

2011 ANNUAL REPORT





The NATIONAL PHARMACEUTICAL COUNCIL (NPC) is the credible and trusted voice of the biopharmaceutical industry on the critical issues of evidence, the value of medicines for patients, and innovation.

NPC's overarching mission is to sponsor, participate in, and promote scientific analyses of the appropriate use of biopharmaceuticals, and the clinical and economic value of improved health outcomes through medical innovation. NPC's strategic focus is on comparative effectiveness research and evidence-based medicine for health care decision-making, to ensure that patients have access to high-quality care. 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.

NPC is dedicated to:

- Promoting the clinical and economic value of improved health outcomes through pharmaceutical innovation;
- Contributing to practical solutions that ensure patients have access to and make appropriate use of prescription medicines;
- Improving health care decision-making by expanding the foundation of evidence for patients and providers to choose treatment options that provide the best clinical value; and
- Advancing research on the appropriate role of prescription medicines in treating patients.

CHAIRMAN'S MESSAGE

2011 was a pivotal year in health care. It marked the first full year of the Patient Protection and Affordable Care Act and the implementation of many important regulations and programs, such as the creation of state health exchanges and new rules for accountable care organizations, as well as the continued development of the Patient-Centered Outcomes Research Institute (PCORI), which made strong inroads on its work in comparative effectiveness research (CER). This dynamic environment presented unprecedented challenges as well as tremendous opportunities for the biopharmaceutical industry.

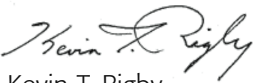
What this means for the National Pharmaceutical Council (NPC), in particular, is that now more than ever, it is important to engage with stakeholders both inside and outside the industry who are working together to shape the ongoing health care policy debate.

NPC has focused its efforts on assuring that our industry's expertise is heard, considered, and most important, valued. Patient health remains the central consideration in NPC's efforts. Leveraging this focus on patient health, NPC is working to strengthen the industry's voice and help stakeholders understand that the biopharmaceutical industry is part of the solution to improving health outcomes.

Building on its more than half a century of expertise, in 2011 NPC continued to sponsor academic and policy research papers and carry out educational activities addressing our industry's most important emerging issues, with a special focus on issues related to comparative effectiveness research. Given our momentum and success this year in gaining attention for our issues, we will continue to engage in similar research and education efforts in 2012.

As noted, CER has emerged as a critical tool in the ongoing battle to improve health care quality and outcomes, and NPC's focus on work to help ensure appropriate generation, assessment, interpretation and use of CER is both timely and critical. We expect CER to remain a major issue in 2012, especially as the PCORI Board of Governors sets out a research agenda and national priorities. Many critical questions will need to be resolved to ensure that CER lives up to its promise to improve health care delivery and patient health outcomes. The multiple opportunities provided by NPC for our members to connect and interact with the PCORI Board, health plan leaders, and other thought leaders in our industry has been one of the organization's most valuable services and will continue to be a priority for 2012.

As I passed the gavel in October to incoming Chairman Rich Fante of AstraZeneca, I did so knowing that NPC is strong and well positioned to continue providing significant contributions to positively shaping the health care environment. As health care issues continue to rapidly evolve, NPC remains committed to its overarching mission of demonstrating the value of improved health outcomes through medical innovation.



Kevin T. Rigby
Vice President of Public Affairs and Communications
Novartis Pharmaceuticals Corporation
Chairman, NPC 2011 Board of Directors



PRESIDENT'S MESSAGE

With all of the attention this year on rising deficits, escalating health care costs and diminished quality, it often feels as if patients are simply pawns in a larger battle being waged in Washington. While the fiscal health of our nation must be attended to, we cannot sacrifice the physical health of our citizenry in the process. All stakeholders involved in health policy must keep the needs of patients front and center in what they do.

At NPC, our priorities are based on achieving the best patient outcomes in the most efficient and valuable way possible and providing evidence that the appropriate use of pharmaceuticals is often an integral part of the solution. Our work over the last year has focused on the intersection between the policy issues and the standards and methods for evidence generation, interpretation and application, as well as on demonstrating the value of health outcomes. This report provides a snapshot of the NPC-supported research, programs, and partnerships in support of those objectives.



In 2011, NPC sponsored research and produced 12 publications, both peer-reviewed and self-published, which collectively represent a comprehensive look at the important emerging issues in comparative effectiveness research (CER) as well as the appropriate use of medications and their impact on the health care system as a whole. This research was widely disseminated and helped inform the ongoing dialogue surrounding the adoption and appropriate use of evidence in health care decision-making.

NPC also dedicated considerable efforts to keeping members up to date on the Patient-Centered Outcomes Research Institute (PCORI). Activities included chronicling its institutional development, meeting with leaders, sharing timely updates regarding evolving plans, providing public comments, and sharing NPC research with various PCORI Board members.

NPC staff and the researchers we work with spoke at a number of high-profile scientific meetings and conferences around the country, serving the equally important goals of sharing the research results and raising the organization's profile with key constituencies.

Providing member value is an important priority for NPC. Ensuring that the industry's voice is heard and providing opportunities for members to interact with other key stakeholders are central to all of our efforts. To this end, NPC sponsored members-only programs such as Town Hall Meetings on the role of quality and performance measures and on disparities in the ability to access data and to communicate CER findings; corporate roundtables; and other company-specific employee events designed to foster a better understanding of emerging industry issues. Additionally, a number of key health care stakeholders addressed NPC's Board of Directors in 2011, including CEOs of leading health insurers, members of Congress, academics, and members of the PCORI Board of Governors, providing NPC Board members with an opportunity to engage with other leaders on important health care issues.

Over the last year we also placed an increased emphasis on outreach. We strengthened our partnerships with other organizations and utilized a variety of communications tools, including a revamped website and social media such as Facebook and Twitter, in order to reach a broader array of health care stakeholders. Since its launch one year ago, NPC's *CER Daily Newsfeed* remains the only daily consolidated source of news and information on CER. We are encouraged by the increased conversation and momentum that have been generated by these efforts.

We greatly appreciate the dedication and involvement of our Board of Directors in shaping our research and program agenda. I'd like to especially recognize our outgoing Chairman Kevin Rigby, under whose leadership we made great strides in increasing NPC's awareness and visibility with key CER stakeholders, as well as improving our infrastructure and business operations.

As we look to the year ahead, the entire NPC staff remains committed to being a trusted and credible source of research and information, particularly on the science of biopharmaceuticals and CER, and to informing health policy in a way that improves value and health outcomes for patients.

A handwritten signature in dark ink that reads "Dan Leonard". The signature is fluid and cursive.

Dan Leonard
President, National Pharmaceutical Council

COMPARATIVE EFFECTIVENESS RESEARCH: NPC'S ROLE IN 2011

The promise of comparative effectiveness research (CER) is that it will provide patients and providers with the information they need to make decisions that will lead to improved health outcomes. Making that a reality is not so simple.

NPC has been examining the issues involved in “getting CER right” so that health care stakeholders can fully understand and prepare for the challenges involved in conducting, accessing, translating, communicating and evaluating CER. Given the growing investment in private and public funding for CER, it is critical that the final products are usable and actionable by stakeholders and not left sitting on a shelf.

For this reason, NPC has been conducting research to address key questions, such as:

- How can appropriate standards for generation and interpretation of CER be harmonized to enable a more predictable environment for payer adoption?
- How can we ensure a broader opportunity for the communication, dissemination and exchange of CER?
- How can society better focus on shifting from simply purchasing health services and products alone to valuing health outcomes for patients?
- How can CER utilize a full range of evidence that considers both direct and indirect benefits to society, such as quality of life, patient functionality and economic productivity?
- What is the impact of heterogeneity, or the needs of individual patients who may respond differently to medicines and treatments based upon age, genetic variation, co-morbidities, or patient preferences?
- How is the CER landscape evolving?

Answering these questions can help organizations conducting health technology assessments and CER, such as the Patient-Centered Outcomes Research Institute (PCORI), a private, non-profit corporation empowered to develop and fund CER, as they prioritize, conduct and disseminate CER. This is why NPC has been actively engaged in providing public comment to PCORI, attending meetings, and sharing information with NPC members on how this process could impact the biopharmaceutical industry in coming years. Additionally, NPC is working with stakeholder organizations to develop principles to assist payers in assessing CER and observational research in particular.

Highlights of the efforts NPC has undertaken in 2011 are in the pages that follow.

RESEARCH

NPC's research and activities are intended to strengthen public understanding of pharmaceutical innovation and of how sound science and evidence can facilitate better—or more predictable—decision-making among health care stakeholders such as payers, providers, the Patient-Centered Outcomes Research Institute (PCORI), and others. These projects also support NPC's overall goal of achieving the best patient outcomes in the most efficient and valuable way possible and providing evidence that the appropriate use of pharmaceuticals is often an integral part of the solution.

Under three main focus areas of the harmonization of research methods, comparative effectiveness research (CER) communication and dissemination, and valuing health care outcomes, NPC delivered a series of research projects, educational activities and outreach opportunities aimed at assisting key decision-makers in:

- Assessing the current environment;
- Understanding the trajectory of issues affecting the industry; and
- Considering policies or solutions to address key issues.

Major research published and disseminated in 2011 included:

- **The Patient-Centered Outcomes Research Institute: Methodology Committee Resource Guide**, a companion publication to NPC's **The Patient-Centered Outcomes Research Institute Resource Guide**, includes information on the most common types of CER, biographical information about the PCORI methodology committee members, and other resources.
- **Comparative Effectiveness Research: Do Employers Care? What Will They Do?** finds that employers are aware of CER, plan to use it to inform health benefit decisions, and will be looking to PCORI as their most trusted source of information. A related article was published in the *Journal of Occupational and Environmental Medicine*.
- **The Impact of Comparative Effectiveness Research on Health and Health Care Spending** and **Blue Pill or Red Pill: The Limits of Comparative Effectiveness Research**, are two peer-reviewed studies—one technical, the other policy-oriented—that provide a quantitative understanding of the cost and quality impacts when patients have unique responses to treatments but their coverage and reimbursement decisions are made based on the response of the “average” patient.
- **Setting Priorities for Comparative Effectiveness Research: From Assessing Public Health Benefits to Being Open With The Public**, published in *Health Affairs*, proposes a framework that private and public research entities could utilize in setting research priorities. The article was authored by NPC Chief Science Officer Dr. Robert Dubois and Research Director for Methods, Evidence and Coverage Dr. Jennifer Graff.
- **The State of Comparative Effectiveness Research and the Environment for Decision Making** examines, through a benchmark survey of stakeholders, the environment for health care decisions, especially the current state of CER and its



impact on medical decision-making. The survey results demonstrated that CER has registered with stakeholders as a major pillar in efforts to improve health care. NPC is conducting the survey again in 2012 to gauge how perceptions may have changed.

- **Synergies at Work: Realizing the Full Value of Health Investments** explains that understanding the full value of improved health, including improvements in workforce productivity, lost time and medical costs, is essential in helping employers seek the best value for their health investments. The study stresses what employers need in health care decision-making, provides a framework for evaluating health-related investments, and supplements the analysis with case studies.
- **Employer Medication Adherence, Comorbidities, and Health Risk Impacts on Workforce Absence and Job Performance** suggests that individual health risks and comorbidity remain significant predictors of reduced workplace productivity, even in a population with a high rate of medication adherence. This research was published in the *Journal of Occupational and Environmental Medicine*.
- **The Productivity Crisis in Pharmaceutical R&D**, published in *Nature Reviews: Drug Discovery*, examines the factors that are driving firm efforts in research and development (R&D) and contributing to the R&D productivity slowdown in recent years.
- **Cost Implications of Improving Blood Pressure Management Among U.S. Adults** and **Cost Implications to Health Care Payers of Improving Glucose Management Among Adults with Type 2 Diabetes**, both published in *Health Services Research*, set out a methodology to estimate the cost of improving the delivery of recommended medical, laboratory, and pharmacologic care required by adults with hypertension or diabetes, respectively, and to identify where opportunities exist for closing the underuse gap.

In 2011, NPC also undertook research to:

- Understand the differences in how the pharmaceutical industry, payers and regulatory agencies access, use, and communicate data and the implications of those differences;
- Explore the role of pharmaceuticals in accountable care organizations;
- Understand the methods that are credible for answering stakeholder CER questions;
- Examine how CER has impacted patient use of treatments/services through a series of high-profile case studies;
- Assess the types and sources of evidence, as well as the processes used by pharmacy and therapeutics (P&T) committees to make coverage and reimbursement decisions. Follow-on projects include developing user-friendly tools to assist P&T committees in assessing observational studies and a pilot study to test a new framework to improve the clarity, consistency, and transparency of their P&T decision-making;
- Develop a prototype of explicit and harmonized methodological guidance that addresses the appropriate and standard comparators and outcomes of interest for the needs of payers and health technology assessment bodies.

Some of this research is targeted for publication in 2012, while other projects are long-term.

In June 2011, NPC posted its first call for proposals for new research, soliciting research focused around the current CER and health care decision-making environment. Proposals were received from academic and other public and private research organizations, and funding decisions will be made in early 2012.

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

PROGRAMS, PARTNERSHIPS AND OTHER OUTREACH

NPC's professional programming advances the public dialogue by drawing on the biopharmaceutical industry's science base and expertise as a resource for reducing uncertainty in care decisions and improving outcomes for patients. Members-only Town Halls, employee programs, and corporate roundtables address emerging industry issues and provide educational opportunities for member employees. Other NPC-sponsored forums and symposia seek to introduce the industry's perspective and expertise to inform the discussion and generate momentum around key issues that could significantly impact the industry and the health care environment in the years ahead.

2011 programs and events included:

MEMBERS-ONLY TOWN HALL MEETINGS

Implications and Opportunities in Quality Measures and Use (May 5)—The federal guidelines for Accountable Care Organizations (ACO) are raising more questions than answers, including the potential role of pharmaceuticals in helping ACOs succeed in meeting financial and quality targets. During this Town Hall hosted by Johnson & Johnson, more than 100 participants heard from quality, ACO and health care experts about these strategic challenges and explored potential opportunities. Experts included Kristi Mitchell, MPH, vice president of evidence based medicine, health information technology practice, Avalere Health, Janet Corrigan, PhD, president and CEO, National Quality Forum, Tricia Barrett, vice president, product development, National Committee for Quality Assurance, Jim Barr, MD, chief medical officer, Optimus Healthcare Partners ACO, and Jeff Petry, vice president, Premier Healthcare Alliance.

Asymmetry in the Ability to Communicate CER Findings (September 23)—NPC members and invited speakers tackled a topic that is now beginning to garner more interest: asymmetry, or inequalities, in the ability of different stakeholders to develop, access, and disseminate health care information. More than 150 participants at this Pfizer-hosted Town Hall explored the differences among health care stakeholders in the ways they can communicate information, gain access to public and private databases, and meet thresholds for applying evidence that is gathered from databases. The pre-publication results of an NPC-funded study on *CER Asymmetries in Access to Data, Evidence Thresholds and Ability to Convey Information* were shared, and presentations included Dr. Tevi Troy, former Deputy Secretary of the US Department of Health and Human Services, on how the FDA views communications issues; Alan Bennett, managing partner of Ropes & Gray, on how pending court cases may change the environment for industry communications; and Dr. Art Caplan, director of the Center for Bioethics at the University of Pennsylvania, on ethical issues related to asymmetries in communication.



Dr. Tevi Troy, former Deputy Secretary of the US Department of Health and Human Services, explained CER communications challenges at a Town Hall meeting.

MEMBERS-ONLY EMPLOYEE EDUCATION AND CORPORATE ROUNDTABLES

NPC frequently works with its member companies to host corporate roundtables and employee educational programs to foster a better understanding of emerging industry issues. Hosted at member company sites, these programs are designed to provide employees at all levels with a better understanding of how CER and related health care policy impact their work. In 2011, GlaxoSmithKline, Novartis Pharmaceuticals Corporation and Boehringer Ingelheim Pharmaceuticals, Inc., hosted these programs.

PARTNERSHIPS

NPC also partners and collaborates with a variety of organizations to fund and share research and host educational events and activities. These organizations include the Health Industry Forum (HIF), the National Health Council (NHC), the National Consumers League (NCL), the National Business Group on Health (NBGH), the National Business Coalition on Health (NBCH), the Academy of Managed Care Pharmacy (AMCP), and the International Society for Pharmacoeconomics and Outcomes Research (ISPOR). In addition, NPC is an active contributor in other organizations with similar research interests, including the Center for Medical Technology Policy (CMTP), the Institute for Clinical and Economic Review (ICER), Pragmatic Approaches to Comparative Effectiveness (PACE), the University of Michigan Center for Value-Based Insurance Design, NEHI, the Drug Information Association, the Personalized Medicine Coalition and the Pharmacy Quality Alliance.

NPC partnerships resulted in the organization playing a significant role in the following 2011 programs and events:

Expanding of Comparative Effectiveness and Patient Centered Outcomes Research in the United States:

Opportunities in Oncology (June 8)—NPC co-sponsored this Friends of Cancer Research conference, which featured Agency for Healthcare Research and Quality Director Dr. Carolyn Clancy, National Institutes of Health Director Dr. Francis Collins, and Food and Drug Administration Center for Drug Evaluation and Research Director Dr. Janet Woodcock.

Drug Information Association (DIA) Annual Meeting (June 19-23)—In addition to moderating a panel discussion on how managed care decision-makers consider CER in determining coverage, NPC was invited to present results of recent NPC-sponsored research on "A Flexible Approach to Evidentiary Standards for Comparative Effectiveness Research." NPC also hosted an exhibit booth at the meeting, which was attended by more than 8,000 professionals who are involved in the discovery, development and lifecycle management of biopharmaceuticals and medical devices.

NBCH National Health Leadership Council Meeting (June 21-23)—The National Business Coalition on Health (NBCH) sought NPC's assistance in developing the program agenda for this high-level meeting, which featured senior executives from business coalitions and all major parties in health care, including purchasers, providers, insurers, and suppliers. The findings of NPC's recent survey examining how employers plan to use CER in making coverage decisions were presented, and NPC President Dan Leonard moderated a panel and presented on the federal landscape for CER.



Chuck Reynolds, President of the Employer Practice at the Benfield Group, discussed the findings from his NPC-sponsored research on employers and CER.

Third National Comparative Effectiveness Summit (October 13-14)—NPC was a sponsor and Chief Science Officer Dr. Robert Dubois served as conference co-chair for this program addressing the implications of CER for pharma, devices and life sciences. The agenda showcased recent NPC research and included sessions on “Heterogeneous Treatment Effects and the Implications of Average-based Policies”; “Asymmetries in Access to Data, Evidence Thresholds and the Ability to Convey Information”; “The Impact of CER on Future Innovation”; and “Avoiding Unintended Consequences: Policy Considerations for an Optimal CER Future.”

Advancing CER Under Health Reform (October 19)—This by-invitation-only program, hosted in conjunction with the Health Industry Forum, took a closer look at how CER could change the health care and business environment. Through a series of interactive discussions, participants examined CER’s impact on medical practice, how CER will influence innovation and industry business practices, and the national push to expand CER. Speakers included members of the PCORI Board of Governors and industry representatives.

PRESENTATIONS

ISPOR 16th Annual International Meeting

(May 21-25)—NPC played an important role in this gathering of more than 2,000 health outcomes researchers and academics. NPC hosted the preconference symposium, “Randomized Controlled Trials (RCTs) vs. Observational Studies: The Next Great Debate in CER.” More than 500 people attended this standing-room only panel discussion, featuring remarks by Dr. Michael Lauer, director of the Division of Cardiovascular Sciences at the National Heart, Lung, and Blood Institute; Brian Sweet, executive director development, managed markets development, at AstraZeneca; and Dr. Marc Berger, executive vice president and senior scientist, life sciences division, at OptumInsight. A second NPC-hosted panel presentation, “When Is the Evidence Adequate? Different Perspectives from Key Health Decision Makers,” featured Dr. Robert Epstein, chief medical officer and senior vice president, medical affairs, for Medco Health; Dr. Steven Pearson, president of the Institute for Clinical and Economic Review; and Dr. Bryan Luce, senior vice president for science policy at United BioSource Corporation. The session “Assessing the Relationship Between Medication Adherence and Employee Productivity,” featured Dr. Kimberly Jinnett, research director at the Integrated Benefits Institute, presenting NPC-sponsored research on medication adherence and productivity. NPC’s exhibit booth attracted hundreds of visitors during the meeting, providing an opportunity for further distribution of latest research.



At a Town Hall meeting, Dr. Art Caplan, Director of the Center for Bioethics at the University of Pennsylvania, said it can be challenging for patients to find accurate health care information.

Agency for Healthcare Research and Quality (AHRQ) Methods Symposium

(June 6-7)—NPC was one of only a few non-academic organizations invited to participate in this forum for scholarly deliberation of new and emerging research methods by scientists working in different disciplines and across settings. NPC Chief Science Officer Dr. Robert Dubois presented preliminary research suggesting that tying coverage or clinical guidelines to “average” results may have untoward effects on health for individual patients.

ADDITIONAL OUTREACH

At speaking engagements throughout 2011, NPC reached health care stakeholders, thought leaders, and new audiences. Results of NPC-sponsored research and other key issues were the focus of NPC presentations at significant industry conferences and events, including:

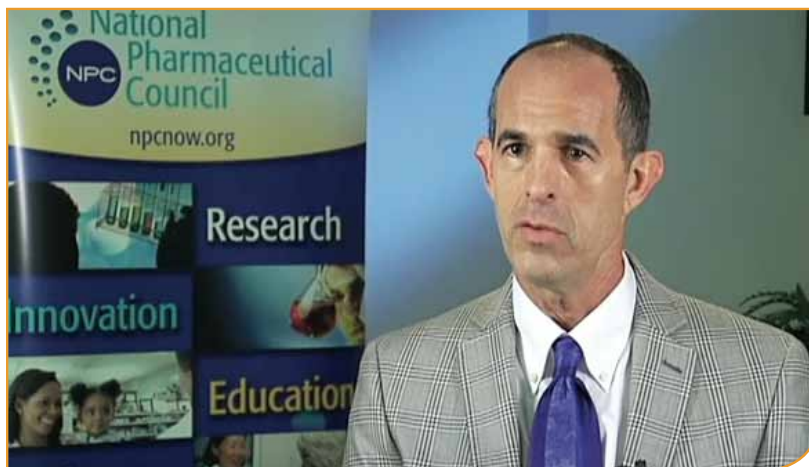
- American Occupational Health Conference panel discussion on CER (March 29)

- Pharmaceutical Care Management Association (PCMA) PBM & Specialty Pharma Summit panel discussion on “Milestones and Challenges for Achieving Meaningful CER” (March 30)
- World Health Care Congress 8th Annual Pharmaceutical, Biotech, and Medical Device Summit presentation on “The Interface Between Comparative Effectiveness Research and Evidence Based Medicine” (April 5)
- Pinsonault Associates Managed Markets Summit presentation on “Is the Pharmaceutical Industry Losing Its Voice? How Dialogue Is Changing In the World of Comparative Effectiveness” (September 28)
- Booz Allen Hamilton panel discussion on “The Federal Government’s Role in Medical Innovation” (October 18)
- National Accountable Care Organization Congress presentation on “The Role of Pharmaceuticals in Achieving ACO Success: Developing a Framework” (November 3)

Videos, slides and other program materials are available on NPC’s website at www.npcnow.org

NPC experts and NPC-sponsored research were quoted in media outlets including *The Pink Sheet*, *Kaiser Health News*, *Inside Health Reform*, *Health News Daily*, *The Hill*, *Congressional Quarterly*, and *Politico Pulse*, among others.

NPC also reached new audiences through online and social media. In 2011, NPC continued to enhance its website through videos featuring subject matter experts and through the *EVIDently Today* blog, both of which helped to drive new visitors to the website. Because online users are increasingly searching for information through social media venues, NPC became more active on Twitter (@npcnow) and LinkedIn, and launched a Facebook page.



NPC Chief Science Officer Dr. Robert Dubois discussed CER prioritization in an online video.

NPC MEMBERS

NPC's membership is composed of the top research-based biopharmaceutical companies in the world. A leading voice for the industry, NPC complements other life science associations by providing in-depth research, analysis and education on emerging issues.

NPC provides members the opportunity to:

- impact US health policy through the delivery of credible, authoritative research
- participate directly in setting the organization's research agenda
- collaborate with leading third-party scientific and policy experts from across key health care sectors
- leverage credibility via NPC relationships with multiple stakeholders
- network with leaders and colleagues across the biopharmaceutical industry
- participate in NPC technical and scientific work groups and research discussions with industry peers, including members-only symposia and Town Hall meetings
- access NPC educational resources, including practical tools, analytical papers, and an expanded video library of symposia and meetings available in the members only section of our website.

NPC MEMBERS 2011

Abbott Laboratories



Johnson & Johnson



AstraZeneca



Merck & Co., Inc.



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Novartis Pharmaceuticals
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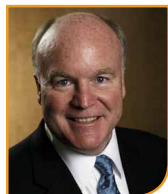


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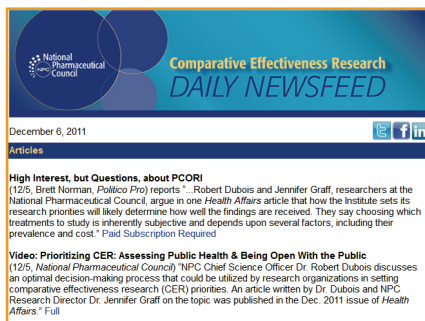
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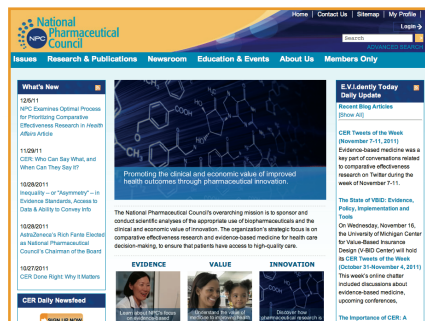
Jennifer S. Graff, PharmD, Research Director, Methods, Evidence & Coverage

Sue Grimes, Administrative Assistant

ADDITIONAL RESOURCES AVAILABLE ONLINE CONTAIN A WEALTH OF INFORMATION ABOUT THE BIOPHARMACEUTICAL INDUSTRY'S MOST PRESSING ISSUES.



daily electronic CER update



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