

# The Patient-Centered Outcomes Research Institute Resource Guide

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Developed by the National Pharmaceutical Council  
September 2010

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.

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# The Patient-Centered Outcomes Research Institute Resource Guide

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## A Letter From the National Pharmaceutical Council

A key provision of the Patient Protection and Affordable Care Act, health reform legislation signed into law in March 2010, establishes the Patient-Centered Outcomes Research Institute (PCORI), a private, non-profit corporation empowered to develop and fund comparative effectiveness research (CER). Overseeing and managing the many important functions of this unique institute will be a board of governors drawn from multiple and varied stakeholder organizations.

The first members of the PCORI Board of Governors must make many crucial decisions in the coming months, decisions that will have significant impact on the future of CER and its utility for patients and health care decision makers. The PCORI Board is charged with establishing the institute and its operations, determining and formally adopting the research priorities and research agenda, and identifying the executive director and other key personnel. In addition, the PCORI Board will work with a standing methodology committee to develop sound and widely accepted standards and methodologies for the conduct of research, and the translation of research results in a useful and understandable way.

To foster a better understanding of the role of the PCORI Board of Governors and of issues related to CER, the National Pharmaceutical Council (NPC) has created *The Patient-Centered Outcomes Research Institute Resource Guide*. This guide provides specifics concerning PCORI's implementation, biographies of the new PCORI Board members, a history of CER in the United States, and other relevant resources. NPC hopes that you will find the guide useful, particularly during the coming months as PCORI operations become established.

As PCORI implementation moves forward, NPC will continue its focus on developing a better understanding of the many intricacies of CER. Among the key tenets of a strong CER enterprise are four considerations that NPC and numerous other stakeholders believe are foundational:

- CER must be conducted and applied appropriately, by starting with good, relevant data; using appropriate methods to analyze that data; and translating the results in a way that is useful, understandable and actionable for patients, providers, and other health care decision makers.
- CER should consider comprehensive measures, addressing patient preferences, health outcomes, and quality of life.
- There should be broad opportunity for discussion of CER findings by all key stakeholders who generate or disseminate this information.
- Harmonizing appropriate standards for CER generation and interpretation will enable a more predictable environment for the adoption and use of evidence in decision making by payers, physicians, patients, and other health care decision makers.

As with any new undertaking, it will take time and thoughtful input from a wide range of interested parties to fully implement PCORI's activities. NPC looks forward to being part of that collaboration.

Sincerely,



Dan Leonard  
President

## PCORI Provisions in the Patient Protection and Affordable Care Act

On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act, a major health care reform bill that establishes a new comparative clinical effectiveness research (CER) entity. The CER entity is a “nonprofit corporation, to be known as the ‘Patient-Centered Outcomes Research Institute’ which is neither an agency nor establishment of the United States Government.” The institute will generate scientific evidence and new information on how diseases, disorders and other health conditions can be treated to achieve the best clinical outcome for patients.

In commissioning research the institute will give preference to contracts with federal agencies, such as the Agency for Healthcare Research and Quality (AHRQ) or the National Institutes of Health (NIH), but may also contract with appropriate private entities to conduct both primary research and systematic reviews of existing research. The institute and its activities will be supported by contributions from both public and private funds, made available to the institute through a Patient-Centered Outcomes Research Trust Fund.

The institute and its activities will be governed by an independent, 21-member board of governors that will include the director of AHRQ and the director of NIH, with the remaining members to be appointed by the US Comptroller General.

Other key provisions in the law include the following:

- The Act calls for establishment of a standing methodology committee, permanent or ad-hoc expert panels for clinical trials, and an expert advisory panel for rare diseases. Within the expert advisory panels, “the institute may include a technical expert of each manufacturer or each medical technology that is included under the relevant topic, project, or category for which the panel is established.”
- The Office of Communication and Knowledge Transfer in AHRQ, in consultation with the NIH, will be in charge of disseminating CER findings to appropriate audiences including physicians, health care providers, vendors of health information technology focused on clinical decision support, patients, payers (federal and private plans), and policy makers.
- The Act requires a report at least every five years on the “extent to which research findings are used by health care decision makers, the effect of the dissemination of such findings on reducing practice variation and disparities in health care and the effect of the research conducted and disseminated on innovation and the health care economy of the United States.”

The legislation also specifies how Patient-Centered Outcomes Research Institute findings can — or cannot — be used.

In particular:

- The institute may not mandate coverage, reimbursement, or policy recommendations;
- The Secretary of the Department of Health and Human Services (HHS) is prohibited from denying coverage based solely on research by the institute;
- The Secretary may not use the institute’s research in a way that treats extending the life of elderly, disabled, or terminally ill patients as of lower value than for a person who is younger, non-disabled or not terminally ill; and
- The institute is prevented from developing or using “a dollars-per-quality adjusted life year (or similar measure that discounts the value of a life because of an individual’s disability) as a threshold to establish what type of health care is cost effective or recommended.”

### Ongoing CER Activities

In 2009, Congress made a major investment in ensuring high-quality, patient-centered health care by allocating \$1.1 billion for CER as part of the American Recovery and Reinvestment Act (ARRA). Of that \$1.1 billion for CER, AHRQ received \$700 million; of that \$700 million, \$400 million was transferred to the Office of the Director of NIH to support CER as well as a variety of other research projects. The remaining \$400 million was allocated to HHS to be disbursed at the discretion of the Secretary. In addition, the federal budget for Fiscal Year 2011 includes \$286 million for CER under AHRQ.

Going forward, the majority of CER activity conducted within the government will be initiated and managed by PCORI.

## PCORI Board of Governors Composition

Under the Patient Protection and Affordable Care Act, the US Comptroller General is charged with appointing the PCORI Board of Governors, which is composed of the following diverse group of stakeholders:

- The Director of the Agency for Healthcare Research and Quality (or a designee)
- The Director of the National Institutes of Health (or a designee)
- 3 members representing patients and health care consumers
- 7 members representing physicians and providers, including 4 representing physicians (at least 1 of whom is a surgeon), 1 nurse, 1 state-licensed integrative health care practitioner, and 1 representative of a hospital
- 3 members representing private payers, of whom at least 1 member shall represent health insurance issuers and at least 1 member shall represent employers who self-insure employee benefits
- 3 members representing pharmaceutical, device, and diagnostic manufacturers or developers
- 1 member representing quality improvement or independent health service researchers
- 2 members representing the federal government or the states, including at least 1 member representing a federal health program or agency.

Board members are appointed to six-year terms, with the exception of the initial appointees. Their terms of appointment are staggered evenly over two-year increments. The law also states that “no individual shall be appointed to the Board for more than two terms,” and “vacancies shall be filled in the same manner as the original appointment was made.”

The US Comptroller General also designates a chairperson and vice chairperson of the board from among the members of the board. These designated members will serve as chairperson or vice chairperson for a period of three years.

**Biographies of the PCORI Board of Governors follow:**



## Debra Barksdale, PhD, RN

**Title:** Associate Professor

**Organization:** University of North Carolina at Chapel Hill School of Nursing

**Board Term:** 2 years (2012)

### Biography:

Debra Barksdale, PhD, RN, is associate professor at the University of North Carolina (UNC) at Chapel Hill School of Nursing in Chapel Hill, North Carolina. She is a researcher, certified nurse practitioner, and educator. Her research program focuses on psychological and physical stress, coping, and cardiovascular responses in African-Americans. Dr. Barksdale is also a research fellow of the UNC Center for Health Promotion and Disease Prevention and a member of the Center's Prevention Steering Committee. She was co-director of a nurse-managed, faith-based primary care center in Detroit, Michigan.

Dr. Barksdale has worked as a family nurse practitioner in urgent care, primary care, and home health care. She is president-elect of the National Organization of Nurse Practitioner Faculty, a fellow of the American Academy of Nurse Practitioners, and a volunteer family nurse practitioner in a clinic for the homeless. She received a BS in nursing from the University of Virginia, a masters in nursing from Howard University, a post-masters in teaching from the University of Pennsylvania, and a PhD in Nursing Research from the University of Michigan.

### Selected Publications/Presentations:

Thompson WM, Barksdale DJ. Physical inactivity in female African-American adolescents: consequences, costs, & care. *J Natl Black Nurses Assoc.* 2010 July;21(1):39-45.

Barksdale DJ, Metiko E. The role of parental history of hypertension in predicting hypertension risk factors in black Americans. *J Transcult Nurs.* 2010 June 30;[Epub ahead of print]

Barksdale DJ. Provider factors affecting adherence: cultural competency and sensitivity. *Ethn Dis.* 2009 Autumn;19(4 Suppl 5):S5-3-7.

Barksdale DJ, Farrug ER, Harkness K. Racial discrimination and blood pressure: perceptions, emotions, and behaviors of black American adults. *Issues Ment Health Nurs.* 2009 February;30(2):104-111.

Cheatham CT, Barksdale DJ, Rodgers SG. Barriers to health care and health-seeking behaviors faced by black men. *J Am Acad Nurse Pract.* 2008 November;20(11):555-562.

Blevins LP, Berry D, Barksdale DJ. Management of cardiovascular disease in African-American women: utility of the metabolic syndrome guidelines. *J Natl Black Nurses Assoc.* 2008 July;19(1):52-62.

Logan JG, Barksdale DJ. Allostasis and allostatic load: expanding the discourse on stress and cardiovascular disease. *J Clin Nurs.* 2008 April;17(7B):201-208.

### About the University of North Carolina at Chapel Hill School of Nursing:

The School of Nursing at UNC-Chapel Hill is nationally recognized as one of the premiere nursing schools in the country, with a tri-fold mission of excellence in nursing education, research and practice.

### Additional Information:

- University of North Carolina at Chapel Hill School of Nursing. <http://nursing.unc.edu/index.php>

## Sources:

University of North Carolina (UNC) at Chapel Hill School of Nursing: Faculty/Staff Directory: Debra J. Barksdale. <http://nursing.unc.edu/directories/search.php?x=863#top>. Accessed September 23, 2010.

Pubmed.gov: Debra Barksdale publications. <http://www.ncbi.nlm.nih.gov/pubmed>. Accessed September 23, 2010.

University of North Carolina (UNC) at Chapel Hill School of Nursing: About Us. <http://nursing.unc.edu/about/index.html>. Accessed September 23, 2010.

GAO Announces Appointments to New Patient-Centered Outcomes Research Institute (PCORI) Board of Governors (press release). Washington, DC: US Government Accountability Office; September 23, 2010. <http://www.gao.gov/press/pcori2010sep23.html>. Accessed September 23, 2010.



## Kerry Barnett, JD

**Title:** Executive Vice President of Corporate Services and Chief Legal Officer

**Organization:** The Regence Group

**Board Term:** 2 years (2012)

### Biography:

Kerry Barnett, JD, is executive vice president of corporate services and chief legal officer of The Regence Group, an affiliation of four not-for-profit Blue Cross/BlueShield plans, based in Portland, Oregon. Mr. Barnett provides strategic direction for communications, public policy and public affairs, human resources, real estate and facilities, and ethics and compliance for Regence and its member Plans in Idaho, Oregon, Utah and Washington. He is the chief compliance officer and the chief legal officer and oversees legal functions of the company.

Prior to joining Regence, he was senior vice president for medical services with ODS Health Plans in Oregon. At ODS, Mr. Barnett managed the performance of the medical insurance business, including claims, customer service, provider contracting and health care services. He also had responsibility for legal, compliance, government, public policy and communications.

Mr. Barnett also served as Oregon's state insurance commissioner and as the governor's legal counsel and senior policy advisor. He is on the Public Policy Committee and on the Strategic Communications Advisory Council of America's Health Insurance Plans. He also serves on the Legal Division Co-op Board of the Blue Cross and Blue Shield Association. He received a BA in English from the University of Rochester and a JD from Yale Law School.

### Selected Presentations/Publications:

Adamy J. Health insurers plan hikes. *The Wall Street Journal*. September 7, 2009.

<http://online.wsj.com/article/SB10001424052748703720004575478200948908976.html>. Accessed September 23, 2010.

Carrol J. Plans look askance at me-too medications. *Care Magazine*. January 2008.

<http://www.managedcaremag.com/archives/0801/0801.biologics.html>. Accessed September 23, 2010.

Musings on payer-pharma relations. *The In Vivo Blog*.

<http://invivoblog.blogspot.com/2009/10/musings-on-payer-pharma-relations.html#links>. October 14, 2009. Accessed September 23, 2010.

### About The Regence Group:

Regence is a 2.5 million member non-profit health care company composed of four Blue Cross/BlueShield plans that offer individual and group medical, dental, vision and life insurance, Medicare and other government programs, and pharmacy benefit management.

Regence is the largest health insurer in the Northwest/Intermountain Region, serving members as Regence BlueShield of Idaho, Regence BlueCross BlueShield of Oregon, Regence BlueCross BlueShield of Utah and Regence BlueShield. Each plan is an independent licensee of the Blue Cross and Blue Shield Association.

### Additional Resources:

The Regence Group. [www.regence.com](http://www.regence.com)

## Sources:

The Regence Group Executive Bios: Kerry E. Barnett: <http://www.regence.com/about/leadership/barnett.jsp>. Accessed September 23, 2010.

The Regence Group: About Us. <http://www.regence.com/about/index.jsp>. Accessed September 23, 2010.

GAO announces appointments to new Patient-Centered Outcomes Research Institute (PCORI) Board of Governors (press release). Washington, DC: US Government Accountability Office; September 23, 2010.

<http://www.gao.gov/press/pcori2010sep23.html>. Accessed September 23, 2010.

Former insurance commissioner Barnett joins Regence. *Portland Business Journal*. January 23, 2004.

<http://www.bizjournals.com/portland/stories/2004/01/19/daily48.html#ixzz10NQ58kPS>. Accessed September 23, 2010.

## Lawrence Becker

**Title:** Director of Strategic Partnerships and Alliances

**Organization:** Xerox Corporation

**Board Term:** 4 years (2014)

### Biography:

Lawrence Becker is director of strategic partnerships and alliances for Xerox Corporation in Rochester, New York, and is responsible for Global HR Vendor Optimization. He is also chairman of the Plan Administration Committee for Xerox's ERISA plans. Since joining Xerox, he has served in several capacities in the benefits, compensation, technology, and operations arenas including as director of benefits. He previously served as vice president of human resources for Baltimore Bancorp and worked for Formica Corporation, Exxon Corporation, and American Can Company in a variety of roles. He is a member of the Executive Board of ERIC (ERISA Industry Council), a member of the Board of Directors and Finance and Audit Committee of the National Quality Forum (NQF) as well as the NQF Steering Committee on Measuring Efficiency across Patient-Focused Episodes of Care. Additionally, he was a member of the Quality Alliance Steering Committee Expansion Workgroup commissioned by the Secretary of Health and Human Services. He is a board member of the Rochester Regional Health Information Operation. He received a BS from Cornell University's Industrial and Labor Relations School.

### Selected Publications/Presentations:

Roundtable Summary: Facilitating Use of Clinical Quality Measures Through Aggregation, April 21-22, 2004, Washington, DC. [http://www.kpihp.org/kpihp/CMS/Files/quality\\_summary.pdf](http://www.kpihp.org/kpihp/CMS/Files/quality_summary.pdf).

Evaluating the Efficiency of Medical Care, Grant Results. September 2010. <http://www.rwjf.org/reports/grr/059667.htm>. Accessed September 23, 2010.

Presentation at National Health Policy Forum on Employer Use of Medicare Private Fee-for-Service Plans as a Retiree Health Benefit, April 11, 2008. [http://www.nhpf.org/library/forum-sessions/FS\\_04-11-08\\_EmployerPFFS.pdf](http://www.nhpf.org/library/forum-sessions/FS_04-11-08_EmployerPFFS.pdf). Accessed September 23, 2010.

### About Xerox Corporation:

Xerox Corporation is a \$22 billion company headquartered in Norwalk, Connecticut, with 130,000 employees in 160 countries. Xerox Corporation develops, manufactures, markets, services, and finances a range of document processing products and services for use in offices around the world. The company also, through subsidiaries, provides network management, consulting, design, and integration services for medium and large companies.

### Additional Information:

- Xerox Corporation. [www.xerox.com](http://www.xerox.com)

### Sources:

GAO announces appointments to new Patient-Centered Outcomes Research Institute (PCORI) Board of Governors (press release). Washington, DC: US Government Accountability Office; September 23, 2010. <http://www.gao.gov/press/pcori2010sep23.html>. Accessed September 23, 2010.

About Xerox. <http://www.xerox.com/about-xerox/enus.html>. Accessed September 23, 2010.

Xerox Corp. Bloomberg Government. <http://www.bgov.com/companies/101678>. Accessed September 23, 2010.



## Carolyn M. Clancy, MD

**Title:** Director

**Organization:** Agency for Healthcare Research and Quality (AHRQ)

**Board Term:** Permanent for AHRQ Director, or Director Designee

### Biography:

Carolyn M. Clancy, MD, was appointed director of the Agency for Healthcare Research and Quality (AHRQ) on February 5, 2003, and reappointed on October 9, 2009. Prior to her appointment, Dr. Clancy was director of AHRQ's Center for Outcomes and Effectiveness Research.

Dr. Clancy, a general internist and health services researcher, is a graduate of Boston College and the University of Massachusetts Medical School. Following clinical training in internal medicine, Dr. Clancy was a Henry J. Kaiser Family Foundation Fellow at the University of Pennsylvania. Before joining AHRQ in 1990, she was also an assistant professor in the Department of Internal Medicine at the Medical College of Virginia.

Dr. Clancy holds an academic appointment at the George Washington University School of Medicine (clinical associate professor, Department of Medicine) and serves as senior associate editor for the journal *Health Services Research*. She serves on multiple editorial boards, including *Annals of Internal Medicine*, *Annals of Family Medicine*, *American Journal of Medical Quality*, and *Medical Care Research and Review*.

Dr. Clancy is a member of the Institute of Medicine and was elected a Master of the American College of Physicians in 2004. In 2009, she was awarded the William B. Graham Prize for Health Services Research.

Dr. Clancy's major research interests include improving health care quality and patient safety and reducing disparities in care associated with patient race, ethnicity, gender, income, and education. As director of AHRQ, she launched the first annual report to Congress on health care disparities and health care quality.

### Selected Publications/Presentations:

Clancy C; The Patient Centered Outcomes Research Institute. Shaping convergent strategies in CER. Washington DC: Agency for Healthcare Research and Quality; June 24, 2010. [https://www.regonline.com/custImages/253701/JJune24CER/Clancy\\_June\\_24.pdf](https://www.regonline.com/custImages/253701/JJune24CER/Clancy_June_24.pdf)

Clancy C, Collin FS. Patient-centered outcomes research institute: the intersection of science and health care. *Sci Transl Med*. 2010 June 23;2(37):18. PMID:20574065

Conway PH, Clancy C. Charting a path from comparative effectiveness funding to improved patient-centered health care. *JAMA*. 2010 March 10;303(10):985-986. PMID: 20215615

Slutsky JR, Clancy CM. Patient-centered comparative effectiveness research: essential for high-quality care. *Arch Intern Med*. 2010 March 8;170(5):403-404. PMID: 20212173

Clancy CM. The promise and future of comparative effectiveness research. *J Nurs Care Qual*. 2010; 25(1):1-4. PMID:20010250

Conway PH, Clancy C. Comparative-effectiveness research-implications of the Federal Coordinating Council's report. *N Engl J Med*. 2009;361(4):328-330. PMID: 19567829

Slutsky JR, Clancy CM. AHRQ's Effective Health Care Program: why comparative effectiveness matters. *Am J Med Qual*. 2009;24(1):67-70. PMID: 19139466

Clancy C. Is the clinical advice you give your patients evidence-based? *Medscape J Med*. 2008;10(11):252. PMID: 19099002

Clancy CM. Interpreting the evidence: helping consumers understand medical information. *Nurs Womens Health*. 2008;12(3):200-202. PMID: 18557848

Cohen SB, Clancy CM. ARHQ and data collection. *Health Aff*. 2008;27(2):586-587. PMID: 18332519

Coopey M, James MD, Lawrence W, Clancy CM. The challenge of comparative effectiveness: getting the right information to the right people at the right time. *J Nurs Care Qual*. 2008;23(1):1-5. PMID: 18281868

Clancy CM. Getting to "smart" health care, comparative effectiveness research is a key component of, but tightly linked with, health care delivery in the Information Age. *Health Aff*. 2006 November/December;25(6):w589-w592.

Clancy CM, Slutsky JR. Advancing excellence in health care: getting to effectiveness. *J Invest Med*. 2005; 53(2):65-66.

Clancy CM, Cronin K. Evidence-based decision making: global evidence, local decisions, the challenge now is to further develop and translate the worldwide evidence base for local application. *Health Aff*. 2005 January/February;24(1):151-162.

Tunis SR, Stryer DB, Clancy CM. Practical clinical trials: increasing the value of clinical research for decision making in clinical and health policy. *JAMA*. 2003 September 24;290(12):1624-1632.

### About the Agency for Healthcare Research and Quality:

AHRQ is the lead federal agency charged with improving the quality, safety, efficiency, and effectiveness of health care for all Americans. As one of 12 agencies within the Department of Health and Human Services, AHRQ supports health services research that will improve the quality of health care and promote evidence-based decision making.

### Additional Information:

- AHRQ Website. [www.ahrq.gov](http://www.ahrq.gov)
- Effective Healthcare Program. [effectivehealthcare.ahrq.gov/](http://effectivehealthcare.ahrq.gov/)
- Health Services Research Journal. [www.hsr.org/](http://www.hsr.org/)

### Sources:

Biography: Carolyn M. Clancy, M.D., Director, AHRQ. Rockville, MD: Agency for Healthcare Research and Quality; April 2010. <http://www.ahrq.gov/about/clancybio.htm>. Accessed September 1, 2010.

Agency for Healthcare Research and Quality (AHRQ) At A Glance. Rockville, MD: Agency for Healthcare Research and Quality; May 2009. AHRQ Publication No. 09-P003. <http://www.ahrq.gov/about/ataglance.htm>.



## Francis S. Collins, MD, PhD

**Title:** Director

**Organization:** National Institutes of Health

**Board Term:** Permanent for NIH Director, or Director Designee

### Biography:

Francis S. Collins, MD, PhD, was officially sworn in on Monday, August 17, 2009 as the 16th director of the National Institutes of Health (NIH). Dr. Collins was nominated by President Barack Obama on July 8, and was unanimously confirmed by the US Senate on August 7.

Dr. Collins, a physician-geneticist noted for his landmark discoveries of disease genes and his leadership of the Human Genome Project, served as director of the National Human Genome Research Institute (NHGRI) at the NIH from 1993-2008. With Dr. Collins at the helm, the Human Genome Project consistently met projected milestones ahead of schedule and under budget. This remarkable international project culminated in April 2003 with the completion of a finished sequence of the human DNA instruction book. On March 10, 2010, Dr. Collins was named a co-recipient of the Albany Medical Center Prize in Medicine and Biomedical Research for his leading role in this effort. While accepting the honor, Dr. Collins declined his portion of the \$500,000 prize in order to comply with government ethics rules.

In addition to his achievements as the NHGRI director, Dr. Collins' own research laboratory has discovered a number of important genes, including those responsible for cystic fibrosis, neurofibromatosis, Huntington's disease, a familial endocrine cancer syndrome, and most recently genes for type 2 diabetes and the gene that causes Hutchinson-Gilford progeria syndrome.

Dr. Collins has a longstanding interest in the interface between science and faith, and has written about this in *The Language of God: A Scientist Presents Evidence for Belief* (Free Press, 2006), which was for many weeks on *The New York Times* bestseller list. He is the author of a new book on personalized medicine, *The Language of Life: DNA and the Revolution in Personalized Medicine* (HarperCollins, 2010).

Dr. Collins received a BS in chemistry from the University of Virginia, a PhD in physical chemistry from Yale University, and an MD with honors from the University of North Carolina at Chapel Hill. Prior to coming to the NIH in 1993, he spent nine years on the faculty of the University of Michigan, where he was a Howard Hughes Medical Institute investigator. He is an elected member of the Institute of Medicine and the National Academy of Sciences. Dr. Collins was awarded the Presidential Medal of Freedom in 2007. In a White House ceremony on October 7, 2009, Dr. Collins received the National Medal of Science, the highest honor bestowed on scientists by the United States government.

### Selected Presentations/Publications:

Clancy C, Collin FS. Patient-centered outcomes research institute: the intersection of science and health care. *Sci Transl Med*. 2010 June 23;2(37):18. PMID:20574065

Lauer MS, Collins FS. Using science to improve the nation's health system: NIH's commitment to comparative effectiveness research. *JAMA*. 2010 June 2;303(21):2182-2183. PMID: 20516419

### Additional Resources:

- National Institutes of Health. [www.nih.gov](http://www.nih.gov)

### Sources:

National Institutes of Health: biographical sketch of Francis S Collins, MD, PhD, <http://www.nih.gov/about/director/directorbio.htm>. Accessed September 16, 2010.



## Allen Douma, MD

**Title:** Chief Executive Officer of Empower LLC and member of the AARP Board of Directors

**Organization:** Empower LLC and AARP

**Board Term:** 2 years (2012)

### Biography:

Allen Douma, MD, is chief executive officer of Empower LLC and a member of the AARP Board of Directors, Class of 2014. He has been active in AARP's programs, serving on the Member and Social Impact Committee, the AARP Insurance Trust, and from 2008-2010, on the Audit and Finance Committee and the National Policy Council. He also helped to develop AARP's "Wise Use of Drugs" campaign and website.

Previously, he served as assistant director of the Oregon Department of Human Services, chief executive officer of Health Responsibility Systems, medical director for Hartford and Travelers Insurance Companies, assistant professor of continuing medical education at George Washington University, and director of health education for the American Medical Association. For several years he worked with the state of Oregon and AARP Oregon to communicate to the public the information generated by the Oregon Drug Effectiveness Review Project (DERP).

For eight years Dr. Douma syndicated and published a column called "Ask the Family Doctor," and co-authored a book, *Informed: An Introduction to Medical Self-Care and Staying Well*.

Dr. Douma is a member of the Southern Oregon University Advisory Board and a board member of the Oregon Healthcare Quality Corporation. In addition, he currently serves on the boards of the Jefferson Regional Health Alliance and PRS Affordable Housing.

Dr. Douma has nearly 25 years of professional experience designing, implementing and evaluating health education and medical self-care products and services for consumer and professional audiences, including the American Medical Association. He has also served as Medical Advisor for The WorkCare Group's publications.

Among his recognitions, Dr. Douma received gubernatorial appointments to the State's Health Policy Commission and Health Council. America Online also honored him with a Best in Breed award. He was also a Robert Wood Johnson Foundation clinical scholar.

Dr. Douma received his PhD in medicine from the Medical College of Virginia and his BA in engineering science from Johns Hopkins University. He completed a fellowship in communications and economics at George Washington University.

### Statement Upon Appointment:

"As a voice for consumers — and as a medical doctor — I know that one size doesn't fit all when it comes to making important health care decisions. This institute has the potential to provide patients and their doctors with the best possible information to make better decisions on what works for them, and I am honored to be chosen to serve."

### Selected Publications/Presentations:

Douma A. Much help with cerebral palsy. *Chicago Tribune*. April 3, 2005.

[http://articles.chicagotribune.com/2005-04-03/features/0504020323\\_1\\_cerebral-palsy-spasticity-weak-muscles](http://articles.chicagotribune.com/2005-04-03/features/0504020323_1_cerebral-palsy-spasticity-weak-muscles). Accessed September 23, 2010.

Douma A. Physician unfazed by misfiring ticker. *Chicago Tribune*. May 29, 2005.

[http://articles.chicagotribune.com/2005-05-29/features/0505290420\\_1\\_irregular-heartbeat-heart-disease-palpitations](http://articles.chicagotribune.com/2005-05-29/features/0505290420_1_irregular-heartbeat-heart-disease-palpitations). Accessed September 23, 2010.

Pfeiffer G, Douma A. *Informed: An Introduction to Medical Self-Care and Staying Well*. WorkCare Publications; December 1992.

Douma A. Q. When I went to see my doctor for a check-up several... *Chicago Tribune*. September 29, 1997.  
[http://articles.chicagotribune.com/1997-09-29/news/9709300062\\_1\\_atrial-fibrillation-electrical-cardioversion-coumadin](http://articles.chicagotribune.com/1997-09-29/news/9709300062_1_atrial-fibrillation-electrical-cardioversion-coumadin).  
Accessed September 23, 2010.

### About the AARP:

For more than 50 years, AARP has been serving its members and society and creating positive social change. AARP's mission is to enhance the quality of life for all in aging, leading positive social change, and delivering value to members through information, advocacy, and service.

### Additional Information:

- AARP. [www.aarp.org](http://www.aarp.org)

### Sources:

AARP leadership profiles: Allen Douma.

[http://www.aarp.org/about-aarp/leadership/info-2010/Allen\\_Douma.html](http://www.aarp.org/about-aarp/leadership/info-2010/Allen_Douma.html). Accessed September 23, 2010.

New board members elected at Pacific Retirement Services, October 21, 2009.

<http://www.pacificretirement.com/press/news/2009/prs-board.htm>. Accessed September 23, 2010.

AARP board member Allen Douma selected to newly created health advisory group, September 23, 2010.

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WorkCare Group Senior Staff: <http://www.workcaregroup.com/staff.html>. Accessed September 23, 2010.

Experienced medical director, successful business owner, and physician named to head up the Office of Medical Assistance Programs, March 8, 2006. <http://www.oregon.gov/DHS/news/2006news/2006-0308b.shtml>. Accessed September 23, 2010.

About AARP. <http://www.aarp.org/about-aarp/>. Accessed September 23, 2010.



## Arnold Epstein, MD

**Title:** John H. Foster Professor and Chair of the Department of Health Policy and Management

**Organization:** Harvard University School of Public Health

**Board Term:** 4 years (2014)

### Biography:

Arnold Epstein, MD, is the John H. Foster Professor and chairman of the Department of Health Policy and Management at the Harvard University School of Public Health, as well as a practicing internist in the Department of Medicine at the Brigham and Women's Hospital. His research interests focus on quality of care and access to care for disadvantaged populations.

Recently, his efforts have focused on public reporting of quality performance data, racial and ethnic disparities in care, and policy changes that affect the quality and efficiency of hospital care. He has published more than 150 articles on these and other topics. His book, *Falling Through the Safety Net, Insurance Status and Access to Health Care*, won the Kulp Wright Award from the American Risk and Insurance Association in 1994 for the best new book on life and health insurance.

During 1993-1994, Dr. Epstein worked in the White House where he had staff responsibility for policy issues related to the health care delivery system, especially quality management. He was vice chair of the Institute of Medicine Committee on Developing a National Report on Health Care Quality. He also served as chairman of the board of AcademyHealth. He was co-chair of the Performance Measurement Coordinating Council of the Joint Commission on Accreditation of Healthcare Organizations, the National Committee on Quality Assurance, and the American Medical Association. He is associate editor for health policy of the *New England Journal of Medicine*, is a member of the Institute of Medicine, and has served on several editorial boards, including *Health Services Research* and the *Annals of Internal Medicine*.

Dr. Epstein received a BA from the University of Rochester, a masters in political science from Harvard, a BMS from Dartmouth Medical School, and an MD from Duke University.

### Statement Upon Appointment:

"More and better information on comparative clinical effectiveness can aid decision making by patients, providers and policymakers. I'm honored to be a part of this new Institute, which will play an important role by providing information to foster use of the most appropriate and effective interventions."

### Selected Publications/Presentations:

Jha AK, Orav EJ, Epstein AM. The effect of financial incentives on hospitals that serve poor patients. *Ann Intern Med*. 2010 September 7;153(5):299-306.

Malin JL, Diamant AL, Leake B, Liu Y, Thind A, Kahn KL, Schneider EC, Epstein AM, Maly RC. Quality of care for breast cancer for uninsured women in California under the breast and cervical cancer prevention treatment act. *J Clin Oncol*. 2010 July 20;28(21):3479-3484.

Epstein AM. Geographic variation in Medicare spending. *N Engl J Med*. 2010 July 1;363(1):85-86. Epub 2010 May 12.

Chen LM, Jha AK, Guterman S, Ridgway AB, Orav EJ, Epstein AM. Hospital cost of care, quality of care, and readmission rates: penny wise and pound foolish? *Arch Intern Med*. 2010 February 22;170(4):340-346.

Epstein AM, Aaron HJ, Baicker K, Hacker JS, Pauly MV. Health care reform in perspective. *N Engl J Med*. 2009 October education, 15;361(16):e30.

Jha AK, Orav EJ, Dobson A, Book RA, Epstein AM. Measuring efficiency: the association of hospital costs and quality of care. *Health Aff.* 2009 May-June;28(3):897-906.

Epstein AM. Revisiting readmissions — changing the incentives for shared accountability. *N Engl J Med.* 2009 April 2;360(14):1457-1459.

Baker CD, Caplan A, Davis K, Dentzer S, Epstein AM, Frist B, Galvin RS, King-Shaw RJ Jr, Lee TH, Oberlander JB, Rosenbaum S, Schroeder SA, Tuckson RV. Health of the nation — coverage for all Americans. *N Engl J Med.* 2008 August 21;359(8):777-780.

Jha AK, Orav EJ, Ridgway AB, Zheng J, Epstein AM. Does the Leapfrog program help identify high-quality hospitals? *Jt Comm J Qual Patient Saf.* 2008 June;34(6):318-325.

Landon BE, Rosenthal MB, Normand SL, Frank RG, Epstein AM. Quality monitoring and management in commercial health plans. *Am J Manag Care.* 2008 June;14(6):377-386.

Malin JL, Schneider EC, Epstein AM, Adams J, Emanuel EJ, Kahn KL. Results of the National Initiative for Cancer Care Quality: how can we improve the quality of cancer care in the United States? *J Clin Oncol.* 2006 February 1;24(4):626-634. Epub 2006 January 9. Erratum in: *J Clin Oncol.* 2006 April 20;24(12):1966.

Showstack J, Lin F, Learman LA, Vittinghoff E, Kuppermann M, Varner RE, Summitt RL Jr, McNeeley SG, Richter H, Hulley S, Washington AE; Ms Research Group. Randomized trial of medical treatment versus hysterectomy for abnormal uterine bleeding: resource use in the Medicine or Surgery (Ms) trial. *Am J Obstet Gynecol.* 2006;194(2):332-338.

### About Harvard University School of Public Health:

Founded in 1922, the Harvard School of Public Health grew out of the Harvard-MIT School for Health Officers, the nation's first graduate training program in public health. During the past eight decades, the school's faculty members — frequently working in collaboration with others at Harvard and around the world — have made landmark contributions revolutionizing public health.

The overarching mission of the Harvard School of Public Health is to advance the public's health through learning, discovery, and communication. To pursue this mission, the school produces knowledge through research, reproduces knowledge through higher education and translates knowledge into evidence that can be communicated to the public, policy makers, and practitioners to advance the health of populations.

### Additional Information:

- Harvard School of Public Health. [www.hsph.harvard.edu/](http://www.hsph.harvard.edu/)

### Sources:

Harvard School of Public Health: Arnold Epstein.  
<http://www.hsph.harvard.edu/faculty/arnold-epstein/>. Accessed September 23, 2010.

Robert Wood Johnson Foundation: Health Policy Fellows.  
<http://www.healthpolicyfellows.org/secure/alumni-bio.php?id=4069#bio>. Accessed September 23, 2010.

Epstein named to PCORI Board of Governors, (news release). Washington, DC: AcademyHealth; September 23, 2010.  
<http://academyhealth.org/Newsroom/NewsDetail.cfm?itemnumber=5681>. Accessed September 23, 2010.

GAO announces appointments to new Patient-Centered Outcomes Research Institute (PCORI) Board of Governors (press release). Washington, DC: US Government Accountability Office; September 23, 2010.  
<http://www.gao.gov/press/pcori2010sep23.html>. Accessed September 23, 2010.

Harvard School of Public Health: About HSPH, milestones and history.  
<http://www.hsph.harvard.edu/about/history-and-milestones/>. Accessed September 23, 2010.

Harvard School of Public Health: About HSPH, mission. <http://www.hsph.harvard.edu/about/index.html>. Accessed September 23, 2010.



## Christine Goertz, DC, PhD

**Title:** Vice Chancellor for Research and Health Policy

**Organization:** Palmer College of Chiropractic and Palmer Center for Chiropractic Research

**Board Term:** 6 years (2016)

### Biography:

Christine Goertz, DC, PhD, is vice chancellor for research and health policy at Palmer College of Chiropractic and Palmer Center for Chiropractic Research in Davenport, Iowa, where her research focuses on quality of outcomes for patients and the importance of provider collaboration in providing high-quality health care. Her work is focused on sub-acute and chronic lower back pain in adult populations. For more than 20 years, she has addressed multidisciplinary science and health policy issues at the state and federal levels, serving as a member of the American Medical Association's Measures Implementation and Evaluation Advisory Committee, chair of the American Chiropractic Association's Performance Measurement Task Force, and a program officer of the National Institutes of Health National Center for Complementary and Alternative Medicine, managing a portfolio focused on musculoskeletal disease, pain and health services research. She is a fellow of the International College of Chiropractors. She received her doctor of chiropractic from Northwestern Health Sciences University and a PhD in Health Services Research Policy and Administration from the University of Minnesota.

### Statement Upon Appointment:

"Dr. Goertz's appointment will ensure that doctors of chiropractic are well represented on this important decision-making Board," said ACA President Rick McMichael, DC. "This is a critical development in our fight to level the health care playing field for patients and providers alike. Having a doctor of chiropractic on the PCORI board will ensure that the chiropractic profession's perspective on health and wellness is an integral part of the discussion and that we will have meaningful opportunities to demonstrate that chiropractic care is essential — a safe, effective, patient-centered treatment option."

### Selected Publications/Presentations:

Meeker WC, Goertz C. More about the evidence in evidence-based integrative medicine programs. *Acad Med*. 2010 February;85(2):186.

### About Palmer College of Chiropractic and Palmer Center for Chiropractic Research:

Established in 1995, the Palmer Center for Chiropractic Research is the largest and most highly funded research effort in the chiropractic educational community. The Palmer Center for Chiropractic Research (PCCR) encompasses all three Palmer campuses and employs a vice chancellor of research and health policy, a research director, 10 full-time dedicated faculty, 8 associate faculty and 23 administrative and professional staff with a total annual budget of approximately \$5 million per year, much of which is supported by grants and contracts.

### Additional Information:

- Palmer Center for Chiropractic Research. [www.palmer.edu/Palmer/Pages/Page.aspx?id=276](http://www.palmer.edu/Palmer/Pages/Page.aspx?id=276)
- Palmer College of Chiropractic. [www.palmer.edu/](http://www.palmer.edu/)

### Sources:

GAO announces appointments to new Patient-Centered Outcomes Research Institute (PCORI) Board of Governors, (press release). Washington, DC: US Government Accountability Office; September 23, 2010. <http://www.gao.gov/press/pcori2010sep23.html>. Accessed September 23, 2010.

ACA member Dr. Christine Goertz appointed to the new Patient-Centered Outcomes Research Institute's Board of Governors. (news release). Arlington, VA: American Chiropractic Association; September 23, 2010, [http://www.acatoday.org/press\\_css.cfm?CID=4103](http://www.acatoday.org/press_css.cfm?CID=4103). Accessed September 23, 2010.

Palmer Center for Chiropractic Research. <http://www.palmer.edu/Palmer/Pages/Page.aspx?id=276>. Accessed September 23, 2010.

Vision of the Palmer Center for Chiropractic Research. <http://www.palmer.edu/Palmer/Pages/Page.aspx?id=621&libID=641>. Accessed September 23, 2010.

## Leah Hole-Curry, JD

**Title:** Program Director, Health Technology Assessment Program

**Organization:** Washington State Health Care Authority

**Board Term:** 2 years (2012)

### Biography:

Leah Hole-Curry, JD, directs Washington State's Health Technology Assessment (HTA) program, created in 2006. The HTA program is a leading state effort to purchase high-quality health care that is proven safe, effective, and cost-effective. The program relies on independent evidence reports and a committee of current practitioners to guide state purchasing decisions of medical technologies. From 2001 to 2006, Ms. Hole-Curry provided regulatory consulting and project management to state Medicaid agencies and the US Department of Health and Human Services — Medicaid, Office of Health Insurance Portability and Accountability Act (HIPAA) Standards, Office for Civil Rights — as a consultant with Fox Systems, Inc. She focused on HIPAA and information technology projects. She was consulted as an authority on HIPAA implementation by local, state, and federal entities; spoke nationally and regionally on HIPAA impacts, especially for public agencies; participated in workgroups; and chaired a national workgroup.

Ms. Hole-Curry began her commitment to improving quality and safety of public health systems working for the Departments of Social and Health Services and Labor and Industries in Washington State, providing contract management and regulatory compliance guidance. Prior to working in the public health care field, she practiced land use, real property, and business law in Olympia, Washington for several years. She received her JD, magna cum laude, at Seattle University School of Law in 1997 and a BA from Evergreen State College.

### Selected Publications/Presentations:

Hole-Curry L. All aboard! Destination: health reform. National Academy for State Health Policy.

[http://www.nashp.org/sites/default/files/conf\\_2009/Hole-Curry.pdf](http://www.nashp.org/sites/default/files/conf_2009/Hole-Curry.pdf). Updated July 14, 2009. Accessed September 23, 2010.

Hole-Curry L. State Purchasing: Using Evidence for Quality.

<http://depts.washington.edu/rchpol/docs/legcon08/Presentations/Hole-Curry.pdf>. November 2008. Accessed September 23, 2010.

### About the Healthcare Technology Assessment Program:

The primary purpose of the Washington State HTA program is to ensure medical treatments and services paid for with state health care dollars are safe and proven to work. HTA serves as a resource for state agencies purchasing health care. HTA contracts for scientific, evidence-based reports about whether certain medical devices, procedures, and tests are safe and work as promoted. An independent clinical committee of health care practitioners then uses the reports to determine if programs should pay for the medical device, procedure, or test.

Participating state agencies include the Health Care Authority; Department of Social and Health Services (Medicaid); Labor and Industries; Department of Corrections; and Department of Veterans Affairs.

### Additional Information:

- Health Technology Assessment Program. [www.hta.hca.wa.gov/](http://www.hta.hca.wa.gov/)
- Washington State Health Care Authority. [www.hca.wa.gov/](http://www.hca.wa.gov/)

### Sources:

National Academy for State Health Policy: Leah Hole-Curry, JD. <http://www.nashp.org/node/1366>. Accessed September 23, 2010.

About Health Technology Assessment Program. <http://www.hta.hca.wa.gov/about.html>. Accessed September 23, 2010.



## Andrew Imparato, JD

**Title:** President and Chief Executive Officer

**Organization:** American Association of People with Disabilities

**Board Term:** 4 years (2014)

### Biography:

Andrew Imparato, JD, is the first full-time president and chief executive officer of the American Association of People with Disabilities (AAPD), a national, nonpartisan membership organization of people with disabilities, their family members and supporters that was founded in 1995. Prior to joining AAPD, he served as general counsel and director of policy for the National Council on Disability, an independent agency advising the President and Congress on public policy issues affecting people with disabilities. He also served as a special assistant to Paul Steven Miller, the commissioner of the Equal Employment Opportunity Commission; counsel to the US Senate Subcommittee on Disability Policy chaired by Senator Tom Harkin; and staff attorney at the Disability Law Center in Boston.

Since Mr. Imparato joined AAPD in 1999, the organization has more than quadrupled its membership, its annual budget, and its staff size. With more than 100,000 members, AAPD is the largest cross-disability membership organization in the US. Mr. Imparato has testified on numerous occasions before congressional committees and his commentary has been featured in print and broadcast media.

His analysis of the US Supreme Court's rulings relating to disability rights appears in *The Rehnquist Court: Judicial Activism on the Right* (H. Schwartz, editor, Hill and Wang, 2002). Mr. Imparato is also the co-author, with civil rights attorney Claudia Center, of an article in the Spring 2003 issue of the *Stanford Law and Policy Review*, "Redefining 'Disability' Discrimination: A Proposal for Restoring Civil Rights for All Workers."

He received a BA from Yale University and a JD from Stanford University Law School.

### Statement Upon Appointment:

"I am delighted and honored to have been asked to help shape this important new Institute by the Government Accountability Office. People with disabilities have much at stake as the parameters for comparative effectiveness research get defined, and all Americans stand to benefit when the interests of health care consumers are kept at the forefront of policy making in this critical area."

### Selected Publications/Presentations:

Tahmincioglu E. Disabilities Act anniversary, but still a long way to go: Twenty years since enactment; little progress in workplace. MSNBC.com. July 26, 2010. <http://www.msnbc.msn.com/id/38403707/ns/business-careers/>.

Wills R. Disabled to herald 20 years of increased public access. *Pittsburgh Tribune-Review*. July 26, 2010. [http://www.pittsburghlive.com/x/pittsburghtrib/news/pittsburgh/s\\_692008.html](http://www.pittsburghlive.com/x/pittsburghtrib/news/pittsburgh/s_692008.html).

### About the American Association of People with Disabilities:

The American Association of People with Disabilities (AAPD), the country's largest cross-disability membership organization, organizes the disability community to be a powerful voice for change — politically, economically, and socially. AAPD was founded in 1995 to help unite the diverse community of people with disabilities, including their families, friends and supporters, and to be a national voice for change in implementing the goals of the Americans with Disabilities Act (ADA).

## Additional Information:

- American Association of People with Disabilities. [www.aapd.com](http://www.aapd.com)
- Twitter. [twitter.com/AndyAAPD](https://twitter.com/AndyAAPD)

## Sources:

American Association of People with Disabilities: Spotlight. <http://www.aapd.com/site/c.pv11kNWJqE/b.5406299/k.FBCC/Spotlight.htm>. Accessed September 23, 2010.

American Association of People with Disabilities: AAPD leadership. [http://www.aapd.com/site/c.pv11kNWJqE/b.5606947/k.88CC/AAPD\\_Leadership.htm](http://www.aapd.com/site/c.pv11kNWJqE/b.5606947/k.88CC/AAPD_Leadership.htm). Accessed September 23, 2010.

AAPD's president and CEO appointed to PCORI Board. Washington, DC: American Association of People With Disabilities; September 23, 2010.

<http://www.aapd.com/site/apps/nlnet/content2.aspx?c=pv11kNWJqE&b=6216075&ct=8710261&notoc=1>. Accessed September 24, 2010.



## Robert L. Jesse, MD, PhD

**Title:** Principal Deputy Under Secretary for Health  
**Organization:** Department of Veterans Affairs (VA)  
**Board Term:** 4 years (2014)

### Biography:

Robert L. Jesse, MD, PhD, is the principal deputy under secretary for health at the US Department of Veterans Affairs (VA) in Washington, DC. He leads clinical policies and programs for the Veterans Health Administration, the nation's largest integrated health care system. Dr. Jesse also serves as VA's national program director for cardiology and as a professor of internal medicine and cardiology at the Virginia Commonwealth University School of Medicine. He has extensive experience in comparative effectiveness, cardiology, cancer, and biochemical research.

Previously, he was chief consultant for medical surgical services in VA's Office of Patient Care Services, where he was instrumental in implementing broad reforms in the delivery of specialty, sub-specialty and emergency care. Prior to assuming national leadership positions in VHA, Dr. Jesse was the chief of the cardiology section at the Richmond VA Medical Center in Virginia. He began his career as the director of the acute cardiac care program at Virginia Commonwealth University's Health System.

Dr. Jesse has published widely in areas of acute cardiac care, systems management and quality in health care. His basic research has focused on platelet physiology and cardiac biomarkers.

Dr. Jesse is a diplomate of the American Board of Internal Medicine with specialty boards in Cardiovascular Medicine. He is a fellow of the American College of Cardiology, and has served as a governor for the College. He is also a fellow of the American Heart Association and is currently the president of the Richmond Metro Chapter of the American Heart Association. In addition, he holds the rank of tenured professor of internal medicine/cardiology within the Virginia Commonwealth University Health System.

Dr. Jesse received his BS in Biochemistry from the University of New Hampshire in 1974 and later worked as a research associate at the Harvard School of Public Health. He received a PhD in Biophysics in 1980 and an MD at the Medical College of Virginia in 1984.

### Selected Publications/Presentations:

Jesse RL. On the relative value of an assay versus that of a test: a history of troponin for the diagnosis of myocardial infarction. *J Am Coll Cardiol*. 2010 May 11;55(19):2125-2128.

Box TL, McDonell M, Helfrich CD, Jesse RL, Fihn SD, Rumsfeld JS. Strategies from a nationwide health information technology implementation: the VA CART story. *J Gen Intern Med*. 2010 January;25 Suppl 1:72-76. Review.

Fihn SD, Vaughan-Sarrazin M, Lowy E, Popescu I, Maynard C, Rosenthal GE, Sales AE, Rumsfeld J, Piñeros S, McDonell MB, Helfrich CD, Rusch R, Jesse R, Almenoff P, Fleming B, Kussman M. Declining mortality following acute myocardial infarction in the Department of Veterans Affairs Health Care System. *BMC Cardiovasc Disord*. 2009 August 31;9:44.

### About the US Department of Veterans Affairs:

The Veterans Health Administration is home to the largest integrated health care system consisting of 153 medical centers, in addition to numerous community-based outpatient clinics, community living centers, Vet centers and domiciliaries. Together these health care facilities provide comprehensive care to more than 5.5 million veterans each year. VHA medical centers provide a wide range of services including traditional hospital-based services such as surgery, critical care, mental health, orthopedics, pharmacy, radiology and physical therapy. In addition, most VHA medical centers offer additional medical and surgical specialty services including audiology and speech pathology, dermatology, dental, geriatrics, neurology, oncology, podiatry, prosthetics, urology, and vision care. Some medical centers also offer advanced services such as organ transplants and plastic surgery.

### Additional Information:

- US Department of Veterans Affairs. [www.va.gov](http://www.va.gov)

### Sources:

US Department of Veterans Affairs: Robert L. Jesse, MD, PhD, Principal Deputy Under Secretary for Health. [http://www1.va.gov/opa/bios/bio\\_jesse.asp](http://www1.va.gov/opa/bios/bio_jesse.asp). Accessed September 23, 2010.

US Department of Veterans Affairs: Health Care, Medical Centers. <http://www1.va.gov/health/MedicalCenters.asp>. Accessed September 23, 2010.



## Harlan Krumholz, MD

**Title:** Harold H. Hines, Jr. Professor of Medicine and Epidemiology and Public Health

**Organization:** Yale University School of Medicine

**Board Term:** 2 years (2012)

### Biography:

Dr. Harlan Krumholz is a professor of medicine and epidemiology and public health at Yale University School of Medicine. He also serves as director of the Robert Wood Johnson Clinical Scholars Program at Yale and Director of the Yale-New Haven Hospital Center for Outcomes Research and Evaluation (CORE).

Dr. Krumholz's research is focused on determining optimal clinical strategies and identifying opportunities for improvement in the prevention, treatment and outcome of cardiovascular disease with emphasis on under-represented populations. Using methods of clinical epidemiology and health services research, he has sought to illuminate the balance of risks, benefits and costs of specific clinical approaches. The research efforts are intended to provide critical information to improve the quality of health care, monitor changes over time, and guide decisions about the allocation of scarce resources.

Dr. Krumholz is currently leading initiatives through the Centers for Medicare and Medicaid Services to develop national measures for public reporting of hospital performance. In an effort to investigate ways that hospitals can improve outcomes through decreasing door-to-balloon times, he initiated and chaired the steering committee of D2B: An Alliance for Quality, an international campaign launched by the American College of Cardiology to implement key evidence-based strategies to achieve guideline recommended door-to-balloon times. He also serves as principal investigator on two multi-center projects sponsored by the National Heart, Lung, and Blood Institute: the VIRGO study, an investigation of issues surrounding the care and outcomes of young women with acute myocardial infarction; and a study examining the effect of a telemonitoring strategy on the outcomes of patients with heart failure.

Dr. Krumholz is an elected member of the Association of American Physicians, the American Society for Clinical Investigation, and the Institute of Medicine. He is also the author of the book, *The Expert Guide to Beating Heart Disease*.

He received his MD from Harvard Medical School and an SM in Health Policy and Management at the Harvard School of Public Health. He did his training in internal medicine at the University of California, San Francisco and in cardiology at Beth Israel in Boston.

### Selected Publications/Presentations:

Yuan CT, Nembhard IM, Stern AF, Brush JE Jr, Krumholz HM, Bradley EH. Blueprint for the dissemination of evidence-based practices in health care. *Issue Brief (Commonw Fund)*. 2010 May;86:1-16.

Krumholz HM. Informed consent to promote patient-centered care. *JAMA*. 2010 March 24;303(12):1190-1191.

Krumholz HM. Outcomes research: myths and realities. *Circ Cardiovasc Qual Outcomes*. 2009 January;2(1):1-3.

Krumholz HM. Outcomes research: generating evidence for best practice and policies. *Circulation*. 2008 July 15;118(3):309-318.

Krumholz HM, Radford MJ, Wang Y, Chen J, Heiat A, Marciniak TA. National use and effectiveness of beta-blockers for the treatment of elderly patients after acute myocardial infarction: National Cooperative Cardiovascular Project. *JAMA*. 1998;280:623-629.

## About the Yale University School of Medicine:

Founded in 1810, the Yale School of Medicine is a world-renowned center for biomedical research, education and advanced health care. Among its 27 departments are one of the nation's oldest schools of public health and the internationally recognized Child Study Center, founded in 1911.

Affiliated institutions include the 944-bed Yale-New Haven Hospital, the Yale Cancer Center, Connecticut Mental Health Center, Pierce Laboratory, and VA Connecticut Healthcare System in nearby West Haven.

The School of Medicine consistently ranks among the handful of leading recipients of research funding from the National Institutes of Health and other organizations supporting the biomedical sciences, and belongs to medical organizations including the Association of American Medical Colleges and the Association of Academic Health Centers.

## Additional Information:

- Yale University School of Medicine. <http://medicine.yale.edu/>
- Twitter: [twitter.com/hmkyale](https://twitter.com/hmkyale)

## Sources:

Biography: Dr. Harlan Krumholz. Washington, DC: Health Rhythm Society; 2010.

[http://www.hrsonline.org/sessions/scientificprogram/openingplenary2010/h-krumholz\\_bio.cfm](http://www.hrsonline.org/sessions/scientificprogram/openingplenary2010/h-krumholz_bio.cfm). Accessed September 23, 2010.

About Yale School of Medicine. <http://medicine.yale.edu/about/>. Accessed September 23, 2010.



## Richard E. Kuntz, MD, MSc

**Title:** Senior Vice President and Chief Scientific, Clinical, and Regulatory Officer

**Organization:** Medtronic, Inc.

**Board Term:** 2 years (2012)

### Biography:

Dr. Richard Kuntz, MD, Msc, is senior vice president and chief scientific, clinical and regulatory officer of Medtronic, Inc. In this role, which he assumed in August 2009, Dr. Kuntz oversees the company's global regulatory affairs, health policy and reimbursement, clinical research activities, ventures and new therapies, strategy and innovation, corporate development, and acquisitions, integrations and divestitures functions.

Dr. Kuntz joined Medtronic in October 2005 as senior vice president and president of Medtronic Neuromodulation, which encompasses the company's products and therapies used in the treatment of chronic pain, movement disorders, spasticity, overactive bladder and urinary retention, benign prostatic hyperplasia, and gastroparesis. In this role he was responsible for the research, development, operations and product sales and marketing for each of these therapeutic areas worldwide.

Dr. Kuntz brings to Medtronic a broad background and expertise in many different areas of health care. Prior to Medtronic he was the founder and chief scientific officer of the Harvard Clinical Research Institute, a university-based contract research organization which coordinates National Institutes of Health and industry clinical trials with the Food and Drug Administration. Dr. Kuntz has directed over 100 multicenter clinical trials and has authored more than 200 original publications. His major interests are traditional and alternative clinical trial design and biostatistics.

Dr. Kuntz also served as associate professor of Medicine at Harvard Medical School, chief of the Division of Clinical Biometrics, and an interventional cardiologist in the division of cardiovascular diseases at the Brigham and Women's Hospital in Boston.

Dr. Kuntz graduated from Miami University, and received his medical degree from Case Western Reserve University School of Medicine. He completed his residency in internal medicine at the University of Texas Southwestern Medical School, and then completed fellowships in cardiovascular diseases and interventional cardiology at the Beth Israel Hospital and Harvard Medical School, Boston. Dr. Kuntz received his master's of science in biostatistics from the Harvard School of Public Health.

### Selected Publications/Presentations:

Kandzari DE, Leon MB, Popma JJ, Fitzgerald PJ, O'Shaughnessy C, Ball MW, Turco M, Applegate RJ, Gurbel PA, Midei MG, Badre SS, Mauri L, Thompson KP, LeNarz LA, Kuntz RE; ENDEAVOR III Investigators. Comparison of zotarolimus-eluting and sirolimus-eluting stents in patients with native coronary artery disease: a randomized controlled trial. *J Am Coll Cardiol*. 2006 December 19;48(12):2440-2447.

Mauri L, O'Malley AJ, Popma JJ, Moses JW, Leon MB, Holmes DR Jr, Teirstein PS, Cutlip DE, Donahoe D, Kuntz RE. Comparison of thrombosis and restenosis risk from stent length of sirolimus-eluting stents versus bare metal stents. *Am J Cardiol*. 2005 May 15;95(10):1140-1145.

Kuntz RE, Wang JC, Mauri L, Cohen DJ. An evidence-based approach to the use of drug-eluting stents in clinical practice. *Am Heart Hosp J*. 2004 Summer;2(3):132-141.

## About Medtronic:

Medtronic, Inc. (Medtronic), incorporated in 1957, is a medical technology company. The company is engaged in research, design, manufacture and sale of products to alleviate pain, restore health and extend life. It manufactures and sells device-based medical therapies. It operates in seven segments: Cardiac Rhythm Disease Management, Spinal, CardioVascular, Neuromodulation, Diabetes, Surgical Technologies and Physio-Control. Its primary customers include hospitals, clinics, third party health care providers, distributors and other institutions, including governmental health care programs and group purchasing organizations. In April 2010, the Company completed the acquisition of Invatec, SpA, a developer of medical technologies for the interventional treatment of cardiovascular disease.

## Additional Information:

- Medtronic Inc. [www.medtronic.com](http://www.medtronic.com)

## Sources:

Medtronic: Richard E. Kuntz biography.

[http://wwwp.medtronic.com/Newsroom/Biography.do?itemId=1142624279550&lang=en\\_US](http://wwwp.medtronic.com/Newsroom/Biography.do?itemId=1142624279550&lang=en_US). Accessed September 23, 2010.

Reuters: Medtronic, Inc. <http://www.reuters.com/finance/stocks/companyProfile?symbol=MDT.N>. Accessed September 23, 2010.



## Sharon Levine, MD

**Title:** Associate Executive Medical Director

**Organization:** The Permanente Medical Group

**Board Term:** 6 years (2016)

### Biography:

Sharon Levine, MD, is a nationally respected expert and frequent speaker on issues of health policy, drug use management, and the design and delivery of health care services. As associate executive director for The Permanente Medical Group of Northern California since 1991 — the largest medical group in the country — she has responsibility for the recruitment, compensation, clinical education, management training, and leadership development for the group's physicians; government and community relations; health policy and external affairs; and pharmacy policy and drug use management.

A board-certified pediatrician, Dr. Levine has practiced with The Permanente Medical Group since 1977. During that time she has held multiple leadership roles, including chief of Pediatrics, chief of Quality, and physician-in-charge of the Fremont Medical Center.

Dr. Levine began her medical career at the Montgomery-Georgetown Pediatric Comprehensive Care Clinic and Georgetown University Community Health Plan. In addition, she has held academic appointments at Tufts University School of Medicine and Georgetown University School of Medicine, and spent two years as a clinical associate at the National Institutes of Health, Institute of Child Health and Human Development, doing research on infant nutrition.

A native of Boston, Dr. Levine received her undergraduate degree from Radcliffe College at Harvard University, and her MD from Tufts University School of Medicine.

### Statement Upon Appointment:

“Sharon is highly valued for her leadership at Kaiser Permanente, and she will bring a wealth of clinical experience and expertise to this important assignment,” said Robert Pearl, MD, executive director and CEO of The Permanente Medical Group and president and CEO of the Mid-Atlantic Permanente Medical Group.”

### Selected Publications/Presentations:

Arrow K, Auerbach A, Bertko J, et al. Toward a 21st-century health care system: recommendations for health care reform. *Ann Intern Med.* 2009 April 7;150(7):493-495.

Levine S. Designing payment policies to promote appropriate utilization. Specialty pharmaceuticals: policies for encouraging access and affordability. Washington DC; October 2, 2008.

<http://healthforum.brandeis.edu/meetings/materials/2008-2-October/CR-SpecialtyPharma-10-2-08.pdf>.

Levine S. Determination of comparative safety and effectiveness in an integrated delivery system. Comparative effectiveness: strategies to change policy and practice. Washington DC; October 17, 2007.

[https://www.ecri.org/Documents/CERC/Levine\\_Slides.pdf](https://www.ecri.org/Documents/CERC/Levine_Slides.pdf).

### About Kaiser Permanente:

Kaiser Permanente is recognized as one of America's leading health care providers and not-for-profit health plans. Founded in 1945, its mission is to provide high-quality, affordable health care services and to improve the health of its members and the communities it serves. Kaiser Permanente currently serves 8.6 million members in nine states and the District of Columbia.

### Additional Information:

- Kaiser Permanente International. <http://xnet.kp.org/kpinternational/index.html>

**Sources:**

Kaiser Permanente International: Faculty. <http://xnet.kp.org/kpinternational/faculty/index.html>. Accessed September 23, 2010.

Kaiser Permanente's Sharon Levine, MD, Appointed to Board of Governors for Patient-Centered Outcomes Research Institute (press release), September 23, 2010. [http://xnet.kp.org/newscenter/pressreleases/ncal/2010/092310levine\\_usgao.html](http://xnet.kp.org/newscenter/pressreleases/ncal/2010/092310levine_usgao.html). Accessed September 24, 2010.



## Freda C. Lewis-Hall, MD, FAPA

**Title:** Senior Vice President and Chief Medical Officer

**Organization:** Pfizer Inc

**Board Term:** 4 years (2014)

### Biography:

Freda C. Lewis-Hall, MD, is senior vice president and chief medical officer for Pfizer Inc, the world's leading research-based pharmaceutical company. As the most senior physician at Pfizer, Dr. Lewis-Hall leads medical, patient safety, regulatory affairs and quality assurance efforts throughout the company, as well as outreach to doctors and other medical professionals.

Prior to joining Pfizer, Dr. Lewis-Hall was at Vertex Pharmaceuticals where she was responsible for clinical and nonclinical development and both medical and regulatory affairs. Dr. Lewis-Hall managed a number of key functions, including regulatory affairs, clinical and nonclinical development, medical affairs and commercial development.

Dr. Lewis-Hall has diverse experience across multiple areas of the pharmaceutical industry. She has served as the senior vice president of US Pharmaceuticals, Medical Affairs at Bristol-Myers Squibb. Prior to her position at Bristol-Myers Squibb, Dr. Lewis-Hall held leadership positions at Pharmacia Corporation, Eli Lilly and Company, the National Institute of Mental Health and the Howard University College of Medicine Department of Psychiatry.

Dr. Lewis-Hall received a bachelor of arts and sciences in natural sciences from Johns Hopkins University and her Medical Doctorate from Howard University Hospital and College of Medicine.

### Selected Publications/Presentations:

Lewis-Hall FC, Wilson MG, Tepner RG, Koke SC. Fluoxetine vs. tricyclic antidepressants in women with major depressive disorder. *J Womens Health*. 1997 June;6(3):337-343.

### About Pfizer:

Pfizer Inc (Pfizer), incorporated on June 2, 1942, is a research-based, global biopharmaceutical company. The Company applies science and its global resources to improve health and well-being at every stage of life. Pfizer's diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many consumer health care products. The Company operates in two business segments: Biopharmaceutical and Diversified. Biopharmaceutical includes the Primary Care, Specialty Care, Established Products, Emerging Markets and Oncology customer-focused units. Diversified includes Animal Health products that prevent and treat diseases in livestock and companion animals, and Consumer Healthcare products. On October 15, 2009, the Company completed its acquisition of Wyeth. In December 2009, Durata Therapeutics, Inc, acquired Vicuron Pharmaceuticals from Pfizer.

### Additional Information:

- Pfizer Website: [www.pfizer.com](http://www.pfizer.com)

### Sources:

Freda C. Lewis-Hall, Pfizer Inc. [http://www.pfizer.com/about/leadership\\_and\\_structure/leadership\\_executives\\_lewishall.jsp](http://www.pfizer.com/about/leadership_and_structure/leadership_executives_lewishall.jsp). Accessed September 10, 2010.

Profile: Pfizer Inc (PFE.N). Reuters. <http://www.reuters.com/finance/stocks/companyProfile?symbol=PFE.N>. Accessed September 10, 2010.



## Steven Lipstein, MHA (PCORI Vice Chair)

**Title:** President and Chief Executive Officer

**Organization:** BJC HealthCare

**Board Term:** 6 years (2016)

### Biography:

Steven Lipstein, MHA, is president and chief executive officer of BJC HealthCare in St. Louis, Missouri. Prior to joining BJC in 1999, he served as executive vice president at the University of Chicago Hospitals and Health System and held executive positions in the Johns Hopkins Hospital and Health System. Mr. Lipstein serves on the St. Louis Regional Health Commission and on the boards of Washington University in St. Louis and the Missouri Hospital Association. In addition, he is a member of the Board of Directors for the American Association of Medical Colleges, serving as chair of the Council of Teaching Hospitals and chair of the Medicare/Medicaid Special Action Committee. Mr. Lipstein also serves as chair of the Eighth District Federal Reserve Bank. He received a BA from Emory University and a masters in health administration from Duke University.

### Selected Publications/Presentations:

Wietecha M, Lipstein SH, Rabkin MT. Governance of the academic health center: striking the balance between service and scholarship. *Acad Med.* 2009 February;84(2):170-176.

### About BJC HealthCare:

BJC HealthCare is one of the largest non-profit health care organizations in the United States, delivering services to residents primarily in the greater St. Louis, southern Illinois and mid-Missouri regions. With net revenue of \$3.2 billion, BJC serves urban, suburban and rural communities. It also includes 13 hospitals and multiple community health locations. Services include inpatient and outpatient care, primary care, community health and wellness, workplace health, home health, community mental health, rehabilitation, long-term care and hospice.

### Additional Information:

- BJC HealthCare. [www.bjc.org](http://www.bjc.org)

### Sources:

GAO announces appointments to new Patient-Centered Outcomes Research Institute (PCORI) Board of Governors (press release). Washington, DC: US Government Accountability Office; September 23, 2010.

<http://www.gao.gov/press/pcori2010sep23.html>. Accessed September 23, 2010.

BJC Leadership. St. Louis, MO: BJC HealthCare. <http://www.bjc.org/?id=2714&sid=1>. Accessed September 23, 2010.

BJC At a Glance. St. Louis, MO: BJC HealthCare. <http://www.bjc.org/?id=2251&sid=1>. Accessed September 23, 2010.



## Grayson Norquist, MD, MSPH

**Title:** Professor and Chairman, Department of Psychiatry and Human Behavior

**Organization:** University of Mississippi Medical Center

**Board Term:** 4 years (2014)

### Biography:

Grayson Norquist, MD, MSPH, is professor and chairman of the Department of Psychiatry and Human Behavior at the University of Mississippi Medical Center in Jackson, Mississippi. His research focuses on the use of telemedicine to reduce disparities in mental health treatment for those living in the Delta region of Mississippi and to improve the quality of care they receive at local community health centers.

Prior to joining the Department of Psychiatry and Human Behavior in 2004, Dr. Norquist served in a number of leadership positions at the National Institute of Mental Health (NIMH), including director of the Division of Services and Intervention Research, a division responsible for clinical, prevention and services research at NIMH. During Dr. Norquist's tenure as director, the division initiated the largest clinical trials ever conducted in mental health. Additionally, he was an associate clinical professor of psychiatry at Georgetown University.

Dr. Norquist sits on the editorial board of *Psychiatric Services*, served on the editorial boards of the *Archives of General Psychiatry* and the *Journal of Mental Health Policy and Economics*, and received various national government and public awards, including the National Institutes of Health (NIH) Director's Award, the NIH Special Service Award, and the National Alliance for the Mentally Ill Exemplary Psychiatrist Award.

He received a BA from the University of Mississippi, received a masters in public health from the UCLA School of Public Health and an MD magna cum laude from the University of Mississippi.

### Selected Publications/Presentations:

Norquist GS. Introduction to the STAR\*D special section. *Psychiatr Serv*. 2009 November;60(11):1437-1438.

Schoenbaum M, Butler B, Kataoka S, Norquist G, Springgate B, Sullivan G, Duan N, Kessler RC, Wells K. Promoting mental health recovery after hurricanes Katrina and Rita: what can be done at what cost. *Arch Gen Psychiatry*. 2009 August;66(8):906-914.

Norquist GS. Contented but not better: problems with satisfaction. *Psychiatr Serv*. 2009 July;60(7):867.

Norquist G, McGuire TG, Essock SM. Cost-effectiveness of depression treatment for adolescents. *Am J Psychiatry*. 2008 May;165(5):549-552.

Zuvekas SH, Rupp A, Norquist G. Cost shifting under managed behavioral health care. *Psychiatr Serv*. 2007 January;58(1):100-108.

Zuvekas SH, Vitiello B, Norquist GS. Recent trends in stimulant medication use among US children. *Am J Psychiatry*. 2006 April;163(4):579-585.

Vitiello B, Zuvekas SH, Norquist GS. National estimates of antidepressant medication use among US children, 1997-2002. *J Am Acad Child Adolesc Psychiatry*. 2006 March;45(3):271-279.

Trivedi MH, Rush AJ, Wisniewski SR, Nierenberg AA, Warden D, Ritz L, Norquist G, Howland RH, Lebowitz B, McGrath PJ, Shores-Wilson K, Biggs MM, Balasubramani GK, Fava M; STAR\*D Study Team. Evaluation of outcomes with citalopram for depression using measurement-based care in STAR\*D: implications for clinical practice. *Am J Psychiatry*. 2006 January;163(1):28-40.

Zuvekas SH, Rupp AE, Norquist GS. The impacts of mental health parity and managed care in one large employer group: a reexamination. *Health Aff.* 2005 November-December;24(6):1668-1671

Zuvekas SH, Rupp AE, Norquist GS. Spillover effects of benefit expansions and carve-outs on psychotropic medication use and costs. *Inquiry.* 2005 Spring;42(1):86-97.

Ursano RJ, Bell C, Eth S, Friedman M, Norwood A, Pfefferbaum B, Pynoos JD, Zatzick DF, Benedek DM, McIntyre JS, Charles SC, Altshuler K, Cook I, Cross CD, Mellman L, Moench LA, Norquist G, Twemlow SW, Woods S, Yager J; Work Group on ASD and PTSD; Steering Committee on Practice Guidelines. Practice guideline for the treatment of patients with acute stress disorder and posttraumatic stress disorder. *Am J Psychiatry.* 2004 November;161(11 Suppl):3-31.

Norquist GS. Improving the lives of the aging mentally ill population: the promise of services research. *Am J Geriatr Psychiatry.* 2003 September-October;11(5):478-480.

Lebowitz BD, Vitiello B, Norquist GS. Approaches to multisite clinical trials: the National Institute of Mental Health perspective. *Schizophr Bull.* 2003;29(1):7-13.

### About the University of Mississippi Medical Center:

The Department of Psychiatry and Human Behavior at the University of Mississippi Medical Center provides mental health services to patients, offers state-of-the-art education and training in psychiatry, psychology and related fields, and pursues research on the brain, human behavior and mental illness.

### Additional Information:

- Department of Psychiatry and Human Behavior, University of Mississippi Medical Center. <http://psych.umc.edu/>

### Sources:

University of Mississippi Medical Center: Department of Psychiatry and Human Behavior Faculty: Grayson S. Norquist. [http://psych.umc.edu/faculty/chairman/grayson\\_norquist.html](http://psych.umc.edu/faculty/chairman/grayson_norquist.html). Accessed September 23, 2010.

Pubmed.gov: Grayson Norquist publications <http://www.ncbi.nlm.nih.gov/pubmed>. Accessed September 23, 2010.

University of Mississippi Medical Center: Department of Psychiatry and Human Behavior. <http://psych.umc.edu/>. Accessed September 23, 2010.



## Ellen V. Sigal, PhD

**Title:** Chairperson and Founder

**Organization:** Friends of Cancer Research

**Board Term:** 6 years (2016)

### Biography:

Ellen V. Sigal, PhD, is chairperson and founder of Friends of Cancer Research, a cancer research think tank and advocacy organization in Arlington, Virginia. During the last 20 years, she has been an advocate for finding new and better treatments for patients through advancing science and research. She has served on the National Cancer Institute Board of Scientific Advisors and the National Institutes of Health Director's Council of Public Representatives. She was a presidential appointee to the National Cancer Advisory Board where she chaired the Budget and Planning Committee that oversees the federal cancer budget. She is currently vice chair of the Board of Directors of the Reagan-Udall Foundation for the Food and Drug Administration and chair of the Public-Private Partnerships Committee of the Foundation for the National Institutes of Health. She is a board member of the American Association of Cancer Research Foundation and Duke University Cancer Center. She received a BA and masters from Brooklyn College and a PhD from Rutgers University.

### Statement Upon Appointment:

"Since the founding of Friends of Cancer Research she has worked vigorously to understand the fundamental drivers of how progress can be made to benefit patients and improve outcomes in cancer," said Dr. Elias Zerhouni, Director of the National Institutes of Health from 2002-2008. "It would be hard, in my opinion, to find a more experienced and thoughtful patient advocate than Ellen Sigal."

### Selected Publications/Presentations:

Schilsky RL, Allen J, Benner J, Sigal E, McClellan M. Commentary: tackling the challenges of developing targeted therapies for cancer. *Oncologist*. 2010;15(5):484-487.

Young RC, Friedman MA, Schilsky RL, Sigal EV. Drug safety and drug efficacy: two sides of the same coin. *Clin Cancer Res*. 2007;13(9):2533-2534.

Sigal EV. Opportunity and challenge. Implementation of comparative effectiveness research: the patient protection and affordable care act. AACR Annual Meeting. April 2010.

<http://www.focr.org/images/stories/pdf/ellen%20aacr%20annual%20meeting%20cer%20panel.pdf>. Accessed September 27, 2010.

Improving medical decisions through comparative effectiveness research: cancer as a case study: a comparative effectiveness white paper. May 2009. [http://focr.org/files/CER\\_REPORT\\_FINAL.pdf](http://focr.org/files/CER_REPORT_FINAL.pdf). Accessed September 27, 2010.

### About Friends of Cancer Research:

Friends of Cancer Research (Friends) is a cancer research think tank based in the Washington, DC area. Working with the entire cancer research and advocacy community, Friends pioneers innovative public-private partnerships, organizes critical policy forums, educates the public, and brings together key stakeholders to overcome the barriers standing between patients and the most promising cancer treatments.

### Additional Information:

- Friends of Cancer Research. [www.focr.org](http://www.focr.org)

### Sources:

Dr. Ellen Sigal named to Patient Centered Outcomes Research Institute Board of Governors. Arlington, VA: Friends of Cancer Research; September 23, 2010. <http://www.focr.org/pcori-board-announcement.html>. Accessed September 23, 2010.



## A. Eugene Washington, MD, MSc (PCORI Chair)

**Title/Organization:** Vice Chancellor, UCLA Health Sciences and Dean, David Geffen School of Medicine at UCLA

**Board Term:** 6 years (2016)

### Biography:

Dr. A. Eugene Washington assumed his role as vice chancellor of UCLA Health Sciences and dean of the David Geffen School of Medicine in February 2010. He is an internationally renowned clinical investigator and health-policy scholar whose wide-ranging research has been instrumental in shaping national health policy and practice guidelines. As vice chancellor and dean, Dr. Washington oversees the UCLA Health System and the David Geffen School of Medicine, and serves as the principal spokesperson for health sciences at UCLA.

Prior to coming to UCLA, Dr. Washington served as executive vice chancellor and provost for University of California, San Francisco (UCSF), where he co-founded the Medical Effectiveness Research Center for Diverse Populations. He also co-founded the UCSF-Stanford Evidence-based Practice Center and, from 1996 to 2004, chaired the Department of Obstetrics, Gynecology, and Reproductive Sciences. He has published extensively in his major areas of research, which include prenatal genetic testing, cervical cancer screening and prevention, noncancerous uterine conditions management, reproductive tract infections, quality of health care and racial/ethnic disparities in health outcomes.

Dr. Washington has earned numerous honors and awards, including the Outstanding Service Medal from the US Public Health Service, and election to the Institute of Medicine (IOM) of the National Academy of Sciences, where he serves on the Governing Council of the IOM. He also serves on the boards of the Robert Wood Johnson Foundation, the California Wellness Foundation, and the Congressionally mandated Scientific Management Review Board of the National Institutes of Health.

Dr. Washington holds an MD from the University of California, San Francisco School of Medicine, an MSc from the Harvard University School of Public Health, an MPH from the University of California, Berkeley School of Public Health, and a BS from Howard University. He completed residencies in preventive medicine at Harvard University and in gynecology and obstetrics at Stanford University, and was a health policy scholar at UCSF's Institute for Health Policy Studies.

### Statement Upon Appointment:

"I am honored to be appointed to the Board of Governors of PCORI and selected to serve as its Chair. This novel undertaking has tremendous promise for measurably improving the quality of health care in the United States and the health of all Americans. I look forward to working with the Board members and other individuals and groups who are committed to attaining this goal."

### Selected Publications/Presentations:

Initial national priorities for comparative effectiveness research, Committee on Comparative Effectiveness Research Prioritization Board on Health Care Services. *Institute of Medicine*. June 2009;194(2):332-338.

Showstack J, Lin F, Learman LA, Vittinghoff E, Kuppermann M, Varner RE, Summitt RL Jr, McNeeley SG, Richter H, Hulley S, Washington AE; Ms Research Group. Randomized trial of medical treatment versus hysterectomy for abnormal uterine bleeding: resource use in the Medicine or Surgery (Ms) trial. *Am J Obstet Gynecol*. 2006;194(2):332-338.

Learman LA, Summitt RL Jr, Varner RE, Richter HE, Lin F, Ireland CC, Kuppermann M, Vittinghoff E, Showstack J, Washington AE, Hulley SB; Medicine or Surgery Research Group. Hysterectomy versus expanded medical treatment for abnormal uterine bleeding: clinical outcomes in the medicine or surgery trial. *Obstet Gynecol*. 2004. May;103(5 Pt 1):824-833.

Kuppermann M, Varner RE, Summitt RL Jr, Learman LA, Ireland C, Vittinghoff E, Stewart AL, Lin F, Richter HE, Showstack J, Hulley SB, Washington AE; Ms Research Group. Effect of hysterectomy vs medical treatment on health-related quality of life and sexual functioning: the medicine or surgery (Ms) randomized trial. *JAMA*. 2004; 291:1447-1455.

Learman LA, Summitt RL Jr, Varner RE, McNeeley SG, Goodman-Gruen D, Richter HE, Lin F, Showstack J, Ireland CC, Vittinghoff E, Hulley SB, Washington AE; Total or Supracervical Hysterectomy (TOSH) Research Group. A randomized comparison of total or supracervical hysterectomy: surgical complications and clinical outcomes. *Obstet Gynecol*. 2003 Sep;102(3):453-462.

Subak LL, Caughey AB, Washington AE. Cost-effectiveness analyses in obstetrics & gynecology. Evaluation of methodologic quality and trends. *J Reprod Med*. 2002. August;47(8):631-639.

Caughey AB, Kuppermann M, Norton ME, Washington AE. Nuchal translucency and first trimester biochemical markers for down syndrome screening: a cost-effectiveness analysis. *Am J Obstet Gynecol*. 2002;187(5):1239-1245.

### About UCLA Health System:

The UCLA Health System is composed of the Ronald Reagan UCLA Medical Center, Santa Monica-UCLA Medical Center and Orthopaedic Hospital, Resnick Neuropsychiatric Hospital at UCLA, Mattel Children's Hospital UCLA, and the UCLA Medical Group with its wide-reaching system of primary-care and specialty-care offices throughout the region. The UCLA Health System is among the most comprehensive and advanced health care systems in the world.

### About the David Geffen Medical School:

The David Geffen Medical School has more than 2,000 full-time faculty members, almost 1,300 residents, more than 750 medical students and almost 400 PhD candidates. The medical school is ranked ninth in the country in research funding from the National Institutes of Health and third in the United States in research dollars from all sources.

### Additional Information:

- David Geffen School of Medicine at UCLA. <http://dgsom.healthsciences.ucla.edu/>
- UCLA Health Sciences. <http://healthsciences.ucla.edu>

### Sources:

UCLA Health Sciences Leadership: Eugene Washington, MD, MSc. <http://www.uclahealth.org/body.cfm?id=1225>. Accessed September 21, 2010.

A. Eugene Washington appointed as dean of the David Geffen School of Medicine and Vice Chancellor of Health Sciences at UCLA, November 4, 2009. <http://newsroom.ucla.edu/portal/ucla/a-eugene-washington-appointed-112067.aspx>. Accessed September 21, 2010.

David Geffen School of Medicine at UCLA: History. <http://dgsom.healthsciences.ucla.edu/about/history>. Accessed September 21, 2010.

About UCLA Health System. <http://www.uclahealth.org/body.cfm?id=41>. Accessed September 21, 2010.

Dr. A. Eugene Washington appointed as chair of the Board of Governors of the Patient-Centered Outcomes Research Institute, September 23, 2010. <http://www.uclahealth.org/body.cfm?id=561&action=detail&ref=1507>. Accessed September 23, 2010.



## Harlan Weisman, MD

**Title:** Chief Science and Technology Officer, Medical Devices and Diagnostics

**Organization:** Johnson & Johnson

**Board Term:** 6 years (2016)

### Biography:

Harlan Weisman, MD, is the chief science and technology officer, Medical Devices and Diagnostics, for Johnson & Johnson in New Brunswick, New Jersey. He is responsible for guiding the Johnson & Johnson Medical Devices and Diagnostics Group's scientific and technical efforts. He has held several other positions, including president of Johnson & Johnson Pharmaceutical Research and Development. He was assistant professor of medicine at Johns Hopkins University School of Medicine and a consultant cardiologist and director of the Experimental Cardiac Pathology Laboratory at Johns Hopkins Hospital. He is a fellow of the American College of Cardiology, the American College of Chest Physicians and the American Heart Association's Councils on Clinical Cardiology and on Arteriosclerosis, Thrombosis, and Vascular Biology. He received a BA from the University of Maryland and an MD from the University of Maryland School of Medicine.

### Selected Publications/Presentations:

Weisman H. Innovation in the age of quality. AdvaMed 2009 MedTech Conference. Washington DC; October 13, 2009.

### About Johnson & Johnson:

Johnson & Johnson manufactures health care products and provides related services for the consumer, pharmaceutical, and medical devices and diagnostics markets. The company sells products such as skin and hair care products, acetaminophen products, pharmaceuticals, diagnostic equipment, and surgical equipment in countries located around the world.

### Additional Information:

- Johnson & Johnson. [www.jnj.com](http://www.jnj.com)

### Sources:

GAO announces appointments to new Patient-Centered Outcomes Research Institute (PCORI) Board of Governors (press release). Washington, DC: US Government Accountability Office; September 23, 2010.

<http://www.gao.gov/press/pcori2010sep23.html>. Accessed September 23, 2010.

AdvaMed Website. <http://www.advamed.org/MemberPortal/Events>. Accessed September 23, 2010.

Johnson & Johnson Website. <http://www.jnj.com>. Accessed September 23, 2010.



## Robert Zwolak, MD, PhD

**Title:** Professor of Surgery

**Organization:** Dartmouth-Hitchcock Medical Center

**Board Term:** 6 years (2016)

### Biography:

Robert Zwolak, MD, PhD, is a vascular surgeon at Dartmouth-Hitchcock Medical Center in Lebanon, New Hampshire, and professor of surgery at the Dartmouth Medical School. He is also chief of surgery at the White River Junction Veterans Administration Medical Center in White River Junction, Vermont, and director of the Non-invasive Vascular Laboratory. He has a special interest in health care policy issues as they relate to vascular surgery and has been instrumental in working with the Society for Vascular Surgery® to create a data registry and form a comparative effectiveness committee. Currently serving as president of the Society for Vascular Surgery®, he has held other positions of leadership including governor of the American College of Surgeons, president of the New England Society for Vascular Surgery, and member of the Society for Vascular Surgery® Board of Directors. He served on the AMA/ Specialty Society Relative Value Update Committee. He received a BS from Rensselaer Polytechnic Institute, a PhD in molecular biology and pathology and an MD from Albany Medical College.

### Selected Publications/Presentations:

Speech at the Partnership to Improve Patient Care (PIPC) Forum on “Delivering on Patient-Centered CER” on July 22, 2010. <http://improvepatientcare.org/delivering-patient-centered-cer-forum-speeches>. Accessed September 23, 2010.

### About Dartmouth-Hitchcock Medical Center:

Dartmouth-Hitchcock Medical Center (DHMC) is New Hampshire’s only academic medical center. Internationally renowned, nationally ranked, and regionally respected, DHMC integrates high-quality patient care, advanced medical education, and translational research to provide a full spectrum of health care.

### Additional Information:

- Society for Vascular Surgery® position statement on comparative effectiveness research in vascular disease management, January 2010. <http://www.vascularweb.org/about/positionstatements/Pages/ComparativeEffectivenessResearch.aspx>. Accessed September 23, 2010
- Dartmouth-Hitchcock Medical Center. [www.dartmouth-hitchcock.org/index.html](http://www.dartmouth-hitchcock.org/index.html)

### Sources:

GAO announces appointments to new Patient-Centered Outcomes Research Institute (PCORI) Board of Governors (press release). Washington, DC: US Government Accountability Office; September 23, 2010. <http://www.gao.gov/press/pcori2010sep23.html>. Accessed September 23, 2010.

Dartmouth-Hitchcock Medical Center: Robert M. Zwolak, MD. [http://www.dhmc.org/providers/dhmc\\_provider\\_747.html](http://www.dhmc.org/providers/dhmc_provider_747.html). Accessed September 23, 2010.

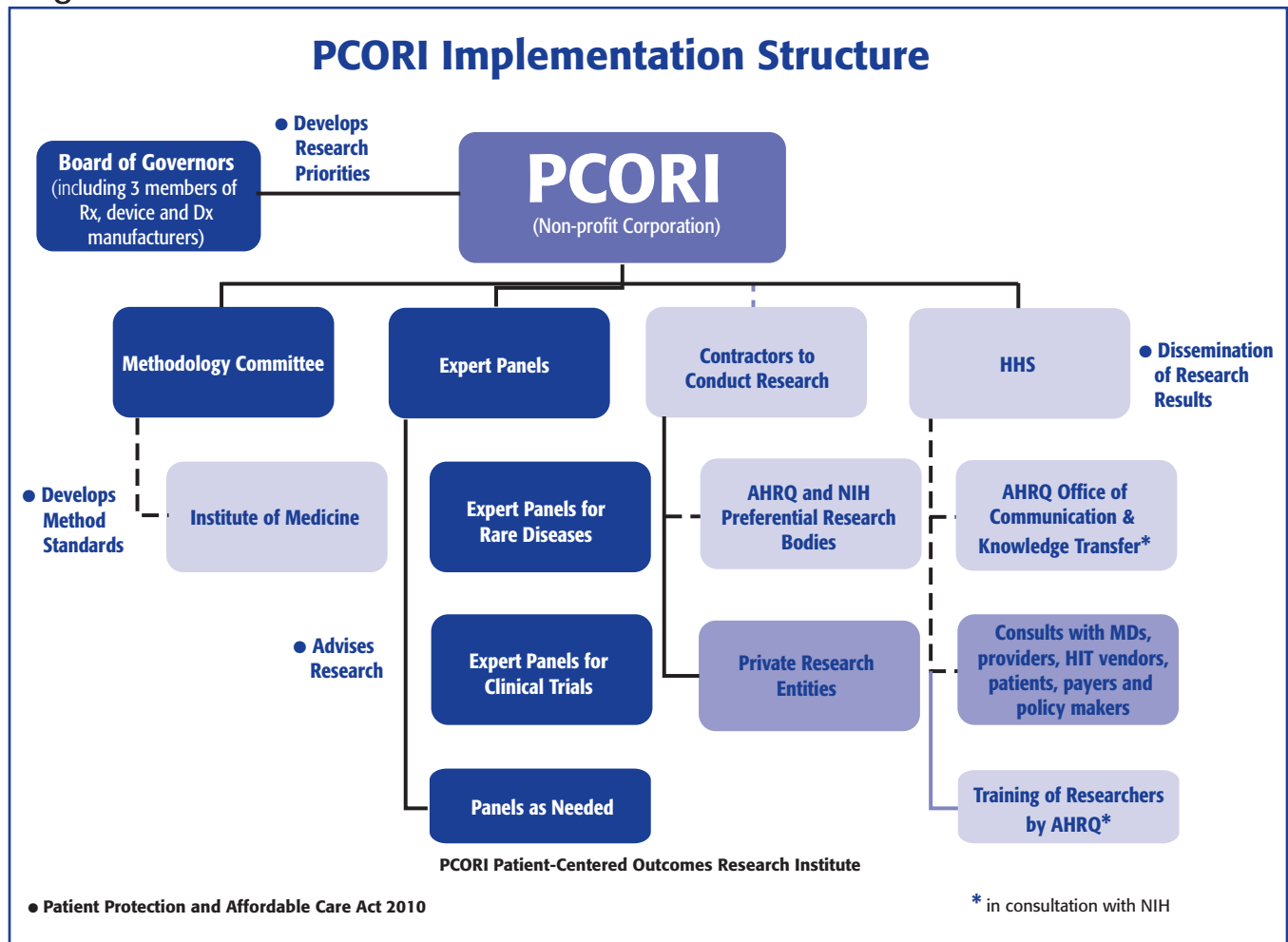
Dartmouth-Hitchcock Medical Center: About D-H. [http://www.dartmouth-hitchcock.org/about\\_dh/dhmc.html](http://www.dartmouth-hitchcock.org/about_dh/dhmc.html). Accessed September 23, 2010.

# PCORI Implementation

The newly appointed members of the PCORI Board of Governors must now begin to build the institute from the ground up. There are numerous details that must be worked out before PCORI can begin its primary mission of spearheading and overseeing millions of dollars for new comparative effectiveness research.

PCORI will receive guidance from a standing methodology committee, permanent or ad-hoc expert panels, expert panels for clinical trials, and an expert advisory panel for rare diseases. Within the expert advisory panels, “the institute may include a technical expert of each manufacturer or each medical technology that is included under the relevant topic, project, or category for which the panel is established.” (Figure 1)

Figure 1



Eighteen months following the establishment of PCORI, the methodology committee must issue methodology guidelines for the conduct of CER. Embedded in the law is very specific language pertaining to transparency, and the importance of opening the CER process for comment by patient groups, health care stakeholders, and the public. PCORI is required to have a public comment period of 45-60 days prior to the adoption of proposed methods, and must also have public comment periods prior to the adoption of national priorities and of the research project agenda.

Once PCORI is functional, the institute must make the research findings it receives available within 90 days to “clinicians, patients and the general public” working through the Office of Communication and Knowledge Transfer at AHRQ. The public comment period for findings of research will be 45-60 days from the release of the research findings drafts.

PCORI is also required to submit several specified reports to Congress and the Administration, and to make these reports publicly available. One of these is an annual report. Another, required at least every five years, is a report on the “extent to which research findings are used by health care decision-makers, the effect of the dissemination of such findings on reducing practice variation and disparities in health care and the effect of the research conducted and disseminated on innovation and the health care economy of the United States.” (Figures 2 and 3)

Figure 2

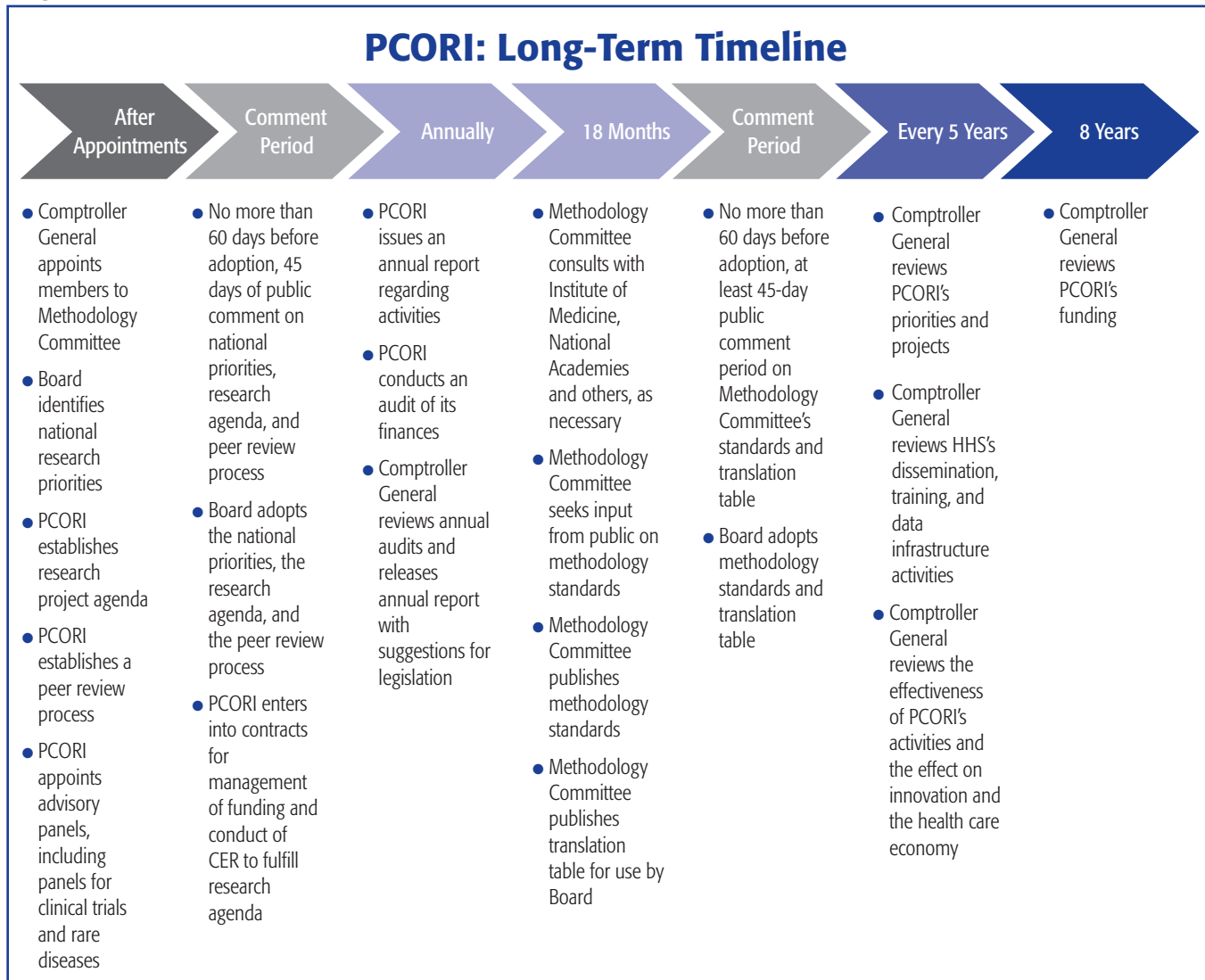
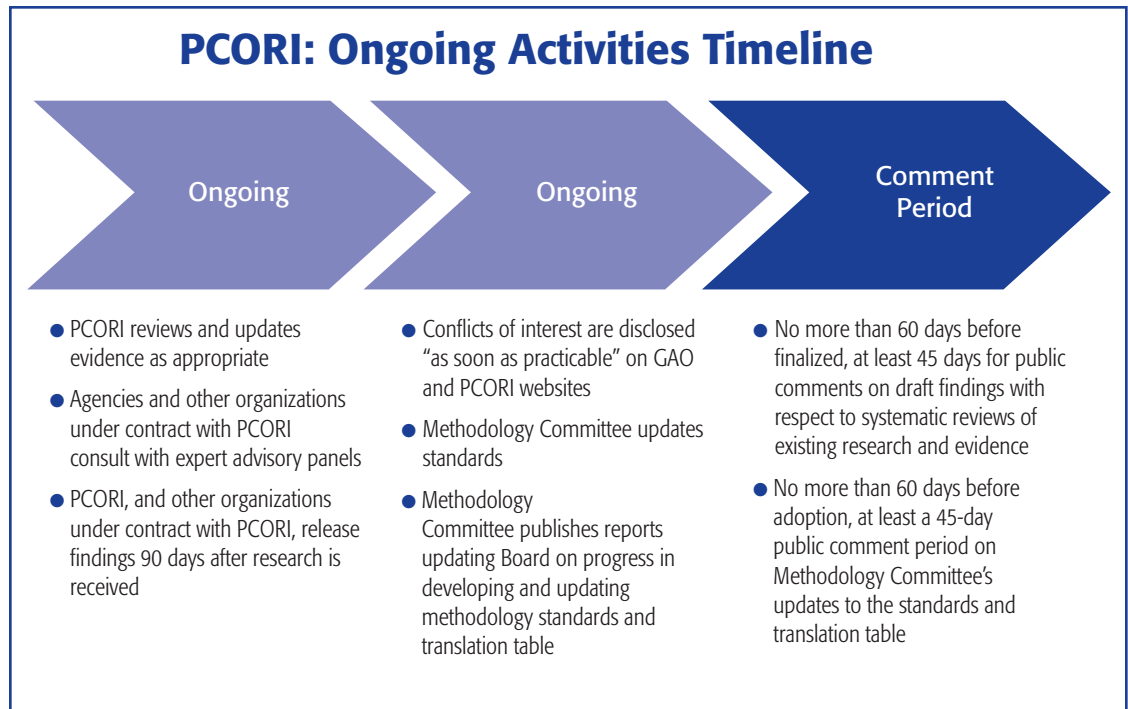


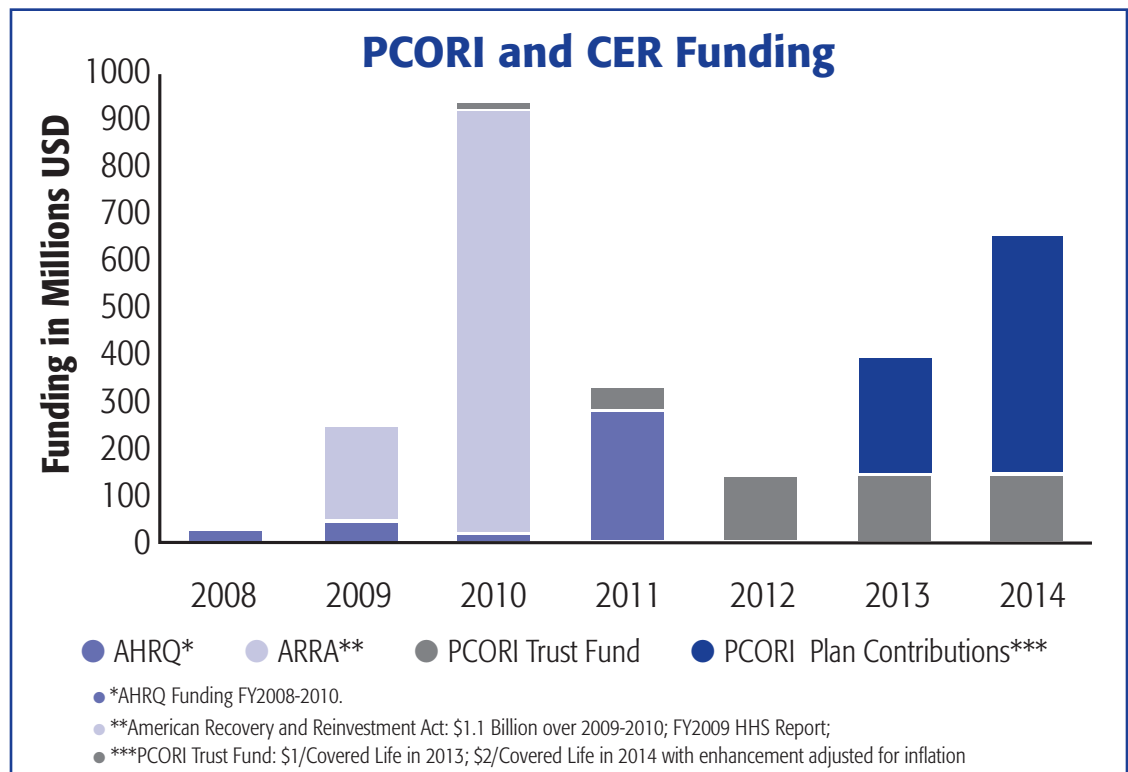
Figure 3



Other required reports include reviews of the "dissemination and training activities and data networks" established by the law, and a review in 2018 of the "adequacy and funding for the institute and activities."

Other clear timelines are set for PCORI's funding, which begins this year. PCORI will be funded by the Patient-Centered Outcomes Research Trust Fund through 2019, which has been allocated \$10 million for 2010, \$50 million for 2011, and \$150 million for 2012. In future years, the trust fund will comprise general revenues, an annual \$2 fee per Medicare beneficiary transferred from the Medicare Trust Fund, and an annual \$2 fee per-covered-life assessed on private health plans, adjusted for health expenditure inflation. Taken together, total sustained annual funding for PCORI could be more than \$650 million. (Figure 4)

Figure 4



## NPC's Key Considerations On Comparative Effectiveness Research

In 2009, NPC presented these considerations before the Institute of Medicine's CER Priority Setting Committee, the Agency for Healthcare Research and Quality, and the Federal Coordinating Council for Comparative Effectiveness Research. NPC developed these considerations to promote the primary goal of CER: supporting the dialogue between health care providers and patients, thus enhancing the quality of patient care.

All of these considerations were incorporated into the health reform law.

1. Provide evidence that will encourage and facilitate good decision making by health care professionals and patients, recognizing and supporting the physician and patient as the center of the decision making process.
2. Encompass all health care services, including devices, diagnostics, health care delivery methods, pharmaceuticals and medical and surgical procedures, and establish priorities for research in an explicit and transparent manner.
3. CER should be rigorous and transparent, and conducted in accordance with a clear set of methods guidelines.
4. Improve the quality of patient care with focus on clinical effectiveness over simply reducing treatment costs; research should be conducted in the context of health care quality improvement above all else.
5. Appropriately consider the needs of patient subgroups who may respond differently to medicines and treatments based on age, genetic variation and co-morbidities.
6. Encourage an all-inclusive approach that allows for multiple organizations to provide input and generate and evaluate evidence in a fully transparent manner.
7. Utilize a full range of types and sources of evidence that consider both direct and indirect benefits to society, such as quality of life, patient functionality and economic productivity.
8. Be current and allow for amendment when new data emerges.
9. Ensure balanced, effective and timely communication of results to consumers, patients, physicians and health care professionals, including any limitations to findings.
10. A publicly funded CER entity must be perceived as a credible and trusted organization and in order to help ensure that, it is best organized as a public-private partnership outside of any agency or government structure.
11. A national CER effort should remain focused on clinical comparative effectiveness. Value and cost-effectiveness should be considered only after clinical outcomes are assessed and determinations of comparative value may best be considered on a regional or local level where health care decision makers can more accurately incorporate variations in health technology acquisition costs.

# A Brief History of Comparative Effectiveness Research And Evidence-Based Medicine

## Introduction

The concepts of evidence-based medicine (EBM) and comparative effectiveness research (CER) are not new. Since the 1970s, health industry leaders and the federal government have turned to Health Technology Assessment (HTA), EBM, and, more recently, CER as means to improve quality and consistency and maximize value in the health care delivery system. However, these concepts have taken on prominence since the 1990s when legislation created the Agency for Health Care Policy and Research (later renamed the Agency for Healthcare Research and Quality, or AHRQ), to support studies on the outcomes of health care services and procedures.

### These efforts have taken different names over the decades:

- 1970s: health technology assessment
- 1980s: effectiveness research
- 1990s: outcomes research
- 2000s: evidence-based medicine and comparative effectiveness research

## An Overview of Early Efforts

Efforts to improve quality and maximize the value of health care services have been undertaken by both governmental and private entities.

### Past governmental efforts include:

- The US Congress Office of Technology Assessment:<sup>1</sup> An agency created by Congress in 1972 to provide analysis of new technologies, including health care, the Office of Technology Assessment was abolished in 1995 as part of the 104<sup>th</sup> Congress' "Contract with America."
- The Institute of Medicine's Council on Health Care Technology: The council was established in 1986 "to promote the development and application of technology assessment in health care and to review health care technologies for their appropriate use."<sup>2</sup> The organization lost public funding in 1989.
- The Agency for Health Care Policy and Research: An early iteration of AHRQ, the agency focused on developing clinical guidelines.<sup>3</sup>
- RxIntelligence: An independent non-profit corporation founded by BlueCross BlueShield in 2000, RxIntelligence conducted cost-benefit, cost-effectiveness analyses of pharmaceutical drugs and provided "evaluation of therapeutic interchangeability of drugs." The entity lasted only two years.<sup>4</sup>

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<sup>1</sup> US Congress, Office of Technology Assessment, *The OTA Legacy: 1972-1995*. Washington, DC; April 1996. <http://www.princeton.edu/~ota/>. Accessed June 15, 2009.

<sup>2</sup> Medical Technology Assessment Directory: A Pilot Reference to Organizations, Assessments, and Information Resources. Institute of Medicine; 1988:633. [http://books.nap.edu/openbook.php?record\\_id=1090&page=633](http://books.nap.edu/openbook.php?record_id=1090&page=633). Accessed June 12, 2009.

<sup>3</sup> Luce B, Cohen RS, Hunter C, Cragin L, Johnson J. *The Current Evidence-Based Medicine Landscape*. April 2008:6.

<sup>4</sup> Luce B, Cohen RS, Hunter C. *A Critical Analysis of the 2008 National Landscape of Evidence-Based Medicine and Comparative Effectiveness Policies*. April 2008:4.

- Medicare Coverage Policy: In July 2006, the Centers for Medicare and Medicaid Services (CMS) issued a guidance document that allowed the agency to integrate evidence-based decision making and research into its coverage determination policies.<sup>5</sup> This policy is still currently in use by CMS and is informed by the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC),<sup>6</sup> which is a working group designed to supplement CMS' internal expertise.

Few of these efforts took hold, primarily because they lost political support due to their perceived threat to innovation, medical autonomy, and market access.<sup>7</sup>

#### Private efforts include:

- Cochrane Collaboration: Founded in 1993, this global non-profit network is dedicated to evaluating health care interventions through systematic reviews. The major product of the Collaboration is the Cochrane Database of Systematic Reviews, which is published quarterly as part of The Cochrane Library.<sup>8</sup>
- Blue Cross/Blue Shield Technology Evaluation Center: Established in 1995, this entity reviews interventions and evidence to determine effectiveness and guide clinical decision making.
- Center for Medical Technology Policy (CMT): CMT was created in 2006 to generate reliable and credible information about the real world risks, benefits and costs of promising new medical technologies. Initial funding was provided by the California Healthcare Foundation and the Blue Shield of California Foundation, with ongoing funding from organizations including the National Pharmaceutical Council.<sup>9</sup>
- Institute for Clinical and Economic Review (ICER): This organization was created by a grant from the Blue Shield of California Foundation in 2006, and produces appraisals of clinical effectiveness and cost effectiveness of medical innovations, with the goal of providing new information to decision makers intent on improving the value of health care services. Ongoing funding is provided by a group of organizations, including the National Pharmaceutical Council.<sup>10</sup>
- ECRI Institute (formerly the Emergency Care Research Institute): ECRI Institute is a non-profit agency and is a Collaborating Center of the World Health Organization (WHO), and an Evidence-based Practice Center (EPC) for AHRQ. ECRI evaluates safety, quality, and cost-effectiveness in health care. It offers more than 10 databases, publications, information services, and technical assistance services.<sup>11</sup>
- Hayes, Inc: This independent organization specializes in health technology assessment reports for health care organizations, including health plans, managed care companies, hospitals, and health networks. Hayes' medical research analysts assess such technologies as medical and surgical procedures, drugs, biologics, diagnostic and screening tests, medical devices and equipment, and complementary and alternative therapies.<sup>12</sup>

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<sup>5</sup> Ibid:24.

<sup>6</sup> Centers for Medicare and Medicaid Services, Medicare Evidence Development and Coverage Advisory Committee. [http://www.cms.hhs.gov/FACA/02\\_MEDCAC.asp](http://www.cms.hhs.gov/FACA/02_MEDCAC.asp). Accessed June 15, 2009.

<sup>7</sup> Bryan R. Luce, PhD, MBA, United BioSource Corporation, presentation to the National Pharmaceutical Council. April 2008.

<sup>8</sup> The Cochrane Collaboration: About the Cochrane Collaboration. <http://www.cochrane.org/docs/descrip.htm>. Accessed June 12, 2009.

<sup>9</sup> The Center for Medical Technology Policy. *About us*. <http://www.cmtmpnet.org/about-cmtmp>. Accessed June 5, 2009.

<sup>10</sup> Institute for Clinical and Economic Review. <http://www.icer-review.org/index.php/support/index.html>. Accessed June 5, 2009.

<sup>11</sup> Luce B, Cohen RS, Hunter C, Cragin L, Johnson J. *The Current Evidence-Based Medicine Landscape*. April 2008:47.

<sup>12</sup> Ibid:48.

- Oregon Drug Effectiveness Review Project: Established in 2003, this project “produces systematic, evidence-based reviews of the comparative effectiveness and safety of drugs in many widely used drug classes, and applies the findings to inform public policy and related activities in local settings.”<sup>13</sup>
- AMCP Format 3.0 for Formulary Submissions: Established by the Academy of Managed Care Pharmacy, the format is a set of guidelines for submitting new and existing pharmaceuticals for a health system’s Pharmacy and Therapeutics Committee. The format requires detailed information, not only on the drug’s safety and efficacy, but also on its overall clinical value (including observational studies of effectiveness and harms, adherence or persistence) and economic value relative to alternative therapies.<sup>14</sup>
- Wellpoint, Inc: In 2010, WellPoint issued its “Use of Comparative Effectiveness Research and Observational Data in Formulary Decision Making: Evaluation Criteria,” which are standardized CER guidelines that Wellpoint will use when evaluating drugs for the purposes of improving health outcomes and providing value for members of its health plans.<sup>15</sup>

It is believed that these private sector activities have succeeded largely because they have been perceived as useful by the market in clinical decision making, purchasing, coverage and formulary placement, and cost containment. For the most part, these initiatives have been insulated from political influence, thus improving their longer term viability.<sup>16</sup>

### Growing Interest in CER in Recent Years

The federal government’s interest in CER has been accelerating over the past few years, with the creation of new initiatives and the expansion of several existing ones.

In 2003, the Medicare Modernization Act (MMA) ensured funding for CER through AHRQ. Today AHRQ’s authority has expanded to generate new knowledge, which it does through a network of research centers and private-public partnerships. In 2005, AHRQ launched its Effective Health Care Program, which has three core mandates:

- To review and synthesize existing knowledge through Evidence-based Practice Centers (EPCs)
- To promote and generate new knowledge through the DEcIDE (Developing Evidence to Inform Decisions about Effectiveness) Research Network
- To compile the findings from the EPCs and DEcIDE Network and then translate that knowledge for consumers, physicians, payers and policy makers.

The program is meant to focus on effectiveness, as on the evidence of the relative benefits and risks of alternative interventions; to determine usability and real-world applicability; to be a transparent and open process; and to drive research forward.<sup>17</sup> Since 2005, AHRQ has published more than 150 reports on various interventions and treatments.<sup>18</sup>

<sup>13</sup> Oregon Health & Science University: Center for Evidence-based Policy Drug Effectiveness Review Project. <http://www.ohsu.edu/ohsuedu/research/policycenter/DERP/index.cfm>. Accessed June 11, 2009.

<sup>14</sup> AMCP Format for Formulary Submissions Version 3.0. October 2009. <http://www.amcp.org/format/pub.pdf>. Accessed September 10, 2010.

<sup>15</sup> Wellpoint use of comparative effectiveness research (CER) and observational data in formulary decision making: evaluation criteria. May 2010. [https://www.wellpointnextrx.com/shared/noapplication/f1/s0/t0/pw\\_b145032.pdf](https://www.wellpointnextrx.com/shared/noapplication/f1/s0/t0/pw_b145032.pdf). Accessed September 17, 2010.

<sup>16</sup> Bryan R. Luce, PhD, MBA, United BioSource Corporation, presentation to the National Pharmaceutical Council. April 2008.

<sup>17</sup> Agency for Healthcare Research and Quality, Effective Health Care: The Program. <http://effectivehealthcare.ahrq.gov/aboutUs.cfm?abouttype=program>. Accessed June 14, 2009.

<sup>18</sup> US Department of Health and Human Services, Agency for Healthcare Research and Quality. FY 2008 Annual Performance Report. <http://www.ahrq.gov/about/cj2009/AHRQ%20FY2008%20Annual%20Performance%20Report.pdf>. Accessed June 5, 2009.

In addition to MMA, the Institute of Medicine's Roundtable on Evidence-Based Medicine (now known as the Roundtable on Value & Science-Driven Health Care) has engaged major stakeholders in an effort to "help transform the way evidence on clinical effectiveness is generated and used to improve health and health care." Through workshops and publications the IOM hopes to engage health care stakeholders and identify key issues that are not being adequately addressed, the nature of the barriers, possible solutions, and policy opportunities in order to achieve its stated goal that "by 2010, 90 percent of clinical decisions will be supported by accurate, timely, and up-to-date clinical information, and will reflect the best available evidence."<sup>19</sup>

**Other ongoing government-supported programs include:**

- US Preventive Services Task Force (USPSTF): Established in 1984, and sponsored by AHRQ since 1998, USPSTF is an independent panel of private-sector experts in prevention and primary care, and conducts assessment of various health services.<sup>20</sup>
- Department of Veterans Affairs and Department of Defense: These entities use data from their patient populations to assess the effectiveness of various interventions and make coverage decisions based on findings. The Department of Veterans Affairs' program is called the Technology Assessment Program (VATAP).<sup>21</sup> The Department of Defense manages these efforts through TRICARE Management Activity,<sup>22</sup> the Department of Defense agency responsible for administering the health benefits of military beneficiaries.

Under the Obama administration significant investment has been made in CER. In January 2009, as part of the economic stimulus law known as the American Recovery and Reinvestment Act (ARRA), Congress set aside \$1.1 billion in funding for CER. Under ARRA, the funding was distributed among the US Department of Health and Human Services, AHRQ, and the National Institutes of Health and must be obligated by September 30, 2010.

In March 2010 President Obama signed into law the Patient Protection and Affordable Care Act, a major health care reform bill that establishes a new CER entity called the Patient-Centered Outcomes Research Institute (PCORI). PCORI is structured as a public-private partnership outside of any agency or government structure.

<sup>19</sup> Institute of Medicine Roundtable on Value & Science-Driven Health Care. <http://www.iom.gov/Activities/Quality/VSRT.aspx>. Accessed September 17, 2010.

<sup>20</sup> Luce B, Cohen RS, Hunter C, Cragin L, Johnson J. *The Current Evidence-Based Medicine Landscape*. April 2008:9.

<sup>21</sup> US Department of Veterans Affairs, VA Technology Assessment Program. <http://www.va.gov/VATAP/index.htm>. Accessed June 15, 2009.

<sup>22</sup> Jacobsen G. CRS report for Congress: comparative clinical effectiveness and cost-effectiveness research: background, history, and overview. October 15, 2007:28. [http://assets.opencrs.com/rpts/RL34208\\_20071015.pdf](http://assets.opencrs.com/rpts/RL34208_20071015.pdf). Accessed June 15, 2009; and Agency for Healthcare Research and Quality – ECRI. <http://www.ahrq.gov/clinic/epc/ecriepc.htm>. Accessed June 15, 2009.

## NPC Resource Materials

Below are additional resource materials from the National Pharmaceutical Council relevant to the ongoing conversations among US health care stakeholders about evidence-based medicine and comparative effectiveness research (CER). Please refer to [www.npcnow.org](http://www.npcnow.org) for the latest research and all NPC documents.

**Additionally, NPC offers several ways to track CER developments:**

- *EVIDently*, a monthly email newsletter with a focus on research, health care policy, and health and productivity issues
- *EVIDently Today*, NPC's blog
- The *CER Newsfeed*, a daily email and online update of the latest news and research related to CER
- NPC's Twitter feed, which can be followed at [www.twitter.com/npcnow](http://www.twitter.com/npcnow).

To receive these free communications or view them online, go to NPC's website, [www.npcnow.org](http://www.npcnow.org).

### Research

Unless noted, all research and commentary/testimony is available online at

[http://www.npcnow.org/Public/Issues/i\\_cer/Comparative\\_Effectiveness\\_Research\\_Main\\_Page.aspx](http://www.npcnow.org/Public/Issues/i_cer/Comparative_Effectiveness_Research_Main_Page.aspx); or go to [www.npcnow.org](http://www.npcnow.org) and click "Issues," then "Comparative Effectiveness Research."

- *Value in Health* Special Issue: Apples and oranges? Assessing comparative effectiveness and comparative value in the US and other countries. June/July 2010;13(suppl s1):S1–S32.
- Is the impact of comparative effectiveness being evaluated? *Health Affairs Blog*, June 30, 2010.
- Good ReseArch for Comparative Effectiveness (GRACE) principles. March 2010. (updated and endorsed by the International Society of Pharmacoepidemiology).
- Demystifying comparative effectiveness research: A case study learning guide (full report and executive summary). 2009.
- Framing the debate/untangling the potential impact of comparative effectiveness research on innovation. 2009.
- National Institute for Health and Clinical Excellence (NICE): how does it work and what are the implications for the US? 2008.
- The current evidence-based medicine landscape. 2008.

### Commentary/Testimony

- Comments submitted to the Department of Health and Human Services on "Request for Information on Development of an Inventory of Comparative Effectiveness Research." August 9, 2010.
- Health care reform, comparative effectiveness research, and P&T decisions, commentary. *Am J Pharm Benefits*. June 2010. [http://ajpblive.com/issues/2010/vol2\\_no3/AJPB\\_192-194](http://ajpblive.com/issues/2010/vol2_no3/AJPB_192-194)
- Comparative effectiveness and real world evidence, commentary by NPC President Dan Leonard. *AJMC*. June 2010. [http://ajmc.com/issue/managed-care/2010/2010-06-vol16-n06/AJMC\\_10jun\\_LeonardCom410to11](http://ajmc.com/issue/managed-care/2010/2010-06-vol16-n06/AJMC_10jun_LeonardCom410to11).
- GRACE principles: recognizing high-quality observational studies of comparative effectiveness, article by Dreyer NA, Schneeweiss S, McNeil BJ, et al. *AJMC*. June 2010. [http://ajmc.com/issue/managed-care/2010/2010-06-vol16-n06/AJMC\\_10junDreyer\\_467to471](http://ajmc.com/issue/managed-care/2010/2010-06-vol16-n06/AJMC_10junDreyer_467to471).
- NPC pleased with establishment of Patient-Centered Outcomes Research Institute. March 25, 2010.
- New NPC report provides guidance on evaluating and interpreting comparative effectiveness studies. December 10, 2009.
- Avalere explores impact of comparative effectiveness research on healthcare innovation. November 17, 2009.
- Leaders in healthcare to examine impact of comparative effectiveness research on personalized medicine. October 27, 2009.
- NPC commends Senate Finance Committee Chairman Baucus for Comparative Effectiveness Research provisions in Chairman's Mark. September 16, 2009.
- NPC response to President Obama's health care address to Congress. September 10, 2009.
- NPC testimony submitted to the Federal Coordinating Council on Comparative Effectiveness Research on the Draft Definition and Strategic Framework for Comparative Effectiveness Research. June 10, 2009.

- NPC testimony before the Federal Coordinating Council on Comparative Effectiveness Research. April 14, 2009.  
<http://www.hhs.gov/recovery/programs/ceer/h1404meeting.html>
- NPC testimony before the Agency for Healthcare Research and Quality. April 3, 2009.  
<http://www.ahrq.gov/about/nac/npc.htm>
- NPC testimony before the Institute of Medicine Comparative Effectiveness Research Committee. March 20, 2009.
- NPC podcast: briefing on clinical comparative effectiveness. February 10, 2009.
- NPC statement on Economic Stimulus Package. February 17, 2009.

## Additional Resources

Below are links to key documents from organizations that have been instrumental in developing the definitions, framework and criteria for CER, such as the Agency for Healthcare Research and Quality (AHRQ), the Federal Coordinating Council for CER, and the Institute of Medicine, among others.

### Agency for Healthcare Research and Quality

- National Advisory Council for Healthcare Research and Quality. <http://www.ahrq.gov/about/council.htm>
- AHRQ's Effective Healthcare Program. <http://effectivehealthcare.ahrq.gov/>
- AHRQ Comparative Effectiveness Spending Plan. <http://www.hhs.gov/recovery/reports/plans/pdf20100610/AHRQ%20CER%20June%202010.pdf>

### Congressional Budget Office

- Research on the Comparative Effectiveness of Medical Treatments. December 2007. <http://www.cbo.gov/ftpdocs/88xx/doc8891/12-18-ComparativeEffectiveness.pdf>
- CBO Budget Options, Volume I: Health Care, 2008. <http://www.cbo.gov/ftpdocs/99xx/doc9925/12-18-HealthOptions.pdf>

### Department of Health and Human Services

- HHS Comparative Effectiveness Research, main page. <http://www.hhs.gov/recovery/programs/cer/index.html>
- Funds for Allocation by the Office of the Secretary Through the Agency for Healthcare Research and Quality: Comparative Effectiveness Research ARRA Spending Plans. <http://www.hhs.gov/recovery/reports/plans/pdf20100610/OS%20CER%20June%202010.pdf>

### Federal Coordinating Council for Comparative Effectiveness Research

- Report to the President and Congress on Comparative Effectiveness Research. June 30, 2009. <http://www.hhs.gov/recovery/programs/cer/cerannualrpt.pdf>

### Institute of Medicine

- Initial National Priorities for Comparative Effectiveness Research. June 30, 2009. <http://www.iom.edu/CMS/3809/63608/71025.aspx>
- Institute of Medicine Comparative Effectiveness Research Committee Public Meetings. March 20, 2009. <http://www.iom.edu/Activities/Research/CERPriorities/2009-SEP-24.aspx>
- Institute of Medicine Roundtable on Value & Science-Driven Health Care <http://iom.edu/Activities/Quality/VSRT.aspx>

### National Institutes of Health

- National Institutes of Health: Comparative Effectiveness Research. ARRA Spending Plans. [http://www.hhs.gov/recovery/reports/plans/pdf20100610/NIH\\_Comparative%20Effectiveness%20%20June%202010.pdf](http://www.hhs.gov/recovery/reports/plans/pdf20100610/NIH_Comparative%20Effectiveness%20%20June%202010.pdf)

### Public Law

- The Patient Protection and Affordable Care Act. <http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf>
- Comparative Effectiveness Research Sections of the American Recovery and Reinvestment Act. <http://www.ahrq.gov/fund/cefarrarexc.htm>



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