



# 2014 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 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](http://www.npcnow.org) and follow NPC on Twitter @npcnow.

## Chairman's Message

The health care landscape continued to undergo significant change in the United States in 2014. Real-world evidence is becoming more broadly utilized; employers are turning to consumer-directed health plans, passing higher deductibles on to consumers; payers are continuing to adjust their formularies and plan offerings; and consumers are being encouraged to become more active participants in their health care. These are just a snapshot of the challenges in today's health environment, where uncertainties continue to abound as all parties adjust to new realities.

In this changing environment, the work of the National Pharmaceutical Council (NPC) is more relevant than ever. By taking a strategic, thoughtful approach to the most pressing issues, NPC is making a critical contribution to advancing health care policy. NPC-sponsored research related to ensuring patient access to medicines, highlighting gaps in accountable care measures, and the appropriate use of research in clinical practice is bringing critical issues to the forefront and providing a sound foundation for decisions that will shape the future of health care.

Along with its research portfolio, NPC also plays a significant role in bringing together stakeholders through education and outreach initiatives where information on the most recent research can be shared and best practices can be developed. Through NPC, as a convener and trusted partner, many diverse entities are collectively searching for solutions that ultimately will improve patient outcomes.

The pace of change and the complex nature of these issues often make it difficult to grasp the current and evolving state of affairs. In 2014, NPC made a concerted effort to explain its work in ways that are easier for broader audiences to comprehend. These efforts are reflected in the numerous research projects, educational events and resources produced by NPC this year and highlighted in this annual report.

As I turned the gavel over to incoming NPC Chairman David Martin in November, I did so knowing that NPC and its members remain fully dedicated to this important work. NPC's research and education initiatives will continue to resonate, and their impact will be felt for years to come.



Jeff Huth  
Senior Vice President, Managed Markets  
Boehringer Ingelheim Pharmaceuticals, Inc.  
2014 Chairman, NPC Board of Directors



## President's Message



2014 was a flagship year for the National Pharmaceutical Council (NPC). We launched our seventh decade of work with a strong agenda, carried out a number of research projects, programs and outreach activities to advance it, and finished the year with a record of accomplishments worthy of our institutional heritage.

Since the organization's founding in 1953, NPC's mission has remained essentially unchanged: to sponsor, participate in and promote scientific analyses of the appropriate use of pharmaceuticals and the clinical and economic value of improved health outcomes through innovation.

In support of that mission, over the last 12 months, NPC published critical research on the importance of patient access to treatments, the challenges in today's evolving payment and delivery environment, and the incorporation of real-world evidence into decision-making. We hosted, sponsored and participated in key industry conferences, webinars and other events to promote and disseminate the findings of that research. And on behalf of our members, we continued to advance the policy dialogue around some of health care's most pressing issues.

These activities shed new light on the importance of using sound evidence and science to support clinical decisions. This has become even more significant in an evolving health care environment where the impact of the Affordable Care Act is beginning to be felt and stakeholders—patients, providers, payers and policymakers, among others—are increasingly responsible for decisions that influence patient care and health outcomes.

These are complex issues that do not always translate easily for the general public. In an effort to increase understanding, in 2014 NPC focused on better communicating their significance to broader audiences. NPC developed a series of infographics and videos, and expanded the use of webinars and social media to enhance general knowledge around access to pharmaceuticals and the use of real-world evidence in health care decision-making.

NPC was honored to welcome Eli Lilly and Company as a new member in early 2014. They join a stellar list of leaders in the biopharmaceutical industry active on our Board of Directors and within our membership. We are proud to bring those members together to help foster an environment that encourages medical innovation and promotes high-quality patient care.

As we look to the year ahead, NPC remains committed to informing health policy in a way that ultimately enhances value and achieves better health outcomes for both individual patients and the population as a whole. New challenges will arise as the health care landscape continues to evolve. We stand ready to meet those challenges.

A handwritten signature in black ink, appearing to read "Dan Leonard". The signature is fluid and cursive, with a long horizontal stroke at the end.

Dan Leonard, MA  
President



NPC's research and activities have been focused on three areas that impact patient health outcomes: recognition that patient differences matter; demonstrating the value of pharmaceuticals in a changing payment and delivery environment; and incorporating high-quality, real-world evidence into health care decision-making.

## Recognition That Patient Differences Matter

Most of the comparative effectiveness and other research conducted today is based on what works for the “average patient” and may not take into account unique factors such as racial and ethnic backgrounds, age, genetics, chronic conditions, disease severity, gender, environment and personal treatment preferences.

These and other factors make patients different and affect how they may respond to a certain treatment. For these reasons, while the “average patient” may respond best to a particular treatment, some patients may experience little to no benefit from it, so other treatment options may be best for them.

NPC's research in the area of individual treatment effects, or heterogeneity, has sought to dispel this “myth of average” and call attention to the challenges that many patients face in finding the treatment that will work best for their conditions. For example, if a medical professional is providing a patient with care based on how the “average” person fared on that treatment, then that patient might not be getting the optimal treatment. Most insurance companies design their policies to meet the needs of the majority of people, so those who may respond differently may have a more difficult time getting coverage for other treatment options.

In early 2014, questions arose regarding limiting access to treatments, especially for patients with conditions that require specialty medicines. The Centers for Medicare and Medicaid Services (CMS) proposed a rulemaking provision related to drug categories or classes of clinical concern and exceptions, commonly referred to as “protected” classes. CMS proposed eliminating protected classes for antidepressants, immunosuppressants and antipsychotics, which would have restricted the treatment options for patients with coverage under Medicare Part D. A number of organizations, including NPC, submitted comments on the proposed provision, which was later withdrawn by CMS.

**Individual Treatment Effects: Implications for Research, Clinical Practice, and Policy**, published in the July issue of the *American Journal of Managed Care*, identified four factors that indicate when it is important to take differences in treatment response into account when making treatment, coverage and policy decisions. The paper also outlined policy recommendations for researchers, providers and payers that can help ensure the right treatment is delivered to the right patient.



NPC President Dan Leonard speaks at NPC's conference focused on the gaps in quality measurement.





To help payers understand and apply the concept of heterogeneity when making formulary decisions, four articles were published in the June issue of the *Journal of Managed Care & Specialty Pharmacy*. **The Good, the Bad and the Different: A Primer on Aspects of Heterogeneity of Treatment Effects** assists health care stakeholders in understanding when it is important to take patients' individual treatment responses into account and provides tools to help payers evaluate when patient differences matter within a study or across studies. These four articles built upon a series of online seminars, "Deciphering Heterogeneity: The Good, the Bad and the Different," developed by NPC in 2013 in conjunction with the University of Arizona College of Pharmacy.

To help researchers understand how to best analyze when patient differences exist, NPC Chief Science Officer Robert W. Dubois, MD, PhD, and NPC research collaborators presented on this topic at the **International Society for Pharmacoeconomics and Outcomes Research (ISPOR) 19th Annual International Meeting** (June 3) in the workshop session, "How Can We Use Randomized Trial Data to Assess Heterogeneity of Treatment Effects? Let Me Count the Ways." NPC's exhibit booth at the ISPOR meeting attracted hundreds of visitors and provided additional opportunities to distribute current research.

At the **Academy of Managed Care Pharmacy (AMCP) Nexus 2014: Connecting Health Care and Innovation**, Dr. Dubois participated on the panel, "Evaluating Companion Diagnostics Using Comparative Effectiveness Research" (October 9), which provided an overview of the key factors necessary to evaluate those tests, introduced a tool for identifying the key value drivers for companion diagnostics, and provided insights on approaches to triage evidence review and improve efficiency.

Additionally, NPC highlighted the importance of individual treatment effects and the relevance of companion diagnostics to target which treatments work best through presentations at the **BIO International Convention** (June 23-26), as well as through its sponsorship of the Friends of Cancer Research's forum, **A Blueprint for Drug/Diagnostic Co-development: Next Generation Sequencing** (September 23).



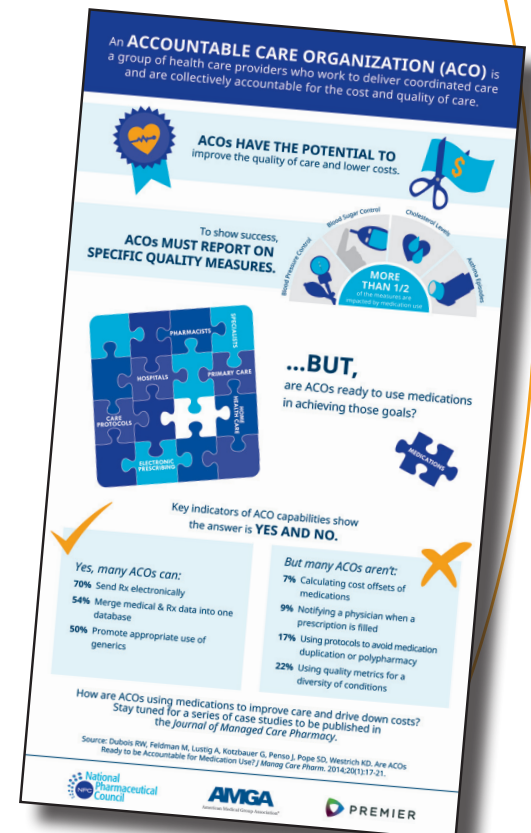
## Value of Pharmaceuticals in a Changing Payment and Delivery Environment

Appropriate use of medicines saves lives, improves health and can reduce costs, which are important considerations in today's changing reimbursement environment. In the last year, payment and delivery models continued to evolve, with a move toward consumer-directed health plans and higher deductibles, further discussions about health benefit designs such as value-based insurance design, and an increased focus on accountable care organizations (ACOs).

As ACOs gain traction among both private and public payers, so do expectations that these networks of health care providers will improve the quality of patient care and reduce overall costs. And with this shift from a fee-for-service payment system, based on the volume of services, to a value-based system, focused on the value of the services performed, quality measures and provider financial incentives could influence priorities and care delivery to the potential detriment of patients with certain conditions. This could result in inappropriate care, which includes both overuse and underuse of services, both of which have significant consequences for patients and health outcomes.

However, research conducted by NPC, the American Medical Group Association (AMGA) and Premier, Inc. shows that most ACOs have not yet developed the capabilities they need to leverage optimal medication use to achieve those goals. **Are ACOs Ready to Be Accountable for Medication Use?**, a peer-reviewed study published in the January *Journal of Managed Care & Specialty Pharmacy*, showed mixed results, finding that ACOs reported high readiness in some areas, but have room for improvement in others. NPC hosted a webinar, **Achieving Quality in ACOs: Are They Ready to Maximize the Value of Pharmaceuticals in Patient Care?** (January 14), to discuss this research and highlight ACOs' readiness in implementing the structures and processes needed to maximize the value of pharmaceuticals. **Best Practices: Improving Patient Outcomes and Costs in an ACO Through Comprehensive Medication Therapy Management**, a case study that examined Fairview Health's experience using comprehensive medication therapy management to improve clinical outcomes and reduce costs, was published in the December issue of the *Journal of Managed Care & Specialty Pharmacy*.

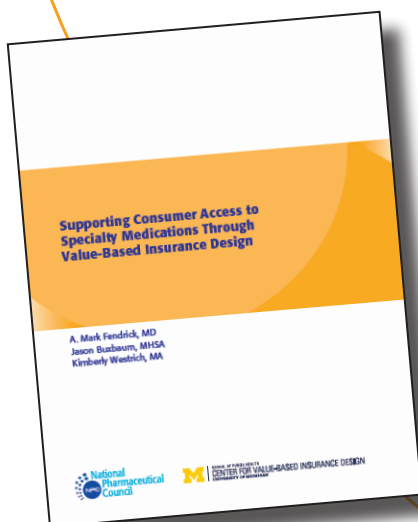
ACOs and their readiness for optimal medication use was further explored during an NPC-sponsored educational symposium, "You Get What You Pay For: Will ACOs Underuse Drugs?" during the **ISPOR 19th Annual International Meeting** (June 1).







Dr. Mark McClellan of the Brookings Institution and Dr. Kate Goodrich of CMS deliver keynote addresses at the “Mind the Gap” conference.



## Accountable Care Measures for High-Cost Specialty Care and Innovative Treatment: You Get What You Pay For—Improving Measures for Accountable Care

is an in-depth research paper published in October by NPC and Discern Health that sheds light on gaps in quality measurement and missed opportunities to promote improvement in patient care and health systems. The research also offers solutions for addressing measure gaps, particularly for specialty care and innovative treatment.

That research also sparked conversation at a major conference, **Mind the Gap: Improving Quality Measurement in Accountable Care Systems** (October 30), sponsored by NPC, the National Health Council and the Pharmacy Quality Alliance, along with 17 additional co-sponsors. The conference featured keynote addresses from Mark McClellan, MD, PhD, director, Health Care Innovation and Value Initiative, Brookings Institution, and Kate Goodrich, MD, director, Quality Measurement and Health Assessment Group, CMS, who said that the recommendations outlined in the research “actually articulate very well some of the things that we at CMS, but also the measurement community writ large, have been thinking about” in terms of quality measures.

The topic was further highlighted by Dr. Dubois, Jonathan F. Nasser, MD, chief clinical transformation officer, Crystal Run Healthcare, and Thomas Valuck, MD, MHSA, JD, partner, Discern Health, during a panel discussion, “Can Quality Measures Promote Optimal Use and Not Underuse of Appropriate Therapies?” at the **Fifth National Accountable Care Congress** (November 11).

Value-based insurance design (V-BID) is a health benefit model built on the principle of lowering or removing financial barriers to essential, evidence-based, high-value clinical services to align patients’ out-of-pocket costs, such as copayments, with the value of the services provided. Driven by the concept of clinical nuance, V-BID recognizes that medical services differ in the benefit they provide, and the clinical benefit derived from a specific service depends on the characteristics of the patient receiving it. The goal of V-BID is to shift the focus from “how much” to “how well” we spend our health care dollars. The concept, and how it could be applied to specialty medications, was explored in-depth via **Supporting Consumer Access to Specialty Medications Through Value-Based Insurance Design**, a booklet published in June by NPC and the Center for Value-Based Insurance Design at the University of Michigan.

A panel of leading health and benefits experts addressed how V-BID could be utilized by payers and purchasers to address challenges with specialty

medications and health care coverage options at an NPC-sponsored webinar on **Access to Specialty Medications and Value-Based Insurance Design** (September 29). NPC Vice President for Health Services Research Kimberly Westrich, MA, moderated a discussion featuring A. Mark Fendrick, MD, director, University of Michigan Center for Value-Based Insurance Design, Will Shrank, MD, MSHS, chief scientific officer and chief medical officer, Provider Innovation and Analytics, CVS Health, and Brian Klepper, PhD, chief executive officer, National Business Coalition on Health.

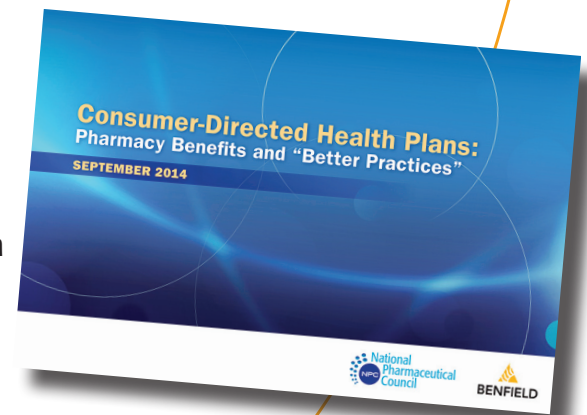
NPC's webinar on **Consumer-Directed Health Plans: Pharmacy Benefits & Best Practices** (July 23) provided a landscape review of employer practices related to their consumer-directed health plans (CDHPs), including how they determine what pharmacy benefits to cover, whether their decisions are impacting low-income or high health care need populations, and whether employers are following good practices when implementing CDHPs. Results of a survey on CDHPs and pharmacy benefit design conducted by The Benfield Group on behalf of NPC were presented at **AMCP's 27th Annual Meeting & Expo** (April 7-10). They also were shared in a chart pack, **Consumer-Directed Health Plans: Pharmacy Benefits and "Better Practices,"** published by NPC in September.

NPC research also looked at how novel specialty therapies, particularly for rheumatoid arthritis, multiple sclerosis and breast cancer, hold promise for arresting disease progression and improving quality of life. The research, **The Value of Specialty Pharmaceuticals—A Systematic Review**, was published in the *American Journal of Managed Care* in June.

At several key conferences throughout the year, Dr. Dubois addressed the ways value determination can be integrated into medical policy decisions. During the second **National Health Insurance Exchange Summit** (May 15), the leading forum on public and private health insurance exchanges and responsive strategies by government, plans and providers, he hosted a discussion on "How Pharmaceuticals and Pharmaceutical Companies Will Participate in the Exchanges." During the Tufts Medical Center **CEVR Symposium on Innovation and Cost-Effectiveness Analysis** (September 10), which NPC co-sponsored, he moderated a panel on "Measuring Attributes of Value." The symposium covered advances in the measurement of value, the inclusion of future innovations into cost-effectiveness analysis calculations, and payers' attitudes toward paying for innovation. And at the **AMCP Nexus 2014: Connecting Health Care and Innovation** (October 7), he participated in the AMCP Foundation Symposium, "Specialty Pharmacy and Patient Care: Are We at a Tipping Point?"



Dr. Mark Fendrick discusses V-BID and specialty medicines at a June Institute of Medicine meeting.







NPC VP for CER Dr. Jennifer Graff and Research Director Mike Ciarametaro collaborate on a research project.

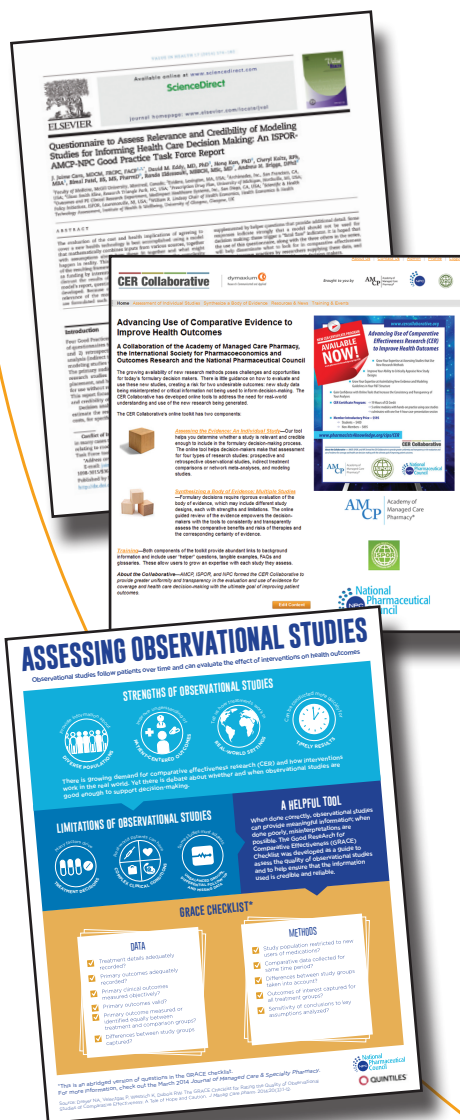
## Incorporating High-Quality, Real-World Evidence Into Health Care Decision-Making

Understanding how treatments work in the real world is an important and complex task. Patient experiences in the real world may differ from the controlled environment of clinical studies. High-quality, real-world evidence can provide meaningful information for health care decision-making, especially when it is made more broadly available. NPC's efforts in this area focused on ways to ensure that real-world evidence is credible and reliable, is interpreted in a consistent manner, and can be communicated by different types of stakeholders.

One of NPC's major initiatives in this area has been the **CER Collaborative**, a joint project with the Academy of Managed Care Pharmacy (AMCP) and the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) to develop online tools, resources and training materials to aid formulary decision-makers, the researchers who are developing information for use by decision-makers, the biopharmaceutical industry and other health care stakeholders. There are more than 1,000 registered users of the CER Collaborative's online tools, which enable health care decision-makers to synthesize and evaluate different types of comparative effectiveness research (CER). In addition, AMCP has incorporated the online tools into its annual National Student Pharmacist Pharmacy & Therapeutics Competition, and several health plans are using the tools as well. These tools were the focus of multiple presentations, webinars and programs throughout the year, including at the **AMCP Annual Meeting & Expo, AMCP Nexus 2014**, and the **ISPOR 17th Annual European Congress**. Related articles also were published in *Value in Health*.

To guide pharmacists and other clinical decision-makers on how to use the tools, the CER Collaborative, in conjunction with the University of Maryland School of Pharmacy, developed the CER Collaborative Continuing Education Certificate, a 19-hour certificate and continuing education credit program. This allows clinical decision-makers to advance their expertise in assessing evidence and making use of the online CER Collaborative tool and resources. The first group of learners completed their training in the fall, and future training will occur in 2015 at AMCP meetings and at department-wide training at managed care and pharmaceutical companies.

Given the growing interest in and demand for information about comparative effectiveness research and questions about the quality of research that will support future health care decision-making, a group of researchers led by NPC and Quintiles developed and tested a checklist to evaluate the quality and usefulness of observational research studies. Published in the March issue of the *Journal of Managed Care & Specialty Pharmacy*, **The GRACE Checklist for Rating the Quality of Observational Studies of Comparative Effectiveness: A Tale of Hope and Caution** includes an 11-item screening tool that can be used to separate observational studies that meet baseline quality criteria from those that do not.





**Real-World Impact of Comparative Effectiveness Research Findings on Clinical Practice**, published in the *American Journal of Managed Care* in June, suggests that changes are needed to enable more consistent translation of research findings into clinical practice. Authored by researchers from NPC, Truven Health Analytics, Harvard Medical School and the University of Michigan, the study evaluated real-world utilization trends before and after the publication of CER findings and the release of relevant clinical practice guidelines (CPGs) from four high-profile CER case studies published within the last decade. Analysis revealed no clear pattern of utilization in the first four quarters after publication. Even when research was included in revised or updated CPGs, researchers were not able to consistently find changes in utilization or clinical practice.



Amgen VP for Global Health Economics Dr. Martin Zagari, NPC Chief Science Officer Dr. Robert Dubois and Optum Labs Chief Medical Officer Dr. Paul Wallace speak at a June AcademyHealth meeting.

To understand when new evidence provides sufficient information to change formulary decision-making, Dr. Dubois chaired a session on “Real-World Evidence: When and Why Is It Fit for Purpose,” at **AcademyHealth’s Annual Research Meeting** (June 8), the premier forum for health services research. The workshop session presented a framework for determining when new evidence, including real-world evidence from observational or pragmatic studies, may provide sufficient information. This topic also was addressed during a June 2 session moderated by NPC Vice President of CER Jennifer Graff, PharmD, at the **ISPOR 19th Annual International Meeting**. Additionally, Dr. Dubois and Sally Morton, PhD, professor and chair, Biostatistics, University of Pittsburgh, presented on “Guidelines and Standards for Observational Studies: Are We Headed for Discourse or Harmony?” at an ISPOR session on June 3.



NPC VP for CER Dr. Jennifer Graff moderates an ISPOR panel discussion with AcademyHealth Director of Strategic Alliances Raj Sabharwal, Tuckson Health Connections Managing Partner Dr. Reed Tuckson, and Institute for Clinical and Economic Review President Dr. Steven Pearson.



NPC President Dan Leonard and VP for Health Services Research Kimberly Westrich share the results of NPC's annual CER survey during a webinar in May.

NPC also weighed in on the use of big data in conducting real-world evidence for use in decision-making in regulatory science and research methodology by co-sponsoring and presenting at two public forums, the University of Maryland Center for Excellence in Regulatory Science program, **Leveraging Big Data II: What Does It Mean for Improving Product Development and Health Care** (February 11) and the AcademyHealth Electronic Data Methods Forum, **Evidence Into Action: Perspectives From Industry and Payers** (June 7). Additionally, NPC teamed with the Healthcare Leadership Council to submit comments to CMS regarding increased access to Medicare Part D Prescription Event data, with the goal of making real-world evidence more broadly available to researchers. The comments were cited in CMS' final rule.

**2014 Comparative Effectiveness Research and the Environment for Health Care Decision-Making**, NPC's annual survey of health care stakeholders, examined the current environment for CER and how stakeholder perceptions of CER have changed during the last four years. By continuing this annual survey, NPC has been able to track changes in which organizations are perceived as influential in areas such as prioritizing, funding, conducting and disseminating CER, as well as to assess the status of other issues affecting the current health care decision-making environment. The 2014 survey revealed continued optimism for the use of CER as a tool for improving health care decision-making, but showed the impact of CER has not yet been realized. It also indicated that the Patient-Centered Outcomes Research Institute (PCORI), the agency charged with overseeing this research, has firmly established its key role in the CER effort. Conducted by Social & Scientific Systems, Inc. on behalf of NPC, the survey was based on feedback from stakeholders, including researchers and thought leaders, representatives of government, insurers and health plans, employers, business coalitions and associations.

NPC presented the 2014 survey findings during a webinar (May 19) moderated by NPC President Dan Leonard, MA, that featured Joe Selby, MD, MPH, executive director of PCORI, Eugene Rich, MD, director of the Center on Health Care Effectiveness and senior fellow at Mathematica Policy Research, and Kimberly Westrich of NPC. Ms. Westrich also presented the survey results during a session on "The Environment for Health Care Decision-Making: Tracking Changes and New Insights" at the **Drug Information Association's (DIA) 50th Annual Meeting** (June 17).





## Health Care Policy Fellowship

NPC, in conjunction with the Milken Institute School of Public Health at The George Washington University, will continue to offer a post-doctoral fellowship in health care policy, with the second fellowship running from July 2015 to June 2017. Given the rapid changes in the health care environment and full implementation of the Affordable Care Act, the next fellowship will focus more broadly on understanding health care policy related to pharmaceuticals. Chuck Shih, PhD, holds the 2013-2015 fellowship, which is intended to address the policy implications of comparative effectiveness research.

## Additional Outreach

Recognizing that people receive and process information in different ways, NPC continued to present its research via its website, social media, videos and infographics—using these communications vehicles to offer shorter, easier-to-understand versions of more complex topics. NPC grew its reach on Twitter and added content to its website and blog, including a redesigned members' only website.

NPC also continued to publish the *CER Daily Newsfeed*®, a popular weekday summary of CER-related activities from around the globe, and *E.V.I.dently*®, its monthly e-newsletter.

The organization's outreach wasn't limited to online efforts. Dr. Dubois continued to pen a regular column, *From Methods to Policy*, for the *Journal of Comparative Effectiveness Research*, and media outlets such as the *Pink Sheet*, *CQ HealthBeat* and *Politico* covered NPC's research and activities and sought NPC's expertise.



NPC Chief Science Officer Dr. Robert Dubois, a Pardee RAND Graduate School alumnus, talks to current students about the NPC and Milken Institute School of Public Health at The George Washington University post-doctoral fellowship in health care policy.



NPC VP for Membership & Operations Kathryn Gleason confers with President Dan Leonard at NPC's exhibition booth.



# NPC Members

NPC's membership includes the top research-based biopharmaceutical companies in the world. NPC provides members the opportunity to:

- Inform U.S. health policy through the delivery of credible, authoritative research
- Participate directly in setting the organization's research agenda
- Collaborate with leading scientific and policy experts from across key health care sectors
- Leverage access and credibility via NPC relationships with multiple stakeholders
- Access and repurpose NPC educational resources, including practical tools, analytical papers and other information available in the members' only section of the NPC website.

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### Recognizing Pat Adams for Her Leadership

*In today's business world, it's not often that one will find dedicated employees who are passionate about their work and care about the direction of an organization. For 33 years, NPC was fortunate to have in Pat Adams an employee who exemplified all of those qualities. NPC would like to thank Pat for her many years of service and wish her all of the best in her retirement.*





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Designer: Diana Enyedi

Photos courtesy of Ian Wagreich; Matthew Talesfore of the Pardee RAND Graduate School's Media Services department; and the National Pharmaceutical Council.



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