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Center for Evidence-based Policy

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To: Federal Coordinating Council on Comparative Effectiveness Research

Fr: Mark Gibson, Deputy Director, Center for Evidence-based Policy

Re: Comments for the Comparative Effectiveness Research Listening Session

Thank you for the opportunity to place these comments regarding comparative effectiveness research (CER) on the record.

I am writing as the Deputy Director of a small policy center that has been organizing and producing CER for state policy makers. Our efforts at the Center for Evidence-based Policy started in 2003. Since that time we have worked with state policy makers to identify policy which can be usefully informed by CER, and to produce research reports that will stand the scrutiny of the public policy process.

We have produced 35 systematic reviews comparing the effectiveness, safety and effects on sub-populations of drugs within classes, and 65 updates of those reviews. We have also produced over 80 other reports summarizing the best evidence available for many other interventions. This information has been primarily used by state Medicaid programs but in some cases it is also used to inform policy for workers' compensation systems, criminal justice systems, employee benefit plans and insurance subsidy programs. The reports have covered both clinical and health system research.

Our experience working with states in this capacity has been rewarding and instructive. The lessons we have learned are useful in addressing many of the issues you are currently facing including:

- How to find independent researchers who do not have financial conflicts of interest in the subjects covered by these reports;
- How to develop questions that are both policy relevant and researchable;
- How to provide input from consumers, industry, and other stakeholders without diminishing the independence and rigor of the research;
- How to maintain the transparency required to assure stakeholders and the public agree that the research is objective and independent, and;
- How to translate evidence findings so policy makers can understand and include in their respective decision making processes.

The lessons we have learned over the past 6 years are too many to fully discuss here so these comments will be limited to three subjects: governance,

stakeholder interface, and clarity of responsibility.

Governance is the central element that will determine whether or not this effort is worth the considerable taxpayer dollars it has been appropriated. It is crucial that those who are assigned responsibility for this enterprise, both now and in the future, are unambiguously dedicated to and answerable to the public good. While every stakeholder must have access to the process sufficient to insure that their voice is heard, persons with financial or other direct conflicts of interest should not make decisions regarding the methods employed in this research, topics covered by the research, nor the content of the research. Stakeholder opinion on these critical issues and their rationale should be heard and seriously considered by those who govern this process. But the decision makers must be accountable only to the public interest.

Much has been said about making the governance of the CER enterprise “independent of politics.” But those who espouse this position offer as an option a governance body that is dominated by those who have a financial interest in the decisions it would make. This would only institutionalize the politics of CER directly into the governance of the work. It would create a situation where an objective view of the evidence could readily be shaded and shaped to serve the financial interests of stakeholders rather than maintaining a clear and focused commitment to the public good. One need only to look at some of the FDA’s more recent problems to preview what could happen if industry, including physicians, were placed in a position to negotiate everything from methods to content. The congress and our national elections are where the politics of these issues should be played out. Those who govern this body must insist on the objectivity and transparency that can only be realized if they are accountable to the public rather than shareholders, and to the country, not profit. Our experience has shown that public officials can govern a comparative effectiveness research process and produce evidence that meets the highest standards.

When governance is focused on the public interest, there must be a way for the governing body to obtain the full spectrum of information needed to inform the decisions it will make. All stakeholders must have an equal opportunity to have their concerns and opinions heard and fully considered. However, this process must not be one of back room lobbying and negotiation. It must be formal, public, and create a clear and thorough record of the positions advocated by patients, disease advocacy groups, public officials, labor leaders, industry representatives and business leaders alike. Our experience has demonstrated the positive effect of including relevant stakeholder research and opinion in this format. Our experience further demonstrates that this approach can get this information to independent researchers without undue interference or pressure so that it can be appropriately incorporated into the research. Verbal communication should be in the form of spoken testimony given in public and on the record so that everyone can judge the validity of the argument presented and the motive of the presenters.

Clarity of responsibility and avoidance of redundancy are the final qualities that will determine the level of success that this effort will achieve. The premise of the Coordinating Council is a very good start and I encourage you and the Secretary to be firm in creating the boundaries between and the duties of the various entities involved. Nothing would be worse than having the research produced by this effort muddied by similar studies using various methods coming up with slightly different results on a given subject. This means that great care must be taken to determine the purpose of a given study, which study design is appropriate for a given subject, and which agency should take responsibility for it. Obviously, a large appropriation has spurred interest in CER within quarters that were previously oblivious to it. This will create pressures from effective advocates to spread the

money to parties that may not be best suited to fill the requirements of such research. Great pains must be taken to ensure that there are clear standards for both researchers and methods involved and that those standards are explicitly and carefully enforced.

Thank you for the opportunity to provide these thoughts. If you need further information or clarification please feel free to contact me at your convenience.

Sincerely,

Mark Gibson
Deputy Director