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Inside the Patient-Centered Outcomes Research Institute: No Promise of Protection from Government Rationing

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The much-awaited release of the Patient-Centered Outcomes Research Institute's (PCORI) priorities and research agenda lacks specifics and fails to answer concerns that its research findings will ultimately be used to limit treatment options.

The PCORI was created in the Patient Protection and Affordable Care Act (PPACA) to advance comparative effectiveness research (CER). The PCORI Board of Governors includes 19 members representing key players in health care, appointed by the Government Accountability Office, as well as the directors of the Agency for Healthcare Research and Quality and the National Institutes of Health, who are presidentially appointed. While the PCORI is statutorily prohibited from linking its research findings to coverage recommendations, its creation, in conjunction with the overall expansion of government in the financing and delivery of health care in PPACA, makes CER a tempting tool to use to drive down future health care costs.

The Good and the Bad of CER. According to PCORI Executive Director Joe Selby, "When you put the issue of patients' and clinicians' need for information at the center, that's just not a partisan issue."[1] He is correct that providing better information to make decisions is a laudable goal. Information on comparative effectiveness has the potential to better inform doctors and patients to make more personalized decisions. However, it also has the potential to allow government to control access to certain treatments.

Including input from patients and stakeholders in the direction of the research does not ensure that findings will advance true patient-centered care, which requires that each patient's lifestyle, preferences, and values be taken into account and that patients and their doctors control decision-making. PCORI's only real influence over whether CER is used in ways that harm patient choice and physician autonomy is more or less limited to how it decides to allocate its relatively small financial resources.

PCORI's Unclear National Priorities and Research Agenda. The first draft of this new report highlights the national priorities set by PCORI and its research agenda.[2] Priorities include comparing options for prevention, diagnosis, and treatment for specific health problems; improving health care systems; informing patients and other stakeholders; addressing disparities among patient populations and health outcomes; and designing research to be

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patient-centered. The institute will fund research and work to inform doctors, patients, and other stakeholders of the findings.

The PCORI research portfolio will extend beyond research on the effectiveness of different treatments and into the effectiveness of health systems and information dispersal and use. In fact, only 40 percent of the institute's funding will go toward traditional CER.

Beyond this, though, the draft provides almost no detail on the specifics of PCORI's research portfolio, doing little more than elaborating on its role and objectives as already outlined in PPACA. This presents several problems.

More specificity is needed. The statute seems to indicate that more details were expected in requiring the institute to outline priorities and an agenda, including information on which conditions and diseases would be prioritized in the research.[3] PCORI purposefully excluded this information, avoiding controversy on the subject. This tactic will allow researchers and stakeholders wider latitude in the focus of their proposals.

But PCORI has finite financial resources, and it remains to be seen how, everything else being equal, the institute will determine who receives funding for proposals on different conditions. As the National Pharmaceutical Council's Robert Dubois asks, "If they get 1,000 grants submitted on 400 different topics, who is going to make the decision on, say, whether they should fund a project on low back pain, but not one on multiple sclerosis?"[4] More insight into PCORI's research portfolio will not be available until mid-2012, when it begins to announce funding decisions.

Cost will be a factor. One factor is made clear by the draft: The institute will advance cost-effectiveness information. The only statutory restriction PPACA places on cost-effectiveness research is that PCORI is not to develop a "dollars-per-quality adjusted life year." But the legislation also indicates that, in identifying national priorities, PCORI is to consider "the effect on national expenditures associated with a health treatment, strategy, or health condition."[5] Moreover, one of the criteria put forth by PCORI for application review and funding decisions is, "Will more information in this priority area help…get better health outcomes for the money invested?"[6] Placing greater research focus on cost information will make CER increasingly enticing as a budgetary constraint tool, especially in Medicare or other government programs—potentially harming quality of care and personalized medical decision-making.

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1. Alex Wayne, "U.S. Panel Measuring Adequacy of Cures Lays Out Broad Agenda," Bloomberg, January 23, 2012, at *http://www.bloomberg.com/news/2012-01-23/health-care-delivery-to-be-analyzed-after-u-s-agency-expands-its-subjects.html?zbrandid=4337&zidType=CH&zid=9879947&zsubscriberId=1024035413&zbdom=http://npc.informz.net* (January 26, 2012).
2. Patient-Centered Outcomes Research Institute, "Draft Priorities for Research and Research Agenda Version 1," January 23, 2012, at *http://www.pcori.org/assets/PCORI-Draft-National-Priorities-and-Research-Agenda2.pdf* (January 26, 2012).
3. Patient Protection and Affordable Care Act, Public law 111-148: "The Institute shall identify national priorities for research, taking into account factors of disease incidence, prevalence, and burden in the United States (with emphasis on chronic conditions), gaps in evidence in terms of clinical outcomes, practice variations and health disparities in terms of delivery and outcomes of care, the potential for new evidence to improve patient health, well-being, and the quality of care, the effect on national expenditures associated with a health care treatment, strategy, or health conditions, as well as patient needs, outcomes, and preferences, the relevance to patients and clinicians in making informed health decisions, and priorities in the National Strategy for quality care…."
4. Julie Appleby, "Panel Sidesteps Controversy on Draft for Comparative Effectiveness Research," *Kaiser Health News*, January 23, 2012, at *http://capsules.kaiserhealthnews.org/index.php/2012/01/panel-sidesteps-controversy-on-draft-for-comparative-effectiveness-research/?zbrandid=4337&zidType=CH&zid=9857510&zsubscriberId=1024035413&zbdom=http://npc.informz.net* (January 26, 2012).
5. Patient-Centered Outcomes Research Institute, "Draft Priorities for Research and Research Agenda Version 1."
6. *Ibid.*

Broad scope creates conflicting goals. One of the priorities put forth by PCORI is to communicate and disseminate research so that it can be used to assist in the decision-making done by patients and doctors, but part of the institute's role is also to address practice variations and disparities in outcomes. It will be difficult to develop a research portfolio that allows the patients and doctors directly involved in each case to make decisions while also streamlining care. The risk of forcing health care into one-size-fits-all standards and the subsequent negative impact on patient care is especially acute when combined with the expansion of the Medicare bureaucracy and other changes under PPACA.

Another one of PCORI's national priorities is to improve health care systems. The institute claims, "New system-level strategies are developed and implemented that have not been rigorously evaluated or tested and are not yet ready for full-scale implementation." Nowhere is this truer than in the new health care law itself, which uses several of the examples PCORI provides (performance measurement, quality improvement, use of incentives, and protocols of treatment) to try to improve quality, reduce costs, and ultimately standardize care. Several studies, including a recent report from the Congressional Budget Office, have already shown some of these strategies to be ineffective.[7] It will be important to note whether PCORI research will come to similar conclusions or whether the institute will merely serve as an echo chamber to support PPACA.

Protecting Against Government Rationing Means Ending Obamacare. Advancing comparative effectiveness research can help patients and strengthen the practice of medicine without risking government rationing of care. Achieving this requires focusing on all of PPACA and the infrastructure it creates for increasing bureaucratic control of medicine, not just on PCORI and the research it produces. Full repeal of the health law must be followed by an overhaul of existing modes of central planning and top-down micromanagement in the delivery of health care.[8] Empowering patients and their doctors to make the right decisions is the only way to advance research and reduce spending without limiting patient choice.

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7. Congressional Budget Office, "Lessons from Medicare's Demonstration Projects on Disease Management, Care Coordination, and Value-Based Payment," *Issue Brief*, January 2012, at *http://www.cbo.gov/ftpdocs/126xx/doc12663/01-18-12-MedicareDemoBrief.pdf* (January 26, 2012).

8. See Stuart M. Butler, Alison Acosta Fraser, and William W. Beach, eds., *Saving the American Dream: The Heritage Plan to Fix the Debt, Cut Spending, and Restore Prosperity*, The Heritage Foundation, 2011, at *http://savingthedream.org*.