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**Beyond “Safe and Effective”:
The Role of the Federal Government in Supporting and
Disseminating Comparative-Effectiveness Research**

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Over the past century, medical advancements have resulted in tremendous health gains for Americans. Although the federal government has played a prominent role in ensuring that new treatments are safe and effective, questions about which medical treatments work best under which circumstances have largely remained unanswered. Thus, the federal government's recent major investments in comparative-effectiveness research have potential to play a significant role helping both patients and health care providers navigate the vast array of available treatment options, as well as to improve the quality, efficiency, and delivery health care system-wide. Yet, the controversial nature of the government's foray into comparative-effectiveness research also suggests that the path toward realizing these goals may be treacherous. This paper describes the rationales for federal support of comparative-effectiveness research and potential models for that involvement, analyzes the federal government's recent investments in the research, and concludes with predictions about the probable outcomes of these investments. While increased federal support for comparative-effectiveness research is unlikely to achieve all of the benefits anticipated by its supporters, it is a crucial step toward ensuring that Americans are able to take full advantage of the benefits of medical innovation.

One of the great successes of the United States health care system has been its ability to encourage the development of innovative drugs, devices and treatments that have dramatically improved the health of Americans. Through the Food and Drug Administration (“FDA”), the federal government has played a key role in this process by standardizing and synthesizing information about these innovations, as well as by serving as a gatekeeper to ensure that only safe and effective drugs and devices enter the market. Nevertheless, despite the efforts of the FDA and other federal and state-level government entities to generate and digest information about medical innovations, this is a task that has so far exceeded the capacity of the government. As a result, while a tremendous amount of information exists about both new and existing drugs, therapies, tests and devices (“treatments”), there is very little useful information available comparing the

costs and effectiveness of different options that are used to treat the same condition.

Furthermore, the private and non-profit sectors have so far also failed to meet this need.

Nearly everyone agrees that more information comparing the effectiveness of different medical treatments is important for the future of the United States health care system. Comparative-effectiveness research (“CER”) has the potential to improve health care quality and efficiency while also decreasing costs. As with many issues in health policy, however, the consensus surrounding the importance of CER is limited.

Proponents of government investment in CER have faced intense criticism about costs, implementation, the role of the government in health care, and the potential slippery slope consequences of CER. As a result, while 2009 and 2010 were years of unprecedented federal investment in CER, the government’s future role in supporting and generating comparative-effectiveness information remains uncertain.

This paper addresses the questions of what role the government can and should play in the generation, dissemination, and use of CER. While some of the uncertainty surrounding the federal government’s recent efforts derives from the political challenges facing the ACA as a whole, the remainder is associated with difficulties inherent to CER. Numerous challenges, both technical and political, will make it difficult to realize the potential benefits of the research in full. Yet, even if the government’s recent initiatives are not entirely successful in controlling health care costs or vastly improving health care quality through more appropriate use of medical treatments, they represent an important step in the right direction. Ultimately, the future of the United States health care system depends on its ability to filter medical innovations not only by their safety and efficacy,

but their relative value in comparison to alternatives. Government sponsored CER has potential to serve an important role in accomplishing this goal.

Part I of this paper defines CER and describes the problems that CER seeks to address, as well as the arguments for and against this type of research. Part II then briefly summarizes some potential models for governmental involvement in CER, and provides examples of how the governments of other countries have supported CER. Part III details the history of governmental participation in CER, including recent investments made by the federal government in the American Recovery and Reinvestment Act of 2009 (“ARRA”)¹ and the Patient Protection and Affordable Care Act of 2010 (“ACA”).² Lastly, part IV identifies some opportunities and challenges associated with these recent investments and provides policy recommendations for, and predictions about, the future of government involvement in CER. Although some of the loftier expectations foisted upon the research by its supporters are unlikely to be realized, the federal government’s recent investments in CER have important potential to both generate valuable information for providers and consumers³ of health care, and improve the norms and metrics against which medical innovations are assessed.

¹ Pub. L. No. 111-5, 123 Stat. 115 (2009).

² Pub. L. No. 111-148, 124 Stat. 119 (2010), as amended by the Health Care and Education Reconciliation Act of 2010, P.L. No. 111-152, 124 Stat. 1029 (2010) (hereinafter “Reconciliation Act”). Hereinafter, references to the ACA describe the Act as amended by the Reconciliation Act.

³ Use of the phrase “health care consumers” has recently faced some criticism. *See* Paul Krugman, *Patients Are Not Consumers*, N.Y. TIMES, April 22, 2011, at A3. My intent is to use the term in a neutral sense, that is, to describe the broad category of individuals and groups who consume health care services (which is not necessarily identical to the set of health care “patients”), but without the implication that they subscribe to any specific behaviors common to consumers of other goods. It is also not my intention to downplay the unique characteristics of the market for health care services or the special nature of the physician-patient relationship.

I. What is CER?

A. Defining CER

In order to define and understand CER, it is first necessary to identify the problems that CER has the potential to ameliorate. Commentators both inside and outside of medicine have grown increasingly frustrated with the reality that less than half of standard medical treatments are supported by scientific evidence of effectiveness.⁴ One 2009 study, for example, found that only 11% of current guidelines issued by the American College of Cardiology and the American Heart Association were supported by the highest level of evidence (including “multiple randomized trials or meta-analyses”).⁵ In addition, many patients in the United States fail to receive care that is recommended on the basis of scientific evidence.⁶ CER is part of a broader movement to remedy this problem by facilitating and encouraging the use of evidence-based medicine (“EBM”).

While there are a number of different ways to define CER,⁷ the ACA defines “comparative clinical effectiveness research” as “research evaluating and comparing

⁴ JOHN DONNOLLY, HEALTH POLICY BRIEF: COMPARATIVE EFFECTIVENESS RESEARCH, 1 (2010), available at <http://www.rwjf.org/files/research/70208.pdf>. Furthermore, it is clear that a wide variety of factors unrelated a treatment’s appropriateness influence the decisionmaking process of health care providers. See, e.g., Danil V. Makarov et al., *The Association Between Diffusion of the Surgical Robot and Radical Prostatectomy Rates*, 49 MED. CARE 333 (2011) (finding hospitals that purchased surgical robots that were very expensive but only of “marginal benefit” in treating prostate cancer conducted many more radical prostatectomies than other hospitals, suggesting the existence of “supply induced demand”).

⁵ Pierluigi Tricoci et al., *Scientific Evidence Underlying the ACC/AHA Clinical Practice Guidelines*, 301 JAMA 831 (2009).

⁶ Elizabeth A. McGlynn et al., *The Quality of Health Care Delivered to Adults in the United States*, 348 NEW ENG. J. MED. 2635 (2003) (reporting that only 54.9% of a random sample of adults surveyed in 12 metropolitan areas received recommended care.).

⁷ For a chart describing how different organizations have defined CER, see COMMITTEE ON COMPARATIVE EFFECTIVENESS RESEARCH PRIORITIZATION, INSTITUTE OF MEDICINE, INITIAL NATIONAL PRIORITIES FOR COMPARATIVE EFFECTIVENESS RESEARCH, 44 (2009)

health outcomes and the clinical effectiveness, risks, and benefits of [two] or more medical treatments, services, and items.”⁸ The statute then goes on to define the relevant “medical treatments, services, and items” as “health care interventions, protocols for treatment, care management, and delivery, procedures, medical devices, diagnostic tools, pharmaceuticals (including drugs and biologicals), integrative health practices, and any other strategies or items being used in the treatment, management, and diagnosis of, or prevention of illness or injury in, individuals.”⁹ I use the ACA definition, rather than, for example, the definitions created by the IOM¹⁰ and the Federal Coordinating Council for Comparative Effectiveness Research¹¹ for the purpose of reports ordered by Congress in ARRA,¹² for the sake of consistency and clarity, as well as because it is the definition that

(hereinafter “IOM NATIONAL PRIORITIES FOR CER”) (including definitions from the Congressional Budget Office, the American College of Physicians, the Medicare Payment Advisory Board, and the Agency for Healthcare Research and Quality, among others); *see also* AHRQ Effective Health Care Program, “What is Comparative Effectiveness Research,” <http://www.effectivehealthcare.ahrq.gov/index.cfm/what-is-comparative-effectiveness-research1/> (last visited March 30, 2011).

⁸ ACA § 6301, to be codified at 42 U.S.C. § (a)(2).

⁹ *Id.*

¹⁰ IOM defines CER as “the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care. The purpose of CER is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels.” IOM NATIONAL PRIORITIES FOR CER, *supra* note 7, at 41.

¹¹ The Council defined CER as “the conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in ‘real world’ settings. The purpose of this research is to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances.” FEDERAL COORDINATING COUNCIL FOR COMPARATIVE EFFECTIVENESS RESEARCH, *infra* note 228, at 16.

¹² *Id.* at xv; Pub. L. No. 111-5, 123 Stat. 115, Title XIII (2009) (“the Secretary [of Health and Human Services] shall enter into a contract with the Institute of Medicine . . . to produce and submit a report to the Congress and the Secretary by not later than June 30,

will govern the Patient-Centered Outcomes Research Institute (“PCORI”), the federal agency that will coordinate the federal government’s substantial new investments in CER.¹³

Generally speaking, CER is different from other forms of health research in three ways: it compares at least two treatments, it analyzes “real-world outcomes” rather than experimental outcomes or general efficacy,¹⁴ and the resulting information is useful for a number of decisionmakers, such as health care providers, consumers, and policymakers (as opposed to, for example, just safety regulators).¹⁵ Although CER is useful in a number of contexts outside of medical treatment, such as public health¹⁶ and health

2009, that includes recommendations on the national priorities for comparative effectiveness research to be conducted or supported with the funds provided in this paragraph and that considers input from stakeholders”).

¹³ See *infra* section III(b)(2).

¹⁴ Efficacy differs from effectiveness in that efficacy refers to “the effective of the treatment under optimal conditions” while effectiveness addresses the treatment’s effects “in routine clinical practice.” GRETCHEN A. JACOBSON, CONGRESSIONAL RESEARCH SERVICE, COMPARATIVE CLINICAL EFFECTIVENESS AND COST-EFFECTIVENESS RESEARCH: BACKGROUND, HISTORY AND OVERVIEW 4-5 (2007).

¹⁵ Louis P. Garrison Jr. et al., *A Flexible Approach To Evidentiary Standards for Comparative Effectiveness Research*, 29 HEALTH AFF. 1812, 1813 (2010).

¹⁶ See generally, e.g., Steven M. Teutsch and Jonathan E. Fielding, *Applying Comparative Effectiveness Research To Public and Population Health Initiatives*, 30 HEALTH AFF. 349 (2011) (advocating for the application of CER to population-level social and environmental determinants of health and discussing the similarities and differences between this type of CER and CER on individual-level medical treatments); Kevin G. Volpp and Anup Das, *Comparative Effectiveness – Thinking beyond Medication A versus Medication B*, 361 NEW ENG. J. MED. 331 (2009) (calling for CER that measures the effectiveness of medical treatments against behavioral and health system interventions); see also Alexander and Stafford, *supra* note 22, at 2489 (calling for comparisons of strategies involving patient behavior or non-physician initiated treatments, such as alternative therapies); McClellan and Benner, *infra* note **Error! Bookmark not defined.**, at 11 (calling for CER on different policies that influence provider adoption of different treatments).

system design,¹⁷ I focus on the use of CER to study medical treatments in order to limit this paper to a manageable scope. Many of the challenges, opportunities, and ideas discussed in this paper, however, are applicable in other contexts as well.

b. Arguments in Against and in Favor of CER

Although the idea of increasing the amount of comparative information available for health care providers and consumers is intuitively appealing, and the broader EBM movement has gained popularity in recent years, proponents of CER have thus far faced an uphill battle.¹⁸ First, comparative effectiveness information is not always available,¹⁹ and even if evidence is available, it may be inadequate to provide a complete picture about how a treatment works in the real world.²⁰ This “residual uncertainty” raises

¹⁷ See Atul Gawande, *The Cost Conundrum*, THE NEW YORKER, June 1, 2009, at 36, 44 (“Congress has provided vital funding for research that compares the effectiveness of different treatments, and this should help reduce uncertainty about which treatments are best. But we also need to fund research that compares the effectiveness of different systems of care—to reduce our uncertainty about which systems work best for communities.”).

¹⁸ Dan Mendelson and Tanisha V. Carino, *Evidence-Based Medicine In The United States – De Rigueur Or Dream Deferred?*, 24 HEALTH AFF. 133, 133 (2005) (“All clinicians and managed care plans believe that their decisions are based on evidence . . . However . . . there is little evidence of EBM’s success in influencing behavior and as a well-accepted foundation for how patient care should be organized, delivered, and financed.”).

¹⁹ For example, because the FDA does not regulate medical or surgical treatments, less information about safety and efficacy is available for those treatments in comparison to drugs and devices. See Lynn M. Etheredge, *A Rapid-Learning Health System*, 26 HEALTH AFF. w107, w112 (2007).

²⁰ *Id.* at w111 (noting that, particularly for drugs, it can difficult to determine the efficacy of a treatment based on clinical trials alone, and sometimes important safety or efficacy information is only available once a drug has been used by a number of patients over a long period of time); Norbert Gleicher, *‘Expert Panels’ Won’t Improve Health Care*, WALL ST. J., Oct. 18, 2009, at A21; Jerome Groopman and Pamela Hartzband, *Why ‘Quality’ Care Is Dangerous*, WALL ST. J., April 8, 2009, at A13 (noting that sometimes scientific evidence about a treatment turns out to be wrong). At the same time, there are costs to waiting for better information to adopt a new treatment. See generally Kalipso Chalkidou et al. *Evidence-Based Decision Making: When Should We Wait For More Information?*, 27 HEALTH AFF. 1642, 1642-1644 (2008).

difficult questions about when scientific evidence is strong enough to alter the behavior of health care providers.²¹

Second, it can take a long time for new information about treatments to diffuse among vast networks of health care providers, if such diffusion ever occurs.²² The Institute of Medicine (“IOM”) estimates that it takes, on average, 17 years for physicians to broadly adopt a treatment found to be more effective than alternatives.²³ This issue is related to a number of separate problems. A non-exhaustive list includes that the designers of clinical trials often fail to plan for dissemination of the studies’ results,²⁴ information distributed in continuing medical education programs may be strongly influenced by industry biases,²⁵ and industry marketing typically favors the use of expensive products regardless of comparative effectiveness evidence.²⁶ Lastly, some health care providers may resist adopting new practices for practical²⁷ or cultural²⁸

²¹ See generally Karl Claxton et al., *When Is Evidence Sufficient?*, 24 HEALTH AFF. 93 (2005).

²² See generally Jerry Avord and Michael Fischer, ‘Bench To Behavior’: *Translating Comparative Effectiveness Research Into Improved Clinical Practice*, 29 HEALTH AFF. 1891 (2010) (“Vaccination against polio, the concept that mid-to-moderate hypertension requires treatment, the use of statins to prevent cardiovascular events, the administration of antibiotics near the time of surgery – all are interventions for which having clear evidence in the medical literature was not adequate in itself to consistently transform practice on a large scale.”); see also G. Caleb Alexander and Randall S. Stafford, *Does Comparative Effectiveness Have a Comparative Edge*, 301 JAMA 2488, 2488-89 (2009).

²³ ANN C. GREINER AND ELISA KNEBEL, INSTITUTE OF MEDICINE, HEALTH PROFESSIONS EDUCATION: A BRIDGE TO QUALITY, 33 (2003).

²⁴ *Id.* at 1892.

²⁵ *Id.* at 1893.

²⁶ *Id.* at 1893-1894.

²⁷ *Id.* at 1894-1985 (noting that physicians may be particularly likely resist adoption of revenue-decreasing new practices, but may also resist adoption due to conceptual objections to EBM).

²⁸ See Posting of Barron H. Lerner to Room for Debate Blog (N.Y. Times), *Are Doctors Too Quick to Cut?: Where Culture Comes In*,

reasons, a problem exacerbated by the reality that most health care providers are not subject to quality controls requiring them to make use of current research.²⁹

A third and related point is that popular culture does not always praise health care providers who invest the time, resources and energy to adopt EBM. An undoubtedly exaggerated example of this dynamic can be seen in the popular television show “House,” about an egocentric but brilliant physician who seems to base diagnostic and treatment decision on intuition, mostly to the exclusion of considerations based on scientific evidence, treatment guidelines, and cost.³⁰ While the vast majority of people probably would prefer that their real health care providers not exhibit the same behaviors as the fictional doctors they watch on television, the ideal of the renegade doctor acting on the basis of individual judgment and experience rather than evidence-based guidelines is not limited to entertainment. Strong political opposition to EBM and CER often references the importance of resisting “cookbook medicine.”³¹ Because, in its strongest form, EBM narrows the range of permissible choices available to health care providers, it

<http://www.nytimes.com/roomfordebate/2011/02/09/are-doctors-too-quick-to-cut/where-culture-comes-in> (Feb. 9, 2011).

²⁹ GREINER, *supra* note 23, at 1895.

³⁰ See Posting of Vickie Williams to Concurring Opinions Blog, *Why House is the True American Health Care Hero and What To Do About It*,

<http://www.concurringopinions.com/archives/2010/10/why-house-is-the-true-american-health-care-hero-and-what-to-do-about-it.html> (Oct. 12, 2010, 20:39 EST); Steven

Pearlstein, *Self-Help for the Health-Care System*, WASH. POST, June 17, 2009 at A12; “Add It Up: Pricing Out A Visit To TV’s ‘Dr. House,’” NPR,

<http://www.npr.org/templates/story/story.php?storyId=127593663> (June 9, 2010).

³¹ Stefan Timmermans and Aaron Mauck, *The Promises And Pitfalls of Evidence-Based Medicine*, 24 HEALTH AFF. 18, 21 (2005) (Critics of EBM tend “to see medicine in traditional terms: It is a ‘craft’ or ‘art,’ in which individual expertise and technique are allowed to shine through and ultimately result in a higher standard of patient care. . . . Instead of revolutionizing care, EBM therefore threatens to bring about stagnation and bland uniformity, derogatorily characterized as ‘cookbook medicine.’”).

threatens the autonomy and discretion otherwise inherent to the work of professionals.³²

Opponents of CER have also cited concerns that EBM has potential to limit consumer autonomy by undervaluing patient preferences.³³

Another important argument against CER involves potential conflicts with the movement toward personalized medicine. Personalized medicine seeks to identify how genetics influence the different levels of effectiveness experienced by subpopulations for a single treatment.³⁴ Opponents believe that CER will result in one-size-fits-all medicine that inhibits the growth of a more granulated approach to patient care. A related concern is that once researchers have generated CER, the research will be applied equally to treatments and patients for which it is appropriate and inappropriate.³⁵

EBM and CER have also faced opposition due to concerns about their implications for health care “rationing.” Although health care is a scarce resource and some form of rationing is inevitable,³⁶ critics of CER have expressed concern that the research will be used to deny insurance coverage for treatments on the basis of cost-

³² *Id.* at 23.

³³ DOCTEUR AND BERENSON, *infra* n. 57 at 9.

³⁴ Robert Epstein and J. Russell Teagarden, *Comparative Effectiveness And Personalized Medicine: Evolving Together Or Apart?*, 29 HEALTH AFF. 1783, 1784 (2010); Alan M. Garber and Sean R. Tunis, *Does Comparative-Effectiveness Research Threaten Personalized Medicine?*, 360 NEW ENG. J. MED. 1925, 1925 (2010).

³⁵ Jerome Groopman, *Health Care: Who Knows ‘Best’?*, N.Y. REV. OF BOOKS, Feb. 11, 2010 (noting that some treatments can be standardized, and other treatments must be tailored to the circumstances of individual patients).

³⁶ See David O. Meltzer and Allan S. Detsky, *The Real Meaning of Rationing*, 304 JAMA 2292, 2293 (2010) (distinguishing health care rationing from other forms of government rationing because individuals are free to purchase any legal health care services; “rationing” in health care generally refers to whether insurance will pay for a particular service); Doyle McManus, *Healthcare has Rationing in Abundance*, L.A. TIMES, Oct. 11, 2009, at A38.

benefit analysis.³⁷ In particular, critics have compared CER efforts in the United States to the British National Institute for Health and Clinical Excellence (“NICE”),³⁸ an agency that both compiles scientific and cost-effectiveness evidence about medical treatments and makes coverage recommendations to the country’s National Health Services (“NHS”).³⁹ This political argument against CER is likely augmented by the reality that EBM is not a well-understood concept among the public, and the general population may have some unrealistic beliefs about physician adoption of scientific research and other issues related to health care quality.⁴⁰

Even if the rationing consequences of CER are less severe than the explicit rationing that occurs in the NHS, observers have noted that the mistakes and biases to

³⁷ See, e.g., Martin Feldstein, *ObamaCare Is All About Rationing*, WALL ST. J., August 18, 2009, at A15 (“Comparative effectiveness could become the vehicle for deciding whether each method of treatment provides enough of an improvement in health care to justify its cost.”); see also Fox, *infra* note 350, at 31 (noting that “[g]iven current problems with hidden rationing in Medicare, CER results are at risk of being distorted [and] relied upon as scientific support for what are, in truth, political and societal decisions about healthcare rationing.”).

³⁸ *Of NICE and Men*, WALL ST. J., July 7, 2009, at A14; Sen. Tom Coburn, *The Health Bill Is Scary*, WALL ST. J., Dec. 16, 2009, at A27 (“CER panels have been used as rationing commissions in other countries such as the U.K., where 15,000 cancer patients die prematurely every year . . . CER panels here could effectively dictate coverage options and ration care”).

³⁹ See generally “About NICE,” <http://www.nice.org.uk/aboutnice/> (last visited March 30, 2011); Nicholas Timmins, *The NICE Way Of Influencing Health Spending: A Conversation With Sir Michael Rawlins*, 28 HEALTH AFF. 1360 (2009) (noting that the overall effect of NICE has been to NHS spending because it usually approves the drugs and treatments that it reviews); Barry Meier, *New Effort Reopens a Medical Minefield*, N.Y. TIMES, May 6, 2009, at B1; see also *infra* notes 131-138, and accompanying text.

⁴⁰ Kristin L. Carman et al., *Evidence That Consumers Are Skeptical About Evidence-Based Health Care*, 29 HEALTH AFF. 1400 (2010) (finding that health care consumers tend to believe that newer and costlier care is of higher quality, more care is better care, also noting that “[t]o the extent that consumers perceive that the application of comparative effectiveness research to decision making could limit their choice of providers, inappropriately interfere with physicians’ recommendations for treatment, or appear to ‘ration’ care based on cost, these efforts will encounter consumer resistance and could lead to a broad consumer backlash.”).

which all research, including CER, is prone can have particularly harmful consequences when providers are incentivized or coerced into implementing the findings of relatively new research.⁴¹ This is not a trivial concern. Scientific evidence, in medicine or otherwise, is far from absolute, and the history of medicine is replete with examples where new evidence has reversed recommendations about formerly well-accepted treatments.⁴² To the extent that aggressive CER promotion results in more rapid adoption of new or different treatments, it has potential to increase the harm that occurs when later research discovers unanticipated side effects or effectiveness problems.

A related concern is that EBM inherently favors existing treatments, which have had time to be studied, over new treatments, fostering a sort of status quo bias against medical innovation in the scope of regular patient care.⁴³ The counter to this argument is that even outside of formal research, medical innovation and the testing of new

⁴¹ Groopman, *supra* n. 35 (noting that researchers are susceptible to (1) falling “in love” with their own research, (2) “confirmation bias,” and (3) “focusing illusion,” i.e. predicting exaggerated and unrealistic results).

⁴² See Groopman and Pamela, *supra* note 20; Groopman, *supra* note 35 (“For example, Medicare specified that it was a ‘best practice’ to tightly control blood sugar levels in critically ill patients in intensive care. That measure of quality was not only shown to be wrong but resulted in a higher likelihood of death when compared to measures allowing a more flexible treatment and higher blood sugar.”); see also Gail Collins, *Medicine on the Move*, N.Y. TIMES, April 7, 2011, at A27 (“We got word this week that estrogen therapy, which was bad, is good again. Possibly. In some cases. This was not quite as confusing as the news last year that calcium supplements, which used to be very good, are now possibly bad. Although maybe not. And the jury’s still out. . . . We certainly want everyone to keep doing studies. But it’s very difficult to be a civilian in the world of science.”).

⁴³ See Patrick L. Taylor, *Overseeing Innovative Therapy without Mistaking It for Research: A Function-Based Model Based on Old Truths, New Capacities, and Lessons from Stem Cells*, 38 J. L. MED. & ETHICS 286, 301 (2010) (“Together with evidence-based approaches and payer insistence on limiting treatment to accepted practice, the current environment encourages a defensive crouch: it is safer to avoid innovative therapy and take refuge in the sanctuary of ‘tried and true,’ where data in sufficient quantity can be shown to payers. Taken too far, that will be the death knell of innovative therapy.”).

treatments should be systematic and purposeful, rather than a post-hoc justification for the default position when scientific evidence about an existing treatment does not exist, or existing research is not widely disseminated. Regardless, if EMB and CER result in a medical culture fearful of innovative treatments applied in a non-research setting, they could hinder the development of new therapies.

Because of the possibility that CER will result in insurers refusing to cover treatments deemed to be comparatively ineffective, some members of medical treatment industries have also opposed CER.⁴⁴ Beyond the argument that CER is problematic simply because it has potential to decrease revenue for these industries, critics have claimed that CER will limit health care innovation because it makes investment in innovation more risky.⁴⁵ Furthermore, to the extent that CER favors treatments that have

⁴⁴ See Jerry Avorn, *Debate about Funding Comparative-Effectiveness Research*, 360 NEW ENG. J. MED. 1927, 1928 (2009); Post of Uwe E. Reinhardt to N.Y. Times Economix Blog, 'Cost-Effectiveness Analysis' and U.S. Health Care, <http://economix.blogs.nytimes.com/2009/03/13/cost-effectiveness-analysis-and-us-health-care/> (March 13, 2009, 06:45 EST); Post of Sarah Rubenstein to Wall Street Journal Health Blog, *Drug Makers Talk Up Comparative Effectiveness, Sort Of*, <http://blogs.wsj.com/health/2009/04/14/drug-makers-talk-up-comparative-effectiveness-sort-of/?KEYWORDS=comparative+effectiveness+research> (April 14, 2009, 08:51 EST) (noting that industry support for CER is limited to the extent that the research is not used to deny insurance coverage for specific treatments).

⁴⁵ DOCTEUR AND BERENSON, *infra* note 56, at 9; Diane Suchetka, *Cleveland Clinic CEO Toby Cosgrove Talks About Health-Care Reform And More At City Club*, Cleveland Plain Dealer, Aug. 19, 2010 (“My concern is that we only pay for [treatments proven effective by CER], we begin to limit what people are willing to do in terms of developing new products’ [said Cleveland Clinic CEO Toby Cosgrove] . . . ‘Right now, a new heart valve takes 10 years to go from concept to clinical. And it takes 10 years more to know if it’s better than the next heart valve. Now, if I was an investor or if I was a manufacturer, would I be interested in essentially putting my dollars down not knowing whether I’m going to get a return on those dollars for 20 years? I think that’s a stretch.’”), available at http://www.cleveland.com/healthfit/index.ssf/2010/08/cleveland_clinic_ceo_toby_cosg.ht ml. Of course, the problem with this argument is its lack of obvious boundaries. In theory, for example, looser FDA efficacy or safety standards would also increase investment in innovation, by decreasing the risk that an expensive innovation would be

already been the subject scientific evaluation, CER could also favor newer, more high-technology treatments over low-technology treatments, such as generic drugs, old treatments or improvements in health care delivery that researchers have not rigorously studied.⁴⁶

Proponents of CER, in contrast, have pointed to a number of important benefits that could spring from more CER. In addition to the benefits inherent to having more scientific information available to health care providers and consumers, such as improved and more transparent competition in the health care industry⁴⁷ and fewer geographic disparities in the use of health care treatments,⁴⁸ proponents have noted that CER has potential to decrease health care costs while improving quality, for example, by reducing waste in the health care system.⁴⁹

excluded from the market. It is far from obvious that we should discourage health care providers and patients from using the most effective treatments simply in order to increase the incentives for medical innovations because, as with safety and non-comparative effectiveness, there are countervailing policy considerations. Furthermore, in countries whose governments support CER, there is no empirical evidence suggesting that those efforts have hindered innovation. Chalkidou, *infra* note 127, at 362-363.

⁴⁶ ELIZABETH DOCTEUR AND ROBERT BERENSON, *infra* n. 56 at 9.

⁴⁷ See Wilensky, *infra* note 83, at w572 - w573.

⁴⁸ See generally Dartmouth Atlas of Health Care, www.dartmouthatlast.org (last visited March 29, 2011); see also 2007 CBO REPORT, *infra* note 84, at 12-15 (describing the results and implications of the Dartmouth Atlas project).

⁴⁹ See generally Ari Hoffman and Steven D. Pearson, 'Marginal Medicine': Targeting Comparative Effectiveness Research To Reduce Waste, 28 HEALTH AFF. w710 (2009) (describing four categories of "waste," or "marginal medicine," for which CER might be helpful: "inadequate evidence of comparative net benefit for any indication," "use beyond the boundaries of established not benefit," "higher cost when established benefit is comparable to other options," and "relatively high cost for incremental benefit compared to other options"); see e.g. Adam G. Elshaug and Alan M Garber, *How CER Could Pay for Itself – Insights from Vertebral Fracture Treatments*, 364 NEW ENG. J. MED. 1390 (2011); but see Rand Health Compare, Analysis of Comparative Effectiveness, <http://www.randcompare.org/analysis-of-options/analysis-of-comparative-effectiveness> (last visited March 30, 2011) (noting that "under some circumstances, using

In recent decades, health care costs in the United States have far outpaced overall inflation.⁵⁰ Although all developed countries have struggled with cost control issues to some extent,⁵¹ American per capita health care costs remain the highest in the world.⁵² As a consequence of the high cost of health care in the United States, many Americans lack health insurance.⁵³ Moreover, the United States' aggregate health statistics are mediocre relative to those of other developed countries,⁵⁴ suggesting that Americans do not get good value for their health care dollars.⁵⁵ Thus, it is clear that there is room for both cost cutting and quality improvement in the United States health care system, and to the extent that CER is capable of contributing to these goals without causing problems

comparative effectiveness research might reduce overall spending, but there is no clear evidence on the direction or magnitude of the relationship”).

⁵⁰ See generally *The Economic Case for Health Reform: Hearing Before the H.R. Comm. on the Budget*, 111th Cong. (2009); BOB LYKE, CONGRESSIONAL RESEARCH SERVICE, *HEALTH CARE REFORM: AN INTRODUCTION*, 4 (2009).

⁵¹ See Gerard F. Anderson et al., *Health Spending In The United States And The Rest Of The Industrialized World*, 24 *HEALTH AFF.* 903, 906 (2005) (noting that “[i]n every [OECD] country, growth in health spending outpaced inflation during the period 1992-2002,” but even though this was a period of relatively stable health care spending in the United States, “health spending as a percentage of [gross domestic product] increased by 1.6 percentage points . . . twice the OECD median”). OECD stands for the Organization for Economic Cooperation and Development, which is a group composed of high-income countries. See “Members and Partners,” http://www.oecd.org/document/25/0,3746,en_36734052_36761800_36999961_1_1_1_1_00.html (last visited March 30, 2011).

⁵² CHRIS L. PETERSON AND RACHEL BURTON, *REPORT FOR CONGRESS: U.S. HEALTH CARE SPENDING: COMPARISON WITH OTHER OECD COUNTRIES* (2007).

⁵³ KAISER FAMILY FOUNDATION, *THE UNINSURED AND THE DIFFERENCE HEALTH INSURANCE MAKES* (2010), <http://www.kff.org/uninsured/upload/1420-12.pdf>.

⁵⁴ See Peter A. Muennig and Sherry A. Glied, *What Changes in Survival Rates Tell Us About U.S. Health Care*, 29 *HEALTH AFF.* 2105 (2010).

⁵⁵ See Michael B. Rothberg et al., *Little Evidence of Correlation Between Growth In Health Care Spending And Reduced Mortality*, 29 *HEALTH AFF.* 1523 (2010) (finding “inconsistent value” associated with health care spending, with areas of good value “as well as areas of apparent waste, where money might be better spent on research to find more-effective therapies.”).

that outweigh its benefits, it could be an important (and relatively pain free)⁵⁶ component of any plan to reform the health care system.

Underlying claims about the potential cost benefits of CER, however, is the assumption that less expensive treatments will be found to be at least as effective as more expensive treatments.⁵⁷ Although there is nothing inherent to CER that requires this to be accurate, past experience suggests that it may be a reasonable assumption.⁵⁸ Even if CER does justify the use of less expensive treatments, however, cost savings will only result if consumers and providers actually alter their behaviors in favor of the lower cost and more effective treatments, an outcome that is not supported by past experience.⁵⁹

Some proponents of CER have also argued that better information about the comparative effectiveness of different treatments will help, rather than hinder, efforts to deliver increasingly personalized medicine to patients. Withholding information from health care providers about the effectiveness of possible treatments certainly does not make it easier to tailor a treatment to a given patient's individual circumstances.⁶⁰ In addition to identifying which treatments are more effective on average, researchers can use CER to identify genetic or environmental subpopulations for which personalized

⁵⁶ Although CER is controversial, the fact that significant investments in CER managed to pass Congress twice in two years suggests that this controversy pales into comparison to any serious effort to enact more stringent methods of cost control.

⁵⁷ ELIZABETH DOCTEUR AND ROBERT BERENSON, HOW WILL COMPARATIVE EFFECTIVENESS RESEARCH AFFECT THE QUALITY OF HEALTH CARE?, 8 (2010), *available at* <http://www.rwjf.org/files/research/20100218qscomparativeeffectiveness.pdf>.

⁵⁸ *Id.* (citing studies that found newer hypertension and anti-psychotic drugs to be no more effective than older, less expensive drugs).

⁵⁹ *Id.*

⁶⁰ Garber, *supra* n. 34, at 1926 (“[W]ith too few appropriately designed studies, physicians, patients, and families often had little guidance about which patients were most likely to benefit from a clinical strategy. Perhaps the most important goal of CER is to broaden and deepen such information, providing tools for matching medical care much more precisely to individual patients.”).

medicine is suitable or new applications for personalized medicine.⁶¹ Beyond personalizing treatments for individual patients, CER also has potential to help providers recommend the best treatment for each unique instance or variation of a given disease.⁶² Most importantly, however, CER might be necessary to prove the relative effectiveness of personalized medicine itself in order to encourage broader adoption among skeptical health care providers.⁶³

Lastly, even if CER is a blunt and imperfect tool, much criticism of CER seem to imply that health care resources are not scarce, and the choice not to adopt CER-based guidelines or insurance coverage rules is free. This is clearly not the case. Despite the United States' remarkably high level of health care spending, roughly fifty million people in the United States remain uninsured.⁶⁴ Holding this figure constant, and assuming the

⁶¹ Epstein and Teagarden, *supra* n. 34, at 1784; C. Daniel Mullins et al., *The Potential Impact Of Comparative Effectiveness Research On The Health Of Minority Population*, 29 HEALTH AFF. 2098, 2100 (2010) (“Ideally, comparative effectiveness research should lead to the opposite of ‘one size fits all’ treatment by producing evidence and insights that are applicable to subgroups of patients.”); see Meier, *supra* note 39 (“Ironically, the motivation for comparative effectiveness is to see what works in practice,’ [said Dr. Mark Helfand, director of the Oregon Evidence-based Practice Center,] ‘rather than overgeneralizing from a few unrepresentative studies.’”).

⁶² Posting of Pauline Chen to Room for Debate Blog (N.Y. Times), *Are Doctors Too Quick to Cut?: Variations and Exceptions*, <http://www.nytimes.com/roomfordebate/2011/02/09/are-doctors-too-quick-to-cut/variations-and-exceptions-in-approaches-to-disease> (Feb. 9, 2011, 19:49 EST). This argument changed the mind of at least one group of stakeholders, cancer groups, during the debate about CER in the ACA. See Iglehart, *infra* note 222, at 1759.

⁶³ *Id.* at 1785 (“There is . . . a paucity of comparative effectiveness data showing the value of personalized medicine. We know from the published literature that genetics can contribute to our understanding of drug response for many commonly used medications . . . Yet routine use of these genetic tests is not supported by many physician specialty organizations, nor is it covered by government or other insurers, because data are lacking.”); MARK McCLELLAN AND JOSHUA BENNER, *COMPARATIVE EFFECTIVENESS RESEARCH: WILL IT BEND THE HEALTH CARE COST CURVE AND IMPROVE QUALITY?*, 8 (2009), available at http://www.brookings.edu/events/2009/0609_health_care_cer.aspx.

⁶⁴ KAISER FAMILY FOUNDATION, *supra* n. 53.

federal government ultimately implements the ACA without significant changes and the projection that the law will reduce the number of uninsured Americans by 32 million is accurate, there will remain at least 23 million uninsured residents in the United States.⁶⁵ While these people are likely to have access to some health care, health insurance status has a significant impact on access to health care; the uninsured often lack regular access to health care services, and they are more likely to delay or forgo necessary health care than the insured.⁶⁶ Thus, to the extent that the imperfection of CER inhibits its use and results in value-less health expenditures, fewer health care resources may be available to assist underserved populations like the uninsured.

Even if the money saved by people with private insurance through use of CER is not diverted toward underserved populations, there is another subpopulation for which such a tradeoff is inevitable. Cash strapped⁶⁷ safety net programs, like Medicaid, often must directly choose between providing more generous benefits to current beneficiaries and expanding or contracting the number of beneficiaries they can serve. For these programs, CER has the potential to increase the amount of information available to policymakers facing difficult tradeoffs, and could also help stretch available funding as far as possible.

⁶⁵ See Congressional Budget Office, Health Care, <http://www.cbo.gov/publications/collections/health.cfm> (last visited April 20, 2011) (“[The Congressional Budget Office] and the [Joint Committee on Taxation] estimate that by 2019, the [ACA] will reduce the number of nonelderly people who are uninsured by about 32 million, leaving about 23 million nonelderly residents uninsured.”).

⁶⁶ KAISER FAMILY FOUNDATION, *supra* note 53.

⁶⁷ See, e.g., Kevin Sack, *For Governors, Medicaid Looks Ripe for Slashing*, N.Y. TIMES, Jan. 28, 2011, at A1 (noting that the Governor of Arizona was seeking federal permission to remove 280,000 adults from its Medicaid program, the Governor of California proposed saving \$1.7 billion through cuts including limiting beneficiaries’ doctor visits and prescriptions, and the Governor of Georgia proposed ending “Medicaid coverage of dental, vision, and podiatry treatments for adults”).

C. *The Issue of Cost Effectiveness*

As described above, one of the most contentious issues surrounding CER is its potential use to “ration” access to costly care. But there is nothing inherent to CER that requires the consideration of costs; it is entirely possible to compare two treatments to determine whether one is more effective for a given purpose without taking their relative costs into account. Thus, the issue of whether CER should take costs into consideration is a separate issue from whether it is beneficial to conduct, or use government funds to subsidize, CER.

Proposals to incorporate cost considerations into CER typically advocate for the use of cost-effectiveness analysis (“CEA”), in addition to comparative effectiveness analysis, to evaluate different treatments. While CEA lacks a standard definition,⁶⁸ generally speaking it is “a method designed to assess the comparative impacts of expenditures on different health interventions.”⁶⁹ A detailed analysis of the many complex issues associated CEA is beyond the scope of this paper. Suffice it to say, however, that CEA involves far more than technical number crunching, and challenging

⁶⁸ Peter D. Jacobson and Matthew L. Kanna, *Cost-Effectiveness Analysis in the Courts: Recent Trends and Future Prospects*, 26 J. HEALTH POL., POL’Y & L. 291, 293 (2001).

⁶⁹ ALAN M. GARBER ET AL., COST-EFFECTIVENESS IN HEALTH AND MEDICINE 26-27 (1996) (Marthe R. Gold et al., eds.). “The first step in [CEA] is to define the lifetime health effects of each intervention. The next step is to calculate the lifetime health care costs that would result from using each intervention. The costs and health benefits of an intervention are then often used to calculate the so-called incremental cost-effectiveness ratio . . . [which] is the difference in costs between the intervention and an alternative, divided by the difference in their health outcomes or effectiveness. This ratio is a measure of value: A low ratio indicates the expenditure has a large positive effect on the patient’s health, while a higher ratio indicates a smaller benefit, a higher cost, or both.” Garber and Sox, *infra* note 349, at 1808.

technical and ethical questions are inherent to any effort to quantify health.⁷⁰ Although researchers have developed a measure called the “Quality Adjusted Life-Year” as an attempt to measure how a treatment impacts the length and the quality of an individual’s life,⁷¹ the tool remains controversial.⁷²

Opponents of incorporating cost into CER often express concerns about the effects such research results might have on health care access, insurance coverage, provider reimbursement, and the health care provider and patient decisionmaking process.⁷³ Even among supporters of CER and CEA, however, there remains controversy over how closely to link the two forms of research. Some observers argue in favor of fully integrating the two forms of analysis.⁷⁴ They contend that cost is necessarily an

⁷⁰ See, e.g., Paul Menzel et al., *Toward a Broader View of Values in Cost-Effectiveness Analysis of Health*, 29 HASTINGS CENTER REP. 7 (1999) (advocating for better incorporation of social values into CEA); Peter J. Neumann and Magnus Johannesson, *From Principle To Public Policy: Using Cost-Effectiveness Analysis*, 13 Health Aff. 206, 207-209 (1994) (describing challenges associated with CEA, including the incorporation of patient preferences). For example, people may value the costs of a treatment’s adverse side effects or the benefits of being relieved a specific condition differently. See Garber and Sox, *infra* note 349, at 1808.

⁷¹ Garber and Sox, *infra* note 349, at 1808.

⁷² See *infra* section III(b)(3).

⁷³ See, e.g., FEDERAL COORDINATING COUNCIL FOR COMPARATIVE EFFECTIVENESS RESEARCH, REPORT TO THE PRESIDENT AND THE CONGRESS, *infra* note 228, at 57.

⁷⁴ See, e.g., American College of Physicians, *Information on Cost-Effectiveness: An Essential Product of a National Comparative Effectiveness Program*, 148 ANNALS INTERNAL MED. 956 (2008) (arguing for an independent federally funded entity that would develop comparative-effectiveness and cost-effectiveness information, but suggesting that “cost should never be used as the sole criterion for evaluating a clinical intervention”); Katherine T. Adams, *Rethinking Comparative Effectiveness Research*, 6 BIOTECHNOLOGY HEALTHCARE 35, 36 (2009) (In an interview with Dr. Donald Berwick, who later became the Center for Medicare & Medicaid Services Administrator, quoting Dr. Berwick as saying “You could make [cost considerations] advisory, or you could make it mandatory, or you could make it a policy rule. But to remain ignorant of the cost implications of a drug that is marginally better than what is already out there is simply bad policy.”).

important element of health care provider and patient decisionmaking.⁷⁵ Similarly, Alan Garber and Harold Sox have argued that because the CER included in the ACA will be partially funded by a tax on the health insurance industry,⁷⁶ the government should include with CER results cost information that would at least be useful to insurance companies when making coverage decisions, even if the government does not conduct CEA itself.⁷⁷ Others have argued that CEA should play a less prominent role in CER. The American Heart Association has taken the position that CER “may include estimates of cost and cost-effectiveness . . . but should focus on enhancing value for patients rather than minimizing costs.”⁷⁸ Even more firmly, health economist Dr. Gail Wilensky has argued that CEA should be entirely separate from any government effort to conduct CER, and that payers should be the group that conducts (and pays for) CEA.⁷⁹

d. Rationales for Government Involvement in CER

Even if the balance of potential harms and benefits favors the pursuit of CER, it does not necessarily follow that any level of government, and much less the federal government, should be involved in CER. In fact, many critics of recent CER initiatives have argued that while CER is beneficial on the whole, it is both unnecessary and

⁷⁵ Garber and Sox, *infra* note 349, at 1809.

⁷⁶ See *infra* note 289 and accompanying text.

⁷⁷ *Id.* at 1809-1810. In a previous editorial, Alan Garber analogized the health care system to a restaurant where the menu contains no prices, noting that in such a circumstances, “we should not be surprised by the size of the bill.” Alan M Garber, *A Menu without Prices*, 148 ANNALS INTERNAL MED. 964 (2008). It is important to distinguish, however, concerns about allowing any payer, including the federal government, to conduct CEA, and concerns about having the same organization conduct the two forms of analysis for fear that CEA would taint the effectiveness research. See 2007 CBO REPORT, *infra* note 84, at 26.

⁷⁸ Raymond J. Gibbons et al., *The American Heart Association’s Principles for Comparative Effectiveness Research*, J. AM. HEART ASS’N 2955, 2955 (2009).

⁷⁹ Gail Wilensky, *Cost-Effectiveness Information: Yes, It’s Important, but Keep It Separate, Please!*, 148 ANNALS INTERNAL MED. 967 (2008).

dangerous for the government to conduct or rely on CER when making important policy decisions.⁸⁰ Furthermore, the possibility of non-governmental actors conducting CER is not just theory, but a reality. Some health insurance and hospitals have long played a role in generating and analyzing CER,⁸¹ and pharmaceutical companies have also begun to test their own products against others on the market.⁸²

The primary economic rationale for government involvement in CER is that CER constitutes a “public good.” A public good is both “non-exclusive” and “non-rivalrous,” meaning that it is impractical to exclude non-payers, but additional users do not inhibit the ability of previous users to enjoy the good, respectively.⁸³ Information about the

⁸⁰ HELEN EVANS, THE HERITAGE FOUNDATION, *COMPARATIVE EFFECTIVENESS IN HEALTH CARE REFORM: LESSONS FROM ABROAD*, 2 (2009), available at <http://www.heritage.org/research/reports/2009/02/comparative-effectiveness-in-health-care-reform-lessons-from-abroad>; MICHAEL F. CANNON, *A BETTER WAY TO GENERATE AND USE COMPARATIVE-EFFECTIVENESS RESEARCH* (2009), available at <http://www.cato.org/pubs/pas/pa632.pdf>; Gottlieb, *infra* note 218; cf. Ronen Avraham, *A Market Solution for Malpractice*, N.Y. TIMES, March 28, 2011, at A31 (arguing for medical malpractice reform whereby health care providers who complied with best practice guidelines created by private sector entities would be immune from liability). Even among supporters of the ACA and its creation of a government agency to support CER, at least two members of Congress initially favored a public-private entity, which they felt could provide “a more efficient and transparent mechanism for the development and dissemination of evidence-based medicine.” Patel, *infra* note 239, at 1778.

⁸¹ See Wilensky, *infra* note 83, at w574.

⁸² See, e.g., Tracy Staton, *AZ Plots Push Into Comparative Effectiveness*, Fierce Pharma, <http://www.fiercepharma.com/story/az-plots-push-comparative-effectiveness/2011-02-03> (Feb. 3, 2011, 11:25 EST) (describing the plans of AstraZeneca, a pharmaceutical company, to conduct CER on its own products); Posting of Shirley S. Wang to Wall Street Journal Health Blog, *Comparing Drugs Is ‘Real World’ Demand, New PhRMA Head Says*, <http://blogs.wsj.com/health/2009/04/06/comparing-drugs-is-real-world-demand-new-phrma-head-says/?KEYWORDS=comparative+effectiveness+research> (April 6, 2009, 08:53 EST).

⁸³ Gail R. Wilensky, *The Policies and Politics of Creating a Comparative Clinical Effectiveness Research Center*, 28 HEALTH AFF. w719, w721 (2009).

comparative effectiveness of different treatments fits within this model.⁸⁴ Although it would be possible to restrict access to the information, such restriction would seem to defeat the purpose of generating the information in the first place, and widespread use of the results of CER would not seem to harm those who originally paid for the research.⁸⁵ Private actors tend to underproduce public goods, which arguably justifies government intervention to increase production to efficient levels.⁸⁶ Some observers disagree that the federal government must intervene in the case of public goods, because private markets will produce them under some circumstances.⁸⁷ In the case of CER, however, the public good problem may lead private actors to produce information narrowly tailored to their interests, resulting in fragmented and duplicative research.⁸⁸

Even if private markets are incapable of producing efficient levels of CER, some observers feel strongly that countervailing interests weigh against government involvement. Government intervention can be costly in terms of tax dollars, government decisions are subject to political influence, and there is no guarantee that the government

⁸⁴ See CONGRESSIONAL BUDGET OFFICE, RESEARCH ON THE COMPARATIVE EFFECTIVENESS OF MEDICAL TREATMENTS 8-9 (2007) (hereinafter “2007 CBO REPORT”).

⁸⁵ Wilensky, *supra* note 83, at w721 – w722.

⁸⁶ MEDICARE PAYMENT ADVISORY BOARD, REPORT TO THE CONGRESS: REFORMING THE DELIVERY SYSTEM 111 (2008) (hereinafter “MEDPAC 2008”); Gail R. Wilensky, *Developing A Center For Comparative Effectiveness Information*, 25 HEALTH AFF. w572, w583 (2006).

⁸⁷ See, e.g., CANNON, *supra* note 80, at 3-4 (noting that “[m]arkets increase the quantity of nonexcludable goods ([for example] lobbying, research, charity) beyond the amount that people are willing to purchase directly, by bundling them with excludable goods ([for example] insurance, advertising, reputation, recreation). . . . Markets create incentives for private actors to overcome the challenges posed by public goods. Innovators who develop ways to solve the free-rider problem can capture the money that others leave on the table.”).

⁸⁸ Wilensky, *supra* note 83, at w722. In addition, past scandals involving research data produced by private health industry actors may contribute to public distrust of privately sponsored research. See Fox, *infra* note 350, at 37-39.

will produce the optimal level of information.⁸⁹ At least one group has also argued that government participation in CER has potential to “crowd out” private investment, because private organizations that would have otherwise paid for CER themselves would seek government funding to support the research.⁹⁰ Nonetheless, given that private producers of CER have not generated enough information to fill the vast knowledge gaps that proponents of CER point to when advocating for more research,⁹¹ it is at least reasonable to argue that the government could play a beneficial role in funding, conducting, or encouraging private entities to engage in more CER.

II. Models for Governmental Participation in CER

Before addressing the models of CER that the government has adopted so far, it makes sense to survey a sample of the broad array of options generally available to governments seeking to engage in CER. These options demonstrate the trade-offs inherent to any effort to support CER through the federal government, such as between

⁸⁹ CANNON, *supra* note 80, at 5.

⁹⁰ *Id.* at 8-9.

⁹¹ For example, a 2010 study found that only approximately one-third of studies on medications published in “high-impact” general medical journals between June 2008 and September 2009 qualified as CER. Michael Hochman and Danny McCormick, *Characteristics of Published Comparative Effectiveness Studies of Medications*, 303 JAMA 951 (2010). See also, e.g., MEDICARE PAYMENT ADVISORY COMMISSION, REPORT TO THE CONGRESS: PROMOTING GREATER EFFICIENCY IN MEDICARE 29 (2007) (hereinafter “MEDPAC 2007”) (“There is not enough credible, empirically based information for health care providers and patients to make informed decisions about alternative services for diagnosing and treatment most common clinical conditions. Many new services disseminate quickly into routine medical care with little or no basis for knowing whether they outperform existing treatments, and to what extent.”). In addition, MedPAC has noted concerns that some industry-sponsored CER studies have been insufficiently objective and transparent. *Id.* at 40-41. The failure of the private sector to produce sufficient CER may be due in part to the reluctance of major payers in the health care industry, and namely, Medicare, to demand and use such information. Peter Orszag, Congressional Budget Office Testimony before the Subcommittee on Health, Committee on Ways and Means, U.S. House of Representatives, 6 (June 12, 2007), available at <http://www.cbo.gov/doc.cfm?index=8209&type=0>.

independence, credibility, and political accountability.⁹² They also provide context to the government's choices, as well as information about the policy implications of those choices that can inform predictions about the future of the government's CER efforts.

A. Domestic Possibilities

In its 2008 Report to Congress, the Medicare Payment Advisory Board (“MedPAC”)⁹³ surveyed the proposals of eight observers.⁹⁴ The proposals included a separate CER agency within HHS, a public-private partnership or a “quasi-governmental entity,” a new organization within AHRQ, or a “nonprofit independent institution.”⁹⁵ Beyond demonstrating that there is a fairly broad range of ways in which the federal government could increase support for CER, this array of options demonstrates that in the years leading up to the passage of ARRA, it was far from obvious how the government could best encourage CER. MedPAC itself argued in favor of a public-private entity, with an independent board that would determine and oversee the organization's research agenda, that would fund CER studies.⁹⁶ The entity would sponsor and conduct research, serve as a “clearinghouse” for published CER literature, and help coordinate existing entities that also participate in CER.⁹⁷ MedPAC also emphasized the importance of strict conflict-of-interest requirements for the entity, as well as other ethics rules.⁹⁸

⁹² See 2007 CBO REPORT, *infra* note 84, at 16-17.

⁹³ MedPAC is “an independent Congressional Agency . . . [that advises] the U.S. Congress on issues affecting the Medicare program.” “About MedPAC,” <http://www.medpac.gov/about.cfm> (last accessed Feb. 10, 2011).

⁹⁴ MEDPAC 2008, *supra* note 86, at 112.

⁹⁵ *Id.*

⁹⁶ See MEDPAC 2008, *supra* note 86, at 111; see also MEDPAC 2007, *supra* note 91, at 41-49.

⁹⁷ MEDPAC 2008, *supra* note 86, at 113-116.

⁹⁸ *Id.* at 119-120.

Another potential opportunity to conduct CER rests within the federal Food and Drug Administration. Because of the role the FDA already plays in compiling some data on drug, and to a lesser extent, device,⁹⁹ safety and efficacy (usually relative to a placebo),¹⁰⁰ the FDA would seem like a natural home for CER.¹⁰¹ One author has gone so far as to argue that the current approval process harms patients, who may receive new treatments that are more effective than a placebo, but less safe and effective than existing treatments.¹⁰²

Indeed, the FDA is already experimenting with the development of a database of aggregated health information that could be used for a broad range of research queries.¹⁰³ So far, the FDA has mainly used this system to react to safety problems, although it has

⁹⁹ Medical devices are subject to a different regulatory regime than drugs. Briefly, the FDA divides devices into three classes based on safety risk, with the lowest class exempt from FDA notification and approval requirements, the middle class subject to a “substantial equivalence” standard with regard to a product already on the market, and the highest class (including devices for which there is no existing substantially equivalent product) subject to premarket approval that includes safety and efficacy analysis. *See generally*, Food and Drug Administration, Overview of Device Regulation, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm#510k> (last visited March 30, 2011).

¹⁰⁰ *See* MEDPAC 2007, *supra* note 91, at 33. In certain circumstances, such as when it would be clearly unethical not to provide an unapproved drug to study participants, the FDA may require proof of superiority to an existing alternative rather than a placebo. Stafford, *infra* note 107, at 230-231.

¹⁰¹ Notably, however, the FDA does not regulate surgical and diagnostic procedures, which limits the impact and scope of any CER that the FDA could undertake without significantly expanding its regulatory reach. MEDPAC 2007, *supra* note 91, at 33.

¹⁰² Alec B. O’Connor, *Building Comparative Efficacy and Tolerability Into the FDA Approval Process*, 303 JAMA 979 (2010).

¹⁰³ Rachel E. Behrman et al., *Developing the Sentinel System – A National Resource for Evidence Development*, 364 NEW ENG. J. MED. 498 (2011). While the Sentinel system is designed to help monitor product safety, however, its value is limited by the system’s failure to consider issues related to cost and scientific evidence. *See* Alexander and Stafford, *supra* note 22, at 2490.

potential for broader use that includes CER.¹⁰⁴ In order to conduct or facilitate CER, however, Congress would need to expand the FDA’s authority to change the type of information it requires from drug and device manufacturers to include data on comparisons to relevant alternative treatments.¹⁰⁵ Furthermore, to ensure high quality CER, as opposed to studies designed to improve the odds of FDA approval, the FDA would likely need to exercise some supervision over the quality of submitted CER studies as well.¹⁰⁶ The FDA could also require the inclusion of comparative effectiveness information on drug labels.¹⁰⁷

Some observers have argued, however, that incorporation of CER into the FDA’s approval process would disrupt the FDA’s “economic role as a market regulator” that facilitates competition in the market for medical treatments by approving all safe and effective drugs and devices for a given condition.¹⁰⁸ In addition, by using CER to serve a gate keeping function, the FDA might inadvertently bar treatments that would have otherwise developed a comparative advantage over time, for example, if new information

¹⁰⁴ See Lynn M. Etheredge, *Creating A High-Performance System For Comparative Effectiveness Research*, 29 HEALTH AFF. 1761, 1762 (2010) (advocating for expansion of the Sentinel Initiative to “systematically collect data on therapies’ effectiveness, starting when a new therapy first enters clinical practice.”).

¹⁰⁵ Wilensky, *supra* note 83, at w574, MEDPAC 2007, *supra* note 91, at 33 (Noting that, in addition to the fact that the agency’s regulatory scope is limited and it usually looks at studies comparing a product to a placebo, even for products required to submit clinical trial results to the FDA, the typical study design is often not conducive to generating useful information for CER. The FDA’s limited authority with regard to post-market surveillance of an approved product is another barrier to the agency’s ability to participate in CER.).

¹⁰⁶ O’Connor, *supra* note 102, at 979-980.

¹⁰⁷ Randall S. Stafford et al., *New, but Not Improved? Incorporating Comparative Effectiveness Information into FDA Labeling*, 361 NEW ENG. J. MED. 1230 (2009).

¹⁰⁸ Garrison Jr. et al., note 15, at 1815.

became available about a drug’s comparative effectiveness or safety within a certain subpopulation.¹⁰⁹

Similarly, the government could use its authority under the Medicare and Medicaid programs to require that treatment manufacturers submit CER information in order to be covered under those programs.¹¹⁰ As of June 2007, for example, CMS had begun to compile evidence about services not covered in the past, and on occasion also collaborated with other federal agencies, such as AHRQ, to sponsor “head-to-head” trials and technological assessments.¹¹¹ Past efforts to incorporate CER into CMS coverage determinations have met political opposition, however, including direct prohibitions from Congress.¹¹² Given this history, and the controversy surrounding the use of CER findings in health insurance coverage determinations, it is clear that increased political support, at the least, would be necessary for CMS to be a viable route toward the generation of more CER studies.¹¹³

Alternately, in 2006 Dr. Gail Wilensky proposed a center, either funded publicly or through user-fees,¹¹⁴ for CER that would “fund prospective trials on key questions for which comparative effectiveness evidence was found missing, in addition to funding systematic reviews of existing research.”¹¹⁵ The center would focus on the generation of new information, and would be located in such a way as to minimize conflict of interest and stakeholder pressure, while maintaining a reputation for producing “objective and

¹⁰⁹ *Id.*

¹¹⁰ Wilensky, *supra* note 83, at w722.

¹¹¹ MEDPAC 2007, *supra* note 91, at 34; 2007 CBO REPORT, *supra* note 84, at 11.

¹¹² MEDPAC 2008, *supra* note 86, at 129; *see also* JACBOSON, *supra* note 14, at 29.

¹¹³ *See* MEDPAC 2008, *supra* note 86, at 130 (noting that additional statutory authority for CMS would probably be necessary for the agency to effectively use CER findings).

¹¹⁴ *Id.* at w583.

¹¹⁵ Wilensky, *supra* note 83, at w577.

credible” data.¹¹⁶ Wilensky called for improved coordination of health services research within the federal government, perhaps by placing the CER center within the Agency for Healthcare Research and Quality (“AHRQ”) or elsewhere in the Department of Health and Human Services (“HHS”), with CER on a particular treatment triggered by FDA approval.¹¹⁷ As an alternative to a federal agency, Wilensky also suggested that the center could exist either as a “quasi-governmental entity” or within the private sector as a not-for-profit organization, although she noted that the latter option lacked support as a realistic possibility, either in the government or the private sector, as of 2006.¹¹⁸

In 2008, Senator Max Baucus (D-MT), proposed the creating of a similar entity, the Health Care Comparative Effectiveness Research Institute, which would have been a nonprofit corporation with the purpose of “advancing the quality and thoroughness of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, and managed clinically through research and evidence synthesis, and the dissemination of research findings.”¹¹⁹ The bill, however, died in committee.¹²⁰

In 2005, AcademyHealth, a non-profit organization focused on health services research,¹²¹ also released a proposal for a center for CER within a larger health services research agency in the federal government, with AHRQ remaining the lead health

¹¹⁶ *Id.*

¹¹⁷ *Id.*, at w578.

¹¹⁸ *Id.*, at w580 – w582.

¹¹⁹ Comparative Effectiveness Research Act of 2008, S. 3408, 110th Cong. (2008).

¹²⁰ For a list providing a sample of some other bills proposed in the 110th Congress to support CER, as well as such bills proposed in the 109th Congress, see JACOBSON, *supra* note 14, at 41-50.

¹²¹ See “About Us – Academy Health,”

<http://www.academyhealth.org/About/content.cfm?ItemNumber=2070> (last visited March 30, 2011).

services research agency.¹²² The organization then discussed four options to accomplish this goal,¹²³ but did not endorse a particular option.¹²⁴ Due to the contentious nature of some CER, in which there may be “winners and losers” within the health care industry,¹²⁵ the report noted that its options would provide varying degrees of political insulation for the research. AcademyHealth also identified five “principles” that should govern Congress’ decision about the placement of a CER entity, including separation of scientific assessment from funding and coverage issues, congressional oversight, stakeholder participation, transparency, and funding for a broad range of research topics.¹²⁶ Although Congress did not ultimately adopt AcademyHealth’s model CER entity in its reauthorization of AHRQ, the organization’s recommendations provide useful analysis about some of the considerations that accompany the balance between government accountability and autonomy from political influences.

B. International Models

¹²² See generally ACADEMYHEALTH, PLACEMENT, COORDINATION, AND FUNDING OF HEALTH SERVICES RESEARCH WITHIN THE FEDERAL GOVERNMENT (2005), available at www.academyhealth.org/files/publications/placementreport.pdf. The report notes that allowing AHRQ to remain the lead agency for health services research “on par with the other HHS agencies” will ensure visibility for the work and also encourage effective interaction with other HHS agencies and Congress. *Id.* at 3.

¹²³ (1) AHRQ would sponsor and conduct the CER, but would be overseen by an “external board and panel of experts;” (2) in addition to the first option, AHRQ would establish an independent Federally Funded Research and Development Center (“FFDRC”); (3) a new, quasi-governmental entity would fund and conduct CER outside of AHRQ; and (4) AHRQ would be converted to a quasi-governmental agency that would conduct CER as well as carry out its existing functions. *Id.* at 11. An FFDRC is a federally funded entity that operates as a private, not-for-profit organization; some FFDRCs are located within other organizations. *Id.* at 15.

¹²⁴ *Id.* at 10-11.

¹²⁵ *Id.* at 9-10.

¹²⁶ *Id.* at 12.

Beyond the models, discussed above, that are designed around existing institutions within, or characteristics of, the United States government, it is also useful to briefly consider the models that other countries have used to generate, support and use CER.¹²⁷ The unique characteristics of the United States health care system suggest that widespread integration of CER into the health delivery system is likely to be more challenging in the United States than in other developed countries.¹²⁸ Nonetheless, one set of authors has noted that CER in other countries tends to be a “demand-driven activity,” in the sense that it serves to meet “the needs of public and private payers, patients, clinical professionals, and policymakers.”¹²⁹ Given that those needs are likely to be, at the least, similar in the United States as in other countries that have developed frameworks for supporting CER, the experiences of those countries may provide some helpful lessons for the road ahead in the United States.¹³⁰

The model most frequently cited by critics of governmental CER efforts in the United States is NICE in the United Kingdom. The United Kingdom has a highly centralized¹³¹ health system, the NHS, which provides care to all residents with no point-

¹²⁷ Notably, however, CER is an American term. Other countries refer to such research as “health technology assessment” or “evidence-informed policymaking.” Kalipso Chalkidou et al., *Comparative Effectiveness Research and Evidence-Based Health Policy: Experience from Four Countries*, 87 MILIBANK Q. 339, 340 (2009).

¹²⁸ For example, because the United States has a “multipayer” system, any organization or institution involved in CER must have strong legitimacy, through the production of “objective and unbiased data,” to support widespread adoption. Wilensky, *supra* note 83, at w576.

¹²⁹ Chalkidou, *supra* note 127, at 344.

¹³⁰ For a general comparison of government-sponsored CER in the United Kingdom, France, Germany and Australia, see *id.* at 345.

¹³¹ Note, however, that “NHS” is divided into four somewhat independent systems, one for each of England, Northern Ireland, Scotland, and Wales. I refer to the NHS as centralized in the sense that it is entirely taxpayer funded, the system’s policies and budget are largely set on a national level, and hospitals and physicians both contract

of-service charge to consumers.¹³² Although the NHS has been the subject of much criticism by opponents of health reform in the United States, and domestic political pressure has also led to some reforms in the system,¹³³ the NHS remains a very popular institution in the United Kingdom.¹³⁴ Within the NHS, NICE analyzes data about medical technologies that are unusually significant in terms of cost, health outcomes, or controversy.¹³⁵ A group of academic experts analyzes CER data, and then a group within NICE, the Technological Appraisal Committee (“TAC”), which is made up of a variety of stakeholders, reviews the evaluation and makes a recommendation. The recommendations of TAC can be appealed, and the NHS may choose whether to adopt NICE’s ultimate recommendations, except to the extent that NICE recommends coverage of a particular drug.¹³⁶ As part of its original mission, NICE explicitly conducts cost-effectiveness analysis for the treatments it studies.¹³⁷ NICE also conducts “budget impact analysis” as part of its evaluation, but the latter does not factor into the entity’s decisions.¹³⁸

directly with the government for all of the services they provide. For a more nuanced description of the NHS, *see generally* SEAN BOYLE, THE ENGLISH HEALTH CARE SYSTEM (2008), available at http://www.commonwealthfund.org/Topics/International-Health-Policy/Countries/~media/Files/Publications/Other/2010/Jun/International%20Profiles/1417_Squires_Intl_Profiles_England.pdf.

¹³² *See generally* “International Health Systems – UK,” <http://www.kaiseredu.org/Issue-Modules/International-Health-Systems/UK.aspx> (last visited March 30, 2011).

¹³³ *See The Final Frontier*, *The Economist*, Jan. 13, 2011.

¹³⁴ *See* Posting of Robert Mackey to The Lede Blog (N.Y. Times), *British Leaders Defend Their Health Service*, <http://thelede.blogs.nytimes.com/2009/08/14/british-leaders-defend-their-health-service/> (Aug. 14, 2009, 12:38 EST).

¹³⁵ Wilensky, *supra* note 83, at w575.

¹³⁶ *Id.* at w576.

¹³⁷ Chalkidou, *supra* note 127, at 350.

¹³⁸ *Id.*

In addition to the United Kingdom, the governments of Australia, Canada and Germany, among other countries and international organizations,¹³⁹ have also developed mechanisms that support CER. Like the United Kingdom, Australia also has a national health system called Medicare, which provides health insurance for citizens, and some residents, of Australia.¹⁴⁰ In order to be included in Australia's national drug formulary, a drug must be recommended by the Pharmaceutical Benefits Advisory Committee ("PBAC").¹⁴¹ The PBAC, however, does not publish the rationales or data supporting its recommendations,¹⁴² and CER efforts are limited to prescription medications.¹⁴³ Like NICE, the PBAC considers cost-effectiveness analysis, but the committee also considers budget impact analysis as part of its recommendations.¹⁴⁴ In support of the committee's efforts, a 2001 study found that the PBAC might play a role in the relatively low prices of pharmaceutical products in Australia.¹⁴⁵

Canada also has universal health insurance coverage through a health system called Medicare, which is administered jointly by the federal, provincial and territorial

¹³⁹ The Cochrane Collaboration is an example of an international organization that reviews health care treatments to support the use of evidence-based medicine. *See* The Cochrane Collaboration, About Us, <http://www.cochrane.org/about-us> (last visited March 29, 2011); *see also* 2007 CBO REPORT, *supra* note 84, at 7.

¹⁴⁰ *See generally* THE COMMONWEALTH FUND, THE AUSTRALIAN HEALTH CARE SYSTEM (2009), available at http://www.commonwealthfund.org/Topics/International-Health-Policy/Countries/~/media/Files/Publications/Other/2010/Jun/International%20Profiles/14_17_Squires_Intl_Profiles_Australia.pdf.

¹⁴¹ Wilensky, *supra* note 83, at w575.

¹⁴² *Id.*

¹⁴³ Chalkidou, *supra* note 127, at 347.

¹⁴⁴ *Id.* at 350.

¹⁴⁵ *See* Australia Productivity Commission, International Pharmaceutical Differences (2001), available at <http://www.pc.gov.au/projects/study/pbsprices/docs/finalreport>.

governments.¹⁴⁶ Since 2003, Canada has had a Common Drug Review (“CDR”) procedure for new drugs. An expert advisory committee analyzes the assessments of reviewers (either within or external to the CDR), and makes a non-binding coverage recommendation to the provinces, territories, and the federal government, which the manufacturer may appeal. Canada’s drug plans, however, follow the CDR’s recommendations approximately 90% of the time.¹⁴⁷ The CDR does not publish either the data or assessment used for its recommendation, but does make its rationale public.¹⁴⁸ Beyond analyzing the comparative effectiveness of new drugs relative to current standard treatments, the CDR also considers the comparative cost effectiveness of the drugs it studies.¹⁴⁹

In Germany, which has universal health insurance through a combination of public and private health insurance plans,¹⁵⁰ a publicly funded private foundation called the Institute for Quality and Efficiency (“IQWiG”) evaluates drugs, treatments and clinical practice guidelines for certain diseases.¹⁵¹ Coverage decision for the public health insurance plans (“Statutory Health Insurance”), which cover approximately 85%

¹⁴⁶ See generally, THE COMMONWEALTH FUND, THE CANADIAN HEALTH CARE SYSTEM (2009), available at http://www.commonwealthfund.org/Topics/International-Health-Policy/Countries/~media/Files/Publications/Other/2010/Jun/International%20Profiles/14_17_Squires_Intl_Profiles_Canada.pdf.

¹⁴⁷ Fiona M. Clement et al., *Using Effectiveness and Cost-effectiveness to Make Drug Coverage Decisions*, 302 JAMA 1437, 1438 (2009).

¹⁴⁸ Wilensky, *supra* note 83, at w576.

¹⁴⁹ Clement, *supra* note 147.

¹⁵⁰ See generally REINHARD BUSSE AND STEPHANIE STOCK, THE GERMAN HEALTH CARE SYSTEM (2009), available at http://www.commonwealthfund.org/Topics/International-Health-Policy/Countries/~media/Files/Publications/Other/2010/Jun/International%20Profiles/14_17_Squires_Intl_Profiles_Germany.pdf.

¹⁵¹ Wilensky, *supra* note 83, at w576.

of the German population,¹⁵² hinge on IQWiG's reports,¹⁵³ although there is an arms-length relationship between IQWiG and the committee that ultimately decides how to transform IQWiG's recommendations into health policy.¹⁵⁴ IQWiG considers scientific evidence about a wide range of medical treatments, and since 2007, the organization has also considered the results of cost-benefit and budget impact analyses.¹⁵⁵ The institute then disseminates the findings of its research through a website targeted at health care consumers.¹⁵⁶

Among countries whose governments sponsor CER, a number of trends are evident. The entities have varying levels of independence from both the central governments that support them and other financial stakeholders.¹⁵⁷ Other trends include emphasis on transparency in topic selection, research analysis and final decisions, concern about scientific standards, the inclusion of mechanism for reconsideration of decisions adverse to stakeholders, and timeliness standards that require technologies to be studied when they are relatively new and diffusion into the market is not yet complete.¹⁵⁸ In addition, the entities often started out without taking into account comparative cost information, but evolved to consider some forms of CEA.¹⁵⁹ The entities tend to conduct research by synthesizing existing studies rather than conducting their own prospective trials of new technology, although evidence development, in the form of supporting

¹⁵² BUSSE, *supra* note 150.

¹⁵³ Wilensky, *supra* note 83, at w576.

¹⁵⁴ Chalkidou, *supra* note 127, at 352-353.

¹⁵⁵ Chalkidou, *supra* note 127, at 347, 350.

¹⁵⁶ Informed Health Online, <http://www.informedhealthonline.org/index.en.html> (last visited March 30, 2011).

¹⁵⁷ Chalkidou, *supra* note 127, at 357.

¹⁵⁸ *Id.*

¹⁵⁹ *Id.* at 357-358.

studies of new technologies, is increasingly important.¹⁶⁰ Studies have found, however, that some of these programs face persistent problems with the strength and quality of the evidence that they analyze, although they address these challenges differently.¹⁶¹ Lastly, proponents of CER tend not to emphasize cost control or rationing, but instead focus on the potential for CER to improve health care quality and reduce waste.¹⁶²

III. Sources of Support for CER To Date

A. Private

In addition to public entities, a number of private companies and organizations participate in generating and analyzing CER.¹⁶³ Historically, a significant source of privately funded and conducted CER has been the Technology Evaluation Center (“TEC”), which is a program run by the Blue Cross/Blue Shield association in partnership with Kaiser Permanente.¹⁶⁴ The TEC conducts approximately 20-25 assessments each year of drugs, devices and medical procedures to evaluate “clinical effectiveness and appropriateness.”¹⁶⁵ Some of these assessments include comparative-effectiveness or cost-effectiveness studies.¹⁶⁶ Despite that the TEC provides its assessments “solely for informational purposes,”¹⁶⁷ the organization does advise local Blue Cross/Blue Shield plans and other entities that make insurance coverage decisions

¹⁶⁰ *Id.* at 358-359.

¹⁶¹ Clement, *supra* note 147, at 1442.

¹⁶² *Id.* at 360.

¹⁶³ *See generally* 2007 CBO REPORT, *supra* note 84, at 8.

¹⁶⁴ Technology Evaluation Center: Kaiser Collaboration, <http://www.bcbs.com/blueresources/tec/kaiser-collaboration.html> (last visited March 30, 2011).

¹⁶⁵ What is the Technology Evaluation Center?, <http://www.bcbs.com/blueresources/tec/what-is-tec.html> (last visited March 30, 2011).

¹⁶⁶ *Id.*

¹⁶⁷ *Id.*

about the degree to which a given technology is likely to improve health outcomes.¹⁶⁸

Other private technology assessment companies, large health insurers, and managed care organizations also conduct this type of research.¹⁶⁹

B. Public

1. Before 2009

Before the financial crisis of 2008 and the deep recession that followed prompted Congress to pass ARRA,¹⁷⁰ the primary federal agency focusing on CER was the Agency for Healthcare Research and Quality (“AHRQ”).¹⁷¹ CER, however, is not the agency’s primary mission, which is generally “to improve the quality, safety, efficiency, and effectiveness of health care for all Americans.”¹⁷²

Originally, AHRQ was named the Agency for Health Care Policy and Research (“AHCPR”). Congress created the AHCPR in 1989 in response to concerns about waste in the health care system and the lack of scientific support for many medical treatments, as well to serve as a replacement for another now-extinct federal agency, the National

¹⁶⁸ TIMOTHY STOLTZFUS JOST, THE MEDICARE COVERAGE DETERMINATION PROCESS IN THE UNITED STATES, IN HEALTH CARE COVERAGE DETERMINATIONS: AN INTERNATIONAL COMPARATIVE STUDY 208 (2005).

¹⁶⁹ *Id.* For an example of a consumer-oriented technology assessment program, see Consumer Reports, Safe and Effective Drug Recommendations from Best Buy Drugs, <http://www.consumerreports.org/health/best-buy-drugs/index.htm> (last visited March 30, 2011).

¹⁷⁰ For a more detailed discussion about the federal government’s history of conducting and using comparative-effectiveness and cost-effectiveness information, see generally JACOBSON, *supra* note 14, at 22-25, 29- 33, 35.

¹⁷¹ The NIH is the primary funder of CER, but because the agency does not “tag” its CER studies, they are not readily identifiable. FEDERAL COORDINATING COUNCIL FOR COMPARATIVE EFFECTIVENESS RESEARCH, *infra* note 228, at 29. In a pilot identification project, the Council found approximately 463 NIH-funded CER studies in the year 2008, compared to 144 studies conducted by AHRQ during the fiscal years 2006-2009. *Id.* at 28-29.

¹⁷² AHRQ At A Glance: Mission, Focus, and Goals, <http://www.ahrq.gov/about/ata glance.htm> (last visited March 30, 2011).

Center for Health Services Research and Health Care Technology Assessment.¹⁷³ The AHCPR was authorized to conduct research, demonstration projects, and trainings, as well as to develop guidelines and disseminate research findings.¹⁷⁴ Advocates for outcomes research, however, made a conscious decision to separate the agency from the Health Care Financing Administration in order to avoid highlighting the cost-containment implications of the research.¹⁷⁵

Health services research generally, however, faced some problems related to the reality that unlike other forms of research, it lacked a large constituency of advocates other than researchers.¹⁷⁶ Despite that the AHCPR had been created during a Republican presidential administration and with the support of key conservative members of Congress, the agency nearly lost its funding during the battles over the federal budget in 1995-1996, when critics argued that it was wasteful and ineffective.¹⁷⁷ Congress' decision in 1992 to direct the agency to consider cost-effectiveness in its assessments generated significant controversy.¹⁷⁸ The AHCPR's links with the failed Clinton health

¹⁷³ See Bradford H. Gray, *The Legislative Battle Over Health Services Research*, 11 HEALTH AFF. 38 (1992) (describing the legislative history of the creation of the AHCPR, and noting that its creation “was driven substantially by outcomes research and the hope that such research might help to prevent unnecessary Medicare spending.”). In analyzing the legislative history of the creation of the AHCPR, Gray emphasizes that the agency serves as a valuable case study regarding the federal government's difficulty in making health policy, even in the face of a “rational response to a significant problem” and bipartisan support. *Id.* at 64-65. The number of agencies that Congress has created and dissolved in relation to CER and similar research, starting in the 1970s and continuing through the present, may be a symptom of this difficulty. See 2007 CBO REPORT, *supra* note 84, at 9.

¹⁷⁴ Gray, *supra* note 173, at 40.

¹⁷⁵ *Id.* at 63.

¹⁷⁶ Bradford H. Gray et al., *AHCPR And The Changing Politic Of Health Services Research*, 22 HEALTH AFF. w3-283, 285 (2003).

¹⁷⁷ *Id.* at 294-296.

¹⁷⁸ JACOBSON, *supra* note 14, at 23.

reform effort, and pushback from surgeons in response to a report that found insufficient evidence to support spinal fusion surgery for low-back pain, also caused the agency political problems.¹⁷⁹

With the support of a number of professional organizations, advocacy groups, and individual supporters, however, the agency survived, albeit with a significantly reduced budget.¹⁸⁰ The agency re-focused its efforts on health care quality issues and dissemination, and also shifted away from the politically controversial practice of directly developing practice guidelines, which were then created by non-governmental organizations through the use of external evidence-based practice centers.¹⁸¹ The agency's 1999 reauthorization legislation¹⁸² removed the word "policy" from its name, thus transforming the agency into AHRQ.¹⁸³

Today, as in the years leading up to the passage of ARRA and the ACA, AHRQ primarily engages in secondary CER, by conducting systematic reviews and syntheses of existing research through its Effective Health Care Program.¹⁸⁴ To accomplish this task,

¹⁷⁹ Gray, *supra* note 176, at 296-298.

¹⁸⁰ *Id.* at 299-301.

¹⁸¹ *Id.* at 302-303.

¹⁸² Healthcare Research and Quality Act of 1999, P.L. 106-129 (1999) (codified at 42 U.S.C. § 299 et seq.).

¹⁸³ Gray, *supra* note 176, at 303.

¹⁸⁴ FEDERAL COORDINATING COUNCIL FOR COMPARATIVE EFFECTIVENESS RESEARCH, *infra* note 228, at 31; Jean R. Slutsky and Carolyn M. Clancy, *AHRQ's Effective Health Care Program: Why Comparative Effectiveness Matters*, 24 AM. J. MED. QUALITY 67 (2009) (in an article written by the Director of AHRQ and the Director of the agency's Center for Outcomes and Evidence, the authors argue that AHRQ's program is unique due to its "relevance, timeliness, and transparency"). The Effective Health Care Program was created by the Medicare Modernization Act of 2003, P. L. 108-173, 108th Cong., § 1013 (2003), to study "the outcomes, comparative clinical effectiveness, and appropriateness of health care items and services . . . and strategies for improving the efficiency and effectiveness of such [Medicare, Medicaid and CHIP], including the ways

AHRQ contracts with 13 “evidence-based centers” that carry out systematic reviews and technology assessments, as well as some cost-effectiveness analyses,¹⁸⁵ about the agency’s 14 priority conditions that are of particular significance to the Medicare, Medicaid or Children’s Health Insurance programs.¹⁸⁶ AHRQ notifies manufacturers when it begins reviews of their products, and solicits public comments and other stakeholder input.¹⁸⁷ The agency then disseminates this information to health care providers and consumers through a series of guides, in the form of documents, videos, and audio files, some of which are also provided in Spanish.¹⁸⁸

Other federal agencies also conduct or support CER. The NIH is the agency within the federal government that funds the most CER through grants,¹⁸⁹ but until

in which such items and services are organized, managed, and delivered under such programs.” *Id.* § 1013(a)(1).

¹⁸⁵ MEDPAC 2007, *supra* note 91, at 37.

¹⁸⁶ The fourteen conditions are: “arthritis and nontraumatic joint disorders; cancer; cardiovascular disease, including stroke and hypertension; dementia, including Alzheimer’s disease; depression and other mental health disorders; developmental delays, attention-deficit/hyperactivity disorder, and autism; diabetes mellitus; functional limitations and disability; infectious diseases, including human immunodeficiency virus and AIDS; obesity, peptic ulcer disease and dyspepsia; pregnancy, including preterm birth; pulmonary disease and asthma; [and] substance abuse.” Slutsky and Clansy, *supra* note 184, at 68. Medicare, Medicaid and the Children’s Health Insurance Program are governed by Titles XVIII, XIX, and XXI, respectively, of the Social Security Act.

¹⁸⁷ *Id.*

¹⁸⁸ See, e.g., Choosing Pain Medicine for Osteoarthritis – Consumer Guide, <http://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=4> (last visited March 30, 2011); Medicamentos Antidepresivos: Guía Para Adultos Con Depresión – Consumer Guide, <http://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=153&returnpage=> (last visited March 30, 2011); Comparative Effectiveness of Management Strategies for Gastrophageal Reflux Disease, <http://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=42> (last visited March 30, 2011).

¹⁸⁹ MEDPAC 2007, *supra* note 91, at 37.

recently it had not sought to identify which of its funded studies qualify as CER.¹⁹⁰ The United States Preventive Services Task Force, an independent panel of scientific experts that works in collaboration with AHRQ, also assesses the effectiveness of a variety of preventive health care services and issues recommendations that serve as the “gold standard” for preventive health care services.¹⁹¹ During fiscal years 2006 through 2009, the Department of Defense (“DoD”) also conducted approximately 25 CER studies, and the Veterans Health Administration (“VHA”) conducted 96.¹⁹²

The VHA’s role in conducting CER relevant to its patient population, and particularly “practical” CER,¹⁹³ is notable; the VHA also sometimes requires that the manufacturers of products it might buy submit cost-effectiveness analyses, particularly with regard to drugs that appear to be marginally more effective, but much more expensive, than alternatives.¹⁹⁴ A prominent example of CER conducted with the support of the VHA was the COURAGE trial (Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation), whose results were published in the *New England Journal of Medicine* in 2007.¹⁹⁵ The study found no additional benefits (in the form of long term death rates, nonfatal heart attacks or hospitalization for acute coronary syndromes) to the use of coronary stents or other scaffolding (“percutaneous coronary intervention” or

¹⁹⁰ See *supra* note 171.

¹⁹¹ U.S. Preventive Services Task Force: About the USPTF, <http://www.uspreventiveservicestaskforce.org/intro.htm> (last visited March 30, 2011); U.S. Preventive Services Task Force, <http://www.ahrq.gov/clinic/uspstfix.htm> (last visited March 30, 2011).

¹⁹² *Id.* at 30.

¹⁹³ *Id.* at 31.

¹⁹⁴ MEDPAC 2007, *supra* note 91, at 37.

¹⁹⁵ Willam E. Boden et al., *Optimal Medical Therapy with or without PCI for Stable Coronary Disease*, 356 *NEW ENG. J. MED.* 1503 (2007). The Congressional Budget Office used this study as an example of CER disproving a widely held belief in its 2007 paper for Congress on CER. 2007 CBO REPORT, *supra* note 84, at 4.

“PCI”) among individuals with stable coronary artery disease, when used for initial disease management purposes.¹⁹⁶ Although the study’s results were groundbreaking, many cardiologists resisted incorporating the findings into everyday practice by failing to conduct tests that would determine whether PCI was appropriate for particular patients given the study’s findings.¹⁹⁷ While some of the resistance likely derived from disagreement with characteristics of the study, the financial incentives facing physicians and device manufacturers also probably played a role, given the high price of stent procedures and the fact that insurers mostly did not restrict coverage of the procedures based on the outcome of the study.¹⁹⁸ The VHA’s experience thus demonstrates the complex nature not only of disseminating CER findings, but ensuring that health care providers accept and incorporate the results into practice.¹⁹⁹ Yet, the VHA is unique because it has a dedicated initiative²⁰⁰ and center²⁰¹ that assist with the implementation of research findings within the VA health care system and tackle these challenges head-on.

In addition to the federally funded CER programs, states have also engaged in activities to generate and use CER.²⁰² The Drug Effectiveness Review Project (“DERP”) at the Oregon Health and Science University conducts systematic comparative-

¹⁹⁶ Boden, *supra* note 195, at 1514.

¹⁹⁷ Keith J. Winstein, *A Simple Health-Care Fix Fizzles Out*, WALL ST. J., Feb. 11, 2010, at A1.

¹⁹⁸ *Id.*

¹⁹⁹ Interestingly, the dissemination of CER regarding PCI as a treatment for acute heart attacks was a success. See Anand D. Naik and Laura A Petersen, *The Neglected Purpose of Comparative-Effectiveness Research*, 360 NEW ENG. J. MED. 1929, 1930 (2009).

²⁰⁰ Quality Enhancement Research Initiative (QUERI), <http://www.queri.research.va.gov/> (last visited March 30, 2011).

²⁰¹ Center for Implementation Practice and Research Support, <http://www.queri.research.va.gov/ciprs.cfm> (last visited March 30, 2011).

²⁰² For charts comparing the types of CER conducted or supported by AHRQ, NIH, the Department of Defense, and the VHA, see MEDPAC 2007, *supra* note 91, at 32.

effectiveness reviews for a self-managed and collaborative group of eleven states, as well as the Canadian Agency for Drugs and Technologies in Health.²⁰³ Although DERP provides members with the findings of CER studies of drugs (which do not include CEA or other cost considerations), members retain total freedom with regard to how the information influences their policy decisions.²⁰⁴ Likewise, the state of Washington also has a health technology assessment program (“HTAP”).²⁰⁵ Unlike DERP, the HTAP explicitly considers whether a studied technology is cost effective.²⁰⁶ Nonetheless, the HTAP has faced problems. For example, when the program sought to incorporate the results of the VHA’s COURAGE study into the state’s health insurance programs by conducting a review of the evidence supporting stents, it encountered significant industry opposition.²⁰⁷ The external firm it hired to conduct the review, for example, decided the study was not feasible after industry leaders and physicians declined to cooperate.²⁰⁸ As

²⁰³ See generally, Drug Effectiveness Review Project (DERP), <http://www.ohsu.edu/xd/research/centers-institutes/evidence-based-policy-center/derp/index.cfm/> (last visited March 30, 2011); MEDPAC 2007, *supra* note 91, at 37. For the current members of DERP, see Participating Organizations, <http://www.ohsu.edu/xd/research/centers-institutes/evidence-based-policy-center/derp/participating-organizations.cfm> (last visited March 30, 2011). For analysis of the challenges and successes of the project, which began in 2003, see generally Peter J. Neumann, *Emerging Lessons From The Drug Effectiveness Review Project*, 25 HEALTH AFF. w262 (2006); see also Mark Gibson and John Santa, *The Drug Effectiveness Review Project: An Important Step Forward*, 25 HEALTH AFF. w272 (2006) (rebutting criticisms of the project).

²⁰⁴ Neumann, *supra* note 203, at w263-w264.

²⁰⁵ MEDPAC 2007, *supra* note 91, at 37; Health Technology Assessment Program (HTA), <http://www.hta.hca.wa.gov/> (last visited March 30, 2011).

²⁰⁶ About the Program, <http://www.hta.hca.wa.gov/about.html> (last visited March 30, 2011).

²⁰⁷ Winstein, *supra* note 197.

²⁰⁸ *Id.* (“We don’t want to end up being our own willing executioners,” said . . . the senior director of health economics for . . . a stent maker” on a call with the firm.).

a consequence, HTAP had to conduct a narrower review that did not follow the COURAGE study.²⁰⁹

2. ARRA

In early 2009, Congress passed the American Recovery and Reinvestment Act. Although the bill was, at least ostensibly, a necessary emergency response to the financial crisis and economic recession that began in December 2007,²¹⁰ it was a controversial piece of legislation.²¹¹ One aspect of the statute that failed to garner much attention before its passage, probably due to the law's fast legislative timeline and complexity, was its significant investments in CER.

Two sections of ARRA address CER. The first, section 804, created the Federal Coordinating Council for Comparative Effectiveness Research (“Coordinating Council”).²¹² The statute described the purpose of the Coordinating Council as fostering “optimum coordination of comparative effectiveness and related health services research conducted or supported by relevant Federal departments and agencies, with the goal of reducing duplicative efforts and encouraging coordinated and complementary use of resources.”²¹³ To meet this objective, the statute required the Coordinating Council to have at most fifteen members that are all federal employees or officers, to be appointed

²⁰⁹ *Id.*

²¹⁰ See Edmund L. Andrews, *Officials Vow to Act Amid Signs of Long Recession*, N.Y. TIMES, Dec. 1, 2008, at A1.

²¹¹ See, e.g., Op-ed, *The Stimulus Tragedy*, WALL ST. J., Feb. 7, 2009, at A1 (arguing the stimulus was too large); Leslie Eaton, *Governors Agree on Woes But Disagree on Stimulus*, WALL ST. J., Feb. 23, 2009, at A3; Paul Krugman, *Failure to Rise*, N.Y. TIMES, Feb. 12, 2009, at A31 (arguing the stimulus was too small).

²¹² Pub. L. No. 111-5, 123 Stat. 115, § 804 (2009).

²¹³ ARRA § 804(c) (2009).

by the President through the Secretary of HHS.²¹⁴ Section 804 required the Council to submit annual reports to Congress and the President about the federal government’s CER efforts, but the law explicitly stated that section 804 did not give the Council authority “to mandate coverage, reimbursement, or other policies for any public or private payer.”²¹⁵ The Coordinating Council, however, was a short-lived endeavor. Section 6302 of the ACA terminated the Council as of the date of its enactment, March 23, 2010, just over a year after the passage of ARRA.

The second section of ARRA that addresses CER is in Title VIII of the statute, which appropriates a total of \$1.1 billion for the research. Of that sum, Congress allocated \$400 million to the National Institutes of Health (“NIH”), \$400 million to the Secretary of HHS (to distribute at her discretion), and \$300 million to AHRQ.²¹⁶ Congress required that the money be spent on “efforts that: (1) conduct, support, or synthesize research that compares the clinical outcomes, effectiveness, and appropriateness of items, services, and procedures that are used to prevent, diagnose, or treat diseases, disorders, and other health conditions; and (2) encourage the development and use of clinical registries, clinical data networks, and other forms of electronic health data that can be used to generate or obtain outcomes data,”²¹⁷ the former of which suggests the definition of CER used by Congress for the purpose of the Stimulus Act. In conjunction with the funds, Congress required HHS to contract with the IOM to issue a

²¹⁴ ARRA § 804(d)(1) (2009). ARRA also required that eight health-related federal agencies have representatives on the board (AHRQ, CMS, the National Institutes of Health, the Office of the National Coordinator for Health Information Technology, the FDA, the Veterans Health Administration and the Department of Defense).

²¹⁵ ARRA §§ 804(e), (g)(1) (2009).

²¹⁶ ARRA Title VIII (2009)

²¹⁷ *Id.*

report on national priorities for CER. Congress then instructed the Secretary of HHS to consider this report, as well as recommendations by the Coordinating Council, when funding CER projects and awarding grants. The statute also ordered that the funded agencies provide reports to Congress, and that grantees allow for public comment on their research, “to the extent feasible.”

ARRA’s provisions on CER generated significant after-the-fact criticism.²¹⁸ For the most part, critics argued that the provisions represented a covert effort at government rationing of health care²¹⁹ and an unjustified interference into the physician-patient relationship.²²⁰ In the aftermath of ARRA, at least one member of Congress went so far

²¹⁸ However, some criticism of ARRA’s CER provisions predated the passage of the law. *See, e.g.,* Scott Gotlieb, *Congress Wants to Restrict Drug Access*, WALL ST. J., Jan. 20, 2009, at A14.

²¹⁹ *See, e.g.,* George F. Will, *Stimulus Math for the GOP*, WASH. POST, Jan. 29, 2009, at A19; Betsy McCaughey, *Government Care’s Assault on Seniors*, WALL ST. J., July 23, 2009, at A15 (“The assault against seniors began with the stimulus package in February. Slipped into the bill was substantial funding for comparative effectiveness research, which is generally code for limiting care based on the patient’s age.”); Betsey McCaughey, *Ruin Your Health With The Obama Stimulus Plan*, Bloomberg, Feb. 9, 2009 (suggesting that ARRA’s investments in CER, in combination with its investments in health information technology, will result in the federal government monitoring “treatments to make sure your doctor is doing what the federal government deems appropriate and cost effective.”). McCaughey’s claim, similar to one made by the Heritage Foundation a few days earlier, was also picked up by Rush Limbaugh. *See* NINA OWCHARENKO, *THE STIMULUS BILL: WHY THE SENATE MUST FIX THE HEALTH CARE PROVISIONS* (2009), available at <http://www.heritage.org/research/reports/2009/02/the-stimulus-bill-why-the-senate-must-fix-the-health-care-provisions>; Rush Limbaugh, “The March To Socialized Medicine Starts In Obama’s Porkulus Bill,” http://www.rushlimbaugh.com/home/daily/site_020909/content/01125111.guest.html (last visited March 30, 2011).

²²⁰ *See* OWCHARENKO, *supra* note 219. In May 2010, a Federal District Court for the Southern District of New York granted the government’s motion to dismiss a suit that argued, among other things, that the CER provisions of ARRA “lay[ed] the groundwork for a permanent government rationing board” and that the Coordinating Council would “prescribe what care, procedures or medications [plaintiffs] will receive in place of the doctors chosen by the Plaintiffs and the Plaintiffs themselves;” the Court noted that such

as to vote against the appointment of Kathleen Sibelius as the Secretary of Health and Human Services because of concerns related to CER.²²¹ On the surface, the strong negative reaction of some Republicans to the inclusion of CER in ARRA was somewhat surprising, both because the general idea of CER, if not the details, is relatively uncontroversial, and because a number of prominent Republicans, including 2008 presidential candidate Senator John McCain, had formerly supported the research.²²² Regardless, concerns over ARRA's investment in CER were still simmering as Congress began in earnest to debate comprehensive reform of the health care system in mid-2009.

Although the retrospective significance of ARRA's investment in CER changed dramatically with the passage of the ACA in the spring of 2010, and any evidence on the impact of CER funded by ARRA on the health system is years away, some results and lessons from the legislation are available today. In response to ARRA's legislative mandate, the IOM released its report to Congress and the President on June 30, 2009.²²³ In its report, the IOM identified the 100 topics, based on stakeholder input, which should take priority in CER research, divided into four quartiles to indicate priority within the list as a whole.²²⁴ The report also included "recommendations for a robust national CER enterprise," in which the IOM advocated for a number of policy reforms that would facilitate an on-going prioritization, monitoring and evaluation process for federally-

assertions were "completely unsupported by the statute." *Hegmann v. Sibelius*, 2010 U.S. Dist. LEXIS 71965, 11 (S.D.N.Y. 2010) (internal quotations omitted).

²²¹ Jane Zhang, *Sen. Kyl Explains His Vote Against Sibelius*, WALL ST. J., April 21, 2009, at.

²²² John K. Iglehart, *The Political Fight Over Comparative Effectiveness Research*, 29 HEALTH AFF. 1757, 1758 (2010). AHRQ and its predecessor also had bipartisan support, although conservative support for the agency partially broke down during the 1990s. See *supra* notes 173-183 and accompanying text.

²²³ IOM NATIONAL PRIORITIES FOR CER, *supra* note 7.

²²⁴ *Id.* at 3-12.

sponsored CER, with a high degree of transparency and public involvement.²²⁵ The IOM also called for additional research into CER methods, improved data collection methods, increased capacity in the CER workforce, and a sustained effort to diffuse CER findings.²²⁶

On the same day that the IOM published its report, the Federal Coordinating Council for Comparative Effectiveness Research²²⁷ released its Report to the President and the Congress.²²⁸ To gather information for the report, the Council held a series of “listening sessions,” in which a variety of stakeholders had an opportunity to provide testimony and comments on the subject of CER.²²⁹ The comments generally focused on research prioritization, infrastructure development (including “human and scientific capital, organizational capacity, and data capacity”), research methodology, care delivery, knowledge transfer, cost, health disparities, and personalized medicine.²³⁰ Notably, in its report, the Council focused on the “patient centered” aspect of CER,²³¹ which it suggested could help answer the question of “which therapeutic choice works best for

²²⁵ *Id.* at 140-146.

²²⁶ *Id.* at 146-159.

²²⁷ For the Council’s membership, *see* Federal Coordinating Council for Comparative Effectiveness Research Membership, <http://www.hhs.gov/recovery/programs/os/cerbios.html> (last visited March 30, 2011). For summaries of the Council’s meetings pre-report meetings, *see* FEDERAL COORDINATING COUNCIL FOR COMPARATIVE EFFECTIVENESS RESEARCH, REPORT TO THE PRESIDENT AND THE CONGRESS, *supra* note 228, at 59-64.

²²⁸ FEDERAL COORDINATING COUNCIL FOR COMPARATIVE EFFECTIVENESS RESEARCH, REPORT TO THE PRESIDENT AND THE CONGRESS (2009), *available at* <http://www.hhs.gov/recovery/programs/cer/cerannualrpt.pdf>.

²²⁹ Summaries and transcripts from these listening sessions are available at Comparative Effectiveness Research Funding, <http://www.hhs.gov/recovery/programs/cer/index.html> (last visited March 30, 2011).

²³⁰ FEDERAL COORDINATING COUNCIL FOR COMPARATIVE EFFECTIVENESS RESEARCH, REPORT TO THE PRESIDENT AND THE CONGRESS, *supra* note 228, at 53-59 (summarizing trends in the comments and testimony).

²³¹ For the Council’s definition of CER, *see supra* note 11.

whom, when, and in what circumstances” and help patients “take responsibility for their care.”²³² In a preview of how advocates for CER would frame the issue in the ACA, the report notes that CER can also be called “patient-centered health research or patient-centered outcomes research to illustrate its focus on patient needs.”²³³ The Council recommended that the Secretary of HHS spend ARRA’s \$400 billion in discretionary funds primarily on data infrastructure, and then on “dissemination and translation of CER findings, priority populations, and priority types of interventions” secondarily.²³⁴

Congress required the three federal agencies to award the funds provided by September 30, 2010.²³⁵ By August 2010, the federal government had allocated at least 82.8 percent of the \$1.1 billion in CER funding included in ARRA, although only half of that amount had already been awarded to specific grantees.²³⁶ Of the amount allocated, roughly half was designated for “evidence development and synthesis activities.”²³⁷ Most of the rest went toward building CER capacity, approximately 7% was aimed at efforts to translate and disseminate evidence, and a total of approximately 5% was or will be spent to set priorities and engage stakeholders.²³⁸

3. *The ACA*

²³² *Id.* at 3.

²³³ *Id.* at 4. The Council identified several priority subpopulations, “including racial and ethnic minorities, individuals with disabilities, children, persons with multiple chronic conditions, and the elderly,” based on underrepresentation in previous research, increased disease burden, and health disparities. *Id.* at 18.

²³⁴ *Id.* at 44-48.

²³⁵ Joshua S. Benner et al., *An Evaluation Of Recent Federal Spending On Comparative Effectiveness Research: Priorities, Gaps, And Next Steps*, 29 HEALTH AFF. 1768, 1769 (2010).

²³⁶ *Id.*

²³⁷ *Id.* at 1770.

²³⁸ *Id.*

Although ARRA’s investment in CER arguably set the stage for prominent inclusion of CER in Congress’ effort to reform the health care system,²³⁹ it did not provide a clear picture of what a permanent expansion of federal CER efforts would look like. When Congress shifted its primary focus toward health reform in the spring of 2009, it became apparent that CER was one of the issues for which there was a difference of opinion between members of the Senate and the House of Representatives, in addition to the recently diverged positions on the issue held by members of Congress from the two major political parties.²⁴⁰ One of the early major bills debated in the Senate, the “Affordable Health Choices Act” (also known as the “Senate HELP Committee bill” or the “Kennedy bill” due to Senator Kennedy’s role in forming the bill before his death later that year), included a “Center for Health Outcomes Research and Evaluation” within AHRQ.²⁴¹ Although the bill expressly provided that the Center’s “reports and recommendations [would] not be construed as mandates for payment, coverage, or treatment,”²⁴² the bill faced stiff opposition by Senate republicans.²⁴³

²³⁹ While ARRA may have been the first major legislative step toward increased federal support for CER, as well as increased public scrutiny and political controversy for the issue, it is important to note that support for the research in Congress started with the Democratic take-over of Congress in 2007. See Kavita Patel, *Health Reform’s Tortuous Route To The Patient-Centered Outcomes Research Institute*, 29 HEALTH AFF. 1777, 1777-1778 (2009) (providing details about legislative efforts to support CER between 2007 and 2009). Patel notes that CER was supported in the platforms of both Barack Obama and John McCain during the 2008 election. *Id.* at 1778.

²⁴⁰ *Id.*

²⁴¹ S. 1679, 111th Cong. § 219 (2009).

²⁴² *Id.*

²⁴³ Patel, *supra* note 239, at 1779 (noting that Sen. Mike Enzi (R-WY) suggested that the bill created “a new bureaucracy to dictate which treatments you pay for,” other Republicans compared the center to NICE in the United Kingdom, and Republican senators proposed more than twenty amendments to eliminate the center from the bill on the first day of its markup in the HELP Committee).

The first major bill debated by the House was H.R. 3200, “America’s Affordable Health Choices Act of 2009.”²⁴⁴ The bill included CER provisions²⁴⁵ similar to those Democrats had sought (and failed) to include in one of the House’s versions of a reauthorization bill for the Children’s Health Insurance Program in 2007.²⁴⁶ Like the Senate HELP bill, the bill’s Center for Comparative Effectiveness Research would have been located with AHRQ.²⁴⁷ Although there was some dissent among the House Democrats about whether a fully public agency was the best way to support CER, they decided to commit to the model.²⁴⁸ Thus, the health reform bill that ultimately passed by the House on November 7, 2009²⁴⁹ (“House Bill”) called for a center within AHRQ “to conduct, support, and synthesize research . . . with respect to the outcomes, effectiveness, and appropriateness of health care services and procedures in order to identify the manner in which diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically.”²⁵⁰

In contrast, the bill passed by the Senate on December 24, 2009²⁵¹ included the Patient-Centered Outcomes Research Institute (“PCORI”).²⁵² Senate Republicans opposed the PCORI, much as they had opposed the inclusion of CER in the HELP bill, and the United States Preventive Services Task Force amplified their concerns through its

²⁴⁴ H.R. 3200, 111th Cong. (2009).

²⁴⁵ H.R. 3200, 111th Cong. § 1401 (2009).

²⁴⁶ H.R. 3162, 110th Cong. § 904 (2007).

²⁴⁷ *Id.*

²⁴⁸ Patel, *supra* note 239, at 1779.

²⁴⁹ See Carle Hulse and Robert Pear, *Sweeping Health Care Plan Passes House*, N.Y. TIMES, Nov. 8, 2009, at A1.

²⁵⁰ H.R. 3962, 111th Cong. § 1401(a) (2009).

²⁵¹ See Robert Pear, *Senate Passes Health Care Overhaul on Party Line Vote*, N.Y. TIMES, Dec. 25, 2009, at A1.

²⁵² H.R. 3590, 111th Cong. (2009).

release of revised breast cancer screening guidelines while the bill was still pending.²⁵³

Yet, the PCORI remained largely intact through the passage of the ACA and its amendment by the Reconciliation Act.

Section 6301 of the ACA creates the PCORI.²⁵⁴ The statute provides that the purpose of the PCORI is “to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the matter in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations, and the dissemination of research findings with respect to the relative health outcomes, clinical effectiveness, and appropriateness of . . . medical treatments.”²⁵⁵

²⁵³ See Patel, *supra* note 239, at 1780; Op-ed, *Liberals and mammography*, WALL ST. J., Nov. 24, 2009, at A22 (“The flap over breast cancer screening has provided a fascinating insight into the political future of ObamaCare. Specifically, the political left supports such medical rationing even as it disavows that any such thing is happening. . . . [T]he distinction between cost effectiveness and clinical effectiveness will be moot if ObamaCare passes. . . . Americans will simply have to accept that the price of government-run health care in the name of redistributive justice is that patients and their doctors must bow to the superior wisdom of HHS task forces.”). In part, Democrats were able to assuage concerns related to the new guidelines by including a section in the ACA requiring group health insurance plans to cover mammography for women according to the most current guidelines *other than* the controversial guidelines of November 2009. ACA § 1001.

²⁵⁴ This section will be codified in Title XI of the Social Security Act, at 42 U.S.C. § 1301 et seq. (sections (a) and (d)), and 42 U.S.C. § 1320e-1 (section (c)), section 937 of the Public Health services Act, at 42 U.S.C. § 299 et seq. (section (b)), and section 9511 of the Internal Revenue Code of 1986 (sections (e) and (f)).

²⁵⁵ ACA § 6301(a).

Toward this end, the law requires the PCORI to identify research priorities and project agenda, as well as to carry out its agenda through research.²⁵⁶ Methodologically, the statute is flexible; while the statute provides for general methodological standards, the Institute may use a variety of research designs, including randomized trials, observational studies, systematic reviews, and any “other methodologies recommended by the methodology committee” established by the law, if adopted by the Board of the PCORI.²⁵⁷ In order to conduct research, the statute authorizes the Institute to contract with other federal agencies as well as non-governmental entities that conduct research, although the Institute must give preference to contracts with the NIH or AHRQ.²⁵⁸ To contract with the PCORI, a research entity must abide by the agency’s transparency, conflict of interest, methodological, privacy, and ethics requirements.²⁵⁹ The entity must also allow its researchers to publish their findings in peer-reviewed “or other” publications, as long as each researcher has signed a data-use agreement with the PCORI and complies with the Institute’s general peer-review process for original research.²⁶⁰ The statute also grants researchers the flexibility to contract for the inclusion of payment

²⁵⁶ Congress accompanied this delegation of authority with the requirement that the PCORI consider a number of factors, including “disease incidence, prevalence, and burden . . . (with emphasis on chronic conditions), gaps in evidence . . . practice variations and health disparities . . . the potential for new evidence to improve patient health, well-being, and the quality of care.” ACA § 6301(a). In addition, the Institute must also consider the effects of a “health care treatment, strategy, or health” condition on national expenditures. *Id.* With regard to the “patient-centered” aspect of the Institute’s mission, it must also take into account “patient needs, outcomes, and preference,” as well as relevance to decisionmakers. *Id.*

²⁵⁷ *Id.*

²⁵⁸ *Id.*

²⁵⁹ *Id.*

²⁶⁰ *Id.*

of research participants' insurance co-pays and co-insurance, when necessary.²⁶¹ Significantly, the PCORI will have access to data collected by CMS through Medicare, Medicaid, and the Children's Health Insurance Program ("CHIP"), in addition to any registries or databases that the PCORI assists in developing,²⁶² although in using this data the Institute remains bound by existing confidentiality and privacy laws.²⁶³ Along with this access, however, is the requirement that the PCORI must periodically "review and update" its research.²⁶⁴

The PCORI has the general authority to appoint expert advisory panels to help set research priorities and agenda, and it must create such panels to advise the agency with regard to randomized clinical trials and rare diseases (to the extent the Institute undertakes studies of rare diseases).²⁶⁵ The Institute must also create a methodology committee "to develop and improve the science and methods of comparative clinical effectiveness research" by updating "scientifically-based" methodological standards on "internal validity, generalizability, feasibility . . . timeliness of research . . . health outcomes measures, risk adjustment, and other relevant aspects of research and assessment."²⁶⁶ This Committee must consider input from stakeholders, experts, decisionmakers, and the public in developing its standards.²⁶⁷

For oversight, the PCORI is subject to annual financial audits, as well as less frequent audits of its "processes," "dissemination and training activities and data

²⁶¹ *Id.*

²⁶² *Id.* The PCORI's authority to assist in "building data for research" can be found in ACA § 6301(b).

²⁶³ ACA § 6301(a).

²⁶⁴ *Id.*

²⁶⁵ *Id.*

²⁶⁶ *Id.*

²⁶⁷ *Id.*

networks,” its “overall effectiveness,” and the “adequacy and use” of its funds.²⁶⁸ The PCORI must also provide a public comment period before the adoption of its list of research priorities, hold public forums, disclose research findings (including processes and methods), provide notice of public comment periods and publish the comments received during those periods, and also make public some of its proceedings.²⁶⁹ In addition, the Institute is subject to conflict of interest disclosure requirements and a prohibition on gifts or donations.²⁷⁰

Beyond encouraging the publication of original research findings in peer-reviewed journals, Congress also mandated that the PCORI make all research findings “available to clinicians, patients, and the general public.”²⁷¹ These findings must be available in a “manner that is comprehensible and useful to patients and providers in making health care decisions,” and must also “fully convey findings” related to the research’s applicability to subpopulations and its interaction with different risk factors.²⁷² The Institute must also convey the limits of the research and discuss what further research may be necessary.²⁷³ Notably, the PCORI may not include with its research findings “practice guidelines, coverage recommendations, payment, or policy recommendations.”²⁷⁴

To further encourage the diffusion of the results of the PCORI’s federally funded CER, Congress also charged the Office of Communication and Knowledge Transfer

²⁶⁸ *Id.*

²⁶⁹ *Id.*

²⁷⁰ *Id.*

²⁷¹ *Id.*

²⁷² *Id.*

²⁷³ *Id.*

²⁷⁴ *Id.*

(“OCKT”) within AHRQ and the NIH with broad dissemination of the Institute’s research results and other federally sponsored CER.²⁷⁵ The OCKT, specifically, must “create informational tools that organize and disseminate research findings for physicians, health care providers, patients, payers, and policy makers,” as well as “develop a publicly available resources database that collects and contains government-funded evidence and research from public, private, not-for profit, and academic sources.”²⁷⁶ In addition, the OCKT must assist in the “timely incorporation” of disseminated research findings into health information technology (“HIT”) clinical decision support tools.²⁷⁷ The OCKT is also responsible for creating a process to receive feedback from health care providers, consumers, HIT vendors, and insurers on the “value” of the CER information it disseminates.²⁷⁸ Meanwhile, AHRQ and the NIH have the responsibility of training researchers to “build capacity” to conduct CER that meets the methodological requirements of the PCORI, and Congress instructed the Secretary of HHS to coordinate relevant federal agencies in building CER data capacity, with the goal of creating and maintaining a “comprehensive, interoperable data network to collect, link, and analyze data on outcomes and effectiveness from multiple sources.”²⁷⁹

Unlike some provisions in the ACA,²⁸⁰ Congress fully appropriated funds for the PCORI. Section 6301(d) orders a fund transfer from the Federal Hospital Insurance Trust

²⁷⁵ ACA § 6301(b).

²⁷⁶ *Id.*

²⁷⁷ *Id.*

²⁷⁸ *Id.*

²⁷⁹ *Id.*

²⁸⁰ See C. STEPHEN REDHEAD ET AL., CONGRESSIONAL RESEARCH SERVICE, DISCRETIONARY FUNDING IN THE PATIENT PROTECTION AND AFFORDABLE CARE ACT (2010) (describing the provisions of the ACA for which Congress authorized, but did not appropriate, funds).

Fund²⁸¹ and the Federal Supplementary Medical Insurance Trust Fund²⁸² to a “Patient-Centered Outcomes Research Trust Fund.”²⁸³ For fiscal year 2013, the PCORI will receive one dollar times the average number of people “entitled to benefits” under Medicare Part A, or enrolled in the Medicare Part B program.²⁸⁴ Then, in fiscal years 2014 through 2019, the PCORI will receive two dollars times the average number of these beneficiaries.²⁸⁵ The statute also provides for an adjustment in the event of an increase in national health expenditures.²⁸⁶ In addition, Congress directly appropriated \$10 million for fiscal year 2010, \$50 million for fiscal year 2011, and \$150 million for fiscal year 2012.²⁸⁷ For fiscal years 2013 through 2019, the Institute will receive \$150 million plus the net revenues from an annual fee on health insurance and self-insurance²⁸⁸ plans.²⁸⁹ Lastly, Congress established the PCORI as a tax-exempt government corporation under section 501(l) of the Internal Revenue Code.²⁹⁰

The controversial political climate surrounding CER exerted influence over the structure of PCORI in a number of ways. First, to address concerns that the ACA’s use

²⁸¹ 42 U.S.C. § 1395i (2006).

²⁸² 42 U.S.C. § 1395t (2006).

²⁸³ ACA § 6301(d).

²⁸⁴ *Id.*

²⁸⁵ *Id.*

²⁸⁶ *Id.*

²⁸⁷ ACA § 6301(e).

²⁸⁸ Self-insurance occurs when a (typically large) employer provides health “insurance” for its employees by paying for their health care costs. Due to the Employee Retirement Income Security Act (“ERISA”), self-insured employers avoid state insurance regulations. *See generally* Jon R. Gabel et al, *Self-Insurance In Times Of Growing And Retreating Managed Care*, 22 HEALTH AFF. 202, 202-204 (2003).

²⁸⁹ ACA § 6301(e)(1). Section 6301(e)(2) imposes on each insurance or self-insurance policy a fee of \$2 times “the average number of lives covered under the policy.”

²⁹⁰ ACA § 6301(f).

of CER will mimic that of NICE in the United Kingdom,²⁹¹ the PCORI is prohibited from using Quality Adjusted Life-years (“QALYs”)²⁹² “as a threshold to determine what type of health care is cost effective or recommended . . . [or] to determine coverage, reimbursement, or incentive programs.”²⁹³ The statute also prohibits the Secretary of HHS from using CER findings to make Medicare coverage decisions “in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, non-disabled, or not terminally ill.”²⁹⁴ The Secretary of HHS also may not use the findings “in a manner that precludes, or with the intent to discourage, an individual from choosing a health care treatment based on how the individual values the tradeoff between extending the length of their life and the risk of disability.”²⁹⁵ Although Congress tempered these restrictions with provisions that allow Medicare coverage determinations to be informed by differences in comparative effectiveness between treatments with regard to extending life due to “age, disability, or terminal illness” or setting differential copayments “based on factors such as cost or type of service,”²⁹⁶ the legislature clearly sought to send a strong message with regard to limits on federal use of CER findings.

²⁹¹ Iglehart, *supra* note 222, at 1758 (“During US health care reform, QALYs quickly became more code language for government-run health care systems and rationing.”).

²⁹² “A QALY gives an idea of how many extra months or years of life of a reasonable quality a person might gain as a result of treatment.” “Measuring Effectiveness and Cost Effectiveness: the QALY,”

<http://www.nice.org.uk/newsroom/features/measuringeffectivenessandcosteffectivenessstheqaly.jsp> (last visited March 30, 2011). For more information, *see generally* Peter J. Neumann and Dan Greenberg, *Is The United States Ready For QALYs?*, 28 HEALTH AFF. 1366 (2009).

²⁹³ ACA § 6301(c), to be codified at 42 U.S.C. § 1320e-1(e).

²⁹⁴ *Id.*

²⁹⁵ *Id.*

²⁹⁶ *Id.*

Second, to assuage fears about CER inhibiting medical treatment innovation,²⁹⁷ the 21-member board of PCORI must be filled with members from a set of stakeholder interest groups, including industry and researchers.²⁹⁸ Industry lobbyists also successfully persuaded Congress to include a provision allowing the board to prohibit the agency from contracting with a researcher for at least five years if research published under a previous contract with PCORI was not “within the bounds of and entirely consistent with evidence and findings produced under the contract with the Institute.”²⁹⁹ Congress, however, struck this section from the final bill before it passed.³⁰⁰

Third, a coalition of unions and employee advocates persuaded Congress to include a “real conflict of interest” disclosure requirement³⁰¹ for PCORI board members.³⁰² Section 6301 includes two defined conflict of interest terms. Under the statute, a “conflict of interest” is “an association, including a financial or personal

²⁹⁷ Iglehart, *supra* note 222, at 1759.

²⁹⁸ ACA § 6301(c), to be codified at 42 U.S.C. § 1320e(f). The complete list of mandatory stakeholder membership includes the Directors of AHRQ and the National Institutes of Health (“NIH”), three representatives of health care consumers, seven representatives of health care providers (including four physicians with at least one surgeon included in that group, one nurse, one integrative health care practitioner, and a hospital), three representatives of private payers (at least one representative of a health insurance issuer and one representative of a self-insured employer), three representatives of the pharmaceutical, device and diagnostic manufacturing industries, one representative of quality improvement or independent health service researchers, and two representatives of the federal or state governments, at least one of which must represent a federal health program or agency.

²⁹⁹ Pub. L. 111-148, 124 Stat. 119 § 6301(a) (2010); *see* Harry P. Selker and Alastair J.J. Wood, *Industry Influence on Comparative-Effectiveness Research Funded through Health Care Reform*, 361 *NEW ENG. J. MED.* 2595, 2596 (2009) (“To allow scientists . . . to be punished for the publication of work that is not approved by this entity is essentially to cede authority over the dissemination of government-funded research to a body that is at least partially controlled by persons with a potential commercial interest in its outcome.”).

³⁰⁰ Pub. L. 111-148, 124 Stat. 119 § 10602(1)(B) (2010).

³⁰¹ ACA § 6301(c), to be codified at 42 U.S.C. § 1320e(f)(2).

³⁰² Iglehart, *supra* note 222, at 1759-1760.

association, that [has] the potential to bias or have the appearance of biasing an individual’s decisions in matters related to the Institute or the conduct of activities under” section 6301.³⁰³ In contrast, a “real conflict of interest” is “any instance where a member of the Board, the methodology committee . . . or an advisory panel . . . or a close relative of such member, has received or could receive either . . . a direct financial benefit of any amount deriving from the result or findings of a study conducted under” section 6301 or “a financial benefit from individuals or companies that own or manufacture medical treatments, services, or items to be studied . . . that in the aggregate exceeds \$10,000 per year” including “honoraria, fees, stock, or other financial benefit and the current value of the member or close relative’s already existing stock holdings, in addition to any direct financial benefit deriving from the results or findings of a” PCORI study.³⁰⁴

Fourth, section 6301 includes rules of construction that make it clear the Institute may not “mandate coverage, reimbursement, or other policies for any public or private payer” or prevent “the Secretary [of HHS] from covering the routine costs of clinical care received by” Medicare, Medicaid, or CHIP beneficiaries.³⁰⁵ Further, the Secretary of HHS may only use the PCORI’s research findings to make Medicare coverage determinations after an “iterative and transparent process which includes public comment and considers the effect on subpopulations,”³⁰⁶ and section 6301 does not alter the coverage of “reasonable and necessary” treatments or allow the Secretary to deny coverage “solely on the basis of” CER.³⁰⁷

³⁰³ ACA § 6301(a).

³⁰⁴ *Id.*

³⁰⁵ ACA § 6301(a).

³⁰⁶ ACA § 6301(c).

³⁰⁷ *Id.*

In the fall of 2010, the Comptroller General appointed 19 members to the PCORI Board.³⁰⁸ The Board met once in 2010, and plans to meet six times in 2011, in locations throughout the United States.³⁰⁹ The PCORI has also established a Program Development Committee,³¹⁰ a Public Affairs and Communications Committee,³¹¹ and a Methodological Committee.³¹² Thus, it remains too early to discern the agencies initial actions and priorities, although the findings of the IOM and the Federal Coordinating Council reports ordered by ARRA³¹³ may provide some limited hints about the agency's future direction.

IV. Opportunities and Challenges for the Future

Although the significant investments in CER included in ARRA and the ACA present an important opportunity to facilitate CER through carefully designed involvement by the federal government, the path forward is sure to include a number of challenges. Some of those challenges are technical. Existing CER infrastructure is fragmented,³¹⁴ the government does not currently have a database that would provide a systematic way for researchers and the public to access federal CER studies, and it is thus

³⁰⁸ For the current membership of the Board, *see* U.S. GAO – Current Membership of the Patient-Centered Outcomes Research Institute (PCORI) Governing Board, http://www.gao.gov/about/hcac/pcori_members.html (last visited March 30, 2011).

³⁰⁹ *See* Patient-Centered Outcomes Research Institute Meetings, <http://www.pcori.org/meetings.html> (last visited March 30, 2011).

³¹⁰ *See* PROGRAM DEVELOPMENT COMMITTEE, REPORT TO PCORI (2011), *available at* http://pcori.org/images/PDC_Report_03-07-2011.pdf.

³¹¹ *See* PUBLIC AFFAIRS AND COMMUNICATIONS COMMITTEE REPORT (2011), *available at* http://www.pcori.org/images/PACC_Report_03-08-2011.pdf.

³¹² *See* REPORT FROM THE METHODOLOGY COMMITTEE TO THE BOARD OF GOVERNORS (2011), *available at* http://www.pcori.org/images/MC_Report_03-08-2011.pdf.

³¹³ *See supra* section III(b)(2).

³¹⁴ *See* FEDERAL COORDINATING COUNCIL FOR COMPARATIVE EFFECTIVENESS RESEARCH, *supra* note 228, at 33.

not even clear how many of such studies exist.³¹⁵ Commentators have called for the creation of a universal, standardized database to include all clinical trial and research data sets, including a rapid-learning, open database for CER studies,³¹⁶ and a National Patient Library to make available to the public the results of federally funded CER.³¹⁷ A clearinghouse for information about federal investment in CER would also be helpful to ensure that spending matches identified priorities and goals.³¹⁸ Regardless of its form, it is clear that some sort of centralized database that organizes and provides access to information about sponsored CER studies and their results will be a necessary first step toward measuring the success of the government’s initiatives and disseminating research results.

Other challenges will be methodological and evidentiary. Although the ACA requires the PCORI’s methodological standard to “provide specific criteria for internal validity, generalizability, feasibility, and timeliness,” this standard governs the research and analysis itself.³¹⁹ In contrast, an evidentiary standard would govern the decision about what type of study (such as a controlled trial) to require of sponsored studies.³²⁰ Because there are several ways to conduct CER, including systematic reviews of existing evidence, meta-analyses, experimental studies (including randomized control trials), and

³¹⁵ FEDERAL COORDINATING COUNCIL FOR COMPARATIVE EFFECTIVENESS RESEARCH, *supra* note 228, at 29 (noting that while AHRQ tracks its funding and studies, there is no standard way to identify CER funded through the NIH). For a chart of existing research “person-level” research databases within the federal government, *see id.* at 64-68.

³¹⁶ Etheredge, *supra* note 104, at 1763-1764.

³¹⁷ Jeffrey C. Lerner et al., *The Case For A National Patient Library*, 29 HEALTH AFF. 1914 (2010).

³¹⁸ Benner, *supra* note 235, at 1774.

³¹⁹ Garrison et al., *supra* note 15, at 1816.

³²⁰ *Id.* For a general overview of some methods of conducting CER, see 2007 CBO REPORT, *supra* note 84, at 20-25.

non-experimental studies (including retrospective and prospective observational studies),³²¹ this is not necessarily a simple decision.³²² Although randomized clinical trials are the most rigorous form of research, they are expensive and time consuming, and their traditional form may require some modification to become more suitable for CER.³²³ In addition, it will be necessary to establish realistic expectations for the timeline and costs of CER, regardless of which research methods the PCORI endorses. Because CER studies may need to have large sample sizes in order to produce significant results about different types of patients, and it may take a long time to fully observe important long-term outcomes, CER may be more costly and time-consuming than other forms of research.³²⁴ In order to fully evaluate the success of the PCORI, it will be important to balance the need for aggressive efforts to generate research findings as quickly as possible with realistic expectations about the time needed to achieve high quality results.

The PCORI, and the range of entities that are likely to use its research, will also have to decide whether to set an evidentiary standard for sponsored CER. The FDA, for example, requires “substantial evidence,” typically based on at least two major double-

³²¹ Nancy A. Dreyer et al., *Why Observational Studies Should Be Among The Tools Used In Comparative Effectiveness Research*, 29 HEALTH AFF. 1818, 1818 (2010).

³²² See Dreyer, *supra* note 321, at 1820-1822 (proposing “criteria for determining which type of study to employ” in different circumstances); see also Rachael L. Fleurence et al., *The Critical Role Of Observational Evidence In Comparative Effectiveness Research*, 29 HEALTH AFF. 1826 (2010) (comparing the benefits and flaws in observational studies and randomized trials); Elshaug and Garber, *supra* note 49, at 1392 (noting that well-designed observational studies have potential to generate information about subgroups excluded from clinical trials, although randomized trials remain important under certain circumstances).

³²³ See generally Bryan R. Luce et al., *Rethinking Randomized Clinical Trials for Comparative Effectiveness Research: The Need for Transformational Change*, 151 ANNALS INTERNAL MED. 206 (2009).

³²⁴ McClellan and Benner, *supra* note **Error! Bookmark not defined.**, at 9.

blind and randomized trials (or one with supporting evidence in some circumstances) to approve a new drug or biological,³²⁵ and a similar standard applies to comparative-effectiveness claims about such products.³²⁶ Other standards apply to other products, and the applicable evidentiary standard, in practice, has depended on “the novelty of the product, the medical need for new therapies for the target condition, and what is known about the product’s effectiveness relative to its risks,” with lower standards applied to treatments that have potential to serve an important unmet need, and higher standards applied to products that seem comparable to approved products or that have an uncertain safety profile.³²⁷ Even for agencies like the FDA, however, that have relatively strict and clear evidentiary standards, expert judgment is still necessarily used to evaluate the evidence.³²⁸ One set of authors has recommended that the PCORI qualify its research by describing its “relative value” based on an estimation of the value of more research on the subject.³²⁹ Regardless of what standard that the PCORI adopts, the credibility of research findings disseminated by the agency would be bolstered by the use of a consistent

³²⁵ Garrison et al., *supra* note 15, at 1813.

³²⁶ See 21 C.F.R. § 202.1(e)(6)(ii) (defining false and misleading advertisements to include comparative claims not supported by “substantial evidence” or “substantial clinical experience”); see also 21 U.S.C. § 355(d) (2006) (section 505 of the Food Drug and Cosmetic Act, which defines “substantial evidence” as “evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof”); 21 C.F.R. § 314.126 (defining “adequate and well-controlled studies” for the purpose of determining whether a claim of efficacy is supported by “substantial evidence” under section 505 of the Food, Drug and Cosmetic Act); 21 C.F.R. § 202.1(e)(4)(ii)(c) (defining “substantial clinical experience”).

³²⁷ Garrison et al., *supra* note 15, at 1814.

³²⁸ *Id.*, at 1815.

³²⁹ *Id.*, at 1814.

measure qualifying the strength of new evidence.³³⁰ Such a standard would assist providers and consumers in evaluating whether to change their current practices, and would provide important context for the new findings.

An additional issue facing the PCORI and other efforts to expand CER is research capacity. A recent study found that the United States has “little or no excess capacity” to conduct additional clinical trials, based on constraints in the supply of both patients and investigators.³³¹ Thus, any expansion in clinical trial-based CER is likely to require the diversion of resources from other research, expanded research capacity through improved efficiency, or increased incentives for investigators and participants to engage in CER.³³² Existing health information privacy rules are also likely to make it difficult to conduct CER using existing patient data (for example, information included in electronic health records),³³³ although some databases of patient-level information to be used for observational studies do exist.³³⁴ In this way, evolving privacy rules and standards for the use of patient information aggregated through health information technology will play a key role in the future of CER.

³³⁰ See Cynthia D. Mulrow and Kathleen N. Lohr, *Proof and Policy from Medical Research Evidence*, 26 J. HEALTH POL., POL'Y & L. 249, 254-259 (2001).

³³¹ Robert B. Griffin and Janet Woodcock, *Comparative Effectiveness Research: Who Will Do The Studies*, 29 HEALTH AFF. 2075, 2076, 2078 (2010) (arguing for the creation of a “federally funded national research infrastructure” that would “provide a mechanism for community-based clinicians to participate in clinical trials” in a less burdensome way and would “reduce the redundancy and inefficiency intrinsic to the ‘cottage industry’ nature of the clinical research process.”).

³³² *Id.*

³³³ See generally Douglas Peddicord et al., *A Proposal To Protect Privacy Of Health Information While Accelerating Comparative Effectiveness Research*, 29 HEALTH AFF. 2082 (2010).

³³⁴ See, e.g., Wilson D. Pace et al., *An Electronic Practice-Based Network for Observational Comparative Effectiveness Research*, 151 ANNALS INTERNAL MED. 338 (2009) (describing the AHRQ-funded Distributed Ambulatory Research in Therapeutics Network).

What is likely to be more challenging than technical and methodological issues, however, will be difficulties associated with realizing the much-touted benefits of CER, including cost control,³³⁵ through widespread adoption of the research's results by health care providers and consumers.³³⁶ Although some federal agencies that conducted CER before ARRA and the ACA have sought to translate their studies into usable information for health care patients and providers,³³⁷ outside of the agencies that conduct research in

³³⁵ See McClellan and Benner, *supra* note **Error! Bookmark not defined.**, at 14 (linking cost control with goals of conducting “high value” research, developing a “robust research infrastructure,” and creating mechanisms “to promote the appropriate use of new evidence in clinical practice and health policy in a timely way”).

³³⁶ In the face of this problem, a new field, “implementation science,” which is the study of methods to promote incorporation of research findings and evidence-based medicine into real-world practice, has emerged. See generally Ann C. Bonham and Mildred Z. Solomon, *Moving Comparative Effectiveness Research Into Practice: Implementation Science And The Role Of Academic Medicine*, 29 HEALTH AFF. 1901, 1902-1903 (2010). Early information from this science suggests four important considerations for the purpose of information dissemination: “the characteristics of the intervention will influence whether clinicians and patients adopt and sustain a new practice. . . . the mindset of people who are expected to implement the new practice is critical the context in which clinicians practice shapes their willingness and ability to adopt new practices . . . [and] the process by which change is implemented can determine whether it is successful.” Atkins, *infra* note 345, at 1908. Thus, factors including the strength of the evidence, its degree of “relative advantage” in terms of time, ease, or profitability, local culture, patient expectations, support for providers changing practice, and the use of a consensus-building process can affect the adoption of the information. *Id.* “Making it easy to do the right thing” thus becomes critically important. *Id.* at 1911. See also Naik and Petersen, *supra* note 199, at 1931 (calling for an “implementation research and development program” to “accelerate the translation of evidence into everyday care, enhance the opportunities for doctors and patients to define value . . . on the basis of their understanding of local contexts and constraints, and allow providers and patients to communicate with researchers and policymakers about clinically important issues earlier in the research process.”).

³³⁷ For example, AHRQ publishes a number of guides on its website that provide summaries of, and recommendations related to, CER studies, and also partners with professional societies, non-profit organizations, and patient advocacy groups to disseminate its findings. See FEDERAL COORDINATING COUNCIL FOR COMPARATIVE EFFECTIVENESS RESEARCH, *supra* note 228, at 35;

connection with directly providing care (like the VHA),³³⁸ dissemination and adoption remain a challenge.³³⁹

In order to ensure that the results of subsidized comparative effectiveness studies reach their target audiences, it is important to incorporate dissemination plans into study design.³⁴⁰ Furthermore, to permanently improve channels for the diffusion of new comparative effectiveness information, it may also be helpful to improve continuing education programs for health care providers,³⁴¹ incorporate the information into health information technology systems,³⁴² and to address marketing for medical treatments.³⁴³ As discussed above, publicly available library of CER results could also help disseminate new information to health care providers and consumers.³⁴⁴ Regardless of how the PCORI or other entities seek to diffuse CER information, however, it is crucial that the information disseminated is relevant to the needs of consumers and providers, in terms of its applicable populations and settings, its comparison to relevant alternative treatments,

³³⁸ FEDERAL COORDINATING COUNCIL FOR COMPARATIVE EFFECTIVENESS RESEARCH, *supra* note 228, at 35; *see, e.g.*, AHRQ: Comparing Medical Treatments subdirectory, <http://www.ahrq.gov/consumer/compare.html> (last visited March 30, 2011). The Center for Disease Control (“CDC”), the DoD, the Substance Abuse and Mental Health Services Administration, the FDA, the Office of Public Health and Science, Office of the National Coordinator for Health Information Technology, and the Health Resources and Services Administration are also involved, to various degrees, in efforts to disseminate research findings. *See* FEDERAL COORDINATING COUNCIL FOR COMPARATIVE EFFECTIVENESS RESEARCH, *supra* note 228, at 36-38.

³³⁹ *See supra* notes 195-198 and accompanying text.

³⁴⁰ Avorn, *supra* note 22, at 1895.

³⁴¹ *See* Bonham and Solomon, *supra* note 336, at 1903 (advocating for academic medicine to play an active role in pushing for the dissemination of CER results).

³⁴² Atkins, *infra* note 345, at 1908.

³⁴³ Avorn, *supra* note 22, at 1896.

³⁴⁴ *See* Lerner, *supra* note 317.

and its consideration of patient preferences.³⁴⁵ It is also likely to be much easier to diffuse CER results when those results are published before widespread adoption of a new technology,³⁴⁶ so it will be important for the PCORI to time its studies of new technologies aggressively.

In addition to delays associated with inertia and challenges associated with disseminating information among a large and diverse population, to the extent that economic incentives either discourage or do not facilitate rapid adoption, diffusion will be all the more difficult. Economic incentives favoring the diffusion of CER findings could derive from the inclusion of research findings in private insurance coverage design³⁴⁷ or through incorporation into the Medicare or Medicaid coverage rules.³⁴⁸ Because the ACA includes strict limits on how the Secretary of HHS may use CER to inform Medicare coverage for specific treatments,³⁴⁹ however, widespread consideration of CER results in insurance coverage design may proceed more slowly than if Medicare were to have authority to lead the way more forcefully.

Even before the passage of the ACA, the structure of Medicare (and Medicaid, to a lesser extent) was not conducive to the inclusion of CER in coverage decisions.

³⁴⁵ See David Atkins et al., *The Veterans Affairs Experience: Comparative Effectiveness Research In A Large Health System*, 29 HEALTH AFF. 1906, 1907-1908 (2010).

³⁴⁶ Alexander and Stafford, *supra* note 22, at 2488; see also Elshaug and Garber, *supra* note 49, at 1392.

³⁴⁷ See generally James C. Robinson, *Comparative Effectiveness Research: From Clinical Information To Economic Incentives*, 29 HEALTH AFF. 1788 (2010) (describing the mechanisms by which private insurers could incorporate CER into their plans).

³⁴⁸ See Steven D. Pearson and Peter B. Bach, *How Medicare Could Use Comparative Effectiveness Research In Deciding On New Coverage And Reimbursement*, 29 HEALTH AFF. 1796 (2010).

³⁴⁹ ACA § 6301(c). Notably, the statute “does not discourage researchers from measuring QALYs or other comprehensive health outcome metrics.” Alan M. Garber and Harold C. Sox, *The Role Of Costs In Comparative Effectiveness Research*, 29 HEALTH AFF. 1805, 1807 (2010).

Medicare is statutorily required to cover only “reasonable and necessary” treatments,³⁵⁰ a standard which does necessarily include comparative or cost effectiveness information.³⁵¹ An effort in 2000 to publish a rule that would require new covered treatments to “add value” failed.³⁵² Furthermore, most Medicare coverage decisions are made on a local level,³⁵³ and because of the program’s prospective payment system, Medicare does not make an explicit coverage determination for most treatments.³⁵⁴ In combination with the fact that Medicare payment rates for a given treatment are roughly cost-based,³⁵⁵ use of

³⁵⁰ Social Security Act § 1862, codified at 42 U.S.C. § 1395y(a) (2006). The test used in local coverage determinations asks whether a treatment is: (1) “safe and effective; (2) not experimental or investigational;” and (3) “appropriate” (i.e. “furnished in accordance with accepted standards of medical practice, furnished in an appropriate setting, ordered or furnished by qualified personnel, able to meet but . . . not exceed, the patient’s medical needs, [and] at least as beneficial as an existing and available medically appropriate alternative.” JOST, *supra* note 168, at 212. In theory, these decisions are supposed to be based on published studies that included randomized control trials or “other definitive study methodologies,” but in practice, factors such as the medical standard of care or consensus play a role when such studies are not available. *Id.* at 212-213. CMS uses a different process for national coverage decisions, but this process lacks clear written criteria. *Id.* at 214-219. See generally Jacqueline Fox, *The Hidden Role of Cost: Medicare Decisions, Transparency and Public Trust*, 79 U. CIN. L. REV. 1 (2011) (criticizing the national coverage decision process); see also *id.* at 8 (noting that although CMS does not have authority to decline to cover a treatment due to its cost, the fact that Medicare operates within a budget set by Congress and Congress must raise revenue to cover increased costs “creates an incentive for CMS to control cost without appearing to violate the law, and provides Congress with an incentive to loosely examine CMS’s cost-saving decisions”).

³⁵¹ Pearson and Bach, *supra* note 348, at 1196-197 (noting the fragmented ways by which the federal government makes Medicare coverage decisions: a single national decision, “a series of separate determinations made by the medical directors of independent contractors in different regions of the country,” through a Congressional mandate, or by non-governmental third parties).

³⁵² 2007 CBO REPORT, *supra* note 84, at 31-32.

³⁵³ See generally JOST, *supra* note 168, at 212-213.

³⁵⁴ See generally *id.* at 210.

³⁵⁵ Pearson and Bach, *supra* note 348, at 1798.

CER by CMS to create economic incentives favoring evidence-based care is quite limited.³⁵⁶

Thus, when the existing Medicare coverage regime is combined with the limits created by the ACA, it becomes clear that a fundamental redesign would be necessary to fully encourage and support use of comparative effectiveness information by health care providers who participate in the Medicare program.³⁵⁷ Because of the roles states play in administering the Medicaid program, universal incorporation of CER results into that program would be complex as well.³⁵⁸ At least in the near term, the lack of political will for such redesign is likely to be a barrier. A 2010 public opinion poll found that while Americans strongly support use of CER to provide additional information to support medical decisionmaking, only approximately half of those polled supported use of comparative-effectiveness information to determine public and private insurance coverage for treatments, and more than sixty percent of respondents opposed using the information to charge patients more for choosing treatments found to be comparatively ineffective.³⁵⁹ In combination with a 2009 poll in which respondents found arguments against the use of evidence-based treatment guidelines to be more persuasive than

³⁵⁶ See Pearson and Bach, *supra* note 348, at 1797-1798 (describing Medicare “coverage” and “reimbursement” as “separate silos” that “demonstrate the arcane complexity of decades of ad hoc updates with no fundamental redesign.”).

³⁵⁷ See, e.g., *id.* at 1798-1800 (proposing a reform to Medicare whereby coverage and reimbursement determinations would be made based on categorizing a new treatment as having “superior effectiveness,” “comparable effectiveness” or “insufficient evidence”); see also 2007 CBO REPORT, *supra* note 84, at 31; Orszag, *supra* note 91, at 18-19.

³⁵⁸ Orszag, *supra* note 91, at 19-20.

³⁵⁹ Alan S. Gerber et al., *The Public Wants Information, Not Board Mandates, From Comparative Effectiveness Research*, 29 HEALTH AFF. 1872, 1874-1875 (2010).

arguments in favor of the guidelines,³⁶⁰ this underscores the reality that even though the PCORI survived the political battle over the ACA, political challenges are likely to play a continuing role in the use of CER resulting from the law.

Furthermore, even if the federal government found a politically feasible way to tie Medicare reimbursement with the findings of CER, it is far from clear that this would result in overall cost savings in the program. Due to the ability of health care providers to offset decreases in fees through increased volume, known as “supplier induced demand” or the “volume response hypothesis,”³⁶¹ savings resulting from CER might be offset by increased expenditures in other areas.³⁶² Even absent this effect, it can take a long time to conduct, analyze, and disseminate the findings of CER, and any significant cost savings resulting from CER are likely to be at least a decade away.³⁶³ Thus, political support for the research is likely to unravel if solely based on the prospect of cost savings, and particularly near-term cost savings. Yet, based on the experiences of the governments of

³⁶⁰ Alan S. Gerber et al., *A National Survey Reveals Public Skepticism About Research-based Treatment Guidelines*, 29 HEALTH AFF. 1882 (2010) (finding that the most support for the statement that “no outside group should come between doctors and patients in making treatment decisions”).

³⁶¹ See generally Morris L. Barer et al., *Fee Controls as Cost Control: Tales from the Frozen North*, 66 MILIBANK Q. 1, 38-46 (1988); see also Miriam J. Laugesen, *Siren Song: Physicians, Congress, and Medicare Fees*, 34 J. HEALTH POL., POL’Y & L. 157, 162-164 (2009) (describing the historical interaction between this characteristic of physician reimbursement and Medicare policy).

³⁶² See also Elshaug and Garber, *supra* note 49, at 1392 (noting that some of the savings associated with CER might be reduced if providers replace discredited treatments with other costly treatments).

³⁶³ 2007 CBO REPORT, *supra* note 84, at 30; see also Orszag, *supra* note 91, at 16 (“Getting to the point where additional research on comparative effectiveness could have a noticeable impact on health spending would itself take several years. . . . Initially, the available results would probably address a relative small number of medical treatments and procedures; additional time would have to elapse before a substantial body of results amassed. And in areas of medicine that involve significant levels of spending, several studies could be needed before a consensus emerged about the appropriate conclusions to be drawn – even if those studies did not generate conflicting results.”).

other countries that have funded CER,³⁶⁴ if the PCORI survives, pressure may mount for the agency to explicitly consider cost information in addition to comparative effectiveness,

As was seen in the controversy surrounding the AHCPR in the 1990s,³⁶⁵ any attempt to combine health care research and policy efforts can be politically hazardous. While the ACA ostensibly did not provide the PCORI with general policymaking authority, the inherent policy implications of CER that pervade section 6301 suggest that the PCORI may face similar challenges. Observers have noted that the AHCPR faced political opposition both because there was a high risk that it would fail to meet high, and “arguably naïve,” expectations, and because it tackled issues related to the distribution of health care dollars, which created political enemies of the endeavor.³⁶⁶ Moreover, close identification with a president’s health policy agenda, while demonstrating an agency’s relevance, can also foster political opposition.³⁶⁷ Lastly, in order for a health research agency to remain viable, it must have a relatively stable constituency of supporters to lobby the political branches on its behalf, which is challenging for forms of research, like CER, that are not well understood and do not necessarily have as discrete a group of supporters as, for example, cancer research conducted through the NIH.³⁶⁸

The PCORI is likely to encounter these same problems. While proponents of CER are right to point to the research’s vast potential to improve health care quality and perhaps lower costs, achieving those goals is sure to be challenging. Particularly with

³⁶⁴ See *supra* note 159, and accompanying text.

³⁶⁵ See *supra* notes 173-183 and accompanying text.

³⁶⁶ Gray, *supra* note 176, at 304.

³⁶⁷ *Id.* at 304-305.

³⁶⁸ See *id.*, at 305.

regard to CER's potential to lower costs, it is naïve to imagine that the PCORI, or any other public or private entity, will alone be able to offer a solution when so many others have failed. Health care cost control is a distributional issue, and in order to save taxpayers and private payers money, someone, whether drug and device manufacturers, physicians, hospitals, or insurance companies, will have to lose money.³⁶⁹ This problem is exacerbated by the fact that the benefits of CER accrue to the entire population, while the costs are highly concentrated among a discrete group of stakeholders.³⁷⁰ Thus, if the political will to resist pressure from powerful financial stakeholders is absent, there is little reason to imagine that the PCORI's research will have much cost-saving effect. Yet, because of the lofty expectations placed upon the agency and the idea of CER, this failure is likely to contribute to political arguments against the PCORI. That is to say that CER proponent's unrealistic claims about the research's potential may not be doing the issue any favors. Furthermore, the fact that the PCORI will be closely tied, at least for the foreseeable future, with a controversial health reform law, is also likely to contribute to the agency's political fragility.

It is worth re-emphasizing that the survival of the PCORI hinges on its ability to achieve the overt support of those who have potential to benefit from its research, which is anyone who uses health care products and services. To reach these constituents, however, the agency will have to expand public understanding of CER, as well as work to dispel fears about the research interfering with the physician-patient relationship or unduly influencing insurance benefits. Even if the PCORI is successful in increasing its

³⁶⁹ See Eugene C. Rich, *The Policy Debate over Public Investment in Comparative Effectiveness Research*, J. GEN. INTERNAL MED. 752, 753 (2009).

³⁷⁰ See Theodore R. Marmor et al., *The Politics of Medical Inflation*, 1 J. HEALTH POL., POL'Y & L. 69, 73-74 (1976).

public support, however, it is unclear whether any level of broad public support could overcome the concentrated opposition of a smaller group of financial stakeholders. The results of the PCORI's CER studies thus may not be enough to have a significant impact on rising health care costs in the United States absent additional major reform of the health care system.

The arguments in favor of government support for CER are robust. While private efforts to compare medical treatments are important and should be encouraged, there is little evidence to suggest that the private sector alone is well suited to meet the informational needs of the health care system as a whole. Not only are private efforts likely to be fragmented, duplicative and of limited accessibility to the general public,³⁷¹ but they have so far left most medical treatments unevaluated.³⁷² This tracks the reality that CER is a public good, for which the government can play an important role in increasing the supply to an efficient level.³⁷³

Yet, some criticisms of CER have served a constructive purpose in ensuring that advocates are not blind to problems associated with the research. Concerns about the interaction between CER and personalized medicine,³⁷⁴ for example, may have contributed to the ACA's conception of the research as helping to identify which treatments work best for which groups of patients under which circumstances, rather than pure head-to-head comparisons that may miss important nuances in treatment suitability.³⁷⁵ Moreover, while it can be frustrating for those who believe in the potential

³⁷¹ Wilensky, *supra* note 83, at w722.

³⁷² *See supra* note 91.

³⁷³ *See supra* notes 83-88 and accompanying text.

³⁷⁴ *See supra* notes 34-35.

³⁷⁵ *Cf. Fox, supra* note 350, at 34-36 ("CER can be useful, but it is extremely complex

of CER to control costs that Congress has imposed such high barriers to the incorporation of research findings into the design of public insurance programs, those barriers may serve to decrease the harm that might be caused by premature adoption of uncertain research findings.³⁷⁶ Finally, in the words of former Congressional Budget Office Director Peter Orszag, “moving the nation toward” a future of lower health care costs and better outcomes “will inevitably be an iterative process in which policy steps are tried, evaluated, and reconsidered.”³⁷⁷ Thoughtful analysis and criticism of the government’s CER endeavors plays an important role in that process.

Ultimately, perhaps the most valuable aspect of the federal government’s recent investment in CER is its potential to alter the norms surrounding medical innovation. While innovation in medical treatments is crucially important to efforts to improve both health and health care services in the United States, innovation itself has no inherent value. Rather, the value of medical innovation comes from its ability to offer improvement relative to the status quo.³⁷⁸ Of course, some failure, both in the form of treatments that do not work and treatments that are less effective than alternatives, is inherent to the process of medical innovation. The answer to that aspect of innovation is not to allow less effective innovations to indefinitely remain part of standard medical

and potentially problematic to implement recommendations based on its results. CER's usefulness depends on a fairly sophisticated level of understanding regarding the meaning of its results and how to use that information. It may be that this complexity is what raises such significant public concerns. . . . The challenge with the information available from CER is to resist over-simplifying, that is, reaching for an easy decision about medical treatments when the data alone does not justify that response.”).

³⁷⁶ See *supra* notes 41-42 and accompanying text.

³⁷⁷ Orszag, *supra* note 91, at 2.

³⁷⁸ Cf. Sean Palfrey, *Daring to Practice Low-Cost Medicine in a High-Tech Era*, 364 NEW ENG. J. MED. e21(1) (2011).

practice, but to continuously study and refine our ideas about which treatments work best under what circumstances, and then to act on that knowledge.

Thus, rightly or wrongly, the number of drugs and devices that can meet the FDA's market entry requirements provides an incomplete picture of the state of medical innovation, and fails to alone incentivize the type of innovation that will move health care in the United States forward. In this way, even if the PCORI is unable to unilaterally transform the United States health care system by enforcing adherence to evidence-based best practices, it may succeed in transforming and improving the standards to which new medical treatments are held, even if the new standards are not firmly binding. To the extent that individuals and institutions are willing to use the data and information provided by the PCORI to hold medicine to standards that are both higher and better aligned with patient interests, then the ACA's experiment with enhanced federal support for CER will have been a success.