

**THE PROMISE OF COMPARATIVE EFFECTIVENESS RESEARCH:**

**TESTIMONY OF**

**THE COALITION FOR HEALTH SERVICES RESEARCH**

**TO THE**

**SUBCOMMITTEE ON HEALTH**

**COMMITTEE ON WAYS AND MEANS**

**UNITED STATES HOUSE OF REPRESENTATIVES**

**JUNE 26, 2007**

The Coalition for Health Services Research (Coalition) is pleased to offer this testimony for the record regarding the promise of comparative effectiveness research. The Coalition's mission is to support research that leads to accessible, affordable, high-quality health care. As the advocacy arm of AcademyHealth, the Coalition represents the interests of 3,800 researchers, scientists, and policy experts, as well as 135 organizations that produce and use health services research.

Health care in the United States has the potential to improve people's health dramatically, but often falls short and costs too much. Health services research is used throughout the health care field to understand how to better finance the costs of care, measure and improve the quality of care, and improve coverage and access to affordable services. As an emerging science in the broader field of health services research, comparative effective research—where pharmaceuticals, medical devices and medical procedures used to treat the same conditions are evaluated for their relative safety, effectiveness, and cost—has great potential to improve health care quality and patient outcomes while ensuring that consumers receive the best care at the best value. When optimally funded, comparative effectiveness research has the promise to inform health care decisions that are:

- **Patient-specific**, enabling doctors to make individualized treatment decisions according to patient characteristics (sex, age, and race/ethnicity).
- **Evidence-based**, providing patients and practitioners with the timely, scientific information they need to evaluate which treatment options will help them achieve better outcomes.
- **Value-driven**, empowering patients to make informed decisions in the face of rising health care costs and myriad treatment options.

There are increasing examples that demonstrate how comparative effectiveness research provides the scientific basis needed to make better decisions when it comes to the care we give and receive:

- The Agency for Healthcare Research and Quality (AHRQ) found that episiotomies—a preemptory incision intended to prevent pregnant women from tearing tissue during labor—has no positive benefit, and probably results in more complications and causes more pain than if no incision was made during childbirth.<sup>i</sup> The report will save millions of women from having to undergo this painful procedure, not to mention the costs saved by eliminating the routine use of this procedure.
- Another AHRQ study found that drugs can be as effective as surgery in management of gastroesophageal reflux disease (GERD)—where stomach acid enters the esophagus, causing heartburn and potential esophageal damage.<sup>ii</sup> GERD is one of the most common health conditions among older Americans and results in \$10 billion annually in direct health care costs. Knowing that, for the majority of patients, drugs can be as effective as surgery in relieving the symptoms could result in significant health care savings and improved quality of life.

- The National Institute of Mental Health (NIMH) found that, within a class of antipsychotic drugs, the older, less expensive drug (Perphenazine) was just as effective and caused no worse side effects than the three newer, more expensive drugs in treating patients with schizophrenia. One of the newer drugs (Zyprexa) was slightly more effective in controlling systems than the other drugs, but at the cost of serious side effects.<sup>iii</sup> This study enables greater flexibility in care and informs patients and providers about costs and quality of care.
- In a study of more than 2,200 patients funded mostly by the Veterans' Administration, researchers found that those who underwent non-emergency angioplasty—a procedure where a tiny wire-mesh tube called a stent is placed in an artery to hold it open—were no less likely to suffer a heart attack or die than those who took only aspirin and other medicines to lower blood pressure and cholesterol and prevent clots, along with adopting lifestyle changes.<sup>iv</sup> The procedure, often performed to relieve chest pain and to reduce the risk of having or dying from a heart attack, costs about \$50,000 and has become one of the most common medical procedures in the United States.

As these examples suggest, comparative effectiveness research can contribute greatly to better health care at lower cost. It is a true public good, providing a basis for improvements in our health care system that benefit the general public. Americans overwhelmingly agree. According to a 2005 *Research!America* survey, approximately 95 percent of Americans agree that it is important to support research that focuses on how well the health care system works and how it could work better, and that health care services should be based on the best and most recent research available.<sup>v</sup>

Despite the promise of, and general support for, comparative effectiveness research, this type of health services research by definition often results in “winners” and “losers,” making the entity that commissions this research vulnerable and susceptible to attack. For example, if research based on post-marketing surveillance finds that device “A” has better outcomes and fewer risks than drug “B,” one would expect the demand for device “A” to increase at the expense of drug “B.” The manufacturer of drug “B” might then attempt to leverage the political process to discredit the research and, as has happened in the past, exert political pressure to substantially reduce the funding for, or even abolish the entity funding, the research.

Given the potentially controversial nature of comparative effectiveness research findings, in September 2005 AcademyHealth issued a report that provided guidance on the placement, structure, and funding of comparative effectiveness research (see appendix A).<sup>vi</sup> The AcademyHealth report recommended that comparative effectiveness research be established either within AHRQ or through the creation of a new entity that would, in varying degrees, be linked the lead agency for health services research. As part of this recommendation, the report identifies four structural options for the placement of this critical research function. These options range from fully embedding the comparative effectiveness function in an established

federal agency to placing it, along with all other health services research, in a new, quasi-governmental organization (see also Appendix B):

- **Option 1:** AHRQ sponsors and conducts comparative effectiveness studies with oversight and guidance from an external board and panel of experts.
- **Option 2:** AHRQ sponsors and conducts comparative effectiveness studies with oversight and guidance from an external board and panel of experts, and establishes a Federally Funded Research and Development Center (FFRDC).<sup>vii</sup> The FFRDC would undertake syntheses of research commissioned by AHRQ and others for the purpose of making comparative effectiveness findings.
- **Option 3:** With AHRQ remaining as currently structured, create a new, separate quasi-governmental entity for comparative effectiveness research.
- **Option 4:** Reconstitute AHRQ as a quasi-governmental entity, retaining most of its existing functions and adding comparative effectiveness research.

AcademyHealth assessed these four options against five principles designed to further guide policymakers' deliberations on comparative effectiveness research (see also Appendix C).

- Comparative effectiveness research is a subset of the broader field of health services research, so increased investments in comparative effectiveness research should not be at the expense of investments in a robust health services research portfolio.
- Given the potentially controversial nature of comparative effectiveness findings, this research must be based on scientific evidence and be kept separate from funding and coverage decisions.
- As a subset of the field of health services research, comparative effectiveness research must be closely linked to AHRQ—as the lead agency for health services research—to ensure that findings are consistent with the best available research, methods, and data.
- Since comparative effectiveness research as a public good requires significant federal investment and has the potential to affect the delivery and cost of health care for all Americans, the entity commissioning or conducting this research should be subject to congressional oversight.
- Stakeholders should be involved in developing the research agenda and ensuring the validity of the research produced. Ensuring transparency in the prioritization, conduct, and dissemination of research will promote public

acceptance of the research findings and strengthen support for the program's mission.

The entity's overall funding and ability to recruit the expertise needed are critical factors that should inform the choice among these options – the best arrangement for a budget of \$50 million might not be the best if \$5 billion were to be made available for this function. It may also be desirable to have portions of this responsibility undertaken by a combination of entities. Under such a scenario, the lead agency for health services research might commission and undertake the research studies, an affiliated entity might do the assessments based on that research, and an independent quasi-governmental entity might develop consensus studies on the methods and data to be used for these studies and assessments.

Regardless of how this research program is structured and governed in the future, AcademyHealth and its Coalition recognize that comparative effectiveness research will require a significant investment to realize its potential. For example, some experts suggest that a robust comparative effectiveness program should be funded at a level of \$4–\$6 billion annually to meet the U.S. health system's demands. Comparatively, the federal government last year spent nearly \$32 billion on health research, of which only 5 percent—about \$1.5 billion—was apportioned to health services research. The federal government's comprehensive investment in comparative effectiveness research across the various agencies conducting and funding this work is unknown, as this information is not systematically collected. However, we do know that AHRQ's comparative effectiveness program was appropriated \$15 million in fiscal 2007 (and \$15 million in each of the previous three fiscal years).<sup>viii,ix</sup> Congress should increase and expand the sources of funding for conducting and coordinating a wide spectrum of comparative effectiveness research, including systematic reviews of existing literature, analysis of administrative data and clinical registries, and pragmatic, prospective, head-to-head trials. Doing so would ultimately help patients, providers, payers, and policymakers make rational choices about new and existing health services, and assure that our investments in basic and clinical research are integrated into health care delivery. After all, increased spending on new medicines and equipment is wasted if the system does not adopt these new treatments in a safe and efficient manner.

In addition, we believe that increased investment in comparative effectiveness research must be coupled with greater investment in the research infrastructure—the data, methods, and researchers needed to conduct this work and ultimately generate meaningful research and knowledge. The field of health services research has experienced an erosion of investment in its methods, data, and particularly its researchers over the last several years. If left unchecked, these declining investments could threaten the field's capacity to address public and private sector research needs.

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In conclusion, the best health care decisions are based on relevant data and scientific evidence. Increased investment in comparative effectiveness research and the health services research infrastructure will show returns in improved quality, accessibility, and affordability. At a time when America is spending over \$2 trillion annually on health care, we need research—now more than ever—to help us spend our health care dollars more wisely.

The Coalition appreciates the opportunity to submit this testimony for the record and looks forward to working with the Subcommittee as it continues to assess options for structuring and funding a robust comparative effectiveness research capability in the United States. If you have questions or comments about this testimony, please contact Emily Rowe, Director of Government Relations at 202.292.6743 or e-mail at [emily.rowe@academyhealth.org](mailto:emily.rowe@academyhealth.org).

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**Appendix A: Committee on Placement, Funding, and Coordination of Health Services Research within the Federal Government**

(Affiliations at time of committee appointment)

**Sheila Burke, Committee Chair**, Deputy Secretary and Chief Operating Officer, Smithsonian Institution

**Jeanne Lambrew, Ph.D., Vice Chair**, Associate Professor, Department of Health Policy, George Washington University

**David Abernethy**, Senior Vice President, Operations, HIP Health Plans

**Michael Chernew, Ph.D.**, Professor, Department of Health Management and Policy, School of Public Health, University of Michigan

**Jordan Cohen, M.D.**, President, Association of American Medical Colleges

**Judith Feder, Ph.D.**, Dean of Public Policy, Georgetown University

**Harold S. Luft, Ph.D.**, Caldwell B. Esselstyn Professor and Director, Institute for Health Policy Studies, University of California, San Francisco

**Nicole Lurie, M.D.**, Senior Natural Scientist and Alcoa Chair, RAND Corporation

**Donald M. Steinwachs, Ph.D.**, Professor and Chair, Department of Health Policy and Management, Bloomberg School of Public Health, Johns Hopkins University

**Gail Wilensky, Ph.D.**, Senior Fellow, Project HOPE

**Appendix B: Four Options for the Placement of Comparative Effectiveness Research**

<p><b>Option 1:</b> AHRQ sponsors and conducts comparative effectiveness studies with oversight and guidance from an external board and panel of experts.</p>	<ul style="list-style-type: none"> <li>• AHRQ would remain the lead agency for health services research, supporting a broad health services research agenda, including comparative effectiveness.</li> <li>• AHRQ would establish an external board to oversee the development of the comparative effectiveness research agenda and a panel of experts to validate the science used to conduct comparative effectiveness studies.</li> </ul>
<p><b>Option 2:</b> AHRQ sponsors and conducts comparative effectiveness studies with oversight and guidance from an external board and panel of experts, and establishes a Federally Funded Research and Development Center (FFRDC).</p>	<ul style="list-style-type: none"> <li>• AHRQ would remain the lead agency for health services research, supporting a broad health services research agenda, including comparative effectiveness.</li> <li>• AHRQ would establish an external board to oversee the development of the comparative effectiveness research agenda and a panel of experts to validate the science used to conduct comparative effectiveness studies.</li> <li>• AHRQ would also establish an independent FFRDC with the limited mission of reviewing and synthesizing comparative effectiveness research.</li> </ul>
<p><b>Option 3:</b> AHRQ remains as currently structured and a new separate quasi-government entity is established to fund and conduct comparative effectiveness research.</p>	<ul style="list-style-type: none"> <li>• AHRQ would remain the lead agency for health services research, supporting a broad health services research agenda, but not comparative effectiveness.</li> <li>• A new quasi-governmental agency would be established, with both public and private funding, to conduct both intramural and extramural comparative effectiveness studies.</li> </ul>
<p><b>Option 4:</b> AHRQ is reconstituted as a quasi-governmental agency retaining most existing functions and adding comparative effectiveness research.</p>	<ul style="list-style-type: none"> <li>• AHRQ reconstituted as a new quasi-governmental entity would conduct and fund health services research, including comparative effectiveness.</li> <li>• Those AHRQ functions that must be performed by a governmental entity, such as the Medical Expenditure Panel Survey (MEPS), would be transferred to other existing HHS agencies.</li> <li>• The new quasi-governmental entity could be supported by public and private funds.</li> </ul>

### Appendix C: Five Principles to Guide Decisions for the Placement of Comparative Effectiveness Research

<p><b>Principle 1:</b> Overall funding for the field of health services research should continue to support a broad and comprehensive range of topics.</p>	<ul style="list-style-type: none"> <li>• Recognizes that while comparative effectiveness research is important, it is a subset of the broader field of health services research.</li> <li>• Regardless of where comparative effectiveness research is placed, this principle stresses the need to fund a broad health services research portfolio.</li> </ul>
<p><b>Principle 2:</b> Assessments should be based on scientific evidence and kept separate from funding and coverage decisions.</p>	<ul style="list-style-type: none"> <li>• Given the controversial nature of comparative effectiveness findings, this principle stresses the need for a structure that ensures the scientific integrity of comparative effectiveness research.</li> <li>• This principle stresses the need to separate the entity that funds and conducts these studies from the entity directly responsible for making coverage decisions.</li> </ul>
<p><b>Principle 3:</b> Entity commissioning or conducting comparative effectiveness research should maintain close linkage to the lead agency for health services research.</p>	<ul style="list-style-type: none"> <li>• Recognizes that comparative effectiveness research is a subset of the broader field of health services research.</li> <li>• As such, comparative effectiveness research must be closely linked to the lead agency in order to ensure that findings are consistent with the best available research, methods, and data.</li> </ul>
<p><b>Principle 4:</b> Entity commissioning or conducting comparative effectiveness research should be subject to congressional oversight.</p>	<ul style="list-style-type: none"> <li>• Since comparative effectiveness research has the potential to affect the delivery and cost of health care for all Americans, this principle recognizes that the federal government is responsible for ensuring that decisions about what health services and products should be provided are based on sound scientific research.</li> <li>• Since this research requires substantial federal funding (and would not be funded adequately by the private sector alone), this principle recognizes the need for appropriate congressional oversight of public funding to ensure accountability.</li> </ul>
<p><b>Principle 5:</b> Entity commissioning or conducting comparative effectiveness research should involve key stakeholders to assure transparency of the methods and process, promote public acceptance of research findings, and support for the entity's mission.</p>	<ul style="list-style-type: none"> <li>• Given the controversial nature of comparative effectiveness research, this principle recognizes the importance of involving key private sector representatives in developing the research agenda and ensuring the validity of the research produced, thereby increasing public support for the research findings and the entity's mission.</li> <li>• As such, comparative effectiveness research must be funded in an open process to ensure that no one group is perceived as dominating the process and/or skewing the results.</li> </ul>

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<sup>i</sup> Viswanathan, M., et. al. "The Use of Episiotomy in Obstetric Care: A Systemic Review," Agency for Healthcare Research and Quality (May 2004). Available on the Web at [www.ahrq.gov/downloads/pub/evidence/pdf/episiotomy/episob.pdf](http://www.ahrq.gov/downloads/pub/evidence/pdf/episiotomy/episob.pdf)

<sup>ii</sup> Ip, S., et. al. "Comparative Effectiveness of Management Strategies for Gastroesophageal Reflux Disease," Agency for Healthcare Research and Quality (Dec. 2005). Available on the Web at [www.effectivehealthcare.ahrq.gov/reports/final.cfm](http://www.effectivehealthcare.ahrq.gov/reports/final.cfm)

<sup>iii</sup> Lieberman, J.A., et. al. "Effectiveness of Antipsychotic Drugs in Patients with Chronic Schizophrenia," *New England Journal of Medicine*, Vol. 353, No. 12, pp.1209-1223 (Sept. 22, 2005). Available on the Web at <http://content.nejm.org/cgi.content/abstract/353/12/1209>

<sup>iv</sup> Boden, W.E., et. al. "Optimal Medical Therapy with or without PCI for Stable Coronary Disease," *New England Journal of Medicine*, Vol. 356, No. 15, pp. 1503-1516 (April 12, 2007). Available on the Web at <http://content.nejm.org/cgi/content/abstract/356/15/1503>

<sup>v</sup> Woolley, M. and S. Propst. "Public Attitudes and Perceptions about Health-Related Research." *Journal of the American Medical Association*, Vol. 294, No. 11, p. 1382 (Sept. 21, 2005).

<sup>vi</sup> *Placement, Coordination, and Funding of Health Services Research within the Federal Government*, AcademyHealth (Sept. 2005). Available on the Web at <http://www.chsr.org/placementreport.pdf>

<sup>vii</sup> An FFRDC is a private, nonprofit organization that is sponsored by an executive branch agency. The sponsoring agency monitors, funds, and assumes responsibility for the overall activities of the FFRDC. While FFRDCs are not subject to federal personnel rules, the organizations are prohibited from competing for government contracts to ensure their independence, objectivity, and freedom from organizational conflicts of interest.

<sup>viii</sup> Catlin, A., et. al. "National Health Spending in 2005: The Slowdown Continues," *Health Affairs*, Vol. 26, No. 1, pp. 142-153 (Jan./Feb. 2007).

<sup>ix</sup> *Federal Funding for Health Services Research*, Coalition for Health Services Research (Dec. 2006). Available on the Web at <http://www.chsr.org/AHfundingreport1206.pdf>