The National Pharmaceutical Council (NPC) 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, education and promotion of the critical issues of evidence, innovation and the value of medicines for patients. NPC actively participates with a variety of health care stakeholders to demonstrate and communicate the value of biopharmaceuticals and vaccines through practical, evidence-based applications and tools.  

www.npcnow.org
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Celebrating *60 years* of leadership in health policy research
In 1953, representatives from the leading research-based pharmaceutical companies gathered in New York City to found the National Pharmaceutical Council (NPC), an organization dedicated to providing research, analysis and information about the impact of the discoveries made by the pharmaceutical industry on the health of our country. For 60 years, NPC has been carrying out that mission, engaging stakeholders, conducting research on key health policy issues and promoting a health care environment where patients benefit because medical innovation flourishes.

Over the years, NPC’s work has centered on the research-based pharmaceutical industry’s most pressing issues. NPC has addressed concerns about unauthorized substitution at the retail pharmacy level; Medicaid programs and access to medicines; medication noncompliance; formulary restrictions; and Medicare drug benefit education, among other issues.

Most recently, NPC’s work has focused on informing efforts to incorporate comparative effectiveness research (CER) into the health care delivery system. As has been the case so many times over the last six decades, NPC was again ahead of the curve. The organization placed an emphasis on this area prior to the health care reform debate that resulted in passage of the Affordable Care Act (ACA) and put a spotlight on CER. Many of the key questions that NPC has been exploring are now embedded in the work of the Patient-Centered Outcomes Research Institute (PCORI), the research entity created within the ACA.

There are still many health care policy challenges for NPC to tackle during the next few years. These can be categorized in three priority areas: identifying individual patient needs in a population-based system, demonstrating the appropriate role and value of medicines, and supporting best practices in studying and illustrating what happens to patients in the real world.

Research-based pharmaceutical companies have made enormous strides in the past 60 years, creating treatments that have saved countless lives and have improved the quality of even more. NPC is proud to continue its work to support and advance an environment that allows for continued medical innovation and promotes high-quality patient care.

Celebrating 60 years of leadership in health policy research
In 2013, the National Pharmaceutical Council (NPC) marked 60 years as one of the leading trade associations focused on health care policy research in the United States. As we commemorate this institutional milestone, we are proud of the fact that NPC and our member companies have led the way in advancing the use of sound evidence and science to support clinical decisions made by health care stakeholders.

Since the organization’s founding in 1953, NPC’s mission has remained the same: 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. And while this mission is central to our work, the issues we engage in have evolved right along with the frequently changing health care landscape. In 2013, our work focused on three main priority areas:

- demonstrating how an appropriate range of therapies is needed to achieve better health outcomes for both the individual patient and the population at large;
- defining the optimal role and value of biopharmaceuticals in the current and evolving payment and delivery models; and,
- promoting the optimal use of real-world evidence to demonstrate value.

We continued to publish important peer-reviewed research on topics such as understanding and evaluating the impact of individual treatment effects on coverage and decision-making; a framework for understanding evidence adoption; and assessing the comparative effectiveness research (CER) environment, among other projects. We also completed a suite of online tools for evaluating evidence for coverage and health care decision-making as part of our important multi-stakeholder CER Collaborative.

In 2013, NPC also placed additional emphasis on expanding our communications about our research to more audiences. We re-launched our website (www.npcnow.org), making it more user-friendly, incorporating social media and including enhancements such as a fully searchable research library and NPC’s blog, E.V.I.dently Today. We published our monthly e-newsletter E.V.I.dently Today, disseminated the CER Daily Newsfeed and expanded our presence in social media. Additionally, we increased our participation in industry and related events, with NPC staff members and research partners addressing key constituencies at high-profile scientific meetings and conferences.

NPC proudly continues to represent the leaders in the research-based pharmaceutical industry, welcoming Celgene Corporation and Astellas Pharma US, Inc. as new members in 2013.

As we look to the future, we’re honored to support the research-based pharmaceutical industry and to help foster an environment that encourages medical innovation and promotes high-quality patient care.

Dan Leonard
President

**NPC History: 1950s**

- 1953: Incorporated in New York City at Rockefeller Center.
- 1954: Newell Stewart is NPC’s first president.
- 1959: Launches an internship program with the American Pharmaceutical Association that lasted through 1994.
NPC’s research, programs and other activities informed many significant health care policy debates in 2013, while supporting the organization’s overall goal of achieving the best patient outcomes in the most efficient way possible.

Implementation of the Affordable Care Act (ACA) continued to dominate health care policy discussions over the last year, with more issues and challenges coming to the forefront as the details of coverage plans, enrollment options and state health exchanges continued to unfold. Ensuring that patients have access to the right treatments and providing evidence that the appropriate use of pharmaceuticals is often an integral part of the solution were among NPC’s priorities during this critical period.

NPC’s peer-reviewed research projects focused on achieving a better understanding of key issues that will be essential to achieving both optimal care and lower overall health care costs. In 2013, NPC research addressed three main areas: individual treatment effects, the value of pharmaceuticals, and comparative effectiveness research (CER) and real-world evidence.

It is important not only to research key health care issues, but also to widely share the findings of that research in order to advance the nation’s health care policy conversation. Over the last year, NPC increased its participation in industry conferences and related events, expanded outreach and partnerships with groups beyond the research-based pharmaceutical industry, and continued to share findings with and provide timely information to new audiences and stakeholders through symposia, webinars and other communications efforts.

**Individual Treatment Effects**

Evidence shows that “one size fits all” approaches to health care coverage and treatment options, which are currently being considered by some state insurance exchanges, can mean poor outcomes for some patients. Poor responses from individual patients can result in suboptimal care and higher overall costs. Patients, payers and health care providers need to be aware of and sensitive to individual treatment effects, or heterogeneity, and to take them into account when making decisions regarding benefit design, treatment choices and coverage. In 2013, several NPC research projects delved into raising awareness of this issue, understanding

NPC Activities: Research, Programs, Partnerships and Other Outreach

NPC History: 1960s

- 1963: Develops its first of 42 annual compilations, “Pharmaceutical Benefits Under State Medical Assistance Programs.”
- 1965: NPC moves to Washington, D.C.
its implications for patients and the health care system, and considering how to integrate heterogeneity into health care decision-making.

Building on a conference convened by NPC in 2012 on *The Myth of Average: Why Individual Patient Differences Matter*, in October 2013 NPC published a booklet of the same title that explores in layman’s terms the reasons behind differences in treatment effects and offers a checklist that patients can use when talking to their health care providers. The booklet also includes information on the science behind patient differences, the importance of CER that takes these differences into consideration, and the challenges involved in providing health coverage—and access to a range of different treatments—for patients who are not all “average.”

A project funded by NPC and conducted with the University of Maryland, using stage IV prostate cancer as an example, illustrated that heterogeneity—in particular the impact of non-biologic factors such as geography, diet and social issues on treatment outcomes—is not well understood. *The Emerging Relevance of Heterogeneity of Treatment Effect in Clinical Care: A Study Using Stage IV Prostate Cancer as a Model* examined the impact of individual treatment effects on survival, adverse events or health-related quality of life in stage IV prostate cancer patients. The findings were published in the November issue of the *Journal of Comparative Effectiveness Research*.

In the fall of 2013, NPC solicited research proposals to further study this issue through case studies that address patient heterogeneity of treatment effect (HTE), and how HTE should be considered to achieve better health outcomes in compelling clinical areas for both the individual patient and the population. Proposals received by the September 30 deadline are being vetted, and funding for selected projects will be awarded in 2014.

*Heterogeneity in Action: The Role of Passive Personalization in Comparative Effectiveness Research*, published online in *Health Economics* in September, demonstrates how CER, which often describes average effectiveness of treatments for populations of patients, could
impact the personalization of treatments that currently occurs in clinical practice. The study analyzes how population-directed policies may have unintended effects when there are differences in how individual patients respond to treatments, using the example of a “generics only” approach to treat Medicaid patients with schizophrenia with antipsychotic drugs, rather than a less restrictive access that accounts for individual patient differences. Based upon the study results, the authors found that a “one size fits all” approach that does not account for individual differences may lead to decreases in health care quality.

To help clinicians, medical and pharmacy directors and other health care decision-makers better understand and evaluate heterogeneity, NPC funded four online seminars launched by the University of Arizona College of Pharmacy. Now available on the University’s website, Deciphering Heterogeneity: The Good, The Bad and The Different explains how to evaluate CER for individual treatment effects, the implications of applying “average” effects to individual patients or groups, and how individual treatment effects influence patient outcomes.

NPC staff presented on this topic and tested an online tool to assess heterogeneity at a number of key conferences throughout the year. NPC research on heterogeneity was showcased during several sessions at the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) 18th Annual International Meeting (May 18-22), which was attended by more than 2,000 health outcomes researchers and academics. NPC’s exhibit booth attracted hundreds of visitors and provided additional opportunities to disseminate the latest research.

The discussion on heterogeneity will continue in the coming year through research that includes a white paper, an assessment of companion diagnostics on medication choice, and an examination of the impact of heterogeneity on health disparities, among other projects.

**The Value of Pharmaceuticals**

Health care providers are shifting to value-based care models such as accountable care organizations that tie payment and the delivery of health care to measures of quality. These models aim to provide better care for individuals, improve population health and slow cost growth. Many of these models, such as the Centers for Medicare & Medicaid Services’ Medicare Shared Savings Program, include quality benchmarks and incentives for reducing costs. As

**NPC History: 1970s**

- NPC provides educational activities for consumer organizations, federal agencies, medical and pharmacy students and others about the value of branded pharmaceuticals.
providers evaluate optimal care for their patient populations in these new models, prescription medications should be thoughtfully integrated into the benchmarks for quality care. It’s clear that when medications are appropriately used, they can contribute significantly to improving patient outcomes and reducing overall costs. What remains unclear, however, is how evidence is being applied in making coverage decisions. To increase the clarity, consistency and transparency of how evidence is applied by payers during the formulary decision-making process, NPC, Cerner Research and other research experts developed a new assessment tool with input from an expert panel and validation by a group of medical and pharmacy directors. This effort to develop, test and pilot a more structured approach to formulary decision-making was published as a study, Transparency in Evidence Evaluation and Formulary Decision-Making: Conceptual Developments to Real-World Implementation, in the August issue of the peer-reviewed journal Pharmacy and Therapeutics. Although the tool did not hold up when it was tested in a real-world pharmacy and therapeutics environment, it provided valuable insight into how evidence is considered.

NPC shared some of those insights during a webinar, Can We Bring Clarity, Consistency and Transparency to Payer Coverage Decisions? (September 10), and addressed the questions of why some treatments are covered under a health care plan while others are not, and how payers evaluate the information needed to make coverage decisions. Dr. Jennifer Graff, director of CER, NPC, Dr. Saira Jan, director of clinical pharmacy management, Horizon Blue Cross Blue Shield of New Jersey, and Dr. Bonnie Dean, principal investigator, research services, and Dr. Kelly Ko, research scientist, both of Cerner Research, were the featured speakers.

NPC’s research in this arena also was presented at a number of conferences throughout 2013. NPC was a sponsor and Chief Science Officer Dr. Robert Dubois was a panelist on “Achieving Quality in a Bundled Payment Environment: Beware of What You Measure (And Don’t Measure)” and “CMS End Stage Disease Prospective (Bundled) Payment” at the Third National Bundled Payment Summit (June 10-11), a forum on the role of health care payment reforms held as part of D.C. Health Care Innovation Week.

NPC’s work on accountable care organizations and their ability to optimize medication use was shared by Dr. Dubois at the ISPOR 18th Annual International Meeting, the Brookings-Dartmouth ACO Learning Network (May 31), the Academy of Managed Care Pharmacy 25th Annual Meeting & Expo (April 3-5) and the Biopharmaceutical

• 1979: Examination of the Louisiana Medicaid drug program strongly suggests restrictive formularies have an adverse impact on health outcomes and overall costs.
Industry Organization International Convention (April 22-25) and by NPC Research Associate Adam Lustig at the AcademyHealth Annual Research Meeting (June 23-25). During the latter meeting, NPC Director of Policy Research Dr. Daryl Pritchard also presented on “The Impact of Comparative Effectiveness Research on Biomedical Innovation and Population Health.” Additionally, NPC sponsored and presented at the Integrated Benefits Institute/National Business Coalition on Health (NBCH) Health & Productivity Forum (February 25-27), the National Health Insurance Exchange Summit (May 1-3), the National Health Care Innovation Summit (June 10), NBCH’s National Health Leadership Council (June 27), the Twelfth National Quality Colloquium (September 18-20) and the ACO Congress (November 5-7).

NPC’s forthcoming work in this area will examine which patients are in the highest cost populations, and why; and understanding the effects of specialty medications on health outcomes.

Comparative Effectiveness Research (CER) and Real-World Evidence

When it is conducted in a rigorous and high-quality manner, CER has the potential to greatly improve health outcomes for patients. CER can provide patients and their health care providers with better information to guide them in their decisions, especially patients with chronic conditions and those who face multiple health challenges.

The focus of CER has shifted to now address how comparative studies should be designed to answer the practical questions about “effectiveness,” particularly in real-world settings. The question of how a treatment, service or method of delivering care works when applied in real-world, clinical practice environments is the focus of real-world evidence.

In 2013, NPC’s research in this area focused on defining real-world evidence, identifying how stakeholders are using real-world evidence to develop clinical guidelines and make health care decisions, working with experts and end-users to help identify good practices for high-quality real-world evidence and identifying those who can communicate the research.

NPC History: 1980s

- 1980: Mark Knowles becomes NPC president.

To better understand the overall landscape for this research, NPC conducted its third annual survey of key health care stakeholders and published the findings as a booklet, *Comparative Effectiveness Research and the Environment for Health Care Decision-Making*. The survey results showed that there is tempered optimism about CER and health care stakeholders have growing expectations for its use as a tool for improving health care decision-making. Many respondents indicated that they expect CER to have a larger impact during the next three to five years, rather than in the near-term. The survey results also showed that stakeholders are looking increasingly to the Patient-Centered Outcomes Research Institute (PCORI) as a leader in the CER effort. NPC presented the findings during a webinar (March 19) that featured Dan Leonard, president, NPC, Dr. Lisa Simpson, president and CEO, AcademyHealth, and Dr. Joe Selby, executive director, PCORI.

The survey results also were presented by NPC Director of Health Services Research Kimberly Westrich at the *Drug Information Association’s (DIA) 49th Annual Meeting: Advancing Therapeutic Innovation and Regulatory Sciences* (June 23-27), and by NPC Research Associate Adam Lustig at the *AcademyHealth Annual Research Meeting*.

*When Is Evidence Sufficient for Decision-Making? A Framework for Understanding the Pace of Evidence Adoption*, an NPC study published in the July issue of the *Journal of Comparative Effectiveness Research*, outlined influential factors that impact how quickly new medical evidence is adopted and put into practice by health care decision-makers. According to the Institute of Medicine, it takes an average of 17 years for new data, or evidence, to become part of routine care. Using three well-documented cases in which new information was disseminated to the public, the authors developed a framework to determine which factors were most influential in changing clinical practice. The overall goal of the framework is to encourage consideration of the critical factors that affect evidence adoption and help to optimize the pace with which new treatments and new findings about treatments are brought into routine clinical practice.

NPC continued to address those issues via *When Is Evidence “Enough” to Make a Health Care Decision?* (July 31), a webinar led by Dr. Dubois that featured University of Maryland School of Pharmacy Professor Dr. Eleanor Perfetto examining five critical factors that make evidence “enough” to quickly transform into clinical practice.

- 1984: NPC develops a widely viewed PSA on medication adherence featuring professional tennis player Arthur Ashe.
- 1985: NPC headquarters moves to Reston, VA.
NPC also continues to explore ways to enhance the processes used to evaluate evidence. The **CER Collaborative** is a joint project being conducted by NPC with the Academy of Managed Care Pharmacy (AMCP) and the International Society for Pharmacoeconomics and Outcomes Research (ISPOR). The project aims to provide greater uniformity and transparency in the evaluation and use of evidence for coverage and health care decision-making, with the ultimate goal of improving patient outcomes. In 2013, the CER Collaborative developed online tools and training materials to help increase decision-makers’ ability to critically appraise individual studies and synthesize the evidence from a variety of study methods to guide formulary decisions. The materials are available online at www.cercollaborative.org.

Training on the use of the new CER Collaborative materials is underway. The CER Collaborative’s efforts were featured at the **ISPOR 18th Annual International Meeting** during sessions on “Assessing the Evidence for Better Patient Care: Synthesizing the Body of Evidence—A Tool for Formulary Decision-Making” and “Assessing the Evidence for the Health Care Decision Maker.” At the **AMCP 25th Annual Meeting & Expo** (April 3-5) and at the **AMCP Nexus 2013: Connecting Health Care and Innovation** (October 15-18), NPC joined with AMCP and ISPOR to demonstrate the online tool. The tool is being incorporated into requirements for AMCP’s 2014 National Student Pharmacist P&T Competition, and further training efforts will continue in 2014.

NPC also explored ways for patients to evaluate CER. An interactive symposium, **Putting Patients First®: Paving a Path to Useful CER** (September 30), introduced a framework developed by the National Health Council (NHC) and Avalere Health for evaluating CER and making it more meaningful for consumers in their health care decision-making. Co-sponsored by NPC and NHC, the symposium was designed to collect feedback from a broad range of health care stakeholders on a new framework designed to guide the development of CER, help evaluate research applications and assess results, and assist in communicating findings to various audiences. Participants included patients, providers, policymakers, payers, researchers and those who fund research. Featured speakers included Mr. Leonard, Dr. Dubois, Myrl Weinberg, FASAE, CAE, chief executive officer, NHC, Sung Hee Choe, senior manager, Avalere Health, and Dr. C. Daniel Mullins, professor, pharmaceutical health services research, School of Pharmacy, University of Maryland.

A members-only webinar, **Communicating CER Findings** (August 14), continued the work begun by NPC in 2012 to examine the challenges faced by the research-based pharmaceutical

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**NPC History: 1990s**

- 1993: NPC receives Telly Award for excellence in communications for the video, “Spread the Word,” about the value of pharmaceuticals.
- 1996: Karen Williams becomes NPC president.
industry in discussing CER. The webinar featured Tufts Medical Center Economist Dr. Peter Neumann, who outlined possible modifications to Section 114 of the Food and Drug Administration Modernization Act of 1997 as a way to address those communications challenges.

NPC was a sponsor and Dr. Dubois served as a co-chair for the Fifth National Comparative Effectiveness Summit (September 16-18), a leading forum on the role of CER in health system change and health reform. Dr. Dubois presented “Real-World Evidence and Decision-Making: Is It Time Yet?” and Dr. Graff moderated a panel on “How Life Sciences Companies Are Using Comparative Effectiveness Research.”

To further the discussion and thought leadership on CER, Dr. Dubois serves as an associate editor of the bimonthly, peer-reviewed Journal of Comparative Effectiveness Research. Dr. Dubois contributes a regular column, “From Methods to Policy,” which focuses on how CER impacts health care and highlights issues on the horizon for researchers, industry and other stakeholders. Recent columns examined the pros and cons of rapid-learning health care systems, efforts to evaluate evidence and the potential return on investment for CER.

In July 2013, NPC and The George Washington University School of Public Health and Health Services (SPHHS) selected Chuck Shih, PhD, as the first recipient of a new two-year post-doctoral Fellowship in the Policy Impact of CER. The Fellowship aims to combine training in CER and CER programs with an increased understanding of related health care policy. Dr. Shih will be assessing CER’s impact on public health, focusing on the policy ramifications of CER, and identifying the mechanisms through which CER may be used in the health care system.

- Copies of NPC-sponsored research are available in the NPC research library online at www.npcnow.org/research.

- 1996: NPC sponsors research by Dr. Susan Horn that shows greater formulary restrictions are associated with higher costs.
Enhanced Communications

Recognizing the importance of communicating clearly in an increasingly cluttered information environment, in 2013 NPC dedicated significant efforts to enhancing and upgrading its own messaging vehicles and maximizing use of the communications tools available to reach target audiences. In June, NPC re-launched its website—www.npcnow.org—to make it more user-friendly and easily navigable. Enhancements to the site include a fully searchable research library, NPC’s blog, E.V.I.dently Today, an expanded video library and social media capabilities. A redesigned members-only section of the website is in development for launch in 2014.

To complement the new website, NPC redesigned its monthly e-newsletter E.V.I.dently, and its CER Daily Newsfeed, the free online resource that compiles the latest news on CER. NPC also significantly expanded its presence on Twitter (@npcnow).

Throughout the year, journalists continued to turn to NPC experts and NPC-sponsored research as sources in their reporting on the health care landscape. Media outlets including The Pink Sheet, Bloomberg, Pharmaceutical Executive, Politico Pulse, and Drug Industry Daily were among those quoting NPC representatives or citing NPC-sponsored research in 2013.

NPC History: 2000s

- 2001: NPC sponsors Health Affairs special issue and Capitol Hill briefing on the value of medical innovation.
- 2006: “Your Pharmacy Benefit” publication and website launch to help consumers make better use of their new pharmacy benefits under Medicare Part D.
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
- network with leaders and colleagues across the biopharmaceutical industry
- access and repurpose NPC educational resources, including practical tools, analytical papers and other information available in the members-only section of our website.

- 2008: Dan Leonard becomes NPC president.
- 2009: E.V.I.dently, a monthly e-newsletter about comparative effectiveness research, evidence-based medicine and health technology assessment, launches.

www.npcnow.org
NPC History: 2010s

- 2010: The CER Daily Newsfeed launches.
- 2010s: NPC publishes multiple resources on CER, the value of health outcomes and pharmaceutical innovation.

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Left to right: John Gargiulo, Anne Whitaker, Giovanni Caforio. Not pictured: Jeff Huth.
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Mike Derkacz  
General Manager, CNS Business Unit  
Teva Branded Products

• 2012: NPC headquarters moves to Washington, D.C.  

• 2013: NPC celebrates 60 years of leadership in health policy research.
NPC Staff

First row, left to right: Ann Menninger, Kimberly Westrich, Adam Lustig, Alexandra Moorhead.

Back row: Andrea Hofelich, Melissa Baulkwill, Sue Grimes, Daryl Pritchard, Kathryn Gleason, Pat Adams, Dan Leonard, Robert Dubois, Chuck Shih, Jennifer Graff.

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