



Date: August 30, 2011

**To: Patient-Centered Outcomes Research Institute, U.S. Department of Health and Human Services**

**RE: Request for Public Comment on “Patient-Centered Outcomes Research (Working Definition)”**

CCHF Responses to PCORI Questions

**1. Does the definition place appropriate emphasis on, and convey the importance of, the “patient-centeredness” of the PCORI mission?**

Citizens’ Council for Health Freedom is writing to express our deep concern over the definition of so-called “patient-centered outcomes research” (PCOR). We are also concerned that the Institute (PCORI) has requested input on pilot projects to determine methodology for conducting the research and placed an August 31, 2011 deadline on those comments, which is before the Institute has even received and fully evaluated the public’s comments on the definition of the research.

**CONTROVERSIAL RESEARCH**

Comparative effectiveness research (CER) is not "patient-centered." It is government centered. The move to empower government appointees to conduct comparative effectiveness research proved so controversial in the 2009 American Recovery and Reinvestment Act (“economic stimulus”) that the Obama Administration repealed the Federal Coordinating Council for Comparative Effectiveness Research in the Federal health care reform law (Section 6302) and replaced it with the Patient-Centered Outcomes Research Institute (PCORI). Notably, the Finance Committee called PCOR ‘an alternative term’ to comparative effectiveness research (CER).”

**DECEPTIVE DEFINITION**

In the same vein we are concerned that the words within the PCOR definition will mislead the public.

Although the definition adopted by PCORI says the research “helps people make informed health care decisions and allows their voice to be heard in assessing the value of health care options,” the federal health care reform statute specific to PCORI makes it clear that 19 government appointees will be focused on making decisions that will, in concert with the Secretary of the U.S. Department of Health and Human Services, determine coverage decisions for more than 300 million Americans.

## RESEARCH FOR RATIONING

Although the statute states that the comparative effectiveness research (CER) findings are “not be construed as mandates, guidelines, or recommendations for payment, coverage, or treatment.” and that “Nothing...shall be construed as...authorizing the Secretary to deny coverage of items or services under such title SOLELY on the basis of comparative clinical effectiveness research” (my emphasis), the statute also says,

““SEC. 1182. (a) The Secretary MAY only USE evidence and findings from research conducted under section 1181 to make a determination regarding coverage...IF such use is through an iterative and transparent process which includes public comment and considers the effect on subpopulations.” (my emphasis)

This statutory language along with the word “solely” provides a huge loophole for federal control over medical decisions and enables health care rationing.

## THREE MORE CONCERNS

There are other concerns with the assumption in the “MAY only USE” statement: First, who are the lucky few that get deferential treatment because the Secretary deems them part of a “subpopulation”?

Second, what about the medical and preferential distinctions of each individual within the so-called “subpopulations”? In truth, every patient is a “subpopulation” with unique qualities, physiology, DNA, preferences, cultural and religious views, responses to medications, emotional strength, mental aptitude, compliance issues, etc., but the PCORI statute in the federal health care reform law, and these statements are premised on a cookie cutter view of individuals.

Third, most of the public does not know a Federal Register exists nor do they monitor it every day to discover calls for public comment. Few will keep track of every condition or treatment being considered by PCORI or HHS for coverage determinations. There will be many conditions under consideration. The new ICD-10 coding system will increase the number of disease classification codes from 17,000 today to 155,000 two years from now.

## PEOPLE’S VOICE

Thus we do not believe, despite the proposed words within the definition, that PCOR or PCORI will “*help people make informed health care decisions and allow their voice to be heard in assessing the value of health care options.*”

The voice of the people is best heard, and most timely heard, in their doctor’s office, with a doctor who is free to treat them as the patient and the doctor see fit, not as the government dictates.

Despite what is written in PCORI’s Rationale statement (“this recognizes that different people value things differently and that value is in the eye of the beholder”) we do not

believe 19 political appointees sitting around a table can or should determine “value” for more than 300 million Americans.

**2. Is the definition consistent with the intent of the statute that established PCORI?**

The definition of PCOR is not in line with the intent of the PCORI statute. The intent of the statute is to place 19 political appointees in charge of determining the medical research agenda of the nation. The intent is to funnel billions of taxpayer dollars into organizations that agree to conduct government-approved and government-funded research that meets the agenda of the federal government to standardize the practice of medicine and ration health care services.

The definition does not tell the American public the truth about what PCORI will do and how the research will actually be determined and used. As noted in the Federal health care reform law, the plan is to broadly disseminate and incorporate PCORI’s comparative effectiveness research findings into the practice of medicine, using computerized clinical “decision support” tools:

“(b) INCORPORATION OF RESEARCH FINDINGS.—The Office, in consultation with relevant medical and clinical associations, shall assist users of health information technology focused on clinical decision support to promote the timely incorporation of research findings disseminated under subsection (a) into clinical practices and to promote the ease of use of such incorporation.

**3. Is the definition broad enough to include the range of research that PCORI should fund?**

**PCORI #3**

The federal government should not be establishing a national health care research agenda, by committee or other means, or using taxpayer dollars to do it. PCORI is being funded by a diversion of Medicare dollars, leaving less for patient care, and a head-tax on insurance companies. This head-tax will increase the cost of health insurance policies, leaving individuals with fewer dollars to pay for the care that is denied under PCORI’s pronouncements of “value” and “cost effectiveness.”

It is further notable how research often fails to address the impact on individuals in the general population. For various reasons (age, compliance, co-morbidities, etc.) research studies often exclude many individual that will arrive someday at a doctor’s office with the condition that is being studied. Researchers have no idea if the finding of the research would impact the excluded in the same way it impacts those included in the study. This means that research findings must be taken with a grain of salt.

We are further concerned with the statute’s intent to target people with chronic conditions in an effort to address so-called “gaps in evidence in terms of clinical outcomes, practice variations and health disparities.” It is clear that HHS plans to access comprehensive data

on individuals in this research, potentially using patient data to needlessly target providers and to tie the hands of doctors who practice individualized care.

The federal health care reform statute states the extraordinary intrusion into the patient-doctor relationship under PCORI:

“The Secretary shall, with appropriate safeguards for privacy, make available to the Institute such data collected by the Centers for Medicare & Medicaid Services under the programs under titles XVIII, XIX, and XXI, as well as provide access to the data networks developed under section 937(f) of the Public Health Service Act, as the Institute and its contractors may require to carry out this section. The Institute may also request and obtain data from Federal, State, or private entities, including data from clinical databases and registries.”

**4. Does the definition adequately convey the rationale outlined in the rationale document?**

The definition appears to convey much of the Rationale statement, but it does not convey the REQUIREMENTS of the federal health care reform law. At the end of the day, the law rules.

PCORI leadership and members can say that they intend to give patients a voice, uphold individual differences, and meet the individualized needs of patient, but PCORI is a government committee of 19 government appointees.

The language of the law, not the committee’s Rationale statement, is what has the force of law. Yet nothing in the Rationale or the PCOR definition conveys that fact to the public. Nothing gives them a true picture of how their medical records will be used and how the research findings are likely to be used to negatively impact their access to medical care.

**5. Please use the following space to provide any additional comments you have about the definition.**

PCORI #5

The Patient Centered Outcomes Research Institute’s definition of “patient-centered outcomes research” is deceptive.

The definition does not accurately inform the public about the centralized decision-making agenda of the law, the power of the Institute to determine a national research agenda, the power of the Secretary to use the CER research findings to ELIMINATE the patient’s voice (and the doctor’s voice), and the fact that the federal health care reform statute, not the PCORI definition or rationale, is the final word on how PCORI will be used.

This is one reason the Patient Centered Outcomes Research Institute has been given the pejorative name “death panel.” People are rightly concerned about rationing of health care services by a 9 to 5 government committee of people who do not know the patient’s name and have no professional obligation to meet the need of the patient in the exam room who will be impacted by the research agenda and the government-funded research findings.

We believe the Secretary of HHS will use the supposedly objective backdrop of PCORI’s judgments and the supposedly objective findings of government-funded research to determine for all Americans the “value” of various health care options, especially for people with chronic conditions. These decisions are expected to lead to coverage determinations that eliminate access to services valued by many individuals, but deemed by HHS to be “of insignificant value” or “not cost effective.”

People with their doctors will make a million different “value” decisions every day that government officials would not make, cannot understand, and likely disagree with. That’s the American way and that is each American’s right as a free citizen.

“Value” cannot be determined by government or a government-appointed committee. Bias, groupthink, artificial deadlines, pressures of the federal budget, committee member value systems, and individual preferences of committee members will shape the committee’s research priorities and value decisions.

In the world of AUTOMOBILES, this would be like giving government officials the right to fund and conduct research to determine which vehicles have the most value (General Motors, for instance) and to then use that research to limit American’s right to access cars and trucks deemed “of insignificant value” (Ford perhaps). But in the case of health care, individual lives are at stake due to the power of imposed government value judgments.

Thus, PCORI, despite its stated definition of research and it’s stated understanding of the the unique values of individuals, is an expensive, taxpayer-funded danger to patient-centered care, medical innovation, and individual freedom.

The definition of PCOR should warn the public.