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## HEALTH CARE REFORM: TREATMENT EFFECTIVENESS INFORMATION NATIONWIDE

*Robert B Leflar\**

Most of the debate over the Patient Protection and Affordable Care Act (PPACA) and its implementation has centered on access issues: expansion of access to care among the uninsured and underinsured through insurance reforms. True enough, increasing access to care is the law's chief goal. But the law's architects and the new programs' builders aspired to broader objectives. They also sought to advance health care quality and to restrain health care inflation by helping rationalize the practice of medicine.

This paper focuses on the law's attempts, largely ignored in the national debate, to reduce the amount of non-productive, expensive waste in American health care practices, enabling us to deploy our limited resources on what actually improves people's health.

It is clear from comparative international statistics (see Figures 1 and 2) that virtually every other advanced nation operates its health care system with greater efficiency than we operate ours. Further, health care costs have been rising in the United States far more quickly than inflation generally, so that an average family of four paid \$5,800 for health insurance in 1999, but just fourteen years later paid more than \$16,000 (Figure 3)—an inflation rate far outstripping health cost increases in other countries. (Thankfully, the rate of increase of health care inflation seems to be abating recently.)<sup>1</sup> International price comparisons for particular procedures and drugs bring home the radical cost differences to patients needing those procedures or drugs: Americans pay far more than patients in other advanced nations.<sup>2</sup>

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1. See, e.g., David Blumenthal et al., *Health Care Spending—A Giant Slain or Sleeping?*, 369 *NEW ENG. J. MED.* 2551, 2551 (2013) (observing slower growth in health care costs in 2012 but concluding continued cost control efforts are needed).

2. See, e.g., Elisabeth Rosenthal, *The \$2.7 Trillion Medical Bill: Colonoscopies Explain Why U.S. Leads the World in Health Expenditures*, *N.Y. TIMES*, June 2, 2013, at A1, available at [http://www.nytimes.com/2013/06/02/health/colonoscopies-explain-why-us-leads-the-world-in-health-expenditures.html?pagewanted=all&\\_r=0](http://www.nytimes.com/2013/06/02/health/colonoscopies-explain-why-us-leads-the-world-in-health-expenditures.html?pagewanted=all&_r=0).

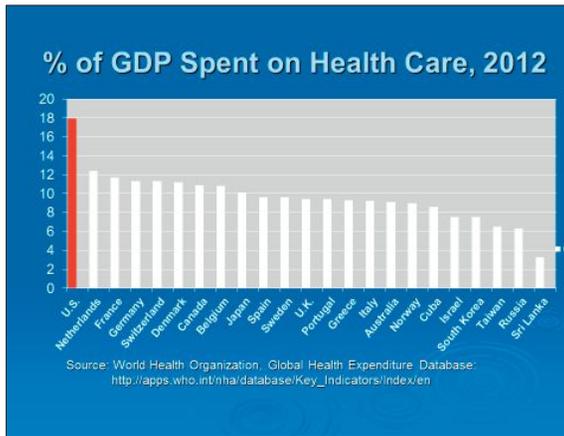


Fig. 1. Percentage of Gross Domestic Product Spent on Health Care, 2012.<sup>3</sup>

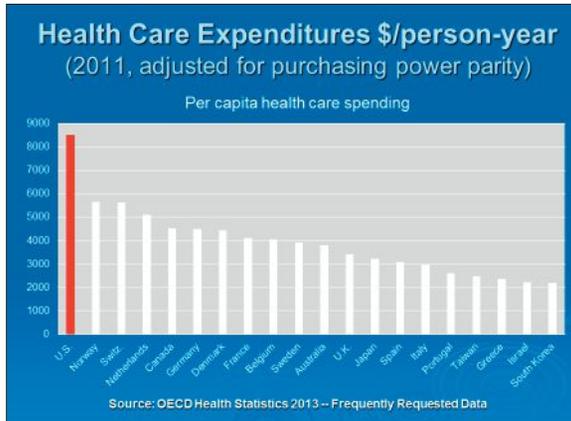


Fig. 2. Health Care Expenditures per Person-Year, 2011.<sup>4</sup>

3. Quick Reports, *Global Health Expenditure Database*, WORLD HEALTH ORG., [http://apps.who.int/nha/database/Key\\_Indicators/Index/en](http://apps.who.int/nha/database/Key_Indicators/Index/en) (last visited Sept. 18, 2014); *Countries: Sri Lanka*, WORLD HEALTH ORG., <http://www.who.int/countries/lka/en/> (last visited November 12, 2014).

4. OECD Indicators, *HEALTH AT A GLANCE 2013*, ORG. FOR ECON. COOPERATION & DEV., at 155 (2013), <http://www.oecd.org/els/health-systems/Health-at-a-Glance-2013.pdf>.

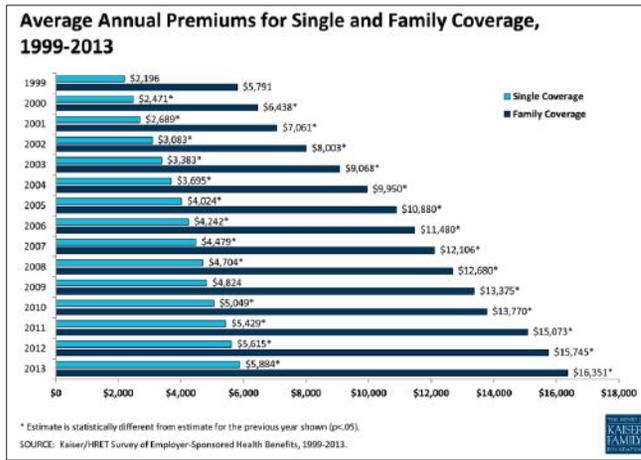


Fig. 3. Average Annual Premiums for Single and Family Coverage, 1999–2013.<sup>5</sup>

What do we get for what we spend? In comparison with other countries, the picture in public health terms looks mostly, but not entirely, bleak.<sup>6</sup> The figures below depict several dimensions on which health outcomes can be compared. These are measures to which the quality of the health care systems contributes some, but not all, of the differences among nations.<sup>7</sup> Perhaps the most disturbing is Figure 9, depicting the relative improvement among leading nations over a 20-year period in life expectancy at birth. The United States rests at the bottom.

5. *Average Annual Premiums for Single and Family Coverage, 1999–2013*, HENRY J. KAISER FAM. FOUND., <http://kaiserfamilyfoundation.files.wordpress.com/2013/08/2013-ehbs-1-11.png> (last visited Sept. 18, 2014).

6. See, e.g., Karen Davis et al., *Mirror, Mirror on the Wall: How the Performance of the U.S. Health Care System Compares Internationally*, COMMONWEALTH FUND, at 7 (2014), <http://www.commonwealthfund.org/publications/fund-reports/2014/jun/mirror-mirror> (ranking the U.S. “last or near last” among eleven advanced nations on dimensions of health care performance such as health outcomes, access, efficiency, and equity).

7. For some measures, such as infant mortality and life expectancy at birth, a country’s educational level, dietary practices, extent of income inequality, and other environmental factors contribute as well.

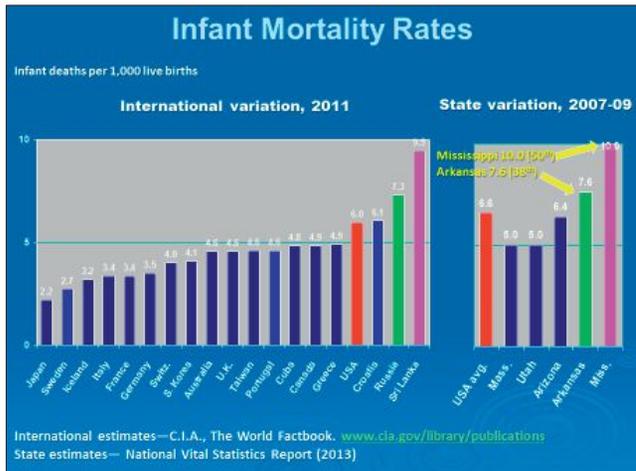


Fig. 4. Infant Mortality Rates, Internationally and by State.<sup>8</sup>

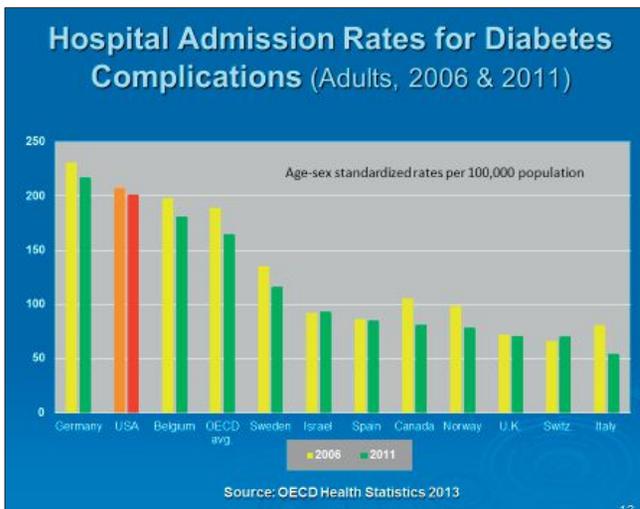


Fig. 5. Hospital Admission Rates for Diabetes Complications.<sup>9</sup>

8. T.J. Mathews & Marian F. MacDorman, *Infant Mortality Statistics from the 2009 Period Linked Birth/Infant Death Data Set*, NAT'L VITAL STAT. REP., at 1, 17 (Jan. 24, 2013), available at [http://www.cdc.gov/nchs/data/nvsr/nvsr61/nvsr61\\_08.pdf](http://www.cdc.gov/nchs/data/nvsr/nvsr61/nvsr61_08.pdf) (state comparisons); *The World Factbook*, CENT. INTELLIGENCE AGENCY (2012), available at <https://www.cia.gov/library/publications/the-world-factbook/rankorder/2091rank.html> (international comparisons). In addition to the quality of health care systems, other factors such as nutrition, education, and relative income inequality contribute to these statistics.

9. OECD Indicators, *supra* note 2, at 109.

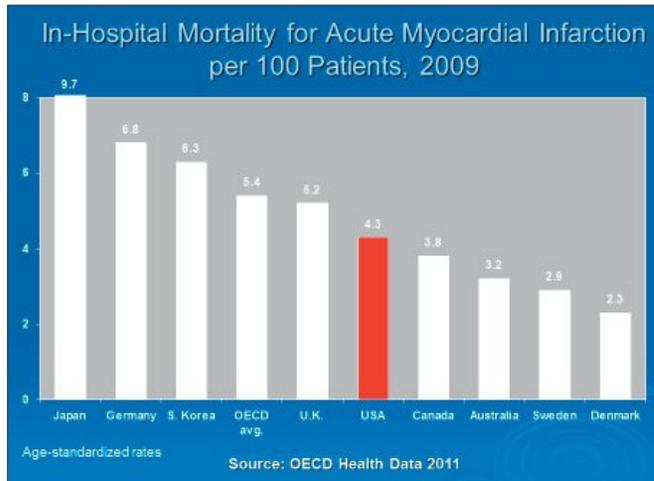


Fig. 6. In-Hospital Mortality for Acute Myocardial Infarction (Heart Attacks).<sup>10</sup>

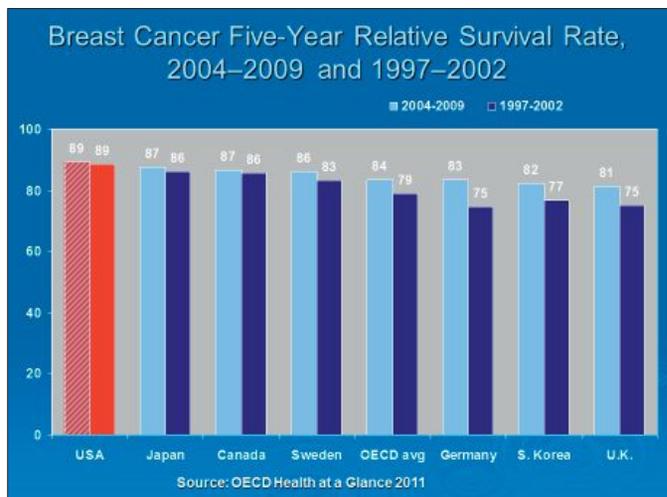


Fig. 7. Breast Cancer 5-year Relative Survival Rates.<sup>11</sup>

10. OECD Indicators, *HEALTH AT A GLANCE 2011*, ORG. FOR ECON. COOPERATION & DEV., at 109 (2011), <http://www.oecd.org/els/health-systems/49105858.pdf> (Fig. 5.3.1).

11. *Id.* at 121 (Figure 5.9.2).

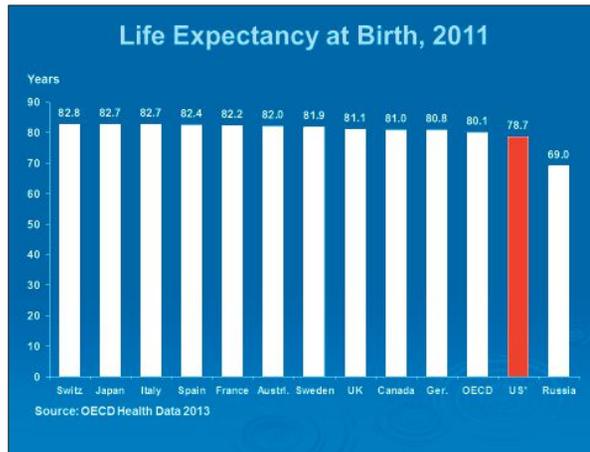


Fig. 8. Life Expectancy at Birth, 2011.<sup>12</sup>

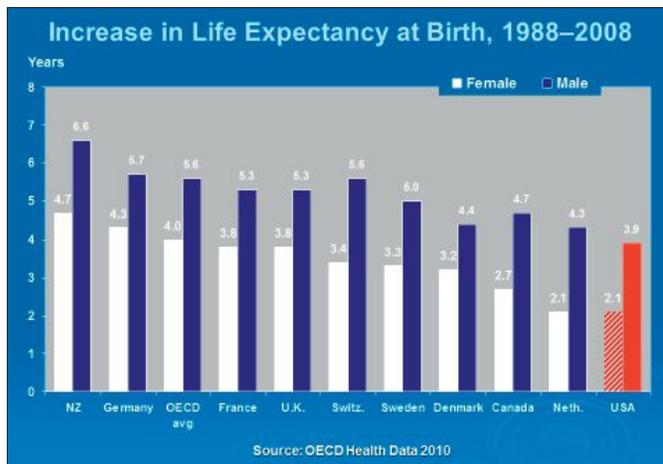


Fig. 9. Increase in Life Expectancy at Birth, 1988-2008.<sup>13</sup>

The conclusion that must be drawn from these comparative statistics is that America spends enormous quantities of money on health care, far more

12. OECD, *OECD Factbook 2014: Economic, Environmental, and Social Statistics*, ORG. FOR ECON. COOPERATION & DEV., at 237 (2014), <http://dx.doi.org/10.1787/factbook-2014-en>.

13. OECD, *OECD Health Data 2010* (2010), reproduced in Gerard F. Anderson & Patricia Markovich, *Multinational Comparisons of Health Systems Data 2010*, COMMONWEALTH FUND, at 61 (2010).

than any other nation, but a substantial proportion of that massive amount of spending does little if any good.<sup>14</sup> Excess administrative costs, duplicative lab tests, unnecessary procedures and diagnostics, procedures to repair previous mistakes, the list goes on: American health care is replete with high-cost, low-value services.<sup>15</sup> Certainly, at the top level, the quality of sophisticated health care in the United States is frequently second to none. But for what we pay, looking at national health outcomes statistics, on the whole we are not getting a good return on our investment. As the Institute of Medicine recently concluded, “[t]he growth rate of health care expenditures is unsustainable, with waste that diverts major resources from necessary care and other priorities at every level—individual, family, community, state, and national.”<sup>16</sup>

What are the reasons for the inefficiency and limited effectiveness of our health care system? There are many. As Dr. Dan Rahn observed in his keynote presentation at this symposium, “Systems are perfectly designed to get the results they get.”<sup>17</sup> Perhaps the most important structural reason is that up to now, the amount of payment that providers receive for their services and that medical product merchants receive for their products has depended chiefly on quantity, not quality. What matters financially is the amount of services and products provided, not the health outcomes for patients.<sup>18</sup> Since physicians control most health care purchasing decisions, and they have not been constrained in most health care settings by cost considerations, incentives for excessive diagnostic tests and other procedures are built into the system.

Atul Gawande’s provocative article, “The Cost Conundrum,” depicted how in some areas a culture of profit rather than professionalism has come to dominate local health care.<sup>19</sup> Gawande focused on the second-highest-cost metropolitan area in the U.S.—McAllen, Texas of all places—and compared

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14. See generally U.S. HEALTH IN INTERNATIONAL PERSPECTIVE: SHORTER LIVES, POORER HEALTH, NATIONAL RESEARCH COUNCIL (Steven H. Woolf & Laudan Aron eds., 2013), available at <http://www.iom.edu/Reports/2013/US-Health-in-International-Perspective-Shorter-Lives-Poorer-Health.aspx>.

15. INSTITUTE OF MEDICINE, BEST CARE AT LOWER COST: THE PATH TO CONTINUOUSLY LEARNING HEALTH CARE IN AMERICA 101–05 (Mark Smith et al. eds., 2013). The Institute of Medicine’s prestigious history as an authoritative source of information on health care policy lends particular weight to its conclusions about waste in health care expenditures.

16. *Id.* at 14, 104.

17. Dr. Rahn, Chancellor, Univ. of Ark. for Med. Scis., Keynote Address at the University of Arkansas at Little Rock Ben J. Alzheimer Symposium on the Affordable Care Act (Feb. 28, 2014) (quoting Dr. Paul Batalden of Dartmouth Medical School and the Institute for Health Improvement).

18. See INSTITUTE OF MEDICINE, *supra* note 15, at 25.

19. Atul Gawande, *The Cost Conundrum*, THE NEW YORKER, June 1, 2009, at 36, available at <http://www.newyorker.com/magazine/2009/06/01/the-cost-conundrum>.

it to El Paso, another Texas border city similar in demographics, income, and medical facilities. Critically ill Medicare patients in McAllen received almost 50% more specialist visits than in El Paso. McAllen patients got “thirty per cent more bone-density studies, sixty per cent more stress tests with echocardiography, . . . and five hundred and fifty per cent more urine-flow studies to diagnose prostate troubles.”<sup>20</sup> McAllen patients got two to three times as many cardiac procedures such as pacemaker and defibrillator implants, cardiac bypass operations, and coronary artery stents. Those differences in number of treatments and amount of costs could not be explained by differences in the patients’ conditions. Gawande’s conclusion: “The primary cause of McAllen’s extreme costs was, very simply, the across-the-board overuse of medicine.”<sup>21</sup>

McAllen is but one striking example of how medical practice in the United States is driven to a large degree by forces other than sound scientific evidence.<sup>22</sup> Instances abound of practice variations that cannot be explained by medical logic or differences in patient health status. As John Wennberg and his colleagues at Dartmouth proved years ago, what treatment a patient will get for a given condition often varies tremendously from one geographical location to another.<sup>23</sup> These irrational practice variations in the Medicare program indicate that considerable expenditures could be saved by the elimination of scientifically unsupported services.<sup>24</sup> The practice variations per-

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20. *Id.* at 38–39.

21. *Id.* at 39. For non-Medicare privately insured patients, the cost disparity between McAllen and El Paso seems much less severe, though it still exists. *See generally* Luisa Franzini et al., *McAllen and El Paso Revisited: Medicare Variations Not Always Reflected in the Under-Sixty-Five Population*, 29 HEALTH AFF. 2302 (2010).

22. The Institute of Medicine has concluded that less than half of all treatments provided to American patients are based on clear scientific evidence. Report Brief, *Initial National Priorities for Comparative Effectiveness Research*, INST. OF MED. (2009), [www.iom.edu/-/media/Files/Report%20Files/2009/ComparativeEffectivenessResearchPriorities/CER%20Report%20brief%2008-13-09.ashx](http://www.iom.edu/-/media/Files/Report%20Files/2009/ComparativeEffectivenessResearchPriorities/CER%20Report%20brief%2008-13-09.ashx); MICHAEL CHERNEW & MARK FENDRICK, LEARNING WHAT WORKS BEST: THE NATION’S NEED FOR EVIDENCE ON COMPARATIVE EFFECTIVENESS IN HEALTH CARE (Institute of Medicine ed., March, 2007).

23. *See, e.g.*, John E. Wennberg & Alan Gittelsohn, *Small Area Variations in Health Care Delivery: A Population-Based Health Information System Can Guide Planning and Regulatory Decision-Making*, 182 SCI. 1102 (1973); *see generally* The Trustees of Dartmouth College, *Understanding of the Efficiency and Effectiveness of the Health Care System*, THE DARTMOUTH ATLAS OF HEALTH CARE, <http://www.dartmouthatlas.org/> (indicating extensive practice variations persist today); *see, e.g.*, Report to the Congress, Regional Variation in Medicare Service Use, MEDICARE PAYMENT ADVISORY COMMISSION (January, 2011), [http://www.medpac.gov/documents/reports/Jan11\\_RegionalVariation\\_report.pdf?sfvrsn=0](http://www.medpac.gov/documents/reports/Jan11_RegionalVariation_report.pdf?sfvrsn=0).

24. *See, e.g.*, JOHN E. WENNBURG, TRACKING MEDICINE: RESEARCHER’S QUEST TO UNDERSTAND HEALTH CARE 5 (Oxford University Press 2010) (40% savings estimate); Elliott S. Fisher, *Medical Care—Is More Always Better?* 349 NEW ENG. J. MED. 1665 (2003) (30% savings estimate). The cost effectiveness of inpatient care for acute myocardial infarctions (heart attacks), for example, ranges across hospitals from about \$5,000 per life year saved to

sist in some cases because of the lack of good evidence for the superiority of one treatment modality over alternative treatments, and in other cases despite clear evidence that one treatment is preferable.<sup>25</sup> Sometimes the variations are influenced by financial conflicts of interest, as when a physician has a stake in an imaging center or receives payments or other values from medical products companies.<sup>26</sup> One recent report, for instance, found that for-profit dialysis chains use significantly more injectable medications compared to nonprofits, at higher costs, but their patients have a higher risk of dying.<sup>27</sup> Another study indicated that a high-cost, high-reimbursement hip fracture fixation device has largely displaced an older, cheaper, and safer method among younger orthopedic surgeons.<sup>28</sup> A broad-based study of drug effectiveness suggested that many older drugs, generally available now in cheaper generic form, outpaced newer (and more expensive) drugs in effectiveness terms.<sup>29</sup> As the Institute of Medicine concluded, “[t]he prevailing approach to paying for health care, based predominantly on individual services and products, encourages wasteful and ineffective care.”<sup>30</sup>

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more than \$100,000. Dana Goldman et al., *Harnessing the Promise of Comparative Effectiveness Research*, HEALTH AFF. BLOG (Sept. 12, 2012), <http://healthaffairs.org/blog/2012/09/12/harnessing-the-promise-of-comparative-effectiveness-research/>; cf. Andrew J. Rettenmaier & Zijun Wang, *Regional Variations in Medical Spending and Utilization: A Longitudinal Analysis of US Medicare Population*, 21 HEALTH ECON. 67, 80–81 (2012) (other scholars offering lower savings estimates).

25. See, e.g., Justin W. Timbie et al., *Five Reasons That Many Comparative Effectiveness Studies Fail to Change Patient Care and Clinical Practice*, 31 HEALTH AFF. 2168, 2168 (2012) (“translating evidence into changes in clinical practice is rarely rapid”).

26. See, e.g., Marc A. Rodwin, *Institutional Corruption and the Pharmaceutical Policy*, 41 J. L. MED. & ETHICS 544 (2013); Sunita Sah & Adriane Fugh-Berman, *Physicians under the Influence: Social Psychology and Industry Marketing Strategies*, 41 J. L. MED. & ETHICS 665, 666–67 (2013).

27. Yi Zhang et al., *Organizational Status of Dialysis Facilities and Patient Outcome: Does Higher Injectable Medication Use Mediate Increased Mortality?* 48 HEALTH SERVICES RES. 949, 964 (2013).

28. See Jeffrey O. Anglen & James N. Weinstein, *Nail or Plate Fixation of Intertrochanteric Hip Fractures: Changing Pattern of Practice*, 90 J. BONE & JOINT SURGERY 700 (2008). See also Peter Whoriskey & Dan Keating, *Spinal Fusions Serve as Case Study for Debate over When Certain Surgeries Are Necessary*, WASH. POST, Oct. 27, 2013, available at [http://www.washingtonpost.com/business/economy/spinal-fusions-serve-as-case-study-for-debate-over-when-certain-surgeries-are-necessary/2013/10/27/5f015efa-25ff-11e3-b3e9-d97fb087acd6\\_story.html](http://www.washingtonpost.com/business/economy/spinal-fusions-serve-as-case-study-for-debate-over-when-certain-surgeries-are-necessary/2013/10/27/5f015efa-25ff-11e3-b3e9-d97fb087acd6_story.html) (reporting on rise in expensive spinal fusion surgeries despite sparse evidence of superiority over alternative cheaper treatments).

29. See Sharon Begley, *New Drugs Trail Many Old Ones in Effectiveness Against Disease*, REUTERS, June 3, 2013, available at [www.reuters.com/assets/print?aid=USL2N0EC1E720130603](http://www.reuters.com/assets/print?aid=USL2N0EC1E720130603) (reporting on Mark Olfson & Steven C. Marcus, *Decline in Placebo-Controlled Trial Results Suggests New Directions for Comparative Effectiveness Research*, 32 HEALTH AFF. 1116 (2013)).

30. INSTITUTE OF MEDICINE, *supra* note 15, at 25.

In response to concerns about high-cost, low-value care, a significant movement is gaining steam to shift from a “pay-for-volume” approach to a “pay-for-performance” approach.<sup>31</sup> This shift is backed by the Affordable Care Act’s provisions encouraging the formation of “Accountable Care Organizations” (ACOs), which are physician-led entities, physician-hospital partnerships, and hospital-led partnerships that are rewarded by Medicare for meeting targets of high-quality care and outcomes for the patients attributed to them, while keeping the cost of caring for those patients within benchmarks set in advance.<sup>32</sup> Initial results indicate that ACOs have achieved significant cost savings, and the number of ACOs has risen rapidly since the new law’s enactment.<sup>33</sup> Concerns do exist on the one hand that federal quality standards may be unrealistically strict,<sup>34</sup> and on the other that the emphasis on cost savings may compromise quality of care and that some ACOs may attempt to meet their targets by discouraging sicker patients from seeking treatment at their facilities.<sup>35</sup> However, at present no empirical data are reported to substantiate these concerns.<sup>36</sup>

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31. Arkansas is a leader in this respect. See *Arkansas Payment Improvement Initiative (APII)*, ARK. CENTER FOR HEALTH IMPROVEMENT, <http://www.achi.net/Pages/OurWork/Project.aspx?ID=47>.

32. See, e.g., Donald M. Berwick, *Making Good on ACOs’ Promise—The Final Rule for the Medicare Shared Savings Program*, 365 *NEW ENG. J. MED.* 1753 (2011), available at <http://www.nejm.org/doi/full/10.1056/NEJMp1111671>; INSTITUTE OF MEDICINE, *supra* note 15, at 239–42. A recent survey found that the vast majority of ACOs are physician-led or jointly led by physicians and hospitals. Carrie H. Colla et al., *First National Survey of ACOs Finds that Physicians Are Playing Strong Leadership and Ownership Roles*, 33 *HEALTH AFF.* 964 (2014), available at [http://www.statecoverage.org/files/HA\\_Physicians\\_in\\_ACOs\\_Survey.pdf](http://www.statecoverage.org/files/HA_Physicians_in_ACOs_Survey.pdf) (51% of ACOs physician-led, 33% jointly physician- and hospital-led, 3% solely hospital-led; but surgeons reluctant to participate).

33. See, e.g., John Reichard, *New Savings Figures Buoy Hopes for Potential of Medicare ACOs*, *WASH. HEALTH POL’Y WEEK IN REV.*, Feb. 3, 2014 (reporting preliminary savings of about \$400 million the first year, shared by providers and the Medicare program), <http://www.commonwealthfund.org/publications/newsletters/washington-health-policy-in-review/2014/feb/february-3-2014/new-savings-figures-buoy-hopes-for-potential-of-medicare-acos>; J. Michael McWilliams et al., *Changes in Patients’ Experiences in Medicare Accountable Care Organizations*, 371 *NEW ENG. J. MED.* 1715 (2014) (finding cost savings and some quality improvements in Medicare ACOs); Lawrence P. Casalino, *Accountable Care Organizations—The Risk of Failure and the Risks of Success*, 371 *NEW ENG. J. MED.* 1750 (2014) (noting positive results of McWilliams study, *supra*, and other studies).

34. See, e.g., John Reichard, *CMS Letter on Quality Standards Aims to Keep Pioneer ACOs from Bolting*, *WASH. HEALTH POL’Y WEEK IN REV.*, Apr. 29, 2013 (reporting pioneer ACOs’ objections to costly federal standards), <http://www.commonwealthfund.org/publications/newsletters/washington-health-policy-in-review/2013/apr/apr-29-2013/cms-letter-on-quality-standards>.

35. ACO proponents respond that these latter concerns should be mitigated by the fact that physicians, not insurers, occupy a leadership role in ACOs, so physicians’ training and ethic of patient care should serve to keep quality-of-care principles at the forefront. Much may depend, however, on the confidence that ACO leaders have in the accuracy of risk ad-

To succeed in the endeavor of reducing low-value, high-cost services, what providers and their patients need is good comparative information about both outcomes and costs: what treatments and procedures are superior in clinical effectiveness, and what treatments and procedures are cost-effective. That kind of information is surprisingly hard to come by.<sup>37</sup>

Addressing the problems of excessive practice variation and the prevalence of high-cost, low-value services and products, health reform advocates proposed creation of a Comparative Effectiveness Research Institute to clarify and publicize evidence about best clinical practices. With power to influence Medicare payment decisions, reform advocates argued, the Comparative Effectiveness Research Institute could be “the silver crowbar to bend the healthcare cost curve without compromising quality.”<sup>38</sup>

As a rational health policy plan, the Comparative Effectiveness Research Institute proposal had much to recommend it. As a political matter, however, the proposal generated a storm of controversy.<sup>39</sup> Opponents expressed fears that such an entity would foist cookbook, “one-size-fits-all” medicine on the public. They raised fears that the entity would ration care—that it would shut off payments for treatment modalities preferred by doctors and patients but disfavored by cost-conscious bureaucrats, thereby restricting physician autonomy and undercutting biomedical innovation.<sup>40</sup> Opponents charged that the entity might arrive at these decisions through secretive unaccountable processes. They expressed fears that it would undervalue the lives of the old, the disabled, and the terminally ill—the specter of Sarah Palin’s “death panels.”<sup>41</sup>

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justment techniques used in setting ACO achievement benchmarks. Personal communication from Mark McClellan, Director, Health Care Innovation & Value Initiative, Brookings Institution, Washington DC, in Tokyo, Japan, July 7, 2014.

36. *Id.*

37. See CHERNEW & FENDRICK, *supra* note 22.

38. Eleanor D. Kinney, *Prospects for Comparative Effectiveness Research under Federal Health Reform*, 21 ANNALS HEALTH L. 79, 84 (2012) [hereinafter Kinney, *Prospects*].

39. For a comprehensive analysis of the development of comparative effectiveness research, its incorporation into the 2010 health reform law, its potential for transforming health care, and the concerns it has raised among various stakeholders in the health care marketplace, see Eleanor D. Kinney, *Comparative Effectiveness Research under the Patient Protection and Affordable Care Act: Can New Bottles Accommodate Old Wine?* 37 AM. J. L. & MED. 522 (2011) [hereinafter Kinney, *Old Wine*].

40. See, e.g., 157 CONG. REC. 42, S1883 (daily ed. Mar. 28, 2011) (statement of Sen. Jon Kyl criticizing comparative effectiveness research entities for potentially enabling government rationing of health care); Corinna Sorenson et al., *The Politics of Comparative Effectiveness Research: Lessons from Recent History*, 39 J. HEALTH POL. POL'Y & L. 139, 140, 142 (2014) (recounting opposition arguments).

41. See Sarah Palin, Statement on the Current Health Care Debate, FACEBOOK (Aug. 7, 2009, 3:26 PM), [https://www.facebook.com/note.php?note\\_id=113851103434](https://www.facebook.com/note.php?note_id=113851103434) (Palin's Facebook post raising specter of “Obama's ‘death panel’”).

As Daniel Callahan,<sup>42</sup> Elizabeth Weeks Leonard,<sup>43</sup> and Alan Maynard<sup>44</sup> among others have pointed out, the idea of top-down rationing is unpopular on this side of the Atlantic. Public opinion research has amply documented Americans' relative distrust of government, compared, for example, with European nations with a strong history of government involvement in health care, such as the United Kingdom and the Scandinavian countries.<sup>45</sup>

What to keep in mind, however, is that we Americans ration health care anyway. At one level, we ration it by limited access to health insurance.<sup>46</sup> At a second level, we ration it by insurance company employees deciding which treatments get paid for, and which are not covered by the insurance policy.<sup>47</sup> Limited resources and high demand inevitably result in rationing of one kind or another; rationing of health care cannot be avoided. The question is how it should be done.

Notwithstanding public reaction against fictional government "death panels," comparative effectiveness research efforts drew support from both sides of the aisle, Republicans as well as Democrats. Seeking at least partial consensus on this topic amid the contentious ideological debate on the overall health reform package, PPACA drafters renamed the new entity. "Comparative Effectiveness Research Institute" was thought to raise too many hackles, especially among politically active and generous promoters in the drug and medical device industries of treatments that might be found lacking in comparative effectiveness. So instead, the PPACA drafters dubbed the new entity the "Patient-Centered Outcomes Research Institute" (PCORI).<sup>48</sup> They re-cast the new entity as a *non*-governmental organization, funded by a

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42. See, e.g., Daniel Callahan, *The Graying of America: Challenges and Controversies: Must We Ration Health Care for the Elderly?* 40 J.L. MED. & ETHICS 10 (2012).

43. Elizabeth Weeks Leonard, *Death Panels and the Rhetoric of Rationing*, 13 NEV. L.J. 872 (2013).

44. Alan Maynard, *Health Care Rationing: Doing It Better in Public and Private Health Care Systems*, 38 J. HEALTH POL. POL'Y & L. 1103 (2013).

45. For a country-by-country overview of public trust levels toward government in the European Union, see Report, *Future of Europe*, TNS OPINION & SOCIAL 22–31 (2012), [http://ec.europa.eu/public\\_opinion/archives/ebs/ebs\\_379\\_en.pdf](http://ec.europa.eu/public_opinion/archives/ebs/ebs_379_en.pdf) (reporting very high trust levels in Scandinavian nations and medium levels in the United Kingdom). For statistics on declining public trust in government in the United States, see *Public Trust in Government, 1958–2013*, PEW RES. CENTER FOR PEOPLE & PRESS (2014), <http://www.people-press.org/2013/10/18/trust-in-government-interactive/>. Peter Neumann's analysis of the issue has been influential. Peter J. Neumann, *Why Don't Americans Use Cost-Effectiveness Analysis?*, 10 AM. J. MANAGED CARE 308 (2004).

46. The 2010 health care reform law, to the extent its access provisions are being implemented by the states, is starting to alleviate this problem.

47. See, e.g., Leonard, *supra* note 43, at 874–79.

48. For accounts of the congressional debate over creation of the new entity, see Sorenson et al., *supra* note 40, at 141–43; Leonard, *supra* note 43, at 883–86; and Kavita Patel, *Health Reform's Tortuous Route to the Patient-Centered Outcomes Research Institute*, 29 HEALTH AFF. 1777 (2010).

mixture of public and private money. Its board is composed of four government agency representatives and seventeen representatives of private stakeholders such as patients, providers, insurers, manufacturers, and researchers. The law defined the Institute's mission as to

assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations, and the dissemination of research findings.<sup>49</sup>

As part of the political maneuvering to get PPACA passed, Congress put rather strict limitations on what PCORI can do with the information it gathers.<sup>50</sup> The Institute is prohibited from making determinations or even recommendations about insurance coverage, and from using the results of its research to promote practice guidelines. Nor may the Secretary of Health and Human Services use the Institute's research findings "in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, not disabled, or not terminally ill."<sup>51</sup> Another provision of the law prohibits the use of the concept of "Quality-Adjusted Life Years" or QALYs,<sup>52</sup> a concept that is routinely employed<sup>53</sup> by health economists, by health policy leaders, and by the United Kingdom's National Institute for Health and Clinical Excellence,<sup>54</sup> but that is specifically off-limits for PCORI's scientists and scholars.<sup>55</sup>

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49. Patient Protection and Affordable Care Act § 6301(a), Pub. L. No. 111-148, 124 Stat. 119, 728 (codified as 42 U.S.C. § 1320e(c) (2012)).

50. One commentator has characterized the result as Congress having "cut [PCORI] off at the knees." Leonard, *supra* note 43, at 881. See also Maynard, *supra* note 44, at 1120 ("the Obama institute is like a carriage without a horse, as PCORI is not permitted to conduct cost-effectiveness analyses").

51. 42 U.S.C. § 1320e-1(c) (2012), added by PPACA, Pub. L. No. 111-148 § 6301(c), 124 Stat. 740.

52. *Id.* § 1320e-1(e) (2012).

53. See, e.g., Matthew D. Adler, *QALYs and Policy Evaluation: A New Perspective*, 6 YALE J. HEALTH POL'Y L. & ETHICS 1, 1 (2006).

54. See, e.g., Richard Cookson, *Can the NICE "End-of-Life Premium" Be Given a Coherent Ethical Justification?* 38 J. HEALTH POL. POL'Y & L. 1131, 1132 (2013) ("[t]he specific metric NICE uses to measure health benefits is the 'quality adjusted life year (QALY)"); Maynard, *supra* note 44, at 1122-23.

55. For a summary of the limitations on PCORI's activities, see Kinney, *Old Wine*, *supra* note 39, at 556-57. See also Peter J. Neumann & Milton C. Weinstein, *Legislating against Use of Cost-Effectiveness Information*, 363 NEW ENG. J. MED. 1495 (2010) (explain-

The *clinical effectiveness* of treatment is considered a proper subject for the Institute's research; the *cost-effectiveness* of treatment is not. Barred from direct influence on government reimbursement policy, the new Institute must fulfill its more limited mission through the effective production, gathering, and dissemination of research results to the medical profession and the general public.

There is much that can be accomplished, however, even within that limited scope, to rationalize medical practice. PCORI has been up and running for three years. It has received strong funding<sup>56</sup> and has launched almost 200 studies "spanning the spectrum of clinical conditions."<sup>57</sup> Its studies tend to concern issues of broad applicability, such as preventing fall-related injuries in the elderly, interventional pain management, and aligning primary and specialty care for older adults with complex chronic conditions.<sup>58</sup> A notable feature of these studies is the involvement of patient and family advisory councils and health systems in their design and governance, with a view to enhancing the translation of study results into clinical practice and public awareness.<sup>59</sup>

It is too early to assess the fruitfulness of PCORI's activities. As yet, its studies are thought to have had little impact, according to a recent survey.<sup>60</sup> And when the studies are completed, they may not directly inform the basis of Medicare payment decisions. But the studies' results will be accompanied by publicity to professionals, to the public—and to health insurance companies, which no doubt will make use of them in *private* coverage decisions and strategies. Moreover, the research PCORI sponsors is complemented by a considerable number of private and professional comparative effectiveness initiatives, such as the "Choosing Wisely" campaign sponsored by the American Board of Internal Medicine.<sup>61</sup> If the results of the PCORI-sponsored studies and their privately sponsored analogues can be incorpo-

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ing usefulness of cost-per-QALY ratios and lamenting the health reform law's possible "chilling effect" on cost-effectiveness research).

56. See Kinney, *Prospects*, *supra* note 38, at 83 (noting large congressional authorizations for comparative effectiveness research).

57. Joseph V. Selby & Steven H. Lipstein, *PCORI at 3 Years—Progress, Lessons, and Plans*, 370 NEW ENG. J. MED. 592, 593 (2014).

58. Information about the variety of studies funded is available on the PCORI website, <http://www.pcori.org/news-room/landing/> (last visited Sept. 18, 2014).

59. Harlan M. Krumholz & Joe V. Selby, *Seeing through the Eyes of Patients: The Patient-Centered Outcomes Research Institute Funding Announcements*, 157 ANNALS INTERNAL MED. 446 (2012).

60. See John Reichard, *Rapid Payoff from Comparative Effectiveness Research Questioned*, WASH. HEALTH POL'Y WEEK IN REV. (May 27, 2014), <http://www.commonwealthfund.org/publications/newsletters/washington-health-policy-in-review/2014/may/may-27-2014/rapid-payoff-from-comparative>.

61. Nancy E. Morden et al., *Choosing Wisely—The Politics and Economics of Labeling Low-Value Services*, 370 NEW ENG. J. MED. 589 (2014).

rated into the daily processes of care—no small task—then the wasteful inefficiencies plaguing American health care can be at least partially mitigated.

Ours is an information-driven society, relentlessly becoming more so. Despite existing barriers (financial, psychological, and ideological) to adoption of treatments proven superior,<sup>62</sup> in the long run the evidence should have an effect. Bioethicist John Marquis has suggested asking any taxpayer, “Should you continue paying taxes to fund expensive treatments lacking evidence that they work as well as cheaper available treatments?”<sup>63</sup> When that conversation takes hold in public discourse, it will build popular support for cost-effectiveness as a pillar of health policy.

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62. See, e.g., Timbie et al., *supra* note 25 (suggesting various reasons for slow pace of change in clinical practice).

63. Marquis’s suggestion is reported in Leonard, *supra* note 43, at 886.