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ARTICLE

HEALTH CARE REFORM'S WILD CARD: THE UNCERTAIN EFFECTIVENESS OF COMPARATIVE EFFECTIVENESS RESEARCH

RICHARD S. SAVER[†]

Comparative effectiveness research (CER) stands out as the intriguing wild card of health care reform. CER compares competing treatments against each other to determine which interventions work best, supplying critical information for medical decisionmaking and health policy. If CER works as planned, it may be one of the few reform measures in the final health care legislation that could flatten the cost curve while also improving quality. Unfortunately, health care reform has so far failed to bet smart and play the CER wild card effectively. While the Patient Protection and Affordable Care Act invests in CER at record levels and creates an entirely new regulatory framework for oversight of the research, the new law does very little to advance the difficult work of translating CER into actual medical practice. First, CER is costly to conduct and its data often raise more questions than answers. Second, the government's CER agenda seems vague and ill-defined, not consistently focusing on generating research that will help clinicians resolve immediate treatment questions. Third, and most important, physicians likely will remain indifferent to and "tune out" CER. Health law and policy are not setting the right incentives for physicians to adapt their practice patterns to CER and, in some respects, exacerbate the physician-engagement difficulties. The reasons for physician indifference to CER include: lack of financial incentives, suspicions of industry bias in the public/private oversight of the research, threats to clinical

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autonomy, a commitment to individualized medicine (encouraged by health law, professional ethics, and medical norms) that remains in tension with CER, concerns that CER is a vehicle for crude cost-cutting, and malpractice liability fears. To be truly effective, the new national CER program requires targeted reforms designed to engage physicians more directly with the research. This Article's principal suggestions include greater linkage of CER with reimbursement and liability incentives, enhanced use of academic detailing, and more support for comparative implementation studies that evaluate different strategies for fostering physician uptake of CER.

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INTRODUCTION

Despite the recent enactment of historic health care reform legislation,¹ serious questions remain whether the entire health care overhaul will implode. Many health policy experts believe that the new law, in primarily focusing on access, does not sufficiently address intractable cost and quality problems in the health care system.² The public shares these concerns.³ As the debate continues, comparative effectiveness research (CER) stands out as the intriguing wild card of health care reform. CER is one of the few reform provisions in the final legislation that, if deployed properly, offers a plausible opportunity to bend the cost curve while also improving the quality of care. Indeed, CER proponents optimistically claim that, over the long haul, CER can radically

¹ See Patient Protection and Affordable Care Act (PPACA), Pub. L. No. 111-148, 124 Stat. 119 (2010) (to be codified as amended in scattered sections of 21, 25, 26, 29, and 42 U.S.C.).

² See, e.g., Elenora E. Connors & Lawrence O. Gostin, *Health Care Reform—A Historic Moment in US Social Policy*, 303 JAMA 2521, 2522 (2010) (“The United States, however, missed a unique opportunity to significantly reduce medical costs and improve quality.”); Douglas Holtz-Eakin & Michael J. Ramlet, *Health Care Reform Is Likely to Widen Federal Budget Deficits, Not Reduce Them*, 29 HEALTH AFF. 1136, 1136-40 (2010) (detailing methodological problems with government projections that found PPACA would reduce the budget deficit); Jonathan Oberlander & Joseph White, *Systemwide Cost Control—The Missing Link in Health Care Reform*, 361 NEW ENG. J. MED. 1131, 1131-33 (2009) (emphasizing that the new law does not restrain spending); Gina Kolata, *Law May Do Little to Help Curb Unnecessary Care*, N.Y. TIMES, Mar. 30, 2010, at D1 (concluding that the new bill does little to help reduce the “nation’s chronic overuse of medical care”); David A. Hyman, *Employment-Based Health Insurance: Is Health Reform a “Game Changer?”* 16-21 (Univ. Ill. Law & Econ., Research Paper No. LE10-010, 2010), available at <http://ssrn.com/abstract=1624311> (making predictions about the cost implications of the new legislation); Ricardo Alonso-Zaldivar, *Health Care Law’s Unfinished Business: Cost Curbs*, ABC NEWS, Apr. 25, 2010, <http://abcnews.go.com/Business/wireStory?id=10470267> (discussing the failure of the health care bill to control costs).

Other commentators, including the former director of the White House Office of Management and Budget (OMB) and the special health policy advisor of the OMB, remain more optimistic. See Peter R. Orszag & Ezekiel J. Emanuel, *Health Care Reform and Cost Control*, 363 NEW ENG. J. MED. 601 (2010) (responding to concerns that the new law would increase the deficit).

³ See, e.g., THE HENRY J. KAISER FAMILY FOUND., KAISER HEALTH TRACKING POLL 1-4 (2010), available at <http://www.kff.org/kaiserpolls/upload/8084-F.pdf> (finding forty-six percent of seniors polled had an unfavorable view of the new law and were concerned about high costs and benefit cuts that could harm quality of care); Mark Trumbull, *Opinion Polls: Obama’s Health Care Reform Law Not a Winner So Far*, CHRISTIAN SCI. MONITOR, Mar. 30, 2010, <http://www.csmonitor.com/USA/Politics/2010/0330/Opinion-polls-Obama-s-health-care-reform-law-not-a-winner-so-far> (noting voters’ concerns that the new law will “erode the quality of care and jack up costs”).

transform the practice of medicine.⁴ Unfortunately, health care reform has so far failed to bet smart and play the CER wild card effectively.

While there are varying and sometimes inconsistent definitions of CER,⁵ it involves, at bottom, comparing competing medical treatments against each other to determine which interventions work best. The new governmental push for CER responds to increasing concerns that physicians often make clinical decisions without a solid foundation of credible medical evidence, particularly evidence as to how treatments compare to each other. A recent Institute of Medicine (IOM) report suggests that sound scientific studies support less than half of the treatments that physicians recommend.⁶ Uncertainties arising from this information gap contribute to unexpected variations in the treatment of patients with similar conditions and can result in costly, ineffective, and even dangerous medical care.⁷

Health care reform has led to both heavy investment in CER and the creation of a new regulatory framework for oversight of the research. Congress took the first major step with the federal stimulus legislation by including an appropriation of \$1.1 billion to fund CER as part of the American Recovery and Reinvestment Act of 2009 (the

⁴ See, e.g., THE COMMONWEALTH FUND COMM'N ON A HIGH PERFORMANCE HEALTH SYS., BENDING THE CURVE: OPTIONS FOR ACHIEVING SAVINGS AND IMPROVING VALUE IN U.S. HEALTH SPENDING 19-21 (2007), available at <http://www.commonwealthfund.org/Content/Publications/Fund-Reports/2007/Dec/Bending-the-Curve-Options-for-Achieving-Savings-and-Improving-Value-in-U-S-Health-Spending.aspx> (projecting the benefits of a CER system); Somnath Saha et al., *Giving Teeth to Comparative-Effectiveness Research—The Oregon Experience*, 362 NEW ENG. J. MED. e18, e18(1)-(3) (2010), <http://www.nejm.org/doi/full/10.1056/NEJMp0912938> (arguing that CER can limit future health care spending by following the example of the health care policies implemented in Oregon).

⁵ See *infra* Section I.D (discussing how definitional questions affect CER implementation).

⁶ INST. OF MED. OF THE NAT'L ACADS., LEARNING WHAT WORKS BEST: THE NATION'S NEED FOR EVIDENCE ON COMPARATIVE EFFECTIVENESS IN HEALTH CARE 2 (2007).

⁷ See, e.g., CONG. BUDGET OFFICE, PUB. NO. 2975, RESEARCH ON THE COMPARATIVE EFFECTIVENESS OF MEDICAL TREATMENTS: ISSUES AND OPTIONS FOR AN EXPANDED FEDERAL ROLE 12 (2007) (“[T]he apparent variation in [treatment] norms indicates that there is not sufficient evidence to determine which approach is most appropriate.”); FED. COORDINATING COUNCIL FOR COMPARATIVE EFFECTIVENESS RESEARCH, U.S. DEP'T OF HEALTH & HUMAN SERVS., REPORT TO THE PRESIDENT AND THE CONGRESS 3 (2009) [hereinafter FEDERAL CER COUNCIL REPORT] (describing some benefits to patients from CER); INST. OF MED. OF THE NAT'L ACADS., INITIAL NATIONAL PRIORITIES FOR COMPARATIVE EFFECTIVENESS RESEARCH 80-84 (2009) (describing information gaps in research that CER should aim to correct); Elliott S. Fisher et al., *Slowing the Growth of Health Care Costs—Lessons from Regional Variation*, 360 NEW ENG. J. MED. 849, 850-51 (2009) (discussing how variations in health care spending show that much care is unnecessary).

Recovery Act).⁸ The recently enacted health care reform law, the Patient Protection and Affordable Care Act (PPACA),⁹ provides an additional stream of CER funding—up to \$500 million per year by 2013 or 2014—and establishes a new oversight entity, the Patient-Centered Outcomes Research Institute (the PCOR Institute), to direct the nation's first comprehensive CER program.¹⁰

CER attracts considerable enthusiasm as a tool for health care reform because it differs from conventional medical research in important ways. Traditional studies ordinarily evaluate an experimental intervention's *general* effectiveness by comparing it to a placebo. CER instead focuses on how effective treatments are *relative* to each other. In other words, traditional research typically asks, "Does this work?" whereas CER asks the question practicing physicians really want to know: "Is this better than that?"¹¹ Also, conventional medical investigations usually evaluate new technology under tightly controlled, highly artificial conditions that exclude many subjects, whereas CER includes treatments already adopted in clinical practice and studies populations more representative of typical patients.¹² As such, CER promises to develop better information for medical decisionmaking in real world settings. In theory, better information will translate to better medical care. Various commentators predict that CER has the power "to reshape major portions of the practice of medicine,"¹³ that it provides "the scientific scaffolding for . . . revolution"¹⁴ in medical practice, and that it ushers health care into a new "era of comparative effectiveness."¹⁵

⁸ Pub. L. No. 111-5, 123 Stat. 115 (2009) (to be codified in scattered sections of 6, 19, 26, 42, and 47 U.S.C.).

⁹ Pub. L. No. 111-148, 124 Stat. 119, 727-38 (2010) (to be codified as amended in scattered sections of 21, 25, 26, 29, and 42 U.S.C.).

¹⁰ See *infra* Section I.C (discussing the creation of the PCOR Institute).

¹¹ Harold C. Sox & Sheldon Greenfield, *Comparative Effectiveness Research: A Report from the Institute of Medicine*, 151 ANNALS INTERNAL MED. 203, 204 (2009).

¹² See *infra* Section I.D.

¹³ Mohammad N. Akhter & Richard A. Levinson, Editorial, *Comparative Effectiveness Research and the Future Practice of Medicine*, 101 J. NAT'L MED. ASS'N 1301, 1301 (2009).

¹⁴ Bob Wachter, *Are We Mature Enough to Make Use of Comparative Effectiveness Research?*, WACHTER'S WORLD (Feb. 21, 2009, 5:48 AM), http://community.the-hospitalist.org/blogs/wachters_world/archive/2009/02/21/are-we-mature-enough-to-make-use-of-comparative-effectiveness-research.aspx.

¹⁵ Joe Jancsurak, *Ushering in an Era of "Comparative Effectiveness,"* MED. DESIGN (Feb. 19, 2009, 9:23 AM), http://medicaldesign.com/letters/comparative_effectiveness_0209 (internal quotation marks omitted); see also Susan Dentzer, *Comparative Effectiveness: Coherent Health Care at Last?*, 29 HEALTH AFF. 1756, 1756 (2010) (describing comparative effectiveness research as a "turning point" for American society).

Rather than revolutionizing medicine, however, this Article cautions that the emerging era of comparative effectiveness is in danger of becoming disappointingly ineffective. Serious legal and policy obstacles jeopardize the health care system's ability to make productive use of governmentally funded CER.

First, CER already has considerable political baggage after being swept into the larger, acrimonious battles over health care reform. Opponents of the Democrats' health care proposals pointedly focused on CER, charging that it would lead to rationing of health care,¹⁶ governmental interference in the doctor-patient relationship,¹⁷ and, more ominously, the empowerment of "death panels."¹⁸ Also, stakeholders waged hard-fought turf battles over how to administer the new national CER program. The new reform law jettisons the federal-commission approach of previous legislation¹⁹ in favor of ceding direct authority to private interests through creation of the PCOR Institute, a nonprofit corporation that will include drug, device, and insurance company representatives on its governing board.²⁰ CER faces longer-term political risks as well. Various physician groups, drug companies, and device manufacturers understandably view CER as a threat because the research may question the necessity and value of their products and

¹⁶ See, e.g., George F. Will, Op-Ed., *Stimulus Math for the GOP*, WASH. POST, Jan. 29, 2009, at A19 ("The CER . . . would dramatically advance government control—and rationing—of health care . . ."); see also Jerry Avorn, *Debate About Funding Comparative Effectiveness Research*, 360 NEW ENG. J. MED. 1927, 1928-29 (2009) (discussing other political charges made against CER during the debate over health care reform).

¹⁷ See, e.g., Betsy McCaughey, *Ruin Your Health with the Obama Stimulus Plan* (Feb. 9, 2009), <http://www.bloomberg.com/apps/news?pid=newsarchive&sid=aLzfDxfbwhzs> (objecting to provisions that would "guide" doctors' decisions).

¹⁸ See, e.g., Victoria Colliver, *Stimulus Prompts Talk of Health Care Rationing*, S.F. CHRON., Feb. 12, 2009, at A12 (explaining the views of CER opponents); Joseph Ashby, "Death Panel" Is Not in the Bill . . . It Already Exists, AM. THINKER (Aug. 15, 2009), http://www.americanthinker.com/2009/08/death_panel_is_not_in_the_bill.html (characterizing CER as leading to "death panels"); Peter Ferrara, *The Absolutely Worst Bill Ever*, AM. SPECTATOR (Nov. 11, 2009, 6:08 AM), <http://spectator.org/archives/2009/11/11/the-absolutely-worst-bill-ever> (describing "death panels" as groups that "have the power to ration and deny you health care").

¹⁹ The earlier Recovery Act had created the Federal Coordinating Council for Comparative Effectiveness Research, an entity akin to a federal commission, to direct the government's new CER program. See *infra* Section I.B.

²⁰ See *infra* Section I.C. Other proposals for administering a national CER program have included folding CER activities into existing agencies such as the National Institutes of Health or the Agency for Healthcare Research and Quality. See, e.g., CONG. BUDGET OFFICE, *supra* note 7, at 15-19 (suggesting organizational strategies for CER oversight); Gail R. Wilensky, *Developing a Center for Comparative Effectiveness Information*, 25 HEALTH AFF. 572 (2006) (describing necessary attributes for CER oversight).

services. These powerful stakeholders can be expected to use the political process to discredit certain studies and to weaken governmental support for CER more generally, as has happened in the past.²¹

While not minimizing these obstacles, this Article contends that health care reform's new push for CER faces a more fundamental problem: lawmakers have essentially defanged CER, deploying it under conditions that will leave it underpowered. In part to appease critics who fear that CER will lead to rationing and crude cost control, a great deal of legislative and political attention has been devoted to restricting its use.²² This leaves unresolved the critical question—what *will be done* with the information?

Not much. Many physicians seem unlikely to change clinical practice patterns, notwithstanding the outcomes of CER studies. Health law and policy are not setting the right incentives for physicians to incorporate CER into regular clinical practice and, in some respects, exacerbate the physician-engagement difficulties. This Article explores why. It also considers how health law and policy tools could better support CER's translation into medical practice.

A key assumption of this Article is that the success of the government's new CER program depends most on targeted physician engagement. The intended audience for a national CER program certainly includes other stakeholders. As CER proponents maintain, comparative effectiveness evidence should empower patients and payers as consumers of health care, equipping them with better information to navigate the complicated health care system.²³ But as a practical matter, very little can be accomplished without meaningful physician participation. Although new models of shared decision-

²¹ For example, the now-defunct Agency for Health Care Policy and Research (AHCPR) issued reports in the mid-1990s questioning the efficacy of common back surgeries. A political backlash, led by surgeon groups and medical device manufacturers, resulted in considerable budget reductions for AHCPR and new limitations on the agency's authority. See MICHAEL F. CANNON, CATO INST., POLICY ANALYSIS NO. 632, A BETTER WAY TO GENERATE AND USE COMPARATIVE-EFFECTIVENESS RESEARCH 7-8 (2009) (cautioning about the dangers of politicization when a federal agency controls research).

²² See *infra* Section I.F.

²³ See, e.g., FEDERAL CER COUNCIL REPORT, *supra* note 7, at 3-4 ("Patients increasingly and appropriately want to take responsibility for their care. Therefore we have a responsibility to provide comparative information to enable informed decision-making. This patient-centered, pragmatic, 'real world' research is a fundamental requirement for improving care for all Americans."); INST. OF MED. OF THE NAT'L ACADS., *supra* note 6, at 6 ("Insurers perhaps most acutely feel the need for much more reliable, rigorous, transparent, and impartial comparative effectiveness information to make decisions in the growing marketplace of medical interventions.").

making between patients and physicians increasingly attract academic and clinical interest,²⁴ physicians continue to perform the fundamental role of gatekeeper. Because of information asymmetries and agency relationships, physicians can induce or control the bulk of health care expenditures.²⁵ The ability of health care payers to direct medical decisionmaking in the absence of physician agreement remains questionable.²⁶ Meanwhile, medical decisionmaking studies raise serious doubts that patients have sufficient capacity, resources, and motivation to use effectiveness information to challenge what their physicians otherwise recommend.²⁷

²⁴ “Shared decisionmaking” refers to a process in which the physician and patient consider outcomes, probabilities, and the patient’s value preferences to reach mutual agreement on a treatment plan. Shared decisionmaking is particularly recommended for situations of medical uncertainty, as the process in part aims to inform the patient about the limited predictive evidence and then determine how to proceed, accounting for the patient’s personal value preferences. Shared decisionmaking differs from the traditional legal-bioethics model of informed consent, which has emphasized the physician’s duty to disclose over joint participation in the decisionmaking. See generally Dominick L. Frosch & Robert M. Kaplan, *Shared Decision Making in Clinical Medicine: Past Research and Future Directions*, 17 AM. J. PREVENTIVE MED. 285, 285 (1999) (reviewing literature on shared decisionmaking and concluding that the process is “an important development in health care”); Stacey L. Sheridan et al., *Shared Decision Making About Screening and Chemoprevention: A Suggested Approach from the U.S. Preventive Services Task Force*, 26 AM. J. PREVENTIVE MED. 56, 59-60 (2004) (defining shared decisionmaking).

²⁵ See Gail B. Agrawal, *Resuscitating Professionalism: Self-Regulation in the Medical Marketplace*, 66 MO. L. REV. 341, 356 (2001) (“Physicians influence or control approximately seventy-five percent of health care spending through their practice patterns.”); Mark A. Hall, *Institutional Control of Physician Behavior: Legal Barriers to Health Care Cost Containment*, 137 U. PA. L. REV. 431, 434 (1988) (estimating that individual practitioners control seventy to ninety percent of health care expenditures).

²⁶ See, e.g., Ana I. Balsa et al., *Clinical Uncertainty and Healthcare Disparities*, 29 AM. J.L. & MED. 203, 205 (2003) (noting that medical practice involves a great deal of physician discretion and “[n]either insurance contracts nor ethical and legal rules do a great deal to narrow the resulting clinical discretion”); Clark C. Havighurst, *The Professional Paradigm of Medical Care: Obstacle to Decentralization*, 30 JURIMETRICS J. 415, 425 (1990) (“[P]ayers are essentially locked into underwriting all care meeting professional standards.”).

²⁷ For example, a recent study published in *Health Affairs* indicates that patients have difficulty understanding what “quality guidelines” and “medical evidence” mean, and that they are dubious about evidence-based information to the extent that it precludes the ability of their physicians to provide individually tailored care. Kristin L. Carman et al., *Evidence That Consumers Are Skeptical About Evidence-Based Health Care*, 29 HEALTH AFF. 1400 (2010). The study suggests that, notwithstanding other credible sources of information, patients will likely continue to “rely heavily on their doctors for information, interpretation, and guidance on treatment options.” *Id.* at 1403. The authors also concluded that patients’ beliefs and attitudes “are often incompatible with evidence-based approaches” to medical care, such as CER. *Id.* at 1405. More generally, despite the theoretical appeal of the patient-as-consumer model, patients often perform poorly as consumers. See, e.g., Mark A. Hall & Carl E. Schneider, *Patients as Consumers: Courts, Contracts, and the New Medical Marketplace*, 106 MICH. L. REV. 643, 644-66

History cautions that it is not easy to change physician behavior, even when good medical data justifies new approaches. Numerous quality-improvement policy initiatives have stalled because information dissemination alone failed to engage physicians in the clinical trenches.²⁸ Indeed, the Congressional Budget Office has questioned whether a national CER program will generate significant cost savings, in part because of doubts that practitioners will quickly adopt the new evidence into actual health care delivery.²⁹ Better effectiveness information does not necessarily affect the adoption of new medical technology or physicians' ultimate choice of treatment. Medical practice remains quite variable, significantly affected by nonclinical factors such as reimbursement incentives and pharmaceutical marketing.³⁰ This variability already presents numerous challenges for health law, complicating medical-technology regulation³¹ and frustrating the malpractice system's attempts to define a uniform standard of care.³²

No doubt, the concerns raised here about CER's future viability may seem unduly pessimistic and even counterintuitive. After all,

(2008); Carl E. Schneider & Mark A. Hall, *The Patient Life: Can Consumers Direct Health Care?*, 35 AM. J.L. & MED. 7, 59-65 (2009).

²⁸ See, e.g., Valerie Weber & Maulik S. Joshi, *Effecting and Leading Change in Health Care Organizations*, 26 J. QUALITY IMPROVEMENT 388, 388-92 (2000) (discussing the limited success of Total Quality Management (TQM) and Quality Improvement (QI) initiatives in hospitals in the 1990s because of lack of physician participation and, at times, physician resistance to changing practice patterns).

²⁹ CONG. BUDGET OFFICE, PUB. NO. 3185, BUDGET OPTIONS VOLUME 1: HEALTH CARE 86-87 (2008); see also Mark McClellan & Joshua Benner, *Comparative Effectiveness Research: Will It Bend the Health Care Cost Curve and Improve Quality?* (noting that critics object that CER "evidence may be outdated by the time it is available"), in ENGELBERG CTR. FOR HEALTH CARE REFORM, BROOKINGS INST., IMPLEMENTING COMPARATIVE EFFECTIVENESS RESEARCH: PRIORITIES, METHODS, AND IMPACT 7, 9 (2009) [hereinafter BROOKINGS INST.].

³⁰ See *infra* Part II.

³¹ See, e.g., Lars Noah, *Informed Consent and the Elusive Dichotomy Between Standard and Experimental Therapy*, 28 AM. J.L. & MED. 361, 394-400 (2002) (examining intricacies of postapproval drug regulation and how physicians deviate from approved uses); Amy L. Wax, *Technology Assessment and the Doctor-Patient Relationship*, 82 VA. L. REV. 1641, 1648-49 (1996) (noting that practitioners base their assessments of cost-benefit tradeoffs for new technologies on "intuition, prejudice, anecdote, or unsubstantiated lore").

³² See, e.g., Mark A. Hall, *The Defensive Effect of Medical Practice Policies in Malpractice Litigation*, 54 LAW & CONTEMP. PROBS. 119, 127 (1991) ("[M]edical science . . . thoroughly fails to conform to the legal ideal of an established standard of care. In most instances, no such definitive standard exists."); William M. Sage, *Managed Care's Crimea: Medical Necessity, Therapeutic Benefit, and the Goals of Administrative Process in Health Insurance*, 53 DUKE L.J. 597, 636 (2003) ("Medical liability law reflects the paradox of wanting health insurers to be objective and consistent about coverage decisions when underlying medical practice is often neither.").

what's not to like about CER? Special-interest-group politics aside, why would ordinary physicians oppose gathering better medical evidence about how treatments compare to each other? Why would they not find such research persuasive? Investigating the relative effectiveness of medical treatments seems inherently positive. Some even view it as a public good, particularly deserving of special governmental support.³³ Also, CER seems a rather neutral reform strategy that, in theory, should appeal to different ends of the political spectrum. Both market-based and regulatory-based approaches for improving health care depend on the availability of good information about the relative value of different medical treatments. Knowledge gaps about differences in the quality of care affect not only patients, but also providers, payers, and regulators, contributing to many system problems.³⁴ Stimulating the production of better information and facilitating data transparency are preferred strategies for advancing important health law and policy objectives and for optimal regulation more generally.³⁵

Notwithstanding the theoretical merits of better information, many physicians will remain skeptical, critical, or—most likely—indifferent about CER. Physicians in the clinical trenches lack strong incentives to consider CER in making medical-treatment decisions. Indeed, for a variety of reasons, they can be expected to “tune out” the research and continue traditional practice patterns.

Part I of this Article analyzes the legislative background, including statutory limitations on the use of CER. It also considers the unclear boundaries between CER and cost-effectiveness analysis, an uncertainty that fuels physicians' fears about rationing and general distrust about the governmental push for CER. Part II discusses why the health care

³³ *Compare* MEDICARE PAYMENT ADVISORY COMM'N, REPORT TO THE CONGRESS: REFORMING THE DELIVERY SYSTEM 107-08 (2008), available at http://www.medpac.gov/documents/jun08_entirereport.pdf (“Because [CER] information can benefit all users and is a public good, the Commission concluded a federal role is necessary to produce the information and make it publicly available.”), with CANNON, *supra* note 21, at 1 (conceding that comparative effectiveness information has public-good characteristics but questioning whether it should receive governmental support).

³⁴ See INST. OF MED. OF THE NAT'L ACADS., *supra* note 6, at 2-3; David A. Hyman, *Regulating Managed Care: What's Wrong with a Patient Bill of Rights*, 73 S. CAL. L. REV. 221, 233-34 (2000).

³⁵ See generally Kristin Madison, *Regulating Health Care Quality in an Information Age*, 40 U.C. DAVIS L. REV. 1577 (2007) (examining the information imperfections in health care markets and how better data can improve regulation); William M. Sage, *Regulating Through Information: Disclosure Laws and American Health Care*, 99 COLUM. L. REV. 1701 (1999) (discussing how greater availability of information can promote competition, strengthen agency relationships, improve productive efficiency, ensure accountability, and foster democratic decisionmaking).

system often lacks credible information about comparative effectiveness and briefly reviews the nonclinical factors that heavily influence physician decisionmaking.

Part III explores the many barriers to translating CER into clinical practice. The research is costly to conduct and may raise more questions than answers. Further, current plans for the national CER program seem overly expansive, extending to investigations that physicians likely will find less useful in resolving immediate treatment decisions. Physicians can be expected to disregard CER for additional reasons, including: lack of financial incentives, suspicions of industry bias in the public/private oversight of the research, clinical autonomy concerns, a commitment to individualized medicine (encouraged by medical ethics, health law, and professional norms) that remains in tension with CER, and malpractice-liability considerations.

Part IV offers legal and policy recommendations for improving the translation of CER into medical practice. The principal suggestions include greater linkage of CER with reimbursement and liability incentives, enhanced use of academic detailing to disseminate the research information, and more funding for comparative *implementation* studies that evaluate different strategies for fostering physician uptake of CER.

I. BACKGROUND: CER STATUTORY PROVISIONS

A. Previous CER Efforts

Combined, the Recovery Act and PPACA invest in CER at record levels and create the nation's first comprehensive CER program. While governmental entities such as the Agency for Healthcare Research and Quality (AHRQ) have supported discrete CER activities in the past, the size and scope of such efforts has been modest.³⁶ No sin-

³⁶ The Recovery Act gave \$300 million in funding to the AHRQ for CER, an amount roughly equal to the agency's entire annual budget. Robert Steinbrook, *Health Care and the American Recovery and Reinvestment Act*, 360 NEW ENG. J. MED. 1057, 1058 (2009). Previous legislation only modestly supported CER—for example, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 provided about \$15 million per year in funding to AHRQ for research into outcomes and comparative clinical effectiveness of certain health care items and services. Pub. L. No. 108-173, § 1013(e), 117 Stat. 2066, 2438-41 (codified at 42 U.S.C. § 299b-7(e) (2006)); INST. OF MED. OF THE NAT'L ACADS., *supra* note 6, at 2; GRETCHEN A. JACOBSON, CONG. RESEARCH SERV., RL34208, COMPARATIVE CLINICAL EFFECTIVENESS AND COST-EFFECTIVENESS RESEARCH: BACKGROUND, HISTORY, AND OVERVIEW 24 (2007).

gle federal agency has focused on CER as its primary activity.³⁷ Private CER efforts have also been limited and poorly coordinated, with results often not made publicly available.³⁸ Moreover, past CER activities have not employed common data infrastructures or followed consistent research methodologies, complicating efforts to share the information and build upon earlier work.³⁹

B. *The American Recovery and Reinvestment Act of 2009*

In what was hailed as an initial “down payment”⁴⁰ for a national CER program, the Recovery Act of 2009 provided \$1.1 billion in financial support for CER, allocated among the Department of Health and Human Services, the National Institutes of Health, and AHRQ.⁴¹ This funding was an unprecedented public investment in CER. The Recovery Act also provided new oversight by creating a federal-commission-type entity, the Federal Coordinating Council for Comparative Effectiveness Research (the Federal CER Council), to coordinate CER efforts among the federal agencies.⁴²

In addition, the Recovery Act directed the IOM to prepare a comprehensive report recommending national priorities for CER after considering input from health-system stakeholders.⁴³ The resulting IOM report, issued in June 2009, listed one hundred “top priority” CER topics.⁴⁴

³⁷ See ELIZABETH DOCTEUR & ROBERT BERENSON, URBAN INST., HOW WILL COMPARATIVE EFFECTIVENESS RESEARCH AFFECT THE QUALITY OF HEALTH CARE?: TIMELY ANALYSIS OF IMMEDIATE HEALTH POLICY ISSUES 5-6 (2010).

³⁸ Critics have called private CER studies conducted by drug and device manufacturers biased because the studies tend to favor the sponsors’ products. Also, health plans and other payers that conduct CER often do not make their studies available to the public. See MEDICARE PAYMENT ADVISORY COMM’N, *supra* note 33, at 116-17. They are no doubt concerned that their competitors would free-ride on their efforts. More generally, private CER efforts have suffered from weak coordination and lack of consistent research methods. Steven Pearson, *From Better Evidence to Better Care: Using Comparative Effectiveness Research to Guide Practice and Policy*, in BROOKINGS INST., *supra* note 29, at 58-59.

³⁹ FEDERAL CER COUNCIL REPORT, *supra* note 7, at 12-13; INST. OF MED. OF THE NAT’L ACADS., *supra* note 7, at 43-51; Pearson, *supra* note 38, at 58-59.

⁴⁰ E.g., AM. MED. ASS’N, H.R. 1, THE “AMERICAN RECOVERY AND REINVESTMENT ACT OF 2009”: EXPLANATION OF COMPARATIVE EFFECTIVENESS RESEARCH (CER) PROVISIONS, available at <http://www.ama-assn.org/ama1/pub/upload/mm/399/arra-cer-provisions.pdf>; Sox & Greenfield, *supra* note 11, at 203.

⁴¹ American Recovery and Reinvestment Act of 2009 (Recovery Act), Pub. L. No. 111-5, tit. VIII, 123 Stat. 115, 176-77.

⁴² Recovery Act § 804, 42 U.S.C.A. § 299b-8 (West Supp. 1A 2010).

⁴³ See Recovery Act, tit. VIII, 123 Stat. 115, 177.

⁴⁴ INST. OF MED. OF THE NAT’L ACADS., *supra* note 7, at 2.

C. *The Patient Protection and Affordable Care Act*

In a rather abrupt departure from the federal-commission-type approach of the previous year's legislation, PPACA abolished the Federal CER Council⁴⁵ and replaced it with an entirely new oversight entity. Instead of employing a purely public oversight model, the new structure cedes significant authority to private interests. A new private nonprofit corporation, the PCOR Institute, will manage the nation's CER program.⁴⁶ Various government officials, such as a representative from the National Institutes of Health, will hold seats on the PCOR Institute's governing board.⁴⁷ The majority of seats, however, are designated for private stakeholders, including representatives of patients, health care providers, drug and device manufacturers, and health insurers.⁴⁸

The statute empowers the PCOR Institute to establish national CER priorities and to enter into contracts with government agencies and private entities for carrying out various research projects.⁴⁹ To assist in these efforts, the PCOR Institute may appoint expert advisory panels.⁵⁰ It is further tasked with developing a standing committee for improving the methodological standards applied to funded CER investigations.⁵¹ Also, the PCOR Institute must ensure appropriate peer review for research that it supports.⁵²

⁴⁵ PPACA § 6302, 42 U.S.C.A. § 299b-8 note (West Supp. 1A 2010).

⁴⁶ *Id.* sec. 6301(a), § 1181, 42 U.S.C.A. § 1320e.

⁴⁷ *Id.* sec. 6301(a), § 1181(f), 42 U.S.C.A. § 1320e(f).

⁴⁸ The members of the PCOR Institute's governing board are to include the Director of the National Institutes of Health and the Director of the AHRQ (or their designees). *Id.* In addition, the Comptroller General of the United States is to appoint additional members as follows: (1) three members representing patients and health care consumers, (2) five members representing physicians and other health care providers, (3) three members representing private payers, (4) three members representing drug and device manufacturers, (5) one member representing quality-improvement or independent-health-services researchers, and (6) two members representing the federal government or the states, including at least one member representing a federal agency or federal health program. *Id.* The initial board of governors, selected by the Comptroller General, includes officials from powerful drug and device firms Johnson & Johnson, Medtronic, and Pfizer, and representatives from influential payers Blue-Cross BlueShield and Xerox. Press Release, U.S. Gov't Accountability Office, GAO Announces Appointments to New Patient-Centered Outcomes Research Institute (PCORI) Board of Governors (Sept. 23, 2010), *available at* <http://www.gao.gov/press/pcori2010sep23.html>.

⁴⁹ PPACA sec. 6301(a), § 1181(e)(d)(2), 42 U.S.C.A. § 1320e(d)(2).

⁵⁰ *Id.* sec. 6301(a), § 1181(e)(d)(4), 42 U.S.C.A. § 1320e(d)(4).

⁵¹ *Id.* sec. 6301(a), § 1181(e)(d)(2), 42 U.S.C.A. § 1320e(d)(2).

⁵² *Id.* sec. 6301(a), § 1181(e)(d)(7), 42 U.S.C.A. § 1320e(d)(7).

In allocating CER funds, the PCOR Institute will have significant resources at its disposal. Transfers from the Medicare program trust funds, as well as revenue from a new tax on health plans, will finance a new CER trust fund.⁵³ The amount available starts at \$10 million in 2010 but increases each year to reach an estimated \$500 million per year by 2013–2014.⁵⁴ However, no expenditures may be made from this trust fund after 2019.⁵⁵ Importantly, PPACA precludes the PCOR Institute from using CER to make coverage determinations or to develop practice guidelines and, similarly, sets narrow limits on federal health plans' ability to use CER for reimbursement decisions, as explained in further detail below.⁵⁶

D. *Definitional Issues*

The new laws fail to clarify many details about the national CER program. First of all, it is not entirely certain what CER means. The Recovery Act did not expressly define the term.⁵⁷ Using the related term “comparative clinical effectiveness research,” PPACA offers a seemingly straightforward definition: “research evaluating and comparing health outcomes and the clinical effectiveness, risks, and benefits of 2 or more medical treatments, services, and items.”⁵⁸

Nonetheless, questions remain. Does the inclusion of “services” and “items” within the definition mean that entire health care delivery systems, not just specific treatments, may be compared? For example, could a funded study investigate whether a difference in effectiveness exists when a physician delivers the same underlying treatment, such as the use of beta-blockers for chronic heart disease, under a traditional fee-for-service system versus managed care? Even

⁵³ *Id.* § 6301(d), 42 U.S.C.A. § 1320e-2.

⁵⁴ *Id.* § 6301(e), 26 U.S.C.A. § 9511; *see also* AM. ASS'N OF MED. COLLS., SUMMARY OF PATIENT-CENTERED OUTCOMES RESEARCH PROVISIONS 11 (2010) (discussing funding for the PCOR trust fund); COAL. FOR HEALTH SERVS. RESEARCH, HEALTH REFORM: WHAT IT MEANS FOR HEALTH SERVICES RESEARCH 3 (2010), *available at* <http://www.chsr.org/CHSRReformSummary.pdf> (estimating \$500 million in funding per year by 2013); Alex Nussbaum et al., *Obamacare's Cost Scalpel*, BUS. WK., Apr. 5, 2010, at 64, 64 (same).

⁵⁵ PPACA § 6301(e), 26 U.S.C.A. § 9511.

⁵⁶ *See infra* Section I.F.

⁵⁷ The Recovery Act described CER only indirectly, and through broad, open-ended language, such as “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.” Recovery Act, Pub. L. No. 111-5, tit. VIII, 123 Stat. 115, 177 (2009).

⁵⁸ PPACA sec. 6301(a), § 1181(a), 42 U.S.C.A. § 1320e(a).

more important, does this definition contemplate comparison of the *costs* of different treatments?⁵⁹

Of course, some degree of imprecision in the statutory definition of CER might be useful. Perhaps Congress meant to avoid a rigid, inflexible approach and leave some discretion to regulators about which aspects of CER to emphasize in different circumstances. Nonetheless, the definitional imprecision creates considerable ambiguity during the critical rollout phase of the new legislation. It also enables lawmakers to avoid, perhaps indefinitely, directly addressing hard but critically important policy choices, such as whether CER should look at treatment costs.

The definitional problems should not be surprising. CER has been an evolving concept, and it continues to mean different things to different stakeholders. In recent years, various public and private entities have developed numerous, and not always consistent, definitions of CER.⁶⁰

In some respects, CER is merely the latest variation of the evidence-based medicine paradigm that has taken hold in medical practice over the past two decades.⁶¹ However, CER involves more than just evidence-

⁵⁹ See *infra* Section I.E.

⁶⁰ The Federal CER 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 CER COUNCIL REPORT, *supra* note 7, at 16. The IOM defined CER somewhat differently, through more of a public health orientation. The IOM definition expressly included population health, not just individual patient experiences, in describing 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.

INST. OF MED. OF THE NAT'L ACADS., *supra* note 7, at 13 (emphasis added). Meanwhile, the Congressional Budget Office had earlier defined CER as “a rigorous evaluation of the impact of different options that are available for treating a given medical condition for a particular set of patients.” CONG. BUDGET OFFICE, *supra* note 7, at 3. For a comprehensive list of varying CER definitions that public and private entities adopted in recent years, see INST. OF MED. OF THE NAT'L ACADS., *supra* note 7, at 34-36 & tbl.2-1.

⁶¹ “Evidence-based medicine” looks to the results of clinical trials and comprehensive data analysis involving large populations of patients to guide individual treatment decisions. It favors reliance on this type of information rather than physicians' tendencies to make treatment decisions based on anecdotal reports from peers, unsyste-

based medicine's preference for using hard data over practitioner intuition and isolated clinical experiences. It is easiest to understand CER by addressing what it is *not*—how it differs from conventional medical research. First, most conceptions of CER stress the *comparative* aspects of the work, the rigorous evaluation of how different treatments fare relative to each other. CER thus differs from traditional evidence-based medicine studies, such as *clinical effectiveness* or simply *efficacy* investigations, which look at an intervention in a more isolated fashion and observe whether it produces any therapeutic benefit.⁶²

A second distinguishing feature of CER is the pragmatic focus on what happens under *real world* clinical conditions. Traditional clinical efficacy studies typically occur under highly controlled, artificial circumstances. Subjects usually receive the exact same interventions in the same uniform manner. Also, the traditional studies often exclude individuals with additional medical problems, or who take multiple medications, as well as individuals of varying age, gender, and health backgrounds.⁶³ Investigators apply these standardization techniques and rigid eligibility criteria to isolate the effect of the studied intervention.⁶⁴ This narrow focus furthers scientific understanding of general disease etiology and, in the case of investigational drugs and devices, helps more efficiently satisfy the Food and Drug Administration (FDA)'s regulatory approval criteria.⁶⁵ However, this means that tradi-

matic observations from isolated clinical experiences, observations during medical-education training, and other less rigorous information sources. See Evidence-Based Med. Working Grp., *Evidence-Based Medicine: A New Approach to Teaching the Practice of Medicine*, 268 JAMA 2420, 2420-25 (1992).

⁶² Sometimes "efficacy" and "effectiveness" are used interchangeably, but there is a technical distinction. Efficacy studies test the given treatment under ideal, uniform conditions that try to minimize the influence of other factors. Effectiveness studies test the treatment under "messier" conditions, such as patients of different health status and varying procedures for administering the treatment, to better represent the circumstances of actual clinical practice. See JACOBSON, *supra* note 36, at 4-5 (discussing the difference between "effectiveness" and "efficacy").

⁶³ See FEDERAL CER COUNCIL REPORT, *supra* note 7, at 17-21; JACOBSON, *supra* note 36, at 5.

⁶⁴ See *Common Questions About Clinical Trials*, YALE CANCER CENTER, <http://www.yalecancercenter.org/trials/questions.html> (last visited Mar. 15, 2011) ("Enrolling participants with similar characteristics helps to ensure that the results of the trial will be due to what is under study and not other factors.").

⁶⁵ Investigational new drugs typically undergo different phases of clinical-trial testing to satisfy FDA approval criteria. Phase I studies establish levels of tolerance to determine safe dosage levels. If deemed nontoxic, a drug passes into Phase II, where it is tested to demonstrate general efficacy and relative safety. Phase III studies involve expanded controlled and uncontrolled clinical trials and more comprehensive evaluations of general efficacy and safety. See 21 C.F.R. § 312.21 (2010) (explaining the

tional research studies are not always persuasive when it comes to making actual decisions for real patients.⁶⁶ In contrast, CER intentionally draws in a wider range of subjects.⁶⁷

Third, CER often evaluates *customary treatments* alongside new approaches, whereas traditional studies focus more heavily on new interventions alone. CER studies can thus provide critical information that calls into question longstanding medical treatments⁶⁸ or, alternatively, that challenges the assumption that “what is newest” is usually “the best.”⁶⁹ Although both can involve looking at existing treatments, CER should not be confused with FDA postmarketing (or Phase IV) studies.⁷⁰ Phase IV studies typically look to safety and efficacy issues with a single product, rather than comparing the effectiveness of different treatments as ordinarily involved in CER.⁷¹

phases of an FDA investigation). However, the FDA typically does not analyze how treatments compare to each other in terms of relative effectiveness. See Alec B. O'Connor, *Building Comparative Efficacy and Tolerability into the FDA Approval Process*, 303 JAMA 979, 979-80 (2010) (arguing that the FDA should consider comparative effectiveness research in its approval decisions so that new but inferior treatments do not replace established treatments); see also Jordan Paradise et al., *Evaluating Oversight of Human Drugs and Medical Devices: A Case Study of the FDA and Implications for Nanobiotechnology*, 37 J.L. MED. & ETHICS 598, 601-02 (2009) (discussing criteria the FDA typically considers during its approval process for medical devices).

⁶⁶ See JACOBSON, *supra* note 36, at 4-5 (discussing how tightly controlled trials are not always applicable to real-life scenarios); Bryan R. Luce et al., *Rethinking Randomized Clinical Trials for Comparative Effectiveness Research: The Need for Transformational Change*, 151 ANNALS INTERNAL MED. 206, 208 (2009) (arguing that tightly controlled studies “do not reach their potential value for health care decision making”).

⁶⁷ CER “relaxes the strict exclusionary criteria that are typically required in [traditional] trials, in order to assess the treatment in the wide range of patients and environments in which the product is *actually used*.” JACOBSON, *supra* note 36, at 5 (emphasis added).

⁶⁸ For example, a recent comparative study of resuscitation treatments found that chest compression and breathing—the traditional resuscitation technique practiced for many years—was generally no more effective than chest compression alone. See Thomas D. Rea et al., *CPR with Chest Compression Alone or with Rescue Breathing*, 365 NEW ENG. J. MED. 423, 432 (2010). Also, chest compression alone had better outcomes in several patient subgroups. Both treatment interventions studied involved trained dispatchers assisting bystanders, who performed the procedures. *Id.*

⁶⁹ JACOBSON, *supra* note 36, at 1.

⁷⁰ For certain drugs, the FDA can condition its approval on the manufacturer conducting additional Phase IV studies after the drug is marketed and adopted in clinical use. The aim of these postapproval studies is to gather more information about the drug once it is used in broader populations and under different conditions than the preapproval clinical trials. See 21 C.F.R. § 312.85 (2010) (detailing the FDA’s authority to require Phase IV studies).

⁷¹ See *id.* (explaining the goals of Phase IV studies); JACOBSON, *supra* note 36, at 5 (distinguishing between Phase IV and effectiveness studies); Barbara J. Evans, *Seven Pillars*

E. Comparative Effectiveness Versus Cost-Effectiveness

What, ultimately, does it mean for one treatment to be more “effective” than another? In the political debates over health care reform, opponents charged that CER would inherently involve some form of cost-effectiveness review, resulting in coverage denial for expensive treatments and treatments for disabled patients and other vulnerable groups.⁷² Even after the passage of PPACA, the degree to which CER differs—if it should differ at all—from cost-effectiveness analysis continues to create controversy. *Cost-effectiveness* analysis considers gains in health from a treatment compared to the expense of offering the treatment (for example, years of life saved per dollar spent).⁷³ This contrasts with pure *clinical-effectiveness* analysis, which looks solely to therapeutic outcomes of a treatment (for example, survival rates).⁷⁴ With CER, however, no clear consensus exists about whether one should compare treatments based on their pure clinical effectiveness, their cost-effectiveness, or some other metric.

PPACA seems to take a pure clinical-effectiveness approach. It uses the key term “comparative *clinical* effectiveness research” and describes research that looks at “*clinical* effectiveness, risks, and benefits,” but nowhere does the statute mention comparing respective costs.⁷⁵ No doubt to make the legislation more politically palatable in light of the concerns about CER and rationing, Congress avoided express discussion of cost comparisons. Indeed, “cost or value of health services is conspicuously absent from the statutory definition of comparative clinical effectiveness.”⁷⁶ Yet rather than siding squarely against incorporating cost-effectiveness analysis into CER, lawmakers simply obfuscated, but did not preclude, the possibility. PPACA does not expressly

of a New Evidentiary Paradigm: The Food, Drug, and Cosmetic Act Enters the Genomic Era, 85 NOTRE DAME L. REV. 419, 488-89 (2010) (discussing postmarket study methodologies).

⁷² See, e.g., Martin Feldstein, Opinion, *ObamaCare Is All About Rationing*, WALL ST. J., Aug. 19, 2009, at A15 (arguing that “rationing health care is central” to President Obama’s strategy to reduce health care costs); see also *infra* Section I.F.

⁷³ See COST-EFFECTIVENESS IN HEALTH AND MEDICINE xviii (Marthe Gold et al. eds., 1996).

⁷⁴ See, e.g., Adrian F. Hernandez et al., *Clinical Effectiveness of Beta-Blockers in Heart Failure*, 53 J. AM. C. CARDIOLOGY 184, 189 (2009) (studying the mortality rate in patients with heart failure who subsequently took beta-blockers).

⁷⁵ PPACA sec. 6301(a), § 1181(a), 42 U.S.C.A. § 1320e(a) (West Supp. 1A 2010) (emphasis added).

⁷⁶ COAL. FOR HEALTH SERVS. RESEARCH, *supra* note 54, at 7.

prohibit the research from encompassing cost comparisons,⁷⁷ and other parts of the statute imply that government-funded CER could occasionally involve cost-effectiveness analysis.⁷⁸ Indeed, key health policy advisors in the Obama Administration say they hope that the research will augment meaningful cost control for the health care system by identifying when the benefits of health care are not sufficient to justify the costs.⁷⁹

The IOM's recent report on national priorities for CER, required by the Recovery Act,⁸⁰ further illustrates the confusion about the government's CER agenda and cost-effectiveness. The IOM lists one hundred high-priority topics for CER studies.⁸¹ In many cases, the report discusses possible CER investigations solely in terms of clinical-effectiveness comparisons. But in some instances, the IOM report calls for comparing both the clinical effectiveness and *cost-effectiveness* of different interventions, such as in the discussion of research evaluating medical-management techniques for type 2 diabetes.⁸² It is not always clear why the IOM report expressly mentions cost-effectiveness for certain priority topics but not others. Congress did not repudiate the IOM report's approach in enacting PPACA, and the IOM report will presumably continue to wield significant influence with regulators in implementing the national CER program.

Incorporating regular cost-effectiveness review into a national CER program has significant policy advantages. When considering whether one treatment is "better" or "more effective" than another, therapeutic and cost considerations become inextricably intertwined. Including

⁷⁷ See *id.* (noting that PPACA's comparative effectiveness provisions do not explicitly proscribe comparative cost-effectiveness research).

⁷⁸ For example, the statute precludes the PCOR Institute from using "a dollars-per-quality adjusted life year (or similar measure that discounts the value of a life because of an individual's disability) as a threshold to establish what type of health care is *cost effective* or recommended." PPACA sec. 6301(c), § 1182(e), 42 U.S.C.A. § 1320e-1(e) (emphasis added). Because the law singles out only this particular form of cost-effectiveness analysis, it leaves open the possibility that other cost-effectiveness comparisons that do not adjust for quality of life in such a manner might be permissible as part of government-funded CER.

⁷⁹ See, e.g., Orszag & Emanuel, *supra* note 2, at 601-02 (identifying the CER initiatives, in the view of the former White House OMB Director and the OMB's special health policy advisor, as part of the important "cost control elements" of the new health care reform legislation); Nussbaum et al., *supra* note 54, at 64-66 (noting that Obama's advisors view CER as a tool to pry savings out of the health care system).

⁸⁰ See *supra* Section I.B.

⁸¹ See INST. OF MED. OF THE NAT'L ACADS., *supra* note 7, at 3 tbl.S-1 (noting the areas of highest priority for CER studies).

⁸² See *id.* at 8 tbl.1.

cost-effectiveness analysis as part of CER does not dictate that treatment decisions should be made solely or even significantly because of cost. But it at least ensures that decisionmakers have a more accurate understanding of the stakes in choosing between treatments.⁸³

However, physicians have generally been wary of a national CER program featuring regular cost-effectiveness review. Many fear that CER will facilitate crude cost-cutting.⁸⁴ The uncertain boundaries between CER and cost-effectiveness analysis intensify these concerns. For example, the American Medical Association (AMA) explained to its members that it had supported the Recovery Act's CER provisions, which conspicuously avoided mentioning cost comparisons, because such support was consistent with the AMA's overall goal of ensuring that "*clinical considerations drive CER analysis*" and that "*cost-effectiveness is subordinate to the consideration of safety and clinical effectiveness.*"⁸⁵

F. *Limitations on Use of CER*

To minimize concerns about rationing, Congress imposed significant limitations on the use of CER. PPACA restricts utilizing CER in federal health care program reimbursement. The statute prohibits the Secretary of Health and Human Services from making Medicare coverage decisions "solely on the basis" of CER.⁸⁶ It further provides that if CER is used to inform a coverage decision, the Medicare program cannot use the evidence to assert that some treatments have less effectiveness because they primarily help patients with an alleged low-

⁸³ See CONG. BUDGET OFFICE, *supra* note 7, at 19-20 (noting the challenges of choosing a research option and how that affects treatment choices).

⁸⁴ See, e.g., FEDERAL CER COUNCIL REPORT, *supra* note 7, at 57 (summarizing physician input from listening sessions and public-comment solicitations and noting the concern that factoring cost into CER "could lead to limiting access and benefits . . . [or be used for] looking for cheaper treatments"); Alvin I. Mushlin & Hassan Ghomrawi, *Health Care Reform and the Need for Comparative-Effectiveness Research*, 362 NEW ENG. J. MED. e6(1), e6(1) (2010), <http://www.nejm.org/doi/full/10.1056/NEJMp0912651> ("[T]here are fears that patients will be denied effective care on the basis of CER's findings.").

⁸⁵ AM. MED. ASS'N, *supra* note 40, at 2 (emphasis added). However, not all physician groups oppose integrating cost-effectiveness analysis with CER. The American College of Physicians has advocated that any national CER program should develop cost-effectiveness information as well. See Am. Coll. of Physicians, *Information on Cost-Effectiveness: An Essential Product of a National Comparative Effectiveness Program*, 148 ANNALS INTERNAL MED. 956, 956 (2008) (calling for government-sponsored CER and cost-effectiveness research).

⁸⁶ PPACA sec. 6301(c), § 1182(b)(2), 42 U.S.C.A. § 1320e-1(b)(2) (West Supp. 1A 2010).

er quality of life.⁸⁷ Also, the Medicare program cannot use CER “in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value” than the needs of other patients.⁸⁸ Moreover, the statute essentially treats CER as mere advisory information by making clear that practice guidelines and coverage recommendations need not incorporate findings from CER.⁸⁹ These constraints parallel and, in certain areas, expand upon earlier limitations imposed upon use of CER under the Recovery Act⁹⁰ and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.⁹¹

These limitations make it difficult for governmental health care programs to use CER in their financing decisions. For example, under the current statutory criteria for Medicare reimbursement, services generally qualify for payment so long as they are “reasonable and necessary.”⁹² There is usually no need to demonstrate that a covered treatment offers better clinical or cost-effectiveness than other treatments.⁹³

⁸⁷ *Id.* sec. 6301(c), § 1182(a), 42 U.S.C.A. § 1320e-1(a).

⁸⁸ *Id.* sec. 6301(c), § 1182(c)(1), 42 U.S.C.A. § 1320e-1(c)(1). Similarly, PPACA prohibits the PCOR Institute from “develop[ing] or employ[ing] a dollars-per-quality adjusted life year (or similar measure that discounts the value of a life because of an individual’s disability) as a threshold to establish what type of health care is cost effective or recommended” and imposes similar constraints on federal health programs. *Id.* sec. 6301(c), § 1182(e), 42 U.S.C.A. § 1320e-1(e).

⁸⁹ *See id.* secs. 6301(a), 10602, § 1181(d)(8)(A)(iv), 42 U.S.C.A. § 1320e-1(d)(8)(A)(iv) (requiring that the PCOR Institute ensure that research findings “do not include practice guidelines, coverage recommendations, payment, or policy recommendations”).

⁹⁰ *See* Recovery Act § 804(g)(1), 42 U.S.C.A. § 299b-8(g)(1) (West Supp. 1A 2010) (stating that the law should not be interpreted to permit the Federal CER Council “to mandate coverage, reimbursement, or other policies” for any health plan, public or private). The Recovery Act also provided that the Federal CER Council’s recommendations were not to “be construed as mandates or clinical guidelines for payment, coverage, or treatment.” *Id.* § 804(g)(2), 42 U.S.C.A. § 299b-8(g)(2).

⁹¹ *See* Pub. L. No. 108-173, § 1013(b), 117 Stat. 2066, 2441 (codified as amended at 42 U.S.C. § 299b-7(b)(2006)) (limiting the scope of changes that can be made based on effectiveness research). The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 provided funds to the AHRQ to perform comparative clinical effectiveness research on various items and services. *Id.* § 1013(e), 117 Stat. at 2441 (codified as amended at 42 U.S.C. § 299b-7(e)). However, the statute also made clear that the AHRQ Director should “not mandate national standards of clinical practice or quality health care standards” and further required that the AHRQ Director provide notice of this prohibition in any recommendations resulting from the funded research. *Id.* § 1013(b).

⁹² 42 U.S.C. § 1395y(a)(1)(A)–(B).

⁹³ Under the “Least Costly Alternative” (LCA) policy, Medicare allowed its contractors, when making local coverage determinations, to limit the amount paid for comparable treatment to the lower cost alternative and to not cover the excess payment for the more expensive intervention. For the most part, Medicare contractors applied these rules to reimbursement for certain drugs and devices. *See* MEDICARE

The Medicare program has tried to incorporate cost-effectiveness as an additional criterion for coverage in the past, but the proposed rule-making generated considerable controversy and has, for the most part, been abandoned or limited.⁹⁴ The availability of more CER information, to be used on a purely elective basis, is therefore unlikely to change things materially. Other criteria in addition to CER must be used to justify changes in Medicare coverage; otherwise the Medicare program invites challenges that it has run afoul of PPACA by making coverage decisions solely on the basis of CER.⁹⁵ Coverage denials of treatments that CER reveals have low effectiveness value can also be challenged—depending on the clinical populations involved—for impermissibly discounting the value of such treatments for the elderly, disabled, and terminally ill.⁹⁶ Also, practice guidelines and coverage recommendations need not pay special heed to CER.⁹⁷ As a result, the link between what CER reveals is comparatively effective and what federal health care programs pay for will remain quite tenuous.

It is similarly uncertain whether CER will materially affect the reimbursement practices of private health plans. The Medicare program traditionally has played a “first mover” role, with private payers

PAYMENT ADVISORY COMM'N, REPORT TO THE CONGRESS: ALIGNING INCENTIVES IN MEDICARE 6-7 (2010) (discussing the LCA and functional equivalence policies behind Medicare's reference pricing strategy). However, the D.C. Circuit Court of Appeals struck down Medicare's attempts to use the LCA policy to limit reimbursement of DuoNeb, an inhalation drug used in treatment of chronic obstructive pulmonary disease. *See Hays v. Sebelius*, 589 F.3d 1279, 1280, 1283 (D.C. Cir. 2009). The implications of the decision for the entire LCA policy are unclear, but apparently as a result of the court ruling, Medicare has instructed its contractors to stop applying the LCA rules when processing reimbursement for drugs covered under Medicare's Part B (Medical Insurance) program. *See CMS Instructs Contractors to Rescind All LCA Provisions in Current LCDs*, HEALTH POL'Y WKLY. (AmerisourceBergen Specialty Grp., Wash., D.C.), Apr. 30, 2010, <https://www.iononline.com/app/Documents/Health%20Policy%20Weekly/2010/April%2030,%202010.pdf>.

⁹⁴ *See* Medicare Program; Criteria and Procedures for Making Medical Services Coverage Decisions that Relate to Health Care Technology, 54 Fed. Reg. 4302, 4308-09 (proposed Jan. 30, 1989) (to be codified at 42 C.F.R. pts. 400, 405) (proposing cost-effectiveness as a criterion). *But see* Medicare Program; Procedures for Making National Coverage Decisions, 64 Fed. Reg. 22,619, 22,620 (Apr. 27, 1999) (withdrawing proposed rule). *See generally* Jacqueline Fox, *Medicare Should, But Cannot, Consider Cost: Legal Impediments to a Sound Policy*, 53 BUFF. L. REV. 577, 577-78 (2005) (arguing that Congress must require Medicare to consider cost-effectiveness).

⁹⁵ *See* PPACA sec. 6301(c), § 1182(b), 42 U.S.C.A. § 1320e-1(b) (West Supp. 1A 2010) (prohibiting using CER as the only basis for denying coverage).

⁹⁶ *See id.* sec. 6301(c), § 1182(c)-(d), 42 U.S.C.A. § 1320e-1(c)-(d).

⁹⁷ *See id.* sec. 6301(a), § 1181(d)(8)(A), 42 U.S.C.A. § 1320e(d)(8)(A) (prohibiting the inclusion of practice or coverage recommendations in the research findings).

following Medicare reimbursement policies.⁹⁸ If the Medicare program is statutorily hampered from incorporating CER more robustly into reimbursement decisions, then there will be little innovation for private health plans to follow. Moreover, Congress included express language in the statute making clear that private health plans can regard CER as they see fit and have no obligation to change their policies based on what the PCOR Institute thinks should be done.⁹⁹ The statute takes a hard line to ensure that CER plays only a limited, passive informational role, providing, for example, that the materials used to disseminate CER “shall . . . not be construed as mandates, guidelines, or recommendations for payment, coverage, or treatment.”¹⁰⁰

Other sections of PPACA, unrelated to the new national CER program, take cautious steps toward more innovative approaches to health care financing. For example, the statute creates a new Center for Medicare and Medicaid Innovation within the Centers for Medicare and Medicaid Services (CMS).¹⁰¹ This entity will test new reimbursement methods that may help control costs “while preserving or enhancing quality of care.”¹⁰² The new law also encourages experimentation with global payments to hospital-physician groups for services bundled together around entire episodes of care.¹⁰³ In addition, the law creates the Independent Medicare Advisory Board, an independent panel with limited authority to recommend spending reductions in the Medicare program.¹⁰⁴ But it is unclear whether the statutory restrictions

⁹⁸ Paul N. Van de Water notes,

As the largest U.S. purchaser and regulator of health care, Medicare exerts a major influence on the rest of the health care system. . . . Its reimbursement and coverage policies have been widely adopted by private insurers and other public programs. For example, many private insurers follow Medicare's lead in approving coverage of new medical technologies.

Paul N. Van de Water, *Medicare Changes Can Complement Health Reform*, CTR. ON BUDGET & POL'Y PRIORITIES, 3 (July 31, 2008), <http://www.cbpp.org/cms/index.cfm?fa=view&id=563>.

⁹⁹ PPACA states that its CER provisions are not to be construed “to permit the [PCOR] Institute to mandate coverage, reimbursement, or other policies for any public or private payer.” PPACA sec. 6301(a), § 1181(j), 42 U.S.C.A. § 1320e(j) (emphasis added).

¹⁰⁰ *Id.* sec. 6301(b), § 937(a)(2)(B), 42 U.S.C.A. § 299b-37(a)(2)(B).

¹⁰¹ *See id.* § 3021(a), 42 U.S.C.A. § 1315a(a).

¹⁰² *Id.*

¹⁰³ *See id.* § 3023, 42 U.S.C.A. § 1395cc-4.

¹⁰⁴ *See id.* sec. 3403, § 1899A, 42 U.S.C.A. § 1395kkk. The Independent Medicare Advisory Board has authority to submit recommendations to reduce the per capita growth rate of Medicare spending if spending exceeds a targeted growth rate. *Id.* sec. 3403, § 1899A(b), 42 U.S.C.A. § 1395kkk(b). But the Board cannot submit pro-

on the use of CER would continue to apply to such demonstration/innovation initiatives.¹⁰⁵ Accordingly, the door has been opened only partially to experimentation with CER and federal health care reimbursement policy. In any event, these demonstration/innovation initiatives will initially be limited in scope and take time to develop. Plus, considerable doubt remains about whether these initiatives have sufficient strength to take hold over the long term and lead to comprehensive change.¹⁰⁶

II. INFORMATION GAPS AND WHAT DRIVES MEDICAL DECISIONMAKING

This Article's attention to CER's probable translation problems is not meant to be a critique of CER generally. Part of the reason for disappointment about how the national CER program is taking shape concerns the tremendous missed opportunities. The health care system critically needs effective CER. And the very reasons why—that

posals that will ration care, increase revenues, or change benefits. *See id.* sec. 3403, § 1899A(c)(2)(A)(ii), 42 U.S.C.A. § 1395kkk(c)(2)(A)(ii) ("The proposal shall not include any recommendations to ration health care, raise revenue or Medicare beneficiary premiums . . ."); Robert A. Berenson, *Implementing Health Care Reform—Why Medicare Matters*, 363 NEW ENG. J. MED. 101, 102 (2010) ("The [Independent Medicare Advisory B]oard's role is carefully circumscribed . . . [and] it is expressly prohibited from recommending increasing revenues; changing benefits, including patient cost sharing; or altering program eligibility.").

¹⁰⁵ For example, the Center for Medicare and Medicaid Innovation might want to test payment models in which coverage decisions are based solely on CER. To do so, it would presumably need authority to ignore the statutory restriction on using CER in this manner. *See supra* note 86 and accompanying text. PPACA does give the Secretary of Health and Human Services authority to waive various Medicare and Medicaid statutory requirements in order to test innovative reimbursement models. *See* PPACA sec. 2001(b), 42 U.S.C.A. § 1396a(gg). But in exercising this waiver authority, the Secretary would need to expressly waive the CER limitation provisions. Given how controversies over linking CER to reimbursement led to such statutory restrictions in the first place, it is not clear that the Secretary would want to take the politically unpalatable step of reopening such debates by waiving the CER limitation provisions.

¹⁰⁶ *See, e.g.,* Berenson, *supra* note 104, at 102-03 (casting doubt on whether enough physicians will participate in the bundled payment initiatives with hospitals and describing how the Independent Medicare Advisory Board's impact will likely be limited); David A. Hyman, *Follow the Money: Money Matters in Health Care, Just Like in Everything Else*, 36 AM. J.L. & MED. 370, 381 (2010) (observing that the Board has limited authority to make fast-track recommendations about physician payments and questioning whether the Board will be able to make significant cost-cutting recommendations without creating a crippling political backlash); Timothy Stoltzfus Jost, *The Independent Payment Advisory Board*, 363 NEW ENG. J. MED. 103, 104-05 (2010) (noting that the Board will most likely focus on cuts to Medicare Advantage plans in the early years, not significant changes in physician reimbursement, and also observing that "[m]any questions remain about how, and indeed whether, the [Board] will work").

solid effectiveness evidence currently plays only a limited role in medical decisionmaking and that many nonclinical factors influence the choice of treatment—underscore the difficulties in engaging physicians to better utilize CER.

Because of medicine's hallowed scientific traditions, the common misconception is that scientific evidence supports customary practices and that physicians can consistently identify right and wrong treatments for most conditions. In reality, uncertainty pervades medicine.¹⁰⁷ Thus, the much repeated story of advice given to a medical school graduating class: “[H]alf of what we teach you here is wrong—unfortunately, we don't know which half.”¹⁰⁸

Achieving consensus among physicians on a best treatment is often difficult. For a particular illness, many possible care pathways may exist, and even the same treatment can present different benefits and harms for otherwise similar patients due to patient-specific responses and genetic differences.¹⁰⁹ Furthermore, nonclinical factors, such as reimbursement incentives, heavily influence physician decisionmaking.¹¹⁰ As a result, the concept of “standard of care” varies significantly, and the lack of good comparative effectiveness data further fragments customary standards. Studies suggest that when evidence about comparative effectiveness is weak, treatment variations tend to be greater between physicians.¹¹¹

Another common misconception concerns the degree of evidence needed for a treatment to become established as custom. Many treatments diffuse into practice without testing through randomized clinical trials or other rigorous evaluations. New surgical and diagnostic procedures generally do not require the approval of the FDA or other regulatory agencies before they are introduced into regular clin-

¹⁰⁷ See MEDICARE PAYMENT ADVISORY COMM'N, *supra* note 33, at 117 (noting the existence of “significant evidence gaps” in medicine and the “[u]ncertainty about clinical effectiveness applies to new and old services”).

¹⁰⁸ Lisa Sanders, *Medicine's Progress, One Setback at a Time*, N.Y. TIMES, Mar. 16, 2003, at SM29; see also Jerome Groopman & Pamela Hartzband, Op-Ed., *Why “Quality” Care Is Dangerous*, WALL ST. J., Apr. 8, 2009, at A13 (attributing a similar quotation to Dr. David Sackett, “a pioneer of [the] ‘evidence-based medicine’” movement).

¹⁰⁹ See, e.g., Barbara J. Evans, *What Will It Take to Reap the Clinical Benefits of Pharmacogenomics?*, 61 FOOD & DRUG L.J. 753, 753-55 (2006) (outlining the regulatory issues raised by the genetic variability of drug response).

¹¹⁰ See *infra* notes 125-134 and accompanying text.

¹¹¹ See CONG. BUDGET OFFICE, *supra* note 7, at 1 (“[T]he extent of the variation in treatments may be greatest when evidence about their relative effectiveness is lacking.”); McClellan & Benner, *supra* note 29, at 10 (suggesting an absence of CER findings is “partly to blame” for greater geographic variation in treatment patterns).

ical practice.¹¹² The FDA approval process for drugs and devices, meanwhile, yields only limited information concerning comparative effectiveness. For new drugs, clinical trial testing typically focuses on satisfying the FDA approval criteria of safety and *general* effectiveness, not *relative* effectiveness.¹¹³ Indeed, because of the limited information generated, commentators have called for new labeling rules that would advise physicians and patients that although the FDA may have approved a new drug, no evidence exists that it actually works better than other medications.¹¹⁴ The FDA approval process for devices yields even more limited data about a product's relative value.¹¹⁵

Clinical practice guidelines serve as another potential source of effectiveness information. However, many existing guidelines suffer from potential bias, advancing the narrow interests of specialty physician groups, drug companies, and other interested parties.¹¹⁶ More problematically, clinical practice guidelines often lack a firm foundation of comparative effectiveness evidence. Rather than synthesizing hard data such as information generated from randomized clinical trials, many practice guidelines are more like consensus statements of professional opinion.¹¹⁷

¹¹² See Lars Noah, *Medicine's Epistemology: Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community*, 44 ARIZ. L. REV. 373, 447 (2002).

¹¹³ See *supra* note 65 and accompanying text (describing the FDA new drug approval process).

¹¹⁴ See Randall S. Stafford et al., *New, But Not Improved? Incorporating Comparative Effectiveness Information into FDA Labeling*, 361 NEW ENG. J. MED. 1230, 1232 (2009) ("In the absence of comparative data, drug and device labels should include a statement indicating that there is no evidence of the product's superiority to other products.").

¹¹⁵ The FDA device-approval process typically gathers safety and effectiveness information only for high-risk devices and produces very little data about relative effectiveness. See *Hearing on Strategies to Increase Information on Comparative Clinical Effectiveness: Hearing Before the Subcomm. on Health of the H. Comm. on Ways & Means*, 110th Cong. 57 (2007) (statement of Mark Miller, Executive Director, Medicare Payment Advisory Commission) (commenting that the FDA approval process does not generate comparative effectiveness evidence); see also O'Connor, *supra* note 65, at 979 ("The current FDA standards for approval fail to assess whether newly approved drugs and devices are less efficacious or less well-tolerated than existing alternatives.").

¹¹⁶ See Ronen Avraham, *Clinical Practice Guidelines—The Warped Incentives in the US Healthcare System* 32-36 (Univ. of Tex. Sch. of Law, Law & Econ. Research Paper Series, No. 181, 2010), available at <http://ssrn.com/abstract=1593133> (identifying flaws in the creation of practice guidelines).

¹¹⁷ See, e.g., Pierluigi Tricoci et al., *Scientific Evidence Underlying the ACC/AHA Clinical Practice Guidelines*, 301 JAMA 831, 833-35 (2009) (finding that the American College of Cardiology and American Heart Association clinical practice guidelines show "consistent gaps in evidence about medical practices").

Also, medical knowledge constantly changes as new treatments and technologies come down the pike. It becomes quite challenging to perform adequate and still relevant assessments with so many moving targets.¹¹⁸ Another reason for information deficits concerning relative effectiveness is that public financing of CER in the United States has traditionally been limited, in contrast to other countries with more robust public CER programs.¹¹⁹

Without the support of reliable comparative effectiveness information, suboptimal medical decisionmaking can result.¹²⁰ Even when physicians make treatment choices with the best intentions, informational deficits regarding relative effectiveness can lead to the selection of ineffective or even inappropriate care.¹²¹

Even worse, and perhaps counterintuitively, it is not easy to remedy the information gap simply by producing more and better evidence. In several instances, physicians did not change practice patterns even after widely disseminated studies suggested that they were choosing inferior treatments.¹²² The common pattern is that “physi-

¹¹⁸ As the Medicare Payment Advisory Commission (MedPAC) has observed, new treatments often “disseminate quickly into routine medical care with little or no basis for knowing whether they outperform existing treatments, and to what extent.” MEDICARE PAYMENT ADVISORY COMM’N, *supra* note 33, at 107.

¹¹⁹ The United Kingdom’s National Health Service has perhaps the most well-known, and controversial, public CER program. The U.K. National Institute for Health and Clinical Excellence (NICE) provides comprehensive technology assessment. See Pearson, *supra* note 38, at 77 box A (describing the structure, function, and methods of NICE). NICE reviews, which include cost-effectiveness analysis, heavily influence the treatments that the National Health Service covers. *Id.*

¹²⁰ See Michael S. Lauer & Francis S. Collins, *Using Science to Improve the Nation’s Health System*, 303 JAMA 2182, 2182 (2010) (noting that, “[t]o the surprise of many,” drugs meant to treat cardiac arrhythmia led to increased rates of arrhythmic death).

¹²¹ See FEDERAL CER COUNCIL REPORT, *supra* note 7, at 10 (“When specific evidence is lacking, clinicians have to rely on their clinical experience . . . [and] these decisions can result in less than optimal, and sometimes inappropriate, treatment choices.”). When solid comparative effectiveness evidence is lacking, less reliable information is left to fill the void. “Unfortunately, the individual physician may be most impressed by observations made in his or her individual practice. This source of evidence is notoriously vulnerable to bias and error.” David M. Eddy, *Variations in Physician Practice: The Role of Uncertainty*, HEALTH AFF., May 1984, at 74, 81.

¹²² For example, in 2007, the *New England Journal of Medicine* published the “COURAGE” (Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation) study. William E. Boden et al., *Optimal Medical Therapy With or Without PCI for Stable Coronary Disease*, 356 NEW ENG. J. MED. 1503 (2007). The research concluded that heart surgery using stents to unclog blocked arteries, a common procedure, often was not more effective than simply treating the cardiac patients with drugs alone or trying drug treatment first and moving to stents only if complications remained. *Id.* at 1509-11. Many expected the research’s publication would lead to significantly de-

cians, hospitals, and patients are slow to respond to new evidence of ineffectiveness.”¹²³ Even information dissemination about safety concerns can have weak influence on physician decisionmaking. For example, physicians have been known to pay little heed to the dire “black box” warnings that the FDA uses to alert physicians about newly discovered dangers associated with certain drugs.¹²⁴

Information dissemination has a modest impact at best because physicians receive and adopt the information in somewhat haphazard and idiosyncratic ways.¹²⁵ Many other factors drive community physicians’ decisionmaking apart from the underlying comparative effectiveness data. The way physicians are paid is a key influence.¹²⁶ Financial incentives powerfully guide physician behavior by engaging and exploiting the individual’s economic self-interest, above and beyond technical appeals to clinical judgment.¹²⁷ A physician’s initial professional education also has long-lasting impact, as physicians may exhibit path dependence, adhering to treatment pathways and decision approaches learned during their medical school and residency training programs.¹²⁸ Also, the views of respected local physician opinion

creased use of stents, but after a brief decline in use of the procedure, stent implants began to increase again. See Keith J. Winstein, *A Simple Health-Care Fix Fizzles Out*, WALL ST. J., Feb. 11, 2010, at A1 (noting that stent implants “are now back at peak levels” and that such studies “have rarely altered medical practice”). Part of the resistance to change may be because physicians and hospitals receive more favorable reimbursement for performing stent implants than for initiating drug therapy alone. Also, a degree of path dependence makes physicians resistant to switching from previous practices.

¹²³ Thom Wilder, *Despite Doubts About CER’s Impact, Studies Should Take Place*, *Researcher Says*, 9 Med. Res. L. & Pol’y Rep. (BNA) No. 7, at 215-16 (Apr. 7, 2010).

¹²⁴ See Jerry H. Gurwitz, Editorial, *Serious Adverse Drug Effects—Seeing the Trees Through the Forest*, 354 NEW ENG. J. MED. 1413, 1414 (2006).

¹²⁵ See Noah, *supra* note 112, at 377 (“[W]e most certainly do not yet enjoy fully evidence-based medical practice.”).

¹²⁶ See Hyman, *supra* note 106, at 371-72 (“It is difficult to overstate the extent to which economic incentives explain the structure, performance, and pathologies of the American health care system.”).

¹²⁷ See, e.g., Alan L. Hillman, *Financial Incentives for Physicians in HMOs: Is There a Conflict of Interest?*, 317 NEW ENG. J. MED. 1743, 1746-47 (1987).

¹²⁸ See, e.g., Arnold M. Epstein et al., *The Effects of Physicians’ Training and Personality on Test Ordering for Ambulatory Patients*, 74 AM. J. PUB. HEALTH 1271, 1272 & tbl.1 (1984) (finding that physicians trained in medical schools with more academic focuses tended to order more tests than other physicians); Sandra H. Johnson, *Polluting Medical Judgment? False Assumptions in the Pursuit of False Claims Regarding Off-Label Prescribing*, 9 MINN. J. L. SCI. & TECH. 61, 76-77 (2008) (observing that physicians’ willingness to disregard evidence-based sources of information partly stems from their experiences as trainees in the hierarchical environment of residency training programs, “where the opinion of the attending physician is revered as authoritative” and, accordingly, crowds out other information sources).

leaders and the recommendations of physician peers can heavily sway community doctors' treatment choices.¹²⁹ Aggressive marketing by drug and device manufactures can also impact physicians' treatment selection.¹³⁰ Other influencing factors include physicians' malpractice risk perceptions,¹³¹ the demands of patients and payers for certain products and services,¹³² physicians' enthusiastic belief in new technology,¹³³ and physicians' intuition and judgment based on isolated clinical experiences.¹³⁴

III. TRANSLATION BARRIERS

While the health care system critically needs high-quality CER, many factors limit the ability to make productive use of the research. Some complications arise from the inherent cost and difficulty of developing high-quality research. Perhaps even more importantly, even with very good CER available, physicians will be hesitant to change or adapt their practice patterns. As already noted, some physicians view CER with deep suspicion as a vehicle for rationing expensive treat-

¹²⁹ See, e.g., Johnson, *supra* note 128, at 76 (“Studies document significant influence of peer opinions on clinical decision making”); Stephen B. Soumerai et al., *Effect of Local Medical Opinion Leaders on Quality of Care for Acute Myocardial Infarction: A Randomized Controlled Trial*, 279 JAMA 1358, 1362-63 (1998) (“[W]hen best practices are clearly defined . . . local opinion leaders can accelerate adoption of effective treatments”); Jane M. Young et al., *Role for Opinion Leaders in Promoting Evidence-Based Surgery*, 138 ARCHIVES SURGERY 785, 789-91 (2003) (finding that most surgeons believe opinion leaders influence surgical practice).

¹³⁰ See DOCTEUR & BERENSON, *supra* note 37, at 3 (arguing that standard medical practice reflects such marketing, among other considerations, rather than medical evidence).

¹³¹ See Ezekiel J. Emanuel & Victor R. Fuchs, *The Perfect Storm of Overutilization*, 299 JAMA 2789, 2790 (2008) (“Medical malpractice laws and the resultant defensive medicine also contribute to overutilization [of health care].”).

¹³² See *id.* at 2790-91 (attributing part of the overutilization of health care to direct-to-consumer marketing); Wilder, *supra* note 123, at 216 (discussing how health care providers were slow to abandon use of high-dose chemotherapy followed by autologous bone marrow transplants for breast cancer despite mounting evidence of the treatment's ineffectiveness, due in part to patient demand).

¹³³ See *infra* Section III.E (discussing how the “technological imperative” can lead to the premature adoption of medical procedures and technology); see also CONG. BUDGET OFFICE, *supra* note 7, at 4 (listing “enthusiasm for the newest technology” as one of the reasons for the spread of new medical technologies despite a lack of proof of their effectiveness).

¹³⁴ See Alain Enthoven, *What Medical Care Is and Isn't*, in CLARK C. HAVIGHURST ET AL., HEALTH CARE LAW AND POLICY 135, 135-36 (2d ed. 1998) (excerpting A. ENTHOVEN, HEALTH PLAN: THE ONLY PRACTICAL SOLUTION TO THE SOARING COSTS OF HEALTH CARE 1-9 (1980)).

ments.¹³⁵ Professional self-interest as well as legitimate therapeutic concerns for patients provide additional reasons for physician resistance. Current legal rules and policy approaches fail to provide sufficient incentives for incorporating CER into regular clinical practice and may even discourage physicians from doing so.

A. *Vagueness and Mission Creep*

The failure to provide a more precise, consistent legislative and regulatory definition for CER¹³⁶ creates vagueness concerns, increasing the risk of fragmented work that lacks common methods and priorities. The confusion over whether CER should include thorough cost-effectiveness analysis is one example.¹³⁷ A comprehensive review of CER drug studies appearing in medical journals to date found that the investigations often did not consider cost (or safety, for that matter),¹³⁸ making the research arguably incomplete and raising concerns of publication bias.¹³⁹ Ideally, the new national CER program would require that government-funded studies use uniform methodologies to facilitate data sharing and improve the quality of the research. Unfortunately, the ambiguous legislative and regulatory guidance so far¹⁴⁰ leaves things unclear by not precluding the possibility that CER could include cost comparisons, but also by not providing consistent, forceful direction as to appropriate methodologies or even when such cost comparisons should be included.

Related to vagueness issues are “mission-creep” concerns. Physicians can be expected to question the new national CER program as unfocused and overly broad, extending to investigations that do not directly advance the originally understood goals of CER. The congressionally mandated IOM report¹⁴¹ exemplifies these problems. The

¹³⁵ See *supra* Section I.E.

¹³⁶ See *supra* Section I.D.

¹³⁷ See *supra* Section I.E.

¹³⁸ See generally Michael Hochman & Danny McCormick, *Characteristics of Published Comparative Effectiveness Studies of Medications*, 303 JAMA 951 (2010).

¹³⁹ Publication bias describes the greater likelihood that studies showing a significant positive result will receive publication opportunities (or are published at all) than equally well-conducted studies that report a negative result. This can lead to a discounting of costs and risks and an overrating of published treatments. See generally Lakshmi Sridharan & Philip Greenland, Editorial, *Editorial Policies and Publication Bias: The Importance of Negative Studies*, 169 ARCHIVES INTERNAL MED. 1022 (2009).

¹⁴⁰ See *supra* Section I.E.

¹⁴¹ See *supra* Section I.B.

IOM identified one hundred high-priority topics for CER.¹⁴² Rather than head-to-head treatment comparisons, about half of the recommendations concern general health care delivery-system issues, such as evaluating different strategies to delineate barriers to care, especially for members of populations that experience health disparities.¹⁴³ Such research, although worthy on its own terms, seems a bit far afield from helping physicians choose between specific treatment options, supposedly one of the main purposes of the new national CER program.¹⁴⁴ The inclusion of research that gets beyond head-to-head treatment comparisons will no doubt disappoint physicians wanting information more immediately relevant to their clinical circumstances.¹⁴⁵

In part, the new CER agenda may appear overly broad, and seemingly untethered, because of the historic opportunities created by the record governmental funding. With so much money at stake, it should not surprise that diverse interest groups have clamored and lobbied heavily for some share of the new CER funds. When the IOM elicited input from stakeholders on national priorities for CER, as required under the Recovery Act, it received over 2600 nominations from more than 1700 respondents within three weeks.¹⁴⁶ But the more diffuse the CER research agenda becomes, and the more it covers general health policy matters, the less likely that the information generated will command the attention of physicians practicing in the clinical trenches.

B. *Costly Studies That Raise More Questions Than Answers*

Another set of complications concerns the significant cost of conducting CER and the uncertain persuasiveness of the data generated.

¹⁴² See INST. OF MED. OF THE NAT'L ACADS., *supra* note 7, at 3 tbl.S-1.

¹⁴³ See *id.*

¹⁴⁴ According to the Federal CER Council, "The purpose of [CER] is to provide information that helps clinicians and patients choose which option best fits an individual patient's needs and preferences." FEDERAL CER COUNCIL REPORT, *supra* note 7, at 3.

¹⁴⁵ As Mark Miller, Executive Director of MedPAC, explained, "we expected to see a lot more drug-drug, device-device, medical treatment versus surgical" comparisons as recommended research priorities. Mark Miller, Remarks at the Public Meeting of the Medicare Payment Advisory Commission 107 (Sept. 17, 2009) [hereinafter Remarks at MedPAC Meeting], available at <http://www.medpac.gov/transcripts/0909MedPAC.pdf>. MedPAC Commissioner Dr. Thomas Dean expressed his surprise "at how vague or kind of non-focused some of the [IOM's priority] recommendations were," as well as his disappointment with the lack of specifics. Thomas Dean, Remarks at MedPAC Meeting, *supra*, at 109. He further opined, "At least from a clinical point of view, that's what we would need to make clinical decisions. From a policy point of view, maybe some of the other broader things." *Id.*

¹⁴⁶ Sox & Greenfield, *supra* note 11, at 203.

1. Cost

The gold standard in medical research—the type of investigation most likely to produce data compelling to the larger medical community—remains the randomized controlled trial (RCT).¹⁴⁷ RCTs are already expensive and time-consuming to conduct for general-efficacy trials.¹⁴⁸ A core feature of CER, however, is the inclusion of distinct patient subgroups to reflect real world circumstances.¹⁴⁹ To achieve this broader focus, comparative effectiveness RCTs will often need to involve more subjects than general-efficacy RCTs, adding to the cost and time required to complete the investigations. Also, to draw conclusions about the value of different treatments relative to each other, CER will likely need to detect small differences in outcomes. These differences may only become statistically significant when observed in a sufficiently large group of subjects. This increases the need to involve larger sample populations, making the studies even more expensive to conduct.¹⁵⁰

2. Secondary Data, Less Rigorous Research Methodologies, and Varying Measures of Effectiveness

Ironically, the CER movement may be a victim of its own success in calling attention to the flimsy foundation of scientific information underlying many current medical practices. The new push for CER has presumably heightened physician interest in better evidence. Yet this raises the question: why should physicians trust that CER is sufficiently “better evidence”?

Indeed, CER studies often cannot be designed with a high degree of scientific rigor. For example, switching some subjects from customary treatments may be seen as inappropriate before the comparative evidence becomes available. Also, it may not be possible to draw sufficiently large study populations from different patient subgroups. Ac-

¹⁴⁷ See ROBERT J. LEVINE, *ETHICS AND REGULATION OF CLINICAL RESEARCH* 211 (2d ed. 1986) (“[T]he RCT is the *gold standard* . . .”); Noah, *supra* note 112, at 381 (listing RCTs as the preferred study model when health professionals are “faced with a clinical problem”). In an RCT, subjects are randomly assigned to receive one of several clinical interventions. The possible interventions include the standard of comparison or control. The control may be the leading customary treatment, a placebo, or no treatment at all. *Study Design*, DUKE UNIV. MED. CTR. ONLINE, <http://www.mcilibrary.duke.edu/subject/ebm/studies.html> (last visited Mar. 15, 2011).

¹⁴⁸ See generally *Analysis of Comparative Effectiveness*, RAND HEALTH COMPARE, <http://www.randcompare.org/analysis-of-options/analysis-of-comparative-effectiveness> (last visited Mar. 15, 2011).

¹⁴⁹ See *supra* Section I.D.

¹⁵⁰ See Luce et al., *supra* note 66, at 208.

cordingly, for many treatment comparisons, the traditional standards for RCTs will need to be loosened; this could mean allocating subjects unequally between different arms of a study or incorporating information from observational studies and other secondary data sources into the base evidence for the RCTs.¹⁵¹ Adjustments in this manner create more flexibility but also invite physician concern about the persuasiveness of the data.¹⁵²

Some CER studies will not utilize RCTs at all, but rather will rely instead on secondary research, such as meta-analysis, systematic reviews of existing literature, observational studies, medical registries review, and analysis of existing claims and medical records.¹⁵³ But physicians have traditionally viewed such secondary research methodologies as less convincing than, and inferior to, carefully structured RCTs.¹⁵⁴ Also, because CER involves more diverse groups of patients than traditional efficacy investigations, it raises “the analytical challenges of making crisp inferences”¹⁵⁵ from base data sets that will be noisier and messier, making it harder to isolate which interventions produced which therapeutic outcomes. This likely will require more frequent use of newer statistical techniques, such as adaptive strategies that change endpoints midstream through a study or that include new treatments for comparison while some data has already been accrued.¹⁵⁶ Yet community practitioners have less familiarity and comfort with these research methods.

Physicians can also legitimately question the basic effectiveness criteria chosen for comparative study. The seemingly simple question, “Is treatment A more effective than treatment B?” is really not so simple. Even if one excludes cost-effectiveness from the definition of CER,¹⁵⁷ considerable uncertainty remains about how to measure treatments against each other. With chronic cancer care, for example, one treatment may offer longer term survival rates or better objective measures, such as tumor shrinkage, but may have less tolerable medication

¹⁵¹ See *id.* (discussing implementation of “adaptive” RCTs).

¹⁵² The goal of making CER pragmatic and quickly responsive to clinicians may conflict at times with the concurrent goal of generating hard scientific data. See Eugene C. Rich, *The Policy Debate over Public Investment in Comparative Effectiveness Research*, 24 J. GEN. INTERNAL MED. 752, 752-53 (2009).

¹⁵³ *Id.* at 752-53.

¹⁵⁴ See Luce et al., *supra* note 66, at 206 (“[RCTs] are the most rigorous method of generating comparative effectiveness evidence . . .”).

¹⁵⁵ Sox & Greenfield, *supra* note 11, at 205.

¹⁵⁶ See Luce et al., *supra* note 66.

¹⁵⁷ See *supra* Section I.E.

side effects or may fare worse in controlling other debilitating symptoms of the underlying cancer.¹⁵⁸ Without greater consensus on what is to be specifically compared in effectiveness studies, individual physicians will regard some CER data as incomplete and unconvincing.

3. Accounting for Individual Patient Differences

Some physicians remain indifferent to or unpersuaded by CER because they doubt whether the research adequately captures each patient's individual circumstances. High-quality CER supposedly accounts for the experiences and treatment responses of different subgroups of patients, making the research more context specific to particular individuals, not just the average patient.¹⁵⁹ PPACA attempts to advance such work by requiring that governmentally funded CER take into account potential effectiveness differences when treatments are used "with various subpopulations, such as racial and ethnic minorities, women, age, and groups of individuals with different comorbidities, [or] genetic and molecular sub-types."¹⁶⁰

But at the end of the day, CER studies can be individually tailored only so much. Translating the studies into clinical practice will require generalizing the experience of some subgroup of patients to the individual patient at hand where inevitable differences in age, gender, health status, medication history, genetics, and other factors still exist. Moreover, in looking primarily at the relative clinical effectiveness of different treatments, CER may not adequately account for other factors that physicians regard as important to their individual patients' medical decisions, such as quality of life, the actual burdens imposed by the treatment, and the treatment's cost.¹⁶¹ No matter how rigorous the research methodologies used to address patient subgroup differences, physicians may rightly be concerned that a particular CER study did not include subjects truly representative of their own patients, especially because treatment responses can be highly patient

¹⁵⁸ Nancy Berlinger & Anne Lederman Flamm, *Define "Effective": The Curious Case of Chronic Cancer*, HASTINGS CTR. REP., Nov.–Dec. 2009, at 17, 18.

¹⁵⁹ See FEDERAL CER COUNCIL REPORT, *supra* note 7, at 6 (calling for CER to account for groups "traditionally under-represented in medical research," such as minorities, children, and those with multiple chronic conditions).

¹⁶⁰ PPACA sec. 6301(a), § 1181(d)(2)(D), 42 U.S.C.A. § 1320e(d)(2)(D) (West Supp. 1A 2010). The law further requires that CER investigations "include members of such subpopulations as subjects in the research as feasible and appropriate." *Id.*

¹⁶¹ *Research Should Be Patient-Focused*, Comparative Effectiveness Council Told, 3 Life Sci. L. & Indus. Rep. (BNA) 657 (2009).

specific. As Medicare Payment Advisory Commission (MedPAC) Commissioner Dr. Thomas Dean has observed,

We're never going to have perfect data. There's always going to be patients who have unique situations, and we have to make sure that our policies allow for that, and that if we make good clinical decisions that don't entirely follow [the CER results], there has to be allowance for that.¹⁶²

4. Accounting for Individual Provider Differences

The flip side of whether CER adequately captures the varying circumstances of each patient is whether it sufficiently accounts for the distinctions between health care providers. This is especially important because CER aims to improve the existing evidence base in part by rigorously evaluating surgical procedures and other treatments not ordinarily subject to regulatory review by the FDA in its oversight of drugs, devices, and biologics.¹⁶³ Provider differences can have a significant influence on the effectiveness of such interventions. Physicians offering the exact same surgical procedure to very similar patients, for example, may still vary considerably in treatment outcomes due to physicians' different experiences and skills.¹⁶⁴

The recent Randomized On/Off Bypass (ROOBY) trial sponsored by the Department of Veterans Affairs¹⁶⁵ serves as a cautionary example of how provider differences can weaken the persuasiveness of CER investigations. Researchers designed the ROOBY trial to test the comparative effectiveness of "off-pump" bypass surgery for cardiac patients.¹⁶⁶ Traditional bypass surgery involves using a heart-lung machine, or "pump," to circulate blood for the patient while physicians stop the heart to perform the surgical connections.¹⁶⁷ The newer off-pump technique avoids use of the machine, and allows surgeons to

¹⁶² Dean, *supra* note 145, at 111-12.

¹⁶³ See *supra* Part II.

¹⁶⁴ PPACA recognizes this by providing that funded research "be designed, as appropriate, to take into account different characteristics of treatment modalities," such as "the impact of the skill of the operator of the treatment modality." PPACA sec. 6301(a), § 1181(d)(2)(E), 42 U.S.C.A. § 1320e(d)(2)(E). Despite such efforts, it remains to be seen whether the research can be designed to overcome physician concerns about this variable.

¹⁶⁵ See generally A. Laurie Shroyer et al., *On-Pump Versus Off-Pump Coronary-Artery Bypass Surgery*, 361 NEW ENG. J. MED. 1827 (2009).

¹⁶⁶ *Id.* at 1828.

¹⁶⁷ Gina Kolata, *Older Bypass Method Is Best, A Study Shows*, N.Y. TIMES, Nov. 5, 2009, at A20.

operate while the heart still beats.¹⁶⁸ The interest in off-pump surgeries developed in part because of concerns that patients even temporarily dependent on the heart-lung machine were at higher risk of developing neuropsychological problems, strokes, and other complications postsurgery—perhaps due to the way in which the pump oxygenates and circulates the blood.¹⁶⁹ Off-pump surgery attracted considerable interest in the past decade, with surgeons performing an estimated twenty percent of bypasses off-pump.¹⁷⁰

Yet the ROOBY trial produced surprising results that called into question the enthusiasm for off-pump surgery. Researchers saw no difference in neuropsychological outcomes between the on-pump and off-pump patient groups, directly challenging the supposed advantages of off-pump surgery.¹⁷¹ Moreover, the investigation found that the off-pump patients had worse therapeutic outcomes overall, requiring more repeat surgeries and also having higher complication rates after one year.¹⁷²

In some respects, the ROOBY trial worked just as optimal CER should. It provided rigorous scientific evidence for physicians to reconsider their medical choices and challenged physicians' often uncritical enthusiasm for technological innovation, demonstrating that newer is not always better. The results, published in the prestigious *New England Journal of Medicine*, made big news in the medical community. In the words of Dr. Eric Peterson, an academic cardiologist at Duke who wrote an editorial accompanying the study,¹⁷³ "This is a big one."¹⁷⁴ Meanwhile, Dr. Michael Lauer, director of cardiovascular sciences at the National Heart, Lung, and Blood Institute, said that he hoped the ROOBY trial would lead to a decline in off-pump surgeries.¹⁷⁵

Yet anecdotal reports suggest that a good number of physicians have not been convinced to change their surgical approaches. For example, Dr. Nirav Patel, a cardiac specialist at New York's Lenox Hill Hospital, told the *New York Times* that he would not alter his practice, which involves an estimated ninety-five percent of his patients receiv-

¹⁶⁸ *Id.*

¹⁶⁹ *Id.*

¹⁷⁰ *Id.*

¹⁷¹ See Shroyer et al., *supra* note 165, at 1827.

¹⁷² *Id.* at 1828-29. The researchers "hypothesized that there would be no difference between the . . . procedures . . ." *Id.* at 1828.

¹⁷³ See Eric David Peterson, *Innovation and Comparative-Effectiveness Research in Cardiac Surgery*, 361 *NEW ENG. J. MED.* 1897 (2009).

¹⁷⁴ Kolata, *supra* note 167.

¹⁷⁵ *Id.*

ing off-pump surgery.¹⁷⁶ Dr. Patel said that he had performed more than 1400 off-pump surgeries, likely more than many of the physicians studied in the ROOBY trial, and he thought that his skills had improved significantly due to the increase in procedure volume.¹⁷⁷ Letters to the editor following the study's medical journal publication similarly warned about the confounding complications posed by physician skill differences and relative experience rates.¹⁷⁸ The quite bumpy road experienced by the ROOBY trial illustrates the considerable difficulties that arise in translating CER into clinical practice.

5. Keeping Pace with Innovation

Some physicians discount CER because of concerns that it cannot keep pace with the rapid speed of medical innovation and shifting views of clinicians. As previously noted, many CER studies will take a long time to complete because the research aims to include a broader range of patient subgroups as subjects,¹⁷⁹ while other CER investigations will be based on secondary review of existing data arising from already completed studies.¹⁸⁰ As such, a time lag occurs between the data collection and the research study's public dissemination. During this interval, what clinicians view as the best competing treatment alternatives may change and, moreover, entirely new treatment approaches may develop. For example, oncologist Leonard Zwelling argues, "Since CER uses analyses of older, previously completed studies or collections of clinical data from disparate hospital records, CER is unlikely to help the individual with a newly diagnosed cancer in 2010.

¹⁷⁶ *Id.*

¹⁷⁷ *Id.*

¹⁷⁸ See, e.g., John D. Puskas et al., Letter to the Editor, *On-Pump Versus Off-Pump CABG*, 362 NEW ENG. J. MED. 851, 851 (2010) ("It is illogical to conduct a randomized trial comparing patient outcomes with alternative surgical techniques among surgical operators who have grossly asymmetric experience and expertise with the two procedures being compared. This is the 'fatal flaw' of the ROOBY trial."). On-pump surgeons in the trial were somewhat more likely to have been residents instead of attending physicians. See Shroyer et al., *supra* note 165, at 1836. Also, the off-pump surgeons might have lacked sufficient experience with that procedure to represent its advantages fairly, while the level of expertise of the cardiac anesthesiologist, another relevant factor in surgical success, was not reported. See Peterson, *supra* note 173, at 1898.

¹⁷⁹ See *supra* Section III.B.3.

¹⁸⁰ See Leonard A. Zwelling, Op-Ed., "Comparative Effectiveness" Research is Always Behind the Curve, WALL ST. J., Mar. 16, 2010, at A23 (arguing that CER cannot keep pace with advances in medicine as it relies on "old data" in a misguided attempt to standardize therapy and reduce costs).

That patient may choose among therapeutic options that were unavailable even a few years ago.”¹⁸¹

Also, the effectiveness of a treatment studied as part of a CER investigation may change over time as physicians develop expert skill in administering it, or as better understanding evolves of how patients’ genetic differences interact with the underlying disease and the proposed treatment. Accordingly, physicians may view some CER studies as stale on arrival.¹⁸²

6. Uncertain Answers

At bottom, CER may not be compelling to some physicians because it often fails to give sufficiently definitive answers. For example, comparison of drug versus surgical treatment for the same illness may reveal that the surgical procedure is more risky in terms of complications and post-treatment morbidity but that it also produces longer lasting improvements among patients who do experience a therapeutic benefit.¹⁸³ Physicians may be left wondering what to make of such data in terms of deciding treatment for the patient at hand. Although CER promises to include broader, more representative study populations, it is difficult to capture these multiple considerations consistently in each investigation. As a result, inherent degrees of uncertainty will always remain even after the results of CER studies roll in. Thus, the research may prove more frustrating than reassuring, as “it often fails to show which treatment is best, and for whom. . . . Instead of giving definitive answers, it opens the door to new questions. . . .”¹⁸⁴ Some physicians can be expected to act conservatively in the face of this uncertainty and call for even more data before they are willing to change longstanding practice patterns.

C. Financial Incentives

Health care financing also increases the risk of physician tune-out because current payment rules fail to reward physicians for adopting

¹⁸¹ *Id.*

¹⁸² See McClellan & Benner, *supra* note 29, at 9 (“[S]ome critics argue that CER results are likely to be misused, and the evidence may be outdated by the time it is available.”).

¹⁸³ See Susan Gilbert, *The Nesting-Egg Problem: Why Comparative Effectiveness Research Is Trickier Than It Looks*, HASTINGS CTR. REP., Nov.–Dec. 2009, at 11, 11-12 (discussing the tendency of CER to “open[] the door to new questions” rather than to give “definitive answers”).

¹⁸⁴ *Id.*

CER into clinical practice. As noted earlier, Medicare reimburses physician services so long as they meet the statutory “reasonable and necessary” coverage criteria.¹⁸⁵ And under Medicare’s physician fee schedule, the Resource-Based Relative Value Scale (RBRVS), physicians generally receive higher payments for services that are considered more intense and that require more physician work effort.¹⁸⁶ Thus, Medicare payments to physicians do not generally depend on whether the physician chose a more clinically effective (or, for that matter, cost-effective) treatment. Moreover, because of the way in which the various financial incentives misalign to encourage the performance of more complex services and more services overall, the current Medicare rules can inadvertently reward physicians for offering treatments less effective than their alternatives.¹⁸⁷

The Medicare approach reflects larger reimbursement trends. PPACA leaves private payers considerable discretion to ignore CER results in setting reimbursement policy.¹⁸⁸ In fact, few payers, public or private, apply reimbursement rules that reward physicians for choosing treatments based on comparative effectiveness. Most payment systems generally remain “quality insensitive.”¹⁸⁹ Physician reimbursement continues to be, for the most part, fee-for-service, under which physicians can generate payment for each discrete reimbursable service they provide, notwithstanding the outcome. Also, most health

¹⁸⁵ 42 U.S.C. § 1395y(a)(1)(A)–(B) (2006); see also *supra* notes 92-94 and accompanying text.

¹⁸⁶ Under Medicare’s RBRVS fee schedule, physicians receive higher payments for services that are considered to require greater skill and time to perform. At bottom, it remains a fee-for-service system, with physicians generally paid based on the reimbursable services that they provide, not on the quality of the outcome. See 42 U.S.C. § 1395w-4 (setting out the rules of payment for physicians’ services); Thomas L. Greaney, *Economic Regulation of Physicians: A Behavioral Economics Perspective*, 53 ST. LOUIS U. L.J. 1189, 1201-02 (2009) (characterizing RBRVS ratemaking as “a politicized . . . process” that results in fees that “have sent distorted economic signals to the market”).

¹⁸⁷ This effect is due to the fact that the RBRVS fee schedule, and the fee-for-service payment system generally, are ordinarily insensitive to the quality of the treatment outcome. For example, “[s]ervices that contribute greatly to high-quality care that are labor- or time-intensive and rely less on technical resources, such as patient education in self-management of chronic conditions and care coordination, tend to be undervalued and are not adequately reflected in current payment arrangements.” INST OF MED. OF THE NAT’L ACADS., REWARDING PROVIDER PERFORMANCE 4 (2007).

¹⁸⁸ See *supra* Section I.F.

¹⁸⁹ Hyman, *supra* note 106, at 372; see also McClellan & Benner, *supra* note 29, at 13 (“[T]he current fee-for-service reimbursement environment provides limited incentives at best to use effective treatments that cost less: virtually all of the treatments, big and small, that vary substantially from area to area receive higher payments when they are used more often, not necessarily when they contribute to better outcomes.”).

plans make coverage decisions with little regard for comparative effectiveness, so physicians can continue to recommend treatments that do not work as well as available alternatives.¹⁹⁰

D. *Bias and Public/Private Oversight*

Suspicious of bias also lead some physicians to question the integrity of the national CER program. As previously noted, in a move that awarded significant authority to private groups, PPACA abolished the previous federal-commission-type oversight structure for CER (the Federal CER Council) and replaced it with the PCOR Institute.¹⁹¹ The PCOR Institute will award publicly funded research contracts, identify national priorities for CER investigations, and set the agenda for and direct the nation's CER program.¹⁹² Yet it is not an agency, governmental unit, or otherwise purely public entity. To be incorporated as a new nonprofit corporation, the PCOR Institute will have a mix of public and private representation on its governing board, with private members in the majority.¹⁹³ Also, three members must represent drug and device manufacturers, and three other members must represent private payers.¹⁹⁴ The initial board of governors, which the Comptroller General selects, includes officials from powerful drug and device firms Johnson & Johnson, Medtronic, and Pfizer, and representatives from influential payers BlueCross BlueShield and Xerox.¹⁹⁵

Taken in its most favorable light, the PCOR Institute is consistent with the "new governance" theory that favors multistakeholder decisionmaking, various degrees of agency delegation and mediated self-regulation, and enlistment of private expertise and resources to address complex public problems.¹⁹⁶ Also, health care regulation already

¹⁹⁰ See Pearson, *supra* note 38, at 72 ("[M]ore often, comparative effectiveness information has little impact at all as coverage is granted even in the absence of good evidence, and payment for new interventions is determined by traditional formulas divorced from consideration of evidence on comparative clinical effectiveness.").

¹⁹¹ See PPACA sec. 6301(a), § 1181, 42 U.S.C.A. § 1320e (West Supp. 1A 2010); *id.* sec. 6302, 42 U.S.C.A. § 299b-8.

¹⁹² *Id.* sec. 6301(a), § 1181(d), 42 U.S.C.A. § 1320e(d).

¹⁹³ See *supra* note 48 (explaining the structure and membership of the PCOR Institute's governing board).

¹⁹⁴ See *id.*

¹⁹⁵ See *id.*

¹⁹⁶ The term "new governance" is intentionally used broadly here to cover different, if somewhat overlapping, schools of thought that favor breaking away from both traditional public regulation and complete deregulation. The various theories have numerous labels, including "new governance," "reflexive law," "responsible regulation," "outsourcing regulation," and "public/private." These approaches share an in-

involves public/private collaborations in various forms.¹⁹⁷ Thus, the fact that private interests will have a significant role in directing the PCOR Institute and, in turn, overseeing the new national CER program is not reason alone to dismiss this regulatory approach as biased or illegitimate.

But as an innovative form of new governance, the PCOR Institute seems poorly conceived. To succeed, new governance collaborations must do more than simply enlist the participation of multiple public and private actors and hope for the best. Fragmentation, opacity, and unaccountability can hinder new governance approaches.¹⁹⁸ Also, new governance models must be careful of agency capture by powerful stakeholders, especially because direct regulation to address power imbalances may be less likely given the influence ceded to private actors.¹⁹⁹ Plus, new governance models must account for real human behavior and the way stakeholders actually behave in collaborative settings.²⁰⁰ Moreover, when it comes to health care, even new gover-

terest in participatory governance structures, tapping the expertise and capacity of private interests and nongovernmental actors, and horizontal rather than vertical oversight. The new governance paradigm also views regulatory power as diffused among and arising from networks of public and private actors operating together through negotiated relationships. See generally IAN AYRES & JOHN BRAITHWAITE, *RESPONSIVE REGULATION: TRANSCENDING THE DEREGULATION DEBATE* (1992); Jody Freeman, *The Private Role in Public Governance*, 75 N.Y.U. L. REV. 543 (2000) (recognizing the pervasive presence of private actors in governance); Nan D. Hunter, "Public-Private" Health Law: *Multiple Directions in Public Health*, 10 J. HEALTH CARE L. & POL'Y 89 (2007) (exploring the development of new governance perspectives in health care law); Orly Lobel, *The Renew Deal: The Fall of Regulation and the Rise of Governance in Contemporary Legal Thought*, 89 MINN. L. REV. 342 (2004) (summarizing theoretical insights of new governance scholars).

¹⁹⁷ The Joint Commission, a private accrediting body for the nation's hospitals and other institutional providers, is one example. One of its committees, which features public and private actors, wields significant influence in public governance by establishing quality standards that are then incorporated into the regulatory conditions of participation in the Medicare program. See Freeman, *supra* note 196, at 610-12 (describing the committee as made up of professional, industrial, and government representatives). More recently, planning initiatives for public health emergencies have demonstrated the importance of public/private collaborations, such as public health departments looking to the business community for help in developing and implementing infectious disease control measures. See Hunter, *supra* note 196, at 106-09 (using the handling of the SARS outbreak to illustrate public/private collaboration).

¹⁹⁸ See John M. Conley & Cynthia A. Williams, *Engage, Embed, and Embellish: Theory Versus Practice in the Corporate Social Responsibility Movement*, 31 J. CORP. L. 1, 32-35 (2005) (summarizing critiques of new governance theories).

¹⁹⁹ See *id.* at 32-33.

²⁰⁰ See *id.* at 35; Gráinne de Búrca, *New Governance and Experimentalism: An Introduction*, 2010 WIS. L. REV. 227, 236-37 (discussing a critique of the new governance model's ability to predict and respond to human tendencies).

nance proponents recognize that without meaningful participation from physicians—who perform key roles as gatekeepers and trusted agents—new governance approaches will usually fail. Indeed, “[t]he role of physicians is crucial in order for new governance in health care to be successful.”²⁰¹

These considerations cast doubt on the PCOR Institute’s likely effectiveness. Although the PCOR Institute includes multiple stakeholders, including physician representatives, it does not sufficiently account for the perspective of ordinary physicians in the clinical trenches. For example, the PCOR Institute could, in theory, increase the interest of frontline practitioners by eliciting their clinical views about the standards that should be applied to CER investigations or the treatment comparisons most needed to improve delivery of care.

Yet the shared governance role of private industry has understandably raised physician concerns of politicized science and industry bias. After all, certain CER studies may discredit the effectiveness of particular drugs and devices or call into question the reimbursement and coverage policies of particular health plans. Will private members of the PCOR Institute’s governing board be able to support and advance independent CER studies that reflect critically on their constituencies’ products and policies? Wary physicians already doubt it. According to Harry Selker and Alastair Wood, the law “ced[es] substantial influence to the medical products industries that have a major interest in the outcomes of such research.”²⁰² They warn that CER should be “free of the potential taint of commercial and political meddling.”²⁰³

In partial recognition of bias concerns, PPACA applies modest conflict-of-interest provisions to PCOR Institute board members.²⁰⁴ Also, the new law requires that most CER investigations undergo peer review and that the PCOR Institute work with an expert methodology committee to develop better and consistent standards, such as criteria

²⁰¹ Louise G. Trubek, *New Governance Practices in US Health Care*, in *LAW AND NEW GOVERNANCE IN THE EU AND THE US* 245, 249 (Gráinne de Búrca & Joanne Scott eds., 2006).

²⁰² Harry P. Selker & Alastair J.J. Wood, *Industry Influence on Comparative-Effectiveness Research Funded Through Health Care Reform*, 361 *NEW ENG. J. MED.* 2595, 2596 (2009).

²⁰³ *Id.* at 2597.

²⁰⁴ Among other things, disclosure of conflicts of interest is required, and members of the governing board are to recuse themselves when they or family members have a direct financial interest of any amount in the results of a CER investigation. PPACA sec. 6301(a), § 1181(f)(2), 42 U.S.C.A. § 1320e(f)(2) (West Supp. 1A 2010). The same disclosure is required when they or their family derive a financial benefit (over \$10,000 annually) from an entity that owns or manufactures a product or service subject to a CER investigation. *Id.* sec. 6301(a), § 1181(a)(4), 42 U.S.C.A. § 1320e(a)(4).

for validity and feasibility, to apply to funded investigations.²⁰⁵ Nonetheless, doubts remain as to whether these safeguards will be sufficient. Many of the conflict-of-interest provisions seem dependent on enforcement by the governing board.²⁰⁶ Plus, this would hardly be the first instance in biomedical research where conflict-of-interest provisions as written in the books are not consistently followed or enforced in actual practice.²⁰⁷

The behind-the-scenes political maneuvering that led to the creation of the PCOR Institute has created additional transparency and accountability concerns. The House of Representatives' health reform bill, which ultimately did not become law, would have utilized a public model for CER oversight by establishing a new center for CER within the Agency for Healthcare and Research Quality (AHRQ).²⁰⁸ But heavy lobbying by the Partnership to Improve Patient Care (PIPC) helped convince Congress to move to a private/public model with the final health reform law.²⁰⁹ PIPC, despite including various medical profes-

²⁰⁵ *Id.* sec. 6301(a), § 1181(d), 42 U.S.C.A. § 1320e(d).

²⁰⁶ For example, the statute simply states that members of the PCOR Institute will be recused when they have an applicable conflict of interest, but does not describe how the recusal request is initiated. *Id.* sec. 6301(a), § 1181(f)(2), 42 U.S.C.A. § 1320e(f)(2). The most likely scenario is that the board as a whole will enforce the recusal provisions against individual board members. Also, the PCOR Institute is supposed to ensure that the members of expert advisory panels disclose conflicts of interest. *Id.* Again, the governing board as a whole would presumably have to undertake such actions.

²⁰⁷ See, e.g., Josephine Johnston, *Conflict of Interest in Biomedical Research* (reporting the close relationship between biomedical research institutions and for-profit businesses), in FROM BIRTH TO DEATH AND BENCH TO CLINIC: THE HASTINGS CENTER BIOETHICS BRIEFING BOOK 31, 32-33 (Mary Crowley ed., 2008); Gardiner Harris & Benedict Carey, *Researchers Fail to Reveal Full Drug Pay*, N.Y. TIMES, June 8, 2008, at A1 ("Universities ask professors to report their conflicts but do almost nothing to verify the accuracy of these voluntary disclosures."); Rick Weiss, "Serious Misconduct" by NIH Expert Found, WASH. POST, June 14, 2006, at A6 (reporting that a researcher traded valuable tissue specimens for money because of "lax oversight").

²⁰⁸ The House reform bill also would have established an independent CER Commission to oversee the activities of the CER program within the AHRQ. Affordable Health Care for America Act, H.R. 3962, 111th Cong. § 1401 (2009).

²⁰⁹ Since the Recovery Act's initial heavy funding for CER, "[a] major goal" of PIPC has been to "give industry a seat at the table" in deciding what CER studies to conduct. Alicia Mundy, *Drug Makers Fight Stimulus Provision*, WALL ST. J., Feb. 10, 2009, at A4; see also Howard Brody, *Now It's Time to Start Clearing the Land Mines..CER*, HOOKED: ETHICS, MED., AND PHARMA (Mar. 23, 2010, 4:59 PM), <http://brodyhooked.blogspot.com/2010/03/now-its-time-to-start-clearing-land.html> ("PIPC has been waging a stealth campaign, superficially applauding CER while trying hard behind the scenes to be sure that CER never gets to grow any teeth."). PIPC indeed publicly applauded the eventual CER provisions in the final health care reform law. See Press Release, P'ship to Improve Patient Care, PIPC Applauds New Health Care Bill's CER Language (Mar. 23, 2010), available at <http://www.improvepatientcare.org/news-media/pipc-applauds-new>

sional societies in its coalition such as the American College of Cardiology, largely represents the pharmaceutical industry. The Pharmaceutical Research and Manufacturers of America, the powerful drug industry trade group, formed the coalition, and PIPC has received support from major pharmaceutical firms such as Merck.²¹⁰

E. *Clinical Autonomy and the Technological Imperative*

Even if very high-quality, bias-free CER data can be produced at a reasonable cost, other factors suggest that physicians will be hesitant to use this information. Sociological studies of medical practice reveal that physicians highly value clinical autonomy, a preference reinforced by medical custom and a strong sense of professionalism.²¹¹ Physicians traditionally resist intrusions on their independent professional judgment and will buck interventions that seem to direct individual treatment decisions.²¹² Physicians can prove quite formidable in evading and undermining attempts to change their practice patterns, including through the effective strategy of passive resistance. Because of their strong preference for and expectations of clinical autonomy, physicians remain especially distrustful of practice guidelines or coverage decisions that do not seem physician driven, but rather appear motivated by institutional politics, cost control, or similar concerns.²¹³ Even initiatives to change practice patterns for quality reasons tend to

health-care-bill's-cer-language (follow the hyperlink under "Attachment") ("This legislation will help ensure that CER is used to help doctors and patients make the best treatment decisions possible . . .").

²¹⁰ Jonathan D. Salant & Aliza Marcus, *Drugmakers Boost Lobbying To Police Drug Comparisons*, BLOOMBERG (Apr. 17, 2010, 16:49 EDT), <http://www.bloomberg.com/apps/news?pid=newsarchive&sid=aHjr0BP1zvgo>.

²¹¹ ELIOT FREIDSON, *PROFESSION OF MEDICINE: A STUDY OF THE SOCIOLOGY OF APPLIED KNOWLEDGE* 23-33, 137-57, 359-82 (Robert Bierstedt ed., 4th prtg. 1972).

²¹² See Barry R. Furrow, *Incentivizing Medical Practice: What (If Anything) Happens to Professionalism?*, 1 WIDENER L. SYMP. J. 1, 5-6 (1996) (noting tensions between independent medical professionals and health care bureaucracies); Hall, *supra* note 25, at 451 (describing "clinical autonomy" as the medical profession's "most sensitive nerve"); Edward A. Pont, *The Culture of Physician Autonomy: 1900 to the Present*, 9 CAMBRIDGE Q. HEALTHCARE ETHICS 98, 100 (2000) (discussing the history of physician reactions to government "encroachment[]").

²¹³ Hall, *supra* note 25, at 450-52; see also Jacqueline Kosecoff et al., *Effects of the National Institutes of Health Consensus Development Program on Physician Practice*, 258 JAMA 2708, 2713 (1987) (noting the difficulty of convincing physicians to follow National Institutes of Health recommendations).

fail unless they sufficiently preserve physicians' ability to exercise independent discretion.²¹⁴

Ensuring greater physician input into the design of CER does not necessarily resolve the clinical-autonomy problems. Studies of medical culture indicate that *individual* autonomy, more so than professional autonomy as a whole, is what matters to the typical physician. Physicians' training and professional orientation make them wary of ceding clinical discretion even to their peers.²¹⁵ The fact that other physicians developed a CER study may thus fail to assuage the individual physician's concerns about loss of professional authority. Indeed, CER relies on sophisticated statistical techniques to draw conclusions from the experiences of groups of patients, rather than relying on an individual physician's impressions from isolated clinical experiences. As with evidence-based medicine generally, this emphasis threatens individual physician autonomy because it gives greater authority to statisticians, institutional managers, academic researchers, and others while seemingly devaluing the weight and influence of the individual clinician's judgment.²¹⁶

Recent physician focus-group discussions conducted by MedPAC staff demonstrate the depth of physicians' clinical autonomy concerns regarding CER.²¹⁷ MedPAC researchers interviewed primary and specialist physicians in a variety of practice settings. Some physician respondents firmly opposed CER. This group worried that payers and the government would use CER to dictate treatment through mandatory practice guidelines. This group further believed that "personal experience with a treatment was enough for them to make treatment decisions."²¹⁸ One physician remarked, "We have our

²¹⁴ See James L. Reinertsen, *Zen and the Art of Physician Autonomy Maintenance*, 138 ANNALS INTERNAL MED. 992, 993-94 (2003) (detailing common arguments that physicians use to defy evidence-based guidelines and protocols). For example, the TQM initiatives introduced in medical centers in the 1990s largely floundered, due in part to clinical autonomy concerns. See Weber & Joshi, *supra* note 28, at 389-92. A more recent example concerns health care institutions' attempts to impose antibiotic-control policies. Although initiated for valid public-health reasons, the control programs have generated resistance because of physicians' desire to control their own work. See Richard S. Saver, *In Tepid Defense of Population Health: Physicians and Antibiotic Resistance*, 34 AM. J.L. & MED., 431, 478-79 (2008).

²¹⁵ See Hall, *supra* note 25, at 462-63.

²¹⁶ See Marc A. Rodwin, *The Politics of Evidence-Based Medicine*, 26 J. HEALTH POL. POL'Y & L. 439, 440-41 (2001) (discussing shifts in power from physicians to other decisionmakers).

²¹⁷ See, e.g., Remarks at MedPAC Meeting, *supra* note 145, at 96-127.

²¹⁸ Joan Sokolovsky, Remarks at MedPAC Meeting, *supra* note 145, at 100-01.

judgment. If we like something, if it works, great. If it doesn't, then we try something else."²¹⁹

Related to physicians' strong desire for professional discretion is the "technological imperative." Under this powerful medical norm, physicians consider use of the latest technologies in the clinic as a sign of improvement in care.²²⁰ Innovation, in this view, reflects medicine working at its best and reinforces the physician's esteemed role as technocratic expert mediating new scientific advances for the benefit of the patient. Accordingly, physicians highly value the clinical autonomy to switch to newer treatments and services when they see fit. However, even with the best of intentions, this can lead some physicians to "embrace new procedures and technologies prematurely, before much evidence exists to support their enthusiasm."²²¹

An anticipated benefit of CER is that it will demonstrate when new treatments really seem to offer little improvement in effectiveness over older treatments.²²² However, getting physicians to be more cautious about embracing new technology will not be easy. The physician's belief in the superiority of her own judgment, rightly or wrongly, is not easily swayed by "better" data. As one commentator observes, doctors "inevitably believe in their technologies and products, making it tricky to get them to willingly lay down their arms."²²³

F. "Individualized" Medicine

As previously noted, some physicians find CER unpersuasive because they believe that it does not sufficiently account for the differences between individual patients.²²⁴ In fact, concern for what works best for the individual patient presents formidable translation barriers, above and beyond questioning the relevance of particular CER data. Physicians' strong commitment to individualized medicine, an orienta-

²¹⁹ *Id.* at 101; see also Mushlin & Ghomrawi, *supra* note 84, at e6(1) ("Unfortunately, there is still a widespread lack of understanding about what CER will do—and fear that it will do more harm than good, in part by threatening individual physicians' autonomy and professionalism.").

²²⁰ See, e.g., Muriel R. Gillick, *The Technological Imperative and the Battle for the Hearts of America*, 50 PERSP. BIOLOGY & MED. 276, 276 (2007) (discussing, as an example of the technological imperative, physicians' uncritical adoption of the left ventricular assist device for treatment of advanced heart failure).

²²¹ Noah, *supra* note 112, at 393-94.

²²² See *supra* subsection III.B.4 (discussing the ROOBY trial that called into question the benefits of off-pump cardiac surgery).

²²³ See Wachter, *supra* note 14.

²²⁴ See *supra* subsection III.B.3.

tion encouraged by medical ethics, health law, and professional norms, remains in significant tension with CER's group-based foundations.

Health care has traditionally been divided between individual and population health, a fragmentation that can undermine overall health care delivery.²²⁵ At the individual health level, a physician provides treatment tailored for a specific patient within the confines of the special doctor-patient relationship. Population health, in contrast, concerns the health of the aggregate number of individuals in the community and involves activities such as infectious-disease control and surveillance reporting to public health agencies.²²⁶ For the community physician, the individual-health paradigm has typically dominated over population health considerations. Physicians' training, medical norms, ethical guidance, and the law surrounding the doctor-patient relationship all emphasize strong fidelity to each patient. This strong emphasis on individualized medicine discourages consideration of the population-health perspective.²²⁷ Doing what is best for a single patient can lead a physician to neglect population-health responsibilities, as has been seen with uneven reporting of infectious diseases to public-health authorities²²⁸ and physicians' imprudent conservation of the antibiotic supply.²²⁹

The dominance of the individual-health paradigm discourages physicians' receptiveness to CER. By privileging evidence gathered from treatment interventions at the group or subgroup level, rather than relying on isolated clinical experiences, CER aims to provide a more scientific foundation for medical decisionmaking. But community physicians, following a predominantly individual-health perspective, favor *any* benefit to the patient at hand. In other words, CER asks whether reliable evidence, generated from the experience of patient

²²⁵ See Arnold J. Rosoff, *Policy Challenges in Modern Health Care*, 26 J. LEGAL MED. 523, 525 (2005) (book review) (“[M]any of the core policy challenges facing health care today involve the interaction between individual health and public health and the inevitable tradeoffs that arise in trying to optimize health at both levels.”).

²²⁶ See LAWRENCE O. GOSTIN, *PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT* 10-11 (2d ed. 2008).

²²⁷ See Saver, *supra* note 214, at 454-61 (listing hindrances to physicians' consideration of the public health perspective and concluding “that many physicians are rather reluctant, passive defenders of population health”).

²²⁸ See, e.g., Janet S. St. Lawrence et al., *STD Screening, Testing, Case Reporting, and Clinical Partner Notification Practices: A National Survey of US Physicians*, 92 AM. J. PUB. HEALTH 1784, 1787 (2002) (finding low physician compliance with laws that require reporting of sexually transmitted diseases, an activity critical to population health surveillance efforts).

²²⁹ See Saver, *supra* note 214, at 460-61.

groups, supports offering treatment *A* over treatment *B* in similar cases. However, the community physician more likely wants to know which treatment—*A*, *B*, or something altogether different—*might* work for *this* patient. Studies suggest physicians have stronger feelings of obligation to individual, known patients than to larger group interests.²³⁰ This bias toward doing what possibly could benefit a particular patient—a bias supported by current legal rules—makes it difficult to advance the broader public interest in many aspects of health policy.²³¹ It similarly complicates physicians' willingness to embrace CER.

Along these lines, some physicians worry that imprudent application of CER presents quality hazards. Under this view, CER generalizes from the results of the larger population as to what is best for a particular patient—an approach that can, unwittingly, lead to worse medical care. Evidence-based medicine guidelines in the past have been discredited by later, more refined evidence-based research that showed significant need to vary “best practices” for different patients. Harvard University physician Jerome Groopman, a frequent critic of the government's new CER agenda, warns that in its zeal to improve the evidence base through CER, the government is imprudently pushing a one-size-fits-all approach that can worsen the quality of care.²³² According to Groopman, CER works best when the medical practices compared are repetitive, mechanical, involve the same basic clinical factors, and therefore can be standardized to a large degree across a group of patients.²³³ But he cautions that many other medical practices are “significantly altered by the condition of the individual patient” or “must be adapted to a particular person.”²³⁴ “[O]nce we depart from such mechanical procedures and impose a single ‘best practice’ on a complex malady, our treatment is too often inadequate.”²³⁵ The MedPAC physician survey similarly indicated that many physicians

²³⁰ See, e.g., Donald A. Redelmeier & Amos Tversky, *Discrepancy Between Medical Decisions for Individual Patients and for Groups*, 322 NEW ENG. J. MED. 1162, 1163-64 (1990).

²³¹ William Sage refers to these duties to individual patients as “relational duties,” which contrast with the physician's “regulatory duties” to advance larger societal goals for the health care system. William M. Sage, *Relational Duties, Regulatory Duties, and the Widening Gap Between Individual Health Law and Collective Health Policy*, 96 GEO. L.J. 497, 500-01 (2008).

²³² Jerome Groopman, *Health Care: Who Knows “Best”?*, N.Y. REV. BOOKS, Feb. 11, 2010, at 12, 13.

²³³ *Id.*

²³⁴ *Id.*

²³⁵ *Id.*

worry that overreliance on CER will interfere with their ability to tailor treatment to individual patients.²³⁶

To be sure, not all proponents of individualized medicine view CER as a threat or as a vehicle for “cookbook” medicine. Physicians such as Pauline Chen argue that CER actually solidifies the individual doctor-patient relationship.²³⁷ According to Chen, evidence of relative ineffectiveness can counter the physician’s bias to try active medical intervention to help the patient when better medical practice might be to pursue a course of watchful waiting or to do nothing at all.²³⁸

Other commentators similarly suggest that, if done right, CER supports rather than undermines the physician’s ability to provide individualized care. “Personalized medicine” emphasizes using individual genetic information to select better treatments and biologically tailoring medical interventions to fit a patient’s circumstances and needs.²³⁹ High-quality CER, if extended broadly to various subgroups of patients, may yield important data for such efforts and significantly advance the practice of personalized medicine.²⁴⁰

But to work in this manner, CER will have to produce compelling results that are broad and deep enough to capture the many genetic and other biological differences between patients. This will necessitate ongoing revision to CER investigations. It will also require confidence that the underlying biological-marker tests are consistent and accurate and that the data reveal meaningful differences in treatment responses among patient subgroups. These preconditions seem daunting. So far, personalized-medicine research has proven more difficult to conduct in practice than initially hoped, and therapies targeted to genetic differences have yielded few real medical breakthroughs.²⁴¹

²³⁶ In summarizing the data, MedPAC commissioner Herb B. Kuhn observed that “this issue of non-interference within the physician-patient relationship is loud and clear.” Herb B. Kuhn, Remarks at MedPAC Meeting, *supra* note 145, at 108.

²³⁷ See Pauline W. Chen, *A Tool to Strengthen the Doctor-Patient Relationship*, HASTINGS CENTER REP., Nov.–Dec. 2009, at 15, 16-17.

²³⁸ *Id.*

²³⁹ Alan M. Garber & Sean R. Tunis, *Does Comparative-Effectiveness Research Threaten Personalized Medicine?*, 360 NEW ENG. J. MED. 1925, 1925 (2009).

²⁴⁰ See FEDERAL CER COUNCIL REPORT, *supra* note 7, at 6 (“[C]omparative effectiveness should complement the trend in medicine to develop personalized medicine—the ability to customize a drug and dose based on individual patient and disease characteristics. One of the advantages of large comparative effectiveness studies is the power to investigate effects at the sub-group level that often cannot be determined in a randomized trial.”).

²⁴¹ See Andrew Pollack, *Patient’s DNA May Be Signal to Tailor Drugs*, N.Y. TIMES, Dec. 30, 2008, at A1, A16 (describing problems with nonpersonalized medicine); Su-

G. Liability Concerns

Liability concerns also dampen physicians' enthusiasm for CER. According to MedPAC's survey of physicians,²⁴² some physicians deeply worry about increased liability exposure if they end up disregarding CER, even when they have valid reasons for doing so, such as individually tailoring treatment to the patient.²⁴³ The concern is that a physician pursuing a care pathway not well supported by CER becomes necessarily vulnerable to claims that she has adopted outmoded, unsound treatments.²⁴⁴ According to classic deterrence theory, physician recognition of liability risk for disregarding CER should be a good thing. This will encourage physicians to change their practice patterns and conform to a CER-influenced standard of care. Alternatively, it will encourage physicians dissatisfied with CER findings to contribute evidence to new CER investigations to improve the quality of information generated. Under this view, physician liability concerns should actually help to translate CER into medical practice more readily.

Although tort deterrence improves the quality of care in theory, the reality has often been messier. The malpractice system experiences high costs and considerable problems in accurately determining departures from the standard of care.²⁴⁵ Also, many other confounding factors can greatly blunt the deterrence effect of the tort system, which may exert the weakest influence over individual physicians, as opposed to hospitals and other institutional providers.²⁴⁶ Thus, without significant changes, the malpractice system will likely

san Gilbert, *Behind the Curtain of Personalized Medicine: The Havasupai Tribe Settlement*, BIOETHICS FORUM (June 14, 2010, 1:50 PM), <http://www.thehastingscenter.org/Bioethicsforum/Post.aspx?id=4705&blogid=140> (discussing the need for continued improvement in personalized medicine techniques like genetic tests).

²⁴² See *supra* notes 217-19 and accompanying text.

²⁴³ See Joan Sokolovsky, Remarks at MedPAC Meeting, *supra* note 145, at 103.

²⁴⁴ See Fay Rozovsky, *A Risk Manager's Tour of the ARRA*, AM. SOC'Y HEALTHCARE RISK MGMT. 5 (May 2009), http://www.ashrm.org/ashrm/education/development/monographs/Mono_ARRA.pdf.

²⁴⁵ See, e.g., David A. Hyman, Commentary, *Medical Malpractice and the Tort System: What Do We Know and What (If Anything) Should We Do About It?*, 80 TEX. L. REV. 1639, 1641-45 (2002) (reporting that instead of fault, the best predictor of the size of a tort award is the severity of disability); David M. Studdert et al., *Claims, Errors, and Compensation Payments in Medical Malpractice Litigation*, 354 NEW ENG. J. MED. 2024, 2025, 2029-31 (2006) (analyzing the costs involved with malpractice suits).

²⁴⁶ See Michelle M. Mello & Troyen A. Brennan, *Deterrence of Medical Errors: Theory and Evidence for Malpractice Reform*, 80 TEX. L. REV. 1595, 1623 (2002) ("[T]he deterrent effect occurs primarily at the institutional level. Individual providers will always lack strong tort incentives to improve care because most are sued so infrequently.").

not provide highly nuanced, fine-tuned incentives with regard to CER. Instead, it will operate crudely, at best.

Moreover, complicating the analysis is that physicians' concerns about liability run in two directions. MedPAC's physician survey, as noted, indicated that some physicians worry about liability when departing from CER.²⁴⁷ But in a lose-either-way scenario, other physicians fear that if they *conform* their practices to CER, they will face *enhanced* liability exposure. These concerns arise for several reasons. Physicians may rightly question whether lay juries will understand the importance of CER, particularly where the research purports to discredit the effectiveness of commonly offered treatments. Physicians who adopt less-is-more treatment strategies based on CER may worry that juries will unfavorably view such actions as stinting on care. Also, as a doctrinal matter, existing medical custom ordinarily defines the standard of care,²⁴⁸ not what research suggests should be done. Physicians may fear that custom will trump CER in hard cases, regardless of whether custom actually works or is more effective than what CER suggests.

The lawsuit against Dr. Daniel Merenstein, a third-year resident practicing in Virginia, stands out as a cautionary tale. Dr. Merenstein wrote a widely discussed 2004 column in the *Journal of the American Medical Association*, detailing how he was sued for not ordering a screening test, the prostate-specific antigen (PSA) test, for a patient who later died of prostate cancer.²⁴⁹ The defense argued that evidence-based medicine practice guidelines amply supported Dr. Merenstein's decision.²⁵⁰ The relevant guidelines questioned the routine ordering of PSA tests in these situations because of false positive results, emotional stress, costs, and other negative factors.²⁵¹ The guidelines instead recommended shared decisionmaking between patients and physicians on whether to order the test.²⁵² Meanwhile, the plaintiff put forth evidence that local custom among physicians in the community was to

²⁴⁷ See Joan Sokolovsky, Remarks at MedPAC Meeting, *supra* note 145, at 103.

²⁴⁸ See *Osborn v. Irwin Mem'l Blood Bank*, 7 Cal. Rptr. 2d 101, 125 (Ct. App. 1992) (“[P]rofessionals are usually held only to a standard of custom and practice . . .”). But see Philip G. Peters, Jr., *The Role of the Jury in Modern Malpractice Law*, 87 IOWA L. REV. 909, 913-917 (2002) (arguing that state courts have been retreating from the traditional rule that custom defines the medical standard of care and replacing it with a reasonable physician standard).

²⁴⁹ See Daniel Merenstein, *Winners and Losers*, 291 JAMA 15 (2004).

²⁵⁰ *Id.* at 15-16.

²⁵¹ *Id.* at 15.

²⁵² *Id.*

order the test routinely.²⁵³ Although the jury found Dr. Merenstein not liable individually, it found against his residency program and awarded the plaintiff \$1 million.²⁵⁴ Dr. Merenstein and others have interpreted the case as a verdict against evidence-based medicine.²⁵⁵ Under this view, the jury disregarded more rigorous, systematic evidence about the PSA test and sanctioned the residency program because other physicians still practiced the older, allegedly inferior way.²⁵⁶ As Dr. Merenstein lamented, the malpractice system appeared to be “punishing the translation of evidence into practice, impeding improvements to care, and ensconcing practices that hurt patients.”²⁵⁷

These concerns, discussed in the context of evidence-based medicine generally, clearly apply to CER. It may be, however, that physicians’ liability fears are overstated. Cases like Dr. Merenstein’s may not accurately reflect how the malpractice system would handle most CER-related disputes.²⁵⁸ This would not be the first instance where physicians overstate liability risks.²⁵⁹ But the concern about enhanced liability exists, whether accurate or not, and such perceptions can powerfully motivate physician behavior. In short, physicians’ liability views make them more tentative about embracing CER in daily clinical practice.

IV. RECOMMENDATIONS

Considerable barriers, including most importantly the lack of strong incentives for physicians to adapt to the evidence, impede health care reform’s rollout of CER. Nonetheless, recognition of the importance of the physician’s gatekeeper role suggests that initiatives targeted to engage physicians more directly could help a great deal. This Part considers a few promising options.

²⁵³ *Id.*

²⁵⁴ *Id.* at 16.

²⁵⁵ See, e.g., Darshak Sanghavi, *Do We Have a Winner?: How to Reform the Broken Medical Malpractice System*, SLATE, Nov. 9, 2009, <http://www.slate.com/id/2235027>.

²⁵⁶ Merenstein, *supra* note 249, at 16.

²⁵⁷ *Id.*

²⁵⁸ See Mark A. Hall et al., Letter to the Editor, 291 JAMA 1697 (2004) (questioning the general applicability of the Merenstein case because the jury may have found against the residency program for other reasons than the adoption of evidence-based practice).

²⁵⁹ See, e.g., Ann G. Lawthers et al., *Physicians’ Perceptions of the Risk of Being Sued*, 17 J. HEALTH POL. POL’Y & L. 463, 463 (1992) (finding that physicians’ perception of the risk of facing a malpractice suit was three times the actual risk); Am. Roentgen Ray Soc’y, *Radiologists Overestimate Their Overall Risk of Malpractice Lawsuits in Breast Imaging*, SCI. DAILY, Feb. 2, 2009, <http://www.sciencedaily.com/releases/2009/02/090202175100.htm> (reporting that radiologists perceived a thirty-five percent risk of being sued in the next five years despite the actual risk being ten percent).

A. Coverage Rules and Financial Incentives

A critical first step is to relax the restrictions on using CER for reimbursement purposes.²⁶⁰ Well-designed financial incentives could jump-start physicians' interest in comparative effectiveness. However, development of such incentives requires that payers have greater flexibility to rely on CER when choosing to cover certain technology or when deciding which procedures should receive higher payments than others. While it is true that PPACA does not absolutely preclude use of CER for reimbursement purposes, it makes it difficult to do so.²⁶¹ It is also true that the new law primarily imposes its restrictions on linking CER with reimbursement on Medicare and other governmental health care programs, not private payers.²⁶² Yet easing the restrictions on Medicare alone could have a beneficial spillover effect for the entire health care system. Medicare covers a significant share of patients in the market overall.²⁶³ As such a large payer, it commands a powerful position to act as "first mover,"²⁶⁴ with private payers more likely to follow.

More flexible application of Medicare's "coverage with evidence development" (CED) rules is one option to develop better synergy between reimbursement and CER. Under the CED rules, Medicare generally can condition payment for a promising new medical treatment on beneficiaries enrolling in a clinical trial that will develop further information about whether the treatment meets Medicare's "reasonable and necessary" coverage criteria.²⁶⁵ Under this approach, Medi-

²⁶⁰ See *supra* Section I.F (explaining PPACA's limitations on CER use).

²⁶¹ See *supra* Section I.F.

²⁶² *Supra* Section I.F.

²⁶³ As of 2008, Medicare covers approximately fifteen percent of United States residents. Ctrs. for Medicare & Medicaid Servs., *Data Compendium, 2009 Edition*, CENTERS FOR MEDICARE & MEDICAID SERVS., tbl.VII.4 (Dec. 2009), http://www.cms.gov/DataCompendium/15_2009_Data_Compendium.asp. Twenty-three percent of total national health care spending is for the Medicare program. HENRY J. KAISER FAMILY FOUND., *MEDICARE SPENDING AND FINANCING: FACT SHEET 1* (2010), available at <http://www.kff.org/medicare/upload/7305-05.pdf>.

²⁶⁴ See *supra* note 98 and accompanying text.

²⁶⁵ For Medicare's general coverage criteria for physician services, see *supra* notes 185-87 and accompanying text. Medicare has formalized its CED approach through an agency guidance document. See *generally* CTRS. FOR MEDICARE & MEDICAID SERVS., *NATIONAL COVERAGE DETERMINATIONS WITH DATA COLLECTION AS A CONDITION OF COVERAGE: COVERAGE WITH EVIDENCE DEVELOPMENT* (2006), available at <https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=8>. Conditioning payment on study participation is a particular form of CED known as "Coverage With Study Participation." *Id.* The CED process is, however, not without its critics. See, e.g., Lars Noah, *Coerced Participation in Clinical Tri-*

care will also generally require that participating physicians not offer the intervention to patients not enrolled in the study.²⁶⁶ The basic point of the CED rules is to “move beyond yes/no coverage decisions”²⁶⁷ that can prove difficult to make in the absence of good information. When applying CED status to a technology, Medicare allows limited access to it, so long as it is part of a clinical trial that can, hopefully, yield more evidence about whether the technology meets Medicare’s regular coverage criteria and should be covered on a program-wide basis.

Yet Medicare has so far used the CED authority on very few occasions.²⁶⁸ Information gathered during CED-reimbursed studies also tends to concern general effectiveness, not comparative effectiveness, due to the statutory criteria for Medicare coverage.²⁶⁹ Changes to the Medicare statute and agency policies that allowed more frequent use of the CED process and that made comparative effectiveness information matter more for future program-wide coverage decisions of treatments introduced initially through the CED rules, would help increase physician receptiveness. Subjecting promising but unclear treatments to CED would allow physicians (and patients) some discretion to adopt new technology, thus respecting physicians’ clinical autonomy concerns and accommodating their interest in exploring new technology.²⁷⁰ Importantly, this would entail individual physicians participating more directly in the generation of comprehensive comparative effectiveness evidence, which hopefully would heighten their in-

als: *Conscripting Human Research Subjects*, 62 ADMIN. L. REV. 329, 366 (2010) (concluding the Centers for Medicare and Medicaid Services’ practices are “heavy-handed” and contravene federal regulations).

²⁶⁶ See CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 265.

²⁶⁷ *MedPAC Cites Challenges to Wide Use of Coverage with Evidence Development*, 8 Med. Res. L. & Pol’y Rep. (BNA) No. 22, at 767 (Nov. 18, 2009).

²⁶⁸ See Peter J. Neumann et al., *Medicare’s National Coverage Decisions for Technologies, 1999–2007*, 27 HEALTH AFF. 1620, 1623 (2008) (“CMS used its CED policy in seven decisions through 2007 . . .”).

²⁶⁹ For the criteria for Medicare coverage, see *supra* notes 185-87 and accompanying text. For complaints about the limitations of CED, see Mindy Yochelson, “*Coverage with Evidence Development*” *Falling Short, Former CMS Official Says*, 9 Med. Res. L. & Pol’y Rep. (BNA) No. 6, at 174 (Mar. 17, 2010). Cf. David Orentlicher, *Making Research a Requirement of Treatment: Why We Should Sometimes Let Doctors Pressure Patients to Participate in Research*, HASTINGS CTR. REP., Sept.–Oct. 2005, at 20, 20-22 (noting the need for better comparative effectiveness information and suggesting that physicians should be able to condition continued care on their patients’ willingness to participate in comparative-efficacy trials).

²⁷⁰ See *supra* Section III.E.

terest in the research results. This would also develop a more robust evidence base to guide future coverage and treatment decisions.

In addition to linking coverage of treatments to evidence of comparative effectiveness, payers could offer physicians financial incentives for adhering to clinical practice guidelines based on solid CER. Guideline implementation studies from different medical disciplines indicate that when physicians receive financial rewards, guideline adherence has been somewhat more successful.²⁷¹ Financial incentives continue to be one of the most powerful tools for driving physician behavior.²⁷² Such incentives can improve the often only short-term impact of educational appeals by giving physicians a continual interest in reevaluating their practice patterns.²⁷³ Also, compared to other implementation measures, such as treatment mandates or outright coverage denials, financial incentives may be more physician friendly because they better preserve physician discretion.²⁷⁴ Financial incentives do not require a particular course of treatment, allowing room for the clinician to tailor care to the particular patient as she sees fit and earn (or not earn) a particular reward. This approach is more compatible with physicians' strong desire for professional autonomy²⁷⁵ and their commitment to individualized medicine.²⁷⁶

Financial incentives cannot eradicate all physician concerns about the persuasiveness of CER. Further, there is a possible danger in trying to override those concerns, some of which raise legitimate therapeutic issues,²⁷⁷ by financially rewarding physicians to follow CER in all cases. Not all CER guidelines will be of high quality. Some may suffer

²⁷¹ Michelle M. Mello, *Of Swords and Shields: The Role of Clinical Practice Guidelines in Medical Malpractice Litigation*, 149 U. PA. L. REV. 645, 682-83 (2001).

²⁷² See, e.g., MARK A. HALL, MAKING MEDICAL SPENDING DECISIONS: THE LAW, ETHICS, AND ECONOMICS OF RATIONING MECHANISMS 171 (1997) (“[T]here is no dispute about whether financial incentives will work . . .”); cf. MARC A. RODWIN, MEDICINE, MONEY & MORALS: PHYSICIANS’ CONFLICTS OF INTEREST 97-105 (1993) (discussing the possible dangers of using financial incentives to increase or decrease services); Fred J. Hellinger, *The Impact of Financial Incentives on Physician Behavior in Managed Care Plans: A Review of the Evidence*, 53 MED. CARE RES. & REV. 294, 311 (1996) (“[F]inancial incentives are a key element in explaining the success of managed care plans in reducing the utilization of health services.”).

²⁷³ See Hall, *supra* note 25, at 480.

²⁷⁴ See, e.g., David Orentlicher, *Paying Physicians More to Do Less: Financial Incentives to Limit Care*, 30 U. RICH. L. REV. 155, 174-77 (1996) (observing that the alternative of caps on specific services would restrict physicians’ ability to tailor care to the needs of a given patient).

²⁷⁵ See *supra* Section III.E.

²⁷⁶ See *supra* Section III.F.

²⁷⁷ See *supra* Sections III.B, III.F.

from lack of rigor or industry bias. Appropriate criteria need to be applied consistently to identify which CER-influenced guidelines are sufficiently credible. Entities such as the PCOR Institute or the AHRQ could play a key role by certifying particular CER-influenced guidelines as high quality.²⁷⁸ The certification process ideally would evaluate guideline credibility based on generally recognized best practices, such as representation of multispecialties among the guideline authors and disclosure by authors of financial conflicts of interest.²⁷⁹

Firmer linkage of financial incentives and CER could not only increase physician receptiveness but also provide a feedback loop that helps improve the quality of CER generally. Well-designed financial incentives—especially those targeted to the performance of groups of physicians instead of individual clinicians—encourage physicians to pool information about treatments, as well as to monitor the treatment choices of other physicians.²⁸⁰ This increased information flow may help better identify where the current state of CER needs improvement. Indeed, even if the initial CER-influenced guidelines are weak or subject to differing clinical opinion, the financial incentives provide a continual reason for physicians to pay attention to comparative effectiveness. This helps combat physician tune-out and challenges physicians to recommend changes for improving the guidelines.²⁸¹

B. *Malpractice Liability Incentives*

Reforms should also address physicians' malpractice liability fears about CER.²⁸² This could be accomplished in several ways. Malpractice-liability-reduction incentives could be linked to physicians' com-

²⁷⁸ Other commentators urge a greater role for the private market in improving the quality of clinical practice guidelines. One such proposal is to have private firms compete in offering high-quality guidelines to physicians. The firms would also be financially responsible for any injuries caused by substandard guidelines that they promulgated, thus aligning the firms' and physicians' incentives for quality improvement. See Avraham, *supra* note 116, at 39-40 (explaining the benefits of private-actor involvement in health care regulation).

²⁷⁹ See generally Roberto Grilli et al., *Practice Guidelines Developed by Specialty Societies: The Need for a Critical Appraisal*, 355 LANCET, Jan. 8, 2000, at 103, 104-05 (evaluating existing guidelines and finding many of them lacking).

²⁸⁰ See Stephen R. Latham, *Regulation of Managed Care Incentive Payments to Physicians*, 22 AM. J.L. & MED. 399, 408 (1996) ("[W]e have good reason to hope that financial incentives will help move providers to pool their information and eliminate some . . . overcare.").

²⁸¹ Cf. Hall, *supra* note 25, at 479 (making a similar point about incentives and guidelines more generally).

²⁸² See *supra* Section III.G.

pliance with guidelines based on solid CER. Research suggests that physicians comply with recommended guidelines at somewhat better rates when they receive a reduction in malpractice insurance premiums in return for following the guidelines.²⁸³ A more comprehensive malpractice-linked initiative would provide liability safe harbors to physicians who comply with guidelines based on solid CER. Under such an approach, physicians would enjoy complete immunity or benefit from a rebuttable presumption that they met the standard of care if they could demonstrate that high-quality evidence of comparative effectiveness supported their treatment choice.

Because such approaches “would give physicians a legal incentive to practice evidence-based medicine, liability reform could be an effective way to foster the uptake of CER findings.”²⁸⁴ Indeed, given physicians’ deep concerns about a malpractice-liability system run amok, they would likely welcome some form of tort relief. As such, this option would prove far more physician-friendly than limiting reimbursement coverage based on CER.²⁸⁵

C. Academic Detailing

Greater use of academic detailing could also increase physician receptiveness to CER. In an attempt to “fight fire with fire,” academic detailing tries to copy the highly successful marketing techniques that pharmaceutical firms use to promote their medications to physicians.²⁸⁶ Academic detailing embraces pharmaceutical firms’ persuasion methods but endeavors to provide more balanced information compared to what physicians learn from drug-company advertising and related sources.²⁸⁷ The persuasion strategies include utilizing physician peer educators to promote the benefits of a particular product through face-to-face meetings, physician interviews to assess baseline knowledge and prescribing motivations, and the deployment of con-

²⁸³ See Mello, *supra* note 271, at 683.

²⁸⁴ Michelle M. Mello & Troyen A. Brennan, *The Role of Medical Liability Reform in Federal Health Care Reform*, 361 NEW ENG. J. MED. 1, 3 (2009).

²⁸⁵ See *id.*

²⁸⁶ See Stephen B. Soumerai & Jerry Avorn, *Principles of Educational Outreach (“Academic Detailing”) To Improve Clinical Decision Making*, 263 JAMA 549 (1990).

²⁸⁷ See PEW PRESCRIPTION PROJECT, FACT SHEET—ACADEMIC DETAILING: EVIDENCE-BASED PRESCRIBING INFORMATION 1 (2009), available at http://www.prescriptionproject.org/tools/fact_sheets/files/0007.pdf (“[T]he approach resembles the marketing approach of drug companies, but instead . . . present[s] balanced, evidence-based information about common prescribing choices without a sales agenda.”).

cise, consistent informational messages in discussing the product.²⁸⁸ Academic-detailing initiatives have demonstrated moderate success in bolstering quality and improving physician adherence to practice guidelines across a variety of medical disciplines.²⁸⁹

With regard to CER, academic detailers could communicate particular comparative effectiveness study information to physicians and encourage them to adapt treatment practices accordingly. Part of the appeal of this approach is that if the right physician representatives are chosen as CER promoters, this can leverage physicians' interest in what their peers do and the influence of local opinion leaders in the medical community,²⁹⁰ which offers more power than simply publicizing CER study results.

Unfortunately, the national CER program does not yet seem to contemplate academic detailing to a significant degree. PPACA does task the Office of Communication and Knowledge Transfer (the Communication Office), a unit within the AHRQ, with general responsibility for dissemination of CER results.²⁹¹ The dissemination methods described in the statute, although not meant to be an exhaustive list, are for the most part more passive educational approaches, such as developing a publicly available database of CER information or using clinical-decision support technology to deliver the information to physicians.²⁹² PPACA further provides that the Communication Office should regularly collect "feedback" from physicians and other stakeholders about the "value of the information disseminated,"²⁹³ perhaps opening the door to useful detailing techniques such as baseline assessments of physicians' knowledge and motivations in ordering certain treatments. But the statute does not expressly mention academic detailing and is largely silent about other interactive methods of information dissemination.

²⁸⁸ See *id.* at 2.

²⁸⁹ See, e.g., *id.* (summarizing evidence showing that "interactive techniques like academic detailing are the most effective means to improve physician practices and patient outcomes"); Michael Allen et al., *Family Physicians' Perceptions of Academic Detailing: A Quantitative and Qualitative Study*, 7 BMC MED. EDUC., no. 36 (2007), <http://www.biomedcentral.com/1472-6920/7/36> (discussing the features of academic detailing that physicians find most educational); James Ducharme, *Clinical Guidelines and Policies: Can They Improve Emergency Department Pain Management?*, 33 J.L. MED. & ETHICS 783, 787 (2005) (concluding that outreach methods are the "most effective, albeit costly, method" of modifying physician behavior).

²⁹⁰ See *supra* note 129 and accompanying text.

²⁹¹ PPACA sec. 6301(b), § 937, 42 U.S.C.A. § 299b-37 (West Supp. 1A 2010).

²⁹² *Id.* sec. 6301(b), § 937(a)(1), 42 U.S.C.A. § 299b-37(a)(1).

²⁹³ *Id.* sec. 6301(b), § 937(c), 42 U.S.C.A. § 299b-37(c).

As such, much depends on how the PCOR Institute, the Communication Office, and other relevant entities will choose to conduct CER dissemination initiatives. In a welcome development, the AHRQ is using some portion of its Recovery Act stimulus funding to support academic detailing. The agency has asked for proposals from contractors to help design academic detailing programs promoting comparative effectiveness information.²⁹⁴ While such initiatives are encouraging, to engage the physician audience effectively, academic detailing should become a more prominent and consistent feature of the national CER program.

D. Comparative Implementation Research

A final recommendation follows from heeding the important insight of the CER movement: anecdotal impressions, best intentions, and custom can be misleading—look instead to solid comparative evidence about what works best. In other words, in seeking to support CER, the health care system should deliberately experiment with, and compare different strategies for, translating it into clinical practice. Many possible methods—such as information dissemination through peer educators or financial incentives for guideline compliance—seem intriguing, but they have not been systematically evaluated against each other in terms of effectiveness rates for fostering CER uptake by physicians. And policymakers and regulators may consider entirely new implementation methods in the future. Given health care reform's record funding for research comparing the effectiveness of different treatments, it seems prudent also to invest heavily in research that compares the effectiveness of different CER *implementation* strategies. As Elizabeth Docteur and Robert Berenson have observed,

[H]owever great the potential importance of new research findings to be generated through new CER, there is greater marginal value to be gained from devoting additional resources to investigating why evidence so often has a limited and slow impact on practice, evaluating policies and practices that improve uptake of treatments with demonstrated effectiveness, disseminating effective implementation strategies, and implementing changes in incentives or other initiatives that prove effective.²⁹⁵

²⁹⁴ See Bronwyn Mixter, *Congressional Leaders Praise AHRQ for Funding "Academic Detailing" Program*, 9 Med. Res. L. & Pol'y Rep. (BNA) No. 8, at 249 (Apr. 21, 2010).

²⁹⁵ DOCTEUR & BERENSON, *supra* note 37, at 10; see also Lauer & Collins, *supra* note 120, at 2183 ("There is increasing recognition that the processes of dissemination and implementation are legitimate targets for rigorous scientific evaluation.").

A viable national CER program simply needs better evidence about what works best for translating the research results into clinical practice. Yet it remains unclear whether the government's new CER agenda will allocate sufficient resources to comparative-implementation research or make effective use of it. The now-disbanded Federal CER Council²⁹⁶ seemingly recognized the critical need for such research, but ultimately downgraded CER's importance by characterizing it as a "secondary investment[]." ²⁹⁷ Somewhat in contrast, the Institute of Medicine (IOM) has advised that "[k]nowledge translation research must be a high priority."²⁹⁸ Yet PPACA provides only lukewarm support for engaging in rigorous comparative analysis of implementation strategies and does not expressly require spending CER funds for such investigations.²⁹⁹ Much therefore depends on the discretion of the PCOR Institute and other relevant entities in implementing the new national CER program. Hopefully, they will follow the IOM's suggested approach by continually looking to and heavily investing in much-needed implementation research.

CONCLUSION

It must be remembered that the new national CER program will not function as a stand-alone proposition. It remains but one component of a more comprehensive reform agenda that will affect the health care system through multifaceted, interconnected levers. For example, PPACA authorizes the newly created Center for Medicare and Medicaid Innovation to explore new payment models in order to provide stronger rewards for quality.³⁰⁰ Also, the new law creates the Independent Medicare Advisory Board to reign in governmental

²⁹⁶ See *supra* notes 42-46 and accompanying text.

²⁹⁷ FEDERAL CER COUNCIL REPORT, *supra* note 7, at 43.

²⁹⁸ INST. OF MED. OF THE NAT'L ACADS., *supra* note 7, at 159.

²⁹⁹ For example, the Communication Office, see *supra* text accompanying note 291, is required to create tools for organizing CER information and to seek feedback from end users about the value of information disseminated. PPACA sec. 6301(b), § 937, 42 U.S.C.A. § 299b-37 (West Supp. 1A 2010). Also, the Comptroller General is supposed to review the national CER program at least every five years, looking to "the effect of the dissemination of such [CER] findings on reducing practice variation and disparities in health care, and the effect of the research conducted and disseminated on innovation and the health care economy of the United States." *Id.* sec. 6301(a), § 1181(g)(2)(A)(iv), 42 U.S.C.A. § 1320e(g)(2)(A)(iv). But the statute does not require that specific amounts of CER funds be spent for implementation research.

³⁰⁰ See *supra* notes 101-06 and accompanying text.

health care spending.³⁰¹ Because CER is not intended to, and need not, shoulder the full responsibilities for bending the cost curve and improving quality of care, this Article's detailed focus on the weak roll-out of CER may seem misplaced.

But these other initiatives will take a long time to implement, and their ultimate impact may be small.³⁰² Moreover, CER's intriguing potential is that it has the theoretical power to reinforce and amplify other reform initiatives significantly. Indeed, a viable CER program seems indispensable to health care reform's ultimate success no matter how reform on the ground evolves and develops in coming years. After all, a solid comparative effectiveness evidence base is needed to address health care system fundamentals, such as deciding which services to support, determining the relative value patients receive from the system, highlighting when common treatment pathways need reexamination, and identifying when spending cuts undermine very effective care.³⁰³ If CER is to complement other reform initiatives in this manner, however, the health care system must do more than simply develop the evidence. It must also be in a position to act on the information generated. In short, to even begin fulfilling some of its promise, CER must be deployed under better starting conditions. This means paying a great deal more attention to how physicians, the critical gatekeepers, will likely respond and directly confronting the serious risks of physician tune-out and indifference.

³⁰¹ *Id.*

³⁰² See *supra* note 106 and accompanying text.

³⁰³ Cf. Mushlin & Ghomrawi, *supra* note 84, at e6(1)-(2) (“[C]hanges in coverage and care delivery must in fact be guided by knowledge about what is valuable to preserve in our health care system.”).