

PHRMA STATEMENT
To The Federal Coordinating Council on Comparative Effectiveness
Research

Randy Burkholder, Associate Vice President, Policy

April 14, 2009

Good afternoon. My name is Randy Burkholder. I am pleased to speak to you today on behalf of the Pharmaceutical Research and Manufacturers of America.

PhRMA supports the development and use of high quality evidence, including comparative effectiveness evidence, for health care decision-making. Our position in support of comparative effectiveness research is described in more detail in policy principles adopted by our Board in 2004 and congressional testimony in 2007.

We strongly support HHS' commitment to operating the Federal Coordinating Council with full openness and transparency, and appreciate the opportunity to speak today. In the time provided I will address three important aspects of government-supported CER – infrastructure needs, operating procedures, and priorities for research.

In the area of infrastructure, the Coordinating Council should consider approaches to governance of CER programs that incorporate the full range of stakeholders from the health care community. Broad representation from all stakeholders, combined with open and transparent procedures, will help ensure that the organization operates independently and without any single sector wielding inappropriate influence. A governance structure that includes a range of perspectives – including payers, patients, providers, minority health

organizations, and experts from the biopharmaceutical research and medical technology sectors -- will ensure that research is centered on the information and health needs of patients and providers, and help promote approaches to CER that support continued medical progress.

Further, providing information to patients and providers to support good health care decisions is a fundamental goal of CER. Yet this goal will not be achieved unless their perspectives are included in the CER process. As the Council develops recommendations on infrastructure, it should consider support for public-private governance structures to support a long-term federal investment in comparative effectiveness research.

The Council also should give particular consideration to advances in health information technology and genetics. As more robust electronic health records are developed and electronic databases linked, they can provide a more complete picture of the “real world” effects of different health interventions. In addition, these advances are important elements of the emerging field of personalized medicine, and their potential already is being demonstrated at the CDC, the VA, and other agencies. It is important for comparative effectiveness research to recognize and take advantage of the advances being made in HIT and genetics.

Regarding operating procedures, PhRMA commends HHS’ commitment to openness and transparency. In support of this goal, we urge the Council to operate according to the procedures described in the Government In Sunshine Act. This would ensure, for example, that meetings are open to the public and announced in advance, and foster accountability to Congress. In addition, the Coordinating Council should work with HHS to define the policies that its agencies will use to ensure that, as required in the Recovery and Reinvestment Act, recipients of CER funds provide an opportunity for comment on the research.

Further, the Council should establish additional procedures for meaningful, ongoing public input in its operation. This should include describing the criteria and rationale for any recommendations it makes on priorities for CER investments, and providing an opportunity for public comment on draft reports and recommendations. These steps will ensure that, as recommended by IOM in 1992, priority setting is “explicit, so that people can trace backwards from results to inputs and so satisfy themselves that the process was fair.”

The research infrastructure that is prioritized by the Council should support a broad range of studies on medical interventions and approaches to organizing, managing and delivering care. This broad scope of research is consistent with the existing CER program at AHRQ, and with the Recovery and Reinvestment Act’s mandate for research on “health care treatments and strategies.”

This scope of research also is consistent with the growing recognition that addressing the needs of patients, particularly the chronically ill, requires greater scrutiny of healthcare delivery systems. This includes comparing the effectiveness of different approaches to care processes, disease management services, care coordination, benefit designs, and other components that directly impact care quality and patient outcomes.

While much attention is appropriately paid to evidence-based care, our delivery system often fails to deliver care that is known to be evidence-based. For example, AHRQ notes there is a “rich body of clinical evidence” supporting diabetes treatments, but “the set of studies designed to help providers, patients, and policymakers improve the standard of care is not as strong.” The need for CER to address evidence gaps across the health system recently has been noted by the IOM in its report “HHS in the 21st Century,” and by members of

MedPAC at their meeting earlier this month. It also was highlighted by a broad range of speakers at a March 20 forum at the IOM on CER research priorities.

PhRMA appreciates this opportunity to provide input to the Council, and looks forward to continuing to work with you in this important effort. Thank you.