



**Anthony J. Principi**  
Senior Vice President  
Federal Government Relations

June 10, 2009

Federal Coordinating Council for Comparative Effectiveness Research  
200 Independence Ave. SW  
Rm. 415F  
Washington, DC, 20201

Attn: Patrick Conway

Re: Response to the Council's Request for Comments on Definition, Prioritization  
Criteria, and Strategic Framework

**Submitted Electronically**

Dear Secretary Sebelius and Distinguished Council Members:

On behalf of Pfizer, I am submitting the following comments to the Federal Coordinating Council's (Council) proposal for a framework on comparative effectiveness research (CER). Pfizer is a research based drug developer that sponsors numerous trials in the U.S. and around the world, to support marketing approvals and to assess comparative effectiveness, post-approval.

Pfizer supports the Council's continued commitment to transparency and public engagement through its solicitation of public input on the definition, prioritization criteria, and strategic framework for CER.

Our comments are structured to respond to three elements contained within the draft documents released by the Council. They build on comments we are submitting related to the Council's proposals on prioritization of comparative effectiveness research.

**Draft Definition of CER**

*"Comparative effectiveness research is the conduct and synthesis of systematic research comparing different interventions and strategies to prevent, diagnose, treat and monitor health conditions. The purpose of this research is to inform patients, providers, and decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances. To provide this information, comparative effectiveness research must assess a comprehensive array of health-related outcomes for diverse patient populations. Defined interventions compared may include medications, procedures, medical and assistive devices and technologies,*

*behavioral change strategies, and delivery system interventions. This research necessitates the development, expansion, and use of a variety of data sources and methods to assess comparative effectiveness.”*

Pfizer recommends that the definition of CER emphasize that the primary intent of CER is to inform patients and providers about which interventions are most effective for a patient’s individual circumstances. The inclusion of the term “decision-makers” following “patients and providers” detracts from this primary focus and may cause confusion over the primary use of CER. To that end, we recommend deleting the reference to other “decision-makers” from the second sentence of the definition.

#### **Draft Prioritization Criteria for CER**

- The prioritization criteria are divided into two categories:
  - Threshold Minimal Criteria (i.e., investment must meet these to be considered)
    - Included within statutory limits of the Recovery Act and Council’s definition of CER
    - Responsiveness to expressed needs and preferences of patients, clinicians, and other stakeholders, including community engagement in research
    - Feasibility of research topic (including time necessary for research)
  - Prioritization Criteria (i.e., the criteria to be deemed scientifically meritorious)
    - Potential impact (based on prevalence of condition, burden of disease, variability in outcomes, and costs of care)
    - Potential to evaluate comparative effectiveness in diverse populations and patient sub-populations
    - Uncertainty within the clinical and public health communities regarding management decisions
    - Addresses need or gap unlikely to be addressed through other funding mechanisms
    - Potential for multiplicative effect (e.g., lays foundation for future CER or generates additional investment outside government)

Pfizer agrees with the criteria to be used to prioritize investments and agrees with the proposed criteria and offer two comments.

First, we recommend the Council call for development of a detailed priority-setting framework that implements – rather than just informs – the proposed criteria. As it stands now, it is unclear how the proposed criteria are interrelated and how they will be used when the Council identifies CER investments. As the only entity mandated by Congress in the American Recovery and Reinvestment Act to prioritize *and* coordinate Federal efforts in CER, the Council must develop a clearly defined, agreed-upon, and actionable priority-setting *process*.

The priority-setting process must:

1. Integrate the values of the users of the research.
2. Consider the information needs of the user by conducting CER on the full spectrum of healthcare interventions used to manage conditions.

3. Be efficient by seeking broad input at the outset, but also having a relatively simple mechanism to identify important research topics.
4. Be sensitive to its political context; be objective, open, and fair; invite input from a broad spectrum of stakeholders; and present the logic of the process clearly and carefully to others.
5. Maintain a transparent process in which methods are explicitly defined, consistently applied, and publicly available for comment.
6. Allow for multiple points of engagement from a diverse group of stakeholders throughout the priority-setting process.
7. Allow for *meaningful* input from patients and clinicians.

Second, specifically related to the proposed criteria, we recommend the Council make three clarifications: (1) clearly define the term “feasibility” in the third threshold criteria; and (2) include both public and private funding mechanisms in the fourth prioritization criteria and (3) recommending an explicit emphasis on known gaps in evidence.

1. While we recognize that all research needs to be done in an efficient and economical manner, we believe that the merit of research projects should be judged, first and foremost, on their potential benefit to the patient or patient population. As presented, the criterion may be interpreted to suggest that research that is expensive, difficult or time consuming may not be considered or prioritized. To that end, we recommend the Council clarify the definition of “feasibility” so that it is explicit that it is the Council’s intent is to fairly and appropriately consider research projects and to balance the cost, complexity or time-frame for completion against the benefit or likely benefit to the patient population or to improving public health.
2. With respect to the fourth prioritization criterion, we are concerned that it does not explicitly recognize CER investments made by the private sector (e.g., industry, private plans, professional societies, and academic research centers). To ensure that the Council appropriately identifies unmet needs or gaps in research, it is important that any analysis take into account the work of the private *and* public sector. To that end, we recommend the criterion should be re-worded to include “public and private” before the term “funding.”

Third, while we recognize that the prioritization criteria emphasize research that is unlikely to be addressed through other funding mechanisms, we would like the Council to prioritize investments in interventions, populations, and conditions where known gaps exist. This is an important distinction because the program’s ability to have maximum impact is predicated upon investing in those areas where current incentives, opportunities, and capacity are limited. Furthermore, the inclusion of such a criterion is actually consistent with the strategic framework that was proposed by the Council. Specifically, the Council identifies it as one of its cross-cutting priorities, under research populations and under research interventions (e.g. procedures).

#### **Draft CER Strategic Framework**

The Council’s proposal for creating a strategic framework that recognizes investments need to be made in the long-term infrastructure of CER, including developing

methodological standards for CER, enhancing the data infrastructure, training new researchers to conduct CER, and developing tools to translate and disseminate CER is sound. Building this infrastructure is a critical step to ensure the research conducted by AHRQ, NIH, and entities that contract with HHS is methodologically sound and based on a robust evidence base that fills important gaps. We also agree with the emphasis on prioritizing research on underserved populations, conditions, and interventions. And as a result, we believe the strategic framework provides a useful way to think about and target potential investment opportunities.

To refine this framework further and ensure its appropriate application, Pfizer has several recommendations. These three recommendations will help crystallize the intent, focus, and implementation of the strategic framework:

1. *Clarify the Federal CER investments to which this framework applies.* The framework refers to “federal” CER needs as opposed to the CER needs of the nation as a whole. It is unclear whether the Council intends this framework to govern all the CER investments authorized under ARRA or solely those funded through discretionary CER appropriations available to the Secretary of the Department of Health and Human Services. Obviously, the value and impact of the framework would be enhanced if it applied to all CER investments made under ARRA. Further, the Council should clarify how this framework supercedes or complements existing CER frameworks in place at the Agency for Healthcare Research and Quality (AHRQ) and the National Institutes of Health (NIH).
2. *Clarify potential CER investment opportunities.* In presenting Figure 2, the “Overview: Framework for Coordinated Federal Investment in CER,” the narrative highlights process steps under each “major activity area.” Based on the presentation of the framework, it is unclear whether these process steps represent investment opportunities or whether these process steps will be completed by the Council in advance of presenting the investment opportunities.
3. *Include private sector investments in inventories.* As stated earlier, we agree with the Council’s efforts to identify gaps and unmet CER needs. However, to truly capture the current investment in CER within the healthcare system, it is important that these inventories appropriately capture not only the federal (public) investment, but also private sector investment. The process to develop the inventories should meaningfully engage private sector stakeholders (e.g., industry, private plans, professional societies, and others) to enable the Council to collect that information.

Once again, we thank the Council for the opportunity to submit comments. We believe the recommendations contained within this submission are important and will help refine the definition, the criteria, and strategic framework. Doing so will help ensure that the investments made will benefit patients and providers by improving their capacity to have more informed conversations about healthcare options and make more qualified decisions about the course of treatment.

We look forward to continued engagement with the Council and other healthcare stakeholders as efforts to implement the CER program move forward.

Sincerely,

*Anthony J. Principi*

Anthony Principi