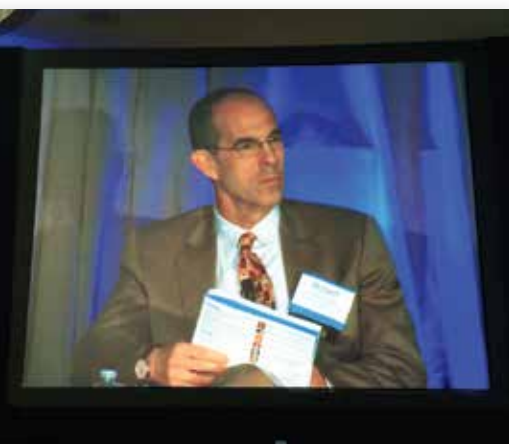
Different types of evidence are utilized by health care stakeholders to make a range of decisions—everything from which treatment path individual patients and their providers select to clinical guidelines and coverage and benefit determinations that guide care for thousands of patients. Challenges remain around accessing data, analyzing this data appropriately, and communicating the findings; understanding how treatments work in the real world is critically important to guide the delivery of care in real-world, clinical practice environments. NPC's work is helping to meaningfully change the quality of real-world evidence developed and ultimately how high-quality, real-world evidence is viewed and used.

Importantly, progress has been made to broaden access to research-quality data over the last year. However, as more data becomes available to the broader health care ecosystem, steps also need to be taken to ensure that the data is assessed to develop credible and reliable evidence; that it can be communicated by all stakeholders; and that it is evaluated and used appropriately by decision makers—particularly in instances that could affect patient decisions and treatment access.

The Importance of Access, Use, and Communication of High-Quality, Real-world Evidence

Several provisions relevant to NPC's work were included in the 21st Century Cures Act (H.R. 6) approved by the U.S. House of Representatives. One provision would amend Section 114 of the Food and Drug Administration (FDA) Modernization Act, which established a special mechanism for biopharmaceutical companies to share health care economic information under certain conditions. The Cures legislation would clarify and expand those circumstances to include clinical information. Although NPC does not engage in advocacy, for many years NPC has conducted work to raise awareness and support broader sharing of evidence with all stakeholders, including hosting conferences and developing peer-reviewed research exploring the inherent challenges in sharing information without running afoul of FDA regulations.





**NPC Chief Science Officer
Dr. Robert Dubois spoke at a
number of conferences in 2015.**

For example, **When Does FDAMA Section 114 Apply? Ten Case Studies**, a peer-reviewed paper published in the April issue of *Value in Health*, examines hypothetical situations to explore whether various types of information could be shared by biopharmaceutical companies under current law. At the **International Society for Pharmacoeconomics and Outcomes Research (ISPOR) 20th Annual International Meeting** in May, NPC research partners presented “How Should the FDA Regulate the Communication of Health Economic Data by Pharmaceutical Companies to Payers?”

During the presentation, NPC noted that while payers are interested in knowing about real-world patients and comparative effectiveness research, biopharmaceutical companies may be hesitant to disseminate such information because of ambiguities in the laws that govern such communications.

Moving forward in 2016, additional changes to or clarification of the laws governing biopharmaceutical communications could come via Congress, the Food and Drug Administration or negotiations on the Prescription Drug User Fee Act (PDUFA VI). Whether any decisions result in significant changes to biopharmaceutical communications remains to be seen, but the need for high-quality, real-world evidence by a variety of health care stakeholders means that economic and clinical information should be broadly communicated by all stakeholders. NPC continues to closely follow developments relating to potential changes in biopharmaceutical communications and the ways that high-quality evidence can be shared with stakeholders.

Another Cures provision concerns allowing “commercial entities” access to publicly funded databases. From Fitbits to insurance claims databases, an enormous amount of health care data is being captured. With greater access to this real-world data, some light can be shed on what is being done well, which approaches work better than others, and where there are areas for improvement. At the end of 2015, however, Congressional action on Cures remained unclear.

That’s why it was so encouraging to hear the announcement from the Centers for Medicare and Medicaid Services (CMS) that it will now allow “innovators and entrepreneurs to access CMS data, such as Medicare claims,” which broadened access to certain publicly funded databases that the agency maintains. Previously, “commercial entities” were barred from accessing this data. This announcement is a positive development for patients, as researchers’ access to this data can incentivize innovation and improve health outcomes, delivery and quality of care. This gives researchers, regardless of their affiliation or funding, access to specific datasets—with strong privacy protections in place—for their research.

This change in policy at CMS is exciting, but access to other federal or state databases remains varied. That’s why NPC has a study, currently in peer-review, about the barriers to access for state and federal publicly funded databases for all researchers. Better access to real-world evidence doesn’t just mean stakeholders can now develop a wider range of new, data-driven health care delivery solutions—it also means real improvements to how care is provided to patients. As CMS has noted, “Increased access to larger volumes of data is driving changes in health

care, discoveries in research and improvements to social services delivery.” In short: as researchers work to tackle a host of health care questions across our system, data has the potential to significantly improve outcomes, transform care delivery, and lower costs.

Adopting Standards—How Creating Agreement Across Guidelines Improves Patient Care and Reduces Costs

The conversation about data and evidence doesn’t end with CMS’ recent announcement or improved access to public databases. Evidence from clinical experience also can provide useful information on how to better manage patients with a particular condition and how to improve medication adherence and other evidence-based solutions. NPC’s research about “evidence from clinical experience” (real-world evidence) and the benefits it offers in understanding how treatments work in the real world dovetailed with the Cures legislation.

The legislation itself calls for a taskforce to identify the current guidelines and standards for conducting and analyzing evidence from clinical experience. NPC’s paper, **Standards and Guidelines for Observational Studies: Quality Is in the Eye of the Beholder**, conducted with the University of Pittsburgh Graduate School of Public Health, compares and contrasts nine different guidelines or standards for conducting these analyses and provides a head start to the taskforce activities. The research identified the need for broader consensus on what should be included in high-quality observational studies among stakeholders based upon the lack of agreement across the various standards and guidelines. Lack of agreement can lead to variations in funding, research methods, publication and ultimately the use of evidence in decision-making. The gaps identified in this paper are increasingly relevant as insights from real-world clinical experience are being sought to improve patient care and reduce costs.

Importantly, these gaps and lack of agreement among standards and guidelines aren’t the only challenges to determining what treatments work best for individual patients. Although real-world evidence can be used to inform research on how a particular treatment impacts patients, payers often rely on other data available at launch to inform their coverage decisions. As new information emerges about how treatments work in typical patients, the lack of consistent use of real-world evidence creates gaps between scientific research, the care provided in practice, and to which treatments patients have access.

A framework developed by NPC and AcademyHealth could help close the gaps between the questions explored by researchers and the answers that health care coverage decision makers need. Published in the September issue of *The American Journal of Managed Care*, **Developing Evidence That Is Fit for Purpose: A Framework for Payer and Research Dialogue**, introduces a framework intended to help harmonize the evidence payers desire for coverage and formulary decisions with the evidence received from researchers and helps guide researchers as to what types of evidence need to be developed in the future. Payers who applied the framework indicated that their primary need is for evidence that illustrates meaningful differences between treatment alternatives and more relevant outcomes for real-world use.

A framework developed by NPC and AcademyHealth could help close the gaps between the questions explored by researchers and the answers that health care coverage decision makers need.



The topic was further discussed by NPC Vice President of Comparative Effectiveness Research Jennifer Graff, PharmD, who presented the framework in a challenge workshop at the AcademyHealth-sponsored **Concordium 2015: Data and Knowledge Transforming Health** in September, which convened organizations working with big data and was designed to advance the development and use of evidence to improve health systems.

In fact, understanding meaningful differences between treatment options is particularly important when looking to biologic and biosimilar therapies. NPC Chief Science Officer Robert W. Dubois, MD, PhD, shared the industry's perspective when he participated on an issue panel, "Distinguishing Biosimilarity—How Can We Generate Real-World Evidence to Support Decision-Making?" at the **ISPOR 20th Annual International Meeting** in May. During the panel, Dr. Dubois shared the impact that biosimilars have on health policy and the industry, particularly as payers, providers, and policymakers increasingly look to use real-world evidence to make reimbursement and treatment determinations.

Helping to Improve Health Outcomes Through Comparative Effectiveness Research

Evidence from clinical experience and comparative effectiveness research (CER) are inextricably linked, and are critical to improving health outcomes and care delivery. Without the real-world data, CER will not be as effective in identifying the benefits and risks of treatments to patients. Yet it is important to consider how CER will impact the biopharmaceutical development process. **Clinical Evidence Inputs to Comparative Effectiveness Research Could Impact the Development of Novel Treatments** (*Journal of Comparative Effectiveness Research*, May) found that the impact to innovation due to uncertainty surrounding the consequences of increased clinical evidence generation and the ultimate use of this evidence calls for a carefully measured approach to CER implementation. Near-term benefits to spending and health need to be balanced with long-term implications for innovation.

To better understand how policymakers in the state Medicaid programs view CER and how they use this research in setting coverage policy, NPC supported a survey of Medicaid medical and pharmacy directors. Published in the March issue of the *Journal of Comparative Effectiveness Research*, **Translating Comparative Effectiveness Research Into Medicaid Payment Policy: Views From Medical and Pharmacy Directors** provides perspectives from respondents in 46 states, a vast majority (90 percent) of whom indicated that they used randomized controlled trials, systematic reviews, and consensus statements from national professional societies in setting coverage policies. Nearly 95 percent of respondents indicated they were "very" or "somewhat" likely to recommend a change in coverage policy if new CER evidence showed a currently covered product had more harms than benefits or if a new product was found to be less clinically effective than a currently covered one. Respondents overwhelmingly agreed that in the future, CER would result in better clinical decision-making and improved quality and health care value.

NPC has been working to help take meaningful steps to improve the transparency, consistency, and clarity of evidence used, including CER, in health care decision-making. One such effort is through the **CER Collaborative**. Formed in 2010

by NPC, ISPOR and the Academy of Managed Care Pharmacy (AMCP), the Collaborative works to improve patient outcomes through greater uniformity and transparency in the evaluation and use of evidence for coverage and health care decision-making. To date more than 3,000 users have accessed the online resources (www.cercollaborative.org) to help health care decision makers synthesize and evaluate different types of CER. In partnership with the University of Maryland School of Pharmacy, the CER Certificate Program, a 19-hour, user-paced online continuing education program, helps learners evaluate studies and apply these skills in a formulary decision. In 2015, in addition to individual learners, biopharmaceutical companies and health insurers sponsored department-wide training for their clinical pharmacists, field-based medical and outcomes-based teams, and drug information specialists using the Collaborative's resources.

In addition, NPC's annual survey of stakeholders, **Comparative Effectiveness Research and the Environment for Health Care Decision-Making**, provides a snapshot of perceptions from key stakeholders across the health care system on the main aspects of the CER process—from setting priorities to translating and disseminating research findings. By conducting this survey annually for the last five years, NPC has been able to track changes in the perception of CER and shed light on other issues in the evolving health care decision-making environment.

The 2015 survey revealed that while stakeholders recognize CER's importance in the health care landscape, they believe its impact on health care decision-making may not be felt for another three to five years. Nearly half of the respondents indicated they are optimistic about a growing movement toward widely agreed-upon research standards, which would provide more consistency in the conduct and evaluation of CER—nearly double the number who responded that way in NPC's first survey in 2011. Survey participants included researchers and thought leaders, representatives of government, insurers and health plans, employers, business coalitions and associations.

NPC presented the 2015 survey findings during a March webinar moderated by NPC President Dan Leonard, MA, and featuring Joe Selby, MD, MPH, executive director, Patient-Centered Outcomes Research Institute; Lisa Simpson, MB, BCh, MPH, FAAP, president and CEO, AcademyHealth; and Kimberly Westrich, MA, vice president, health services research, NPC.

VALUE: THE VALUE OF MEDICINES IS RECOGNIZED AS AN INTEGRAL COMPONENT OF CARE

In 2015, as news headlines were dominated by stories about the costs and value of health care, stakeholders across the health care ecosystem were working on methods to define and measure value; how those methods influence research, payment, and delivery models; and how to ensure that those models drive good outcomes for patients.

Importantly, those efforts were happening in both the public and private sector. Marking its commitment to shift the focus of hospitals, physicians, pharmacists and other providers away from the volume of services performed and toward the quality and value of those services, CMS announced in early 2015 that it would



Several CER Collaborative in-person training sessions were hosted this year.

NPC's submission to ASCO focused on the need to create a more patient-centered framework better suited to inform shared decision-making between patients and providers.

be changing how it reimburses health care providers under Medicare. In doing so, U.S. Department of Health and Human Services Secretary Sylvia Burwell announced a goal to have 90 percent of all Medicare fee-for-service payments tied to quality or value by 2018.

NPC's ongoing research efforts work to define key elements of value and demonstrate their significance to patients, providers and payers, while also broadly identifying both the barriers that prevent the full value generated by biopharmaceuticals from being realized and potential solutions to overcome them.

Moving to Value—Benefits and Ongoing Challenges of New Value Frameworks

In the wake of this changing reimbursement and delivery environment, groups such as the American Society of Clinical Oncology (ASCO) and the Institute for Clinical and Economic Review (ICER) continued their efforts to develop value assessment frameworks. In August, NPC offered feedback to ASCO and the Value in Cancer Care Task Force on their Conceptual Framework to Assess the Value of Cancer Treatment Options.

NPC's submission to ASCO focused on the need to create a more patient-centered framework better suited to inform shared decision-making between patients and providers. In particular, NPC offered four suggestions on how to improve the framework: 1) ensure the framework is used as intended; 2) broaden and sharpen framework components; 3) ensure cost information is relevant to patients; and 4) expand and strengthen the evidence base.

NPC also shared ongoing concerns with ICER regarding its value assessment framework, citing the framework's lack of model transparency, challenges with how the health system value is calculated, and the need to realize the effects of some treatments over a longer time horizon, among other concerns. NPC is continuing to work with ICER to consider changes to its framework.

Enhancing the Value of Care—The Importance of Developing Alternative Payment and Delivery Models

In addition to value frameworks, new payment and delivery models such as accountable care organizations (ACOs), integrated delivery networks, bundled payments and value-based insurance design continued to gain traction in 2015.

An ongoing project supported by NPC, the American Medical Group Association and Premier, Inc. is designed to better understand the role of biopharmaceuticals in helping ACOs achieve their financial and quality goals. Working in conjunction with a group of ACOs, the partners developed a framework for considering the role of biopharmaceuticals in achieving success in a value-based environment. The partners also have developed case studies that highlight best practices in areas such as electronic refill services, physician leadership in a team-based care environment and collaborative opportunities between industry and ACOs.

As part of this project, a case study by NPC and the Marshfield Clinic published in the April issue of the *Journal of Managed Care & Specialty Pharmacy (JMCP)* shows how health information technology can play an important role in ensuring the optimal use of biopharmaceuticals and improving patient safety in an ACO.

Best Practices: An Electronic Drug Alert Program to Improve Patient Safety in an Accountable Care Environment describes Marshfield Clinic's Drug Safety Alert Program, which focuses on prioritizing and communicating safety issues related to medications with the goal of reducing potential adverse events. The study identifies several factors for consideration in the development and ultimate success of an electronic drug safety alert program within an ACO, including leveraging electronic health records, avoiding "alert fatigue or overload" and flagging medication issues that are tied to the quality measures that must be met by ACOs in order to qualify for the Medicare Shared Savings Program.

In October, NPC's Kimberly Westrich led a case study workshop about gaps in quality measures at *The American Journal of Managed Care's* meeting, **ACOs and the Emerging Healthcare Delivery Coalition**. She also participated in the panel discussion, "Accountable Care Organization Readiness: Maximizing the Value of Medications."

In addition, **Solutions for Filling Gaps in Accountable Care Measure Sets**—published in the October issue of *The American Journal of Managed Care*—explores measurement gaps for high-priority conditions and identifies ways to improve measure sets. Researchers examined gaps in accountable care measures as compared with evidence-based guidelines for 20 prevalent and costly conditions such as breast cancer, diabetes, HIV and heart disease.

The study was conducted jointly by experts from NPC, Discern Health, the Brookings Institution and the American Medical Group Association and follows on NPC's 2014 white paper, "Accountable Care Measures for High-Cost Specialty Care and Innovative Treatment: You Get What You Pay For—Improving Measures for Accountable Care," and related conference. In fact, public payers, such as CMS, as well as many private payers and providers, are utilizing the layered measurement approach recommended in the NPC white paper or a variation of the approach. CMS also is using the 2014 white paper as an internal reference guide.

In response to requests from attendees and others who were unable to attend NPC's fall 2014 conference, **Mind the Gap: Improving Quality Measurement in Accountable Care Systems**, NPC hosted a special webinar in February designed to provide additional insights into how CMS identifies priorities for measurement and works with stakeholders to address measure gaps as well as how accountable care systems can use quality measures to balance financial incentives.

The webinar also explored key gaps in accountable care quality measure sets, particularly for high-cost specialty care and innovative treatment. Ms. Westrich moderated the webinar, which featured Kate Goodrich, MD, director, Quality Measurement and Health Assessment Group, CMS, Mark McClellan, MD, PhD, director, Health Care Innovation and Value Initiative, Brookings Institution, and Tom Valuck, MD, JD, partner, Discern Health.



Standing before NPC's exhibition booth, Vice President for Membership and Operations Kathryn Gleason discusses NPC's activities during the ISPOR 20th Annual International Meeting.

NPC President Dan Leonard moderates a panel discussion on biodiversity with Dr. C. Daniel Mullins of the University of Maryland School of Pharmacy, Dr. Gary Puckrein of the National Minority Quality Forum, Dr. Georgia Dunston of the College of Medicine at Howard University, and Adolph Falcon of the National Alliance for Hispanic Health.



Watching the webinar was a required assignment for a University of Maryland School of Pharmacy graduate course on Healthcare Quality and Quality Performance Measurement. The University of Maryland School of Pharmacy also partnered with NPC to develop a continuing education course on quality measures. The course addresses stakeholders' roles in the health care quality improvement cycle, the collaborative processes comprising measure development, and the implementation and use of evidence in continuous health care quality improvement. The course also discusses the types of quality measures and the many health care quality improvement programs being implemented in various health care settings.

NPC continued to be a part of discussions on these topics before payer audiences by participating in the **2015 Armada Specialty Pharmacy Summit** in May, where NPC President Dan Leonard joined a panel discussion, "Value-Based Healthcare Services: Paradigm Shift: Perspectives from Various Market Sectors." Other panelists included Scott Devine, MPH, PhD, executive director, Center for Observational and Real-world Evidence, Merck & Co, Inc.; Denise Kehoe, MBA, RPh, business associate, Rainmakers/BusinessOne Technologies; Sherri Thomas, PharmD, director, H&W Managed Care, Sam's Club; and Tom Woller, MS, RPh, FASHP, senior vice president of pharmacy services, Aurora Health Services.

NPC's Dr. Dubois also addressed the value of medicines at three significant events in 2015. At the **National Summit on Health Care Price, Cost and Quality Transparency** in March, he participated in a panel discussion, "Designing Benefits and Payment to Complement Cost and Quality Transparency." At the **Tenth National Pay-For-Performance Summit**, also in March, Dr. Dubois presented "Paying for Quality: How to Promote Optimal Use of Appropriate Therapies." In November, he presented during a session, "Payment Innovations in Pharmaceuticals and Devices," at the **Accountable Care Congress**.

As health care stakeholders discuss potential new care delivery and payment models—such as bundled payments and risk-sharing agreements (RSAs)—that are emerging as the U.S. health system shifts from a fee-for-service system to one that is performance-based, NPC continues to share its insights with stakeholders across the health system.

At the **ISPOR 20th Annual International Meeting** in May, NPC Research Director Michael Ciarametaro, MBA, presented during a workshop, "Design of Bundled Payment in the Ambulatory Setting of Care." He also addressed this issue in a session, "Bundled Payments Design: Best Practices and Case Studies," at the **Academy of Managed Care Pharmacy's 2015 Nexus** in October.

In addition to bundled payments, RSAs are another type of model that brings together two key stakeholders—payers and biopharmaceutical manufacturers. Under RSAs, they agree to link coverage and reimbursement levels to a drug's real-world effectiveness and/or how frequently it is utilized. These agreements can be a catalyst for generating an enhanced level of real-world evidence.

Private Sector Risk-Sharing Agreements in the U.S.: Trends, Barriers and Prospects, a peer-reviewed study conducted jointly by experts from NPC, the University of Washington, Tufts University and the Office of Health Economics (UK) and published in the September issue of *The American Journal of Managed Care*, examines the use of RSAs in the United States. The study found that there is limited RSA activity in the United States, but interest in the agreements among both payers and manufacturers is strong, and a changing health care environment may generate more activity in this arena in the future. In November, NPC hosted a webinar to discuss the study and address the benefits of RSAs and the barriers to their use in the United States.

NPC also was engaged in conversations about health care costs, sharing a blog series leading up to the day-long **U.S. Department of Health and Human Services (HHS) Pharmaceutical Forum: Innovation, Access, Affordability and Better Health** in November. Lately, prescription drug costs have attracted attention as the driver in increasing health spending, but *all* health costs need to be part of the conversation. The HHS Forum was an opportunity for stakeholders to discuss outdated approaches and provided a medium to discuss new solutions, innovative thinking and collaboration across the entire health care landscape.

ACCESS: PATIENTS HAVE MEANINGFUL ACCESS TO APPROPRIATE MEDICATIONS AND DIAGNOSTIC TOOLS

As the health care landscape shifts from a volume-based system to a value-based system, it is important to maintain the patient voice on what is considered high value versus low value; and to balance the implementation of the new value-based system with eliminating barriers to treatment and supporting innovative new therapies and diagnostic tools. As such, NPC's research efforts also have focused on improving formulary and benefit designs to support patients' access to appropriate therapies, optimizing access under both more progressive and traditional payment and delivery models, and identifying quality gaps and strengthening quality measure design to enhance medical decision-making.

Protecting Patient Access and Understanding Barriers in a Value-Based System

Access to therapies is sometimes based on the results of companion diagnostic tests (CDTs). Diagnostics can offer a multitude of potential benefits and help to determine whether a treatment will be effective and/or safe for an individual patient based on his or her individual characteristics. But assessing the value of these tests can be challenging and can have a real impact on patient access.



**NPC Chief Science Officer
Dr. Robert Dubois shares the
industry's perspective at the ISPOR
20th Annual International Meeting.**

If payers are uncertain whether to provide coverage for companion diagnostics, it could limit the accessibility of targeted cures and treatments for patients.

Improving the Efficiency and Quality of the Value Assessment Process for Companion Diagnostic Tests: The Companion test Assessment Tool,

a peer-reviewed study funded by NPC and co-authored with the University of Washington School of Pharmacy, examined some of the barriers to incorporating a CDT into drug treatment decisions and outlined a framework to assist managed care organizations in determining how to evaluate CDTs. Based on the information gathered from a literature review and interviews with payers, the study authors developed and tested a tool aimed at providing some clarity and consistency in the evaluation of diagnostics.

This tool, along with the CER Collaborative tool and related NPC materials on individual treatment effects, were referenced in AMCP's draft *Format for Formulary Submissions Version 4.0*. The *Format* provides a framework that outlines evidence requirements for biopharmaceutical manufacturers that are responding to an unsolicited request from health care decision makers to support coverage, reimbursement, and/or formulary placement of new and existing drugs, tests, or devices.

The importance of considering individual treatment differences and access to appropriate therapies was reiterated during an April town hall discussion, **Biodiversity and Health Care Quality: The 21st Century Challenge**, hosted by the National Minority Quality Forum (NMQF) and Congressional Black Caucus Health Braintrust and co-sponsored by NPC. NPC President Dan Leonard moderated the discussion, which featured Gary Puckrein, PhD, president and CEO, NMQF; Adolph Falcon, senior vice president, National Alliance for Hispanic Health; Georgia Dunston, PhD, full professor and former chair of the Department of Microbiology in the College of Medicine at Howard University; and C. Daniel Mullins, PhD, professor in the Pharmaceutical Health Services Research Department at the University of Maryland School of Pharmacy.

The Balancing Act—Linking Payment and Delivery Model Design With Individual Patient Access to Appropriate Therapies

Part of the switch to a value-based system has meant that payers have to rethink how they approach payment models for patients with complex or chronic diseases such as hepatitis C, sometimes to the patient's detriment. Payers have previously addressed their budgetary concerns through plans with a low premium and high deductible. Patients with chronic illnesses enrolled in these types of plans often incur high out-of-pocket costs, which may lead to decreased medication adherence. This can mean costly, and avoidable, hospital visits for the patient with the resultant large costs for the overall system. Measuring the value of new therapies will continue to be an important factor as stakeholders continue to consider how to align coverage to a therapy's value to the patient.

As stakeholders explore value-based models, it is important to ensure that any new system is balanced with continuing efforts to eliminate barriers to treatment. For example, employers have increasingly adopted consumer-directed health plans (CDHPs), but NPC has noted that there is a huge variability in deductible levels, coverage of prescription drugs, and the amount of wellness support. These factors

may lead to patients delaying or declining treatments. Instead, other payment models—such as value-based insurance design (V-BID), which links how beneficial a therapy is to the individual patient to how much the patient pays—may offer a better solution for balancing costs with ensuring flexible coverage and protecting patient access to health care services.

During presentations at the **AMCP Managed Care & Specialty Pharmacy Annual Meeting** in April and at **AcademyHealth's Annual Research Meeting** in June researchers considered whether it is acceptable for patients to pay more for medically appropriate treatments. At the AcademyHealth meeting, Dr. Dubois chaired a discussion, "Considering Efficiency and Fairness in the Design of Prescription Drug Benefits: Seeking a Balanced Approach to Improve Patient Access to Medically Appropriate Medication and Manage Drug Costs," that highlighted principles regarding when it is appropriate for patients to pay more out-of-pocket. Incorporating these principles into the next generation of benefit designs can incentivize patients to use the appropriate treatment and ultimately improve patient care.

ADDITIONAL OUTREACH

NPC plays an important role in bringing stakeholders together and encouraging dialogue on key issues that impact health care and the biopharmaceutical industry. By leveraging its relationships with other life science organizations, NPC generates increased collaboration and interaction in support of better health outcomes.

Communicating the impact of its research is an important priority for NPC. In 2015, increased communications efforts focused on demonstrating impact and sharing results with decision makers and stakeholders, including regulatory and oversight bodies, insurers, provider groups, and the media.

NPC research is published and distributed through peer-reviewed publications, white papers, commentaries, and media outreach. In 2015, *Chain Drug Review*, *Pharmaceutical Executive*, *Politico* and *Health IT Analytics* were among the media outlets that sought NPC's expertise. In addition, Dr. Dubois pens a recurring column in the *Journal of Comparative Effectiveness Research*.

NPC continues to produce the *CER Daily Newsfeed*®, a daily summary of CER activities around the world, and *E.V.I.dently*®, a monthly e-newsletter, and to maximize social media through Twitter (@npcnow). Other NPC-produced resources include infographics summarizing research findings and videos and podcasts from conferences and events. These and other resources available online at www.npcnow.org contain a wealth of information about how the biopharmaceutical industry's most pressing issues impact patient health.

LOOKING AHEAD

NPC will continue to fund research that supports moving from anecdotal to routine use of real-world evidence; encourage efforts to build and share credible data; and monitor and evaluate value frameworks. Increasing emphasis will be placed on biopharmaceutical innovation and how it can contribute to health system economic sustainability and improved patient outcomes.



NPC's research staff includes Kimberly Westrich, vice president for health services research, Jennifer Graff, vice president for comparative effectiveness research, and Michael Ciarametaro, director of research.

NPC MEMBERSHIP

NPC IS UNIQUE AMONG ORGANIZATIONS based in the Washington, DC area. Similar to a trade association, it is supported by membership that includes 21 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 by a director on the Board and further helps to shape the organization's research agenda through participation on the various Board-level committees, as well as on the Research and Communications Work Groups. NPC's interaction with leading scientific and policy experts from across key health care sectors, as well as with multiple stakeholder organizations, provides member input through a wide range of speakers and collaborations.

NPC members have public access to extensive resources, ranging from the full pipeline of NPC-sponsored research to such signature offerings as the *CER Daily Newsfeed*® (aggregates all of the day's news on comparative effectiveness research) and *E.V.I.dently*® (monthly e-newsletter summarizing NPC activities). 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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