HARNESSING COMPARATIVE EFFECTIVENESS RESEARCH TO BEND THE COST CURVE AND ACHIEVE SUCCESSFUL HEALTH REFORM: AN ASSESSMENT OF CONSTITUTIONAL BARRIERS TO LIMITING HEALTH CARE TREATMENT OPTIONS

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Imagine a man who suddenly experiences severe chest pain, shortness of breath, and increased sweating. This man is rushed to an emergency room, where he is diagnosed with coronary artery disease, a condition that constricts the small blood vessels which supply oxygen and blood to the heart and can lead to a heart attack. What if, with the mere push of a button, a physician could establish an ideal treatment for this patient, taking into consideration the quality of various treatment options, as well as the patient’s age, gender, race, ethnicity, co-morbidities such as diabetes, and a variety of other factors that are all unique to this patient?

Undeniably, there is a growing interest in such personalized medicine among both the American public and the federal government. Unfortunately, such individualized treatment is not currently possible for heart disease, nor is it available for a variety of other relatively common health afflictions. A patient who presents in a modern-day U.S. emergency room with coronary artery disease would likely discover different doctors recommending widely varying treatments. But these variations are mainly a result of lingering uncertainties regarding the best approach for treating this condition, rather than efforts to provide patients with individualized treatments.

Achieving such individualized and highly effective treatment is an important underlying goal of clinical comparative effectiveness research (CER), a term which is just beginning to trickle into the vocabulary of average Americans. Yet greater personalization of medical

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2 See Shara Yurkiewicz, The Prospects for Personalized Medicine, 40 HASTINGS CENTER REP. 14, 14–15 (2010) (noting that “[t]he federal government has demonstrated its commitment to personalized medicine” and describing how the direct-to-consumer market for genetic testing has expanded rapidly in recent years).

3 See Michael S. Lauer, Comparative Effectiveness Research: The View from the NHLBI, 53 J. AM. CARDIOLOGY 1084, 1084 (2009) (describing regional variations in the practice of medicine); David Haynes, Health Care Research: Finding What Works, MILWAUKEE J. SENTINEL, May 19, 2010, at A12 (indicating that patients in Wisconsin were 107% more likely to have angioplasty if they lived in Milwaukee rather than La Crosse and 120% more likely to have heart bypass surgery if they lived in Wausau rather than Madison); see also CONG. BUDGET OFFICE, PUB. NO. 2975, RESEARCH ON THE COMPARATIVE EFFECTIVENESS OF MEDICAL TREATMENTS: ISSUES AND OPTIONS FOR AN EXPANDED FEDERAL ROLE (2007), available at http://www.cbo.gov ftpdocs/88xx/doc8891/12-18-ComparativeEffectiveness.pdf#37 (“Without hard evidence . . . decisions about what treatments to recommend often depend on the individual experience and judgment of physicians.”); Patrick H. Conway & Carolyn Clancy, Editorial, Charting a Path from Comparative Effectiveness Funding to Improved Patient-Centered Health Care, 303 JAMA 985, 986 (2010) (noting that “[t]he challenges and frustrations for clinicians and patients of daily clinical decisions necessarily made under conditions of uncertainty are self-evident”); Alan M. Garber & Sean R. Tunis, Does Comparative-Effectiveness Research Threaten Personalized Medicine, 360 NEW ENG. J. MED. 1925, 1926 (2009) (noting that “with too few appropriately designed studies, physicians, patients, and families have often had little guidance about which patients were most likely to benefit from a clinical strategy”).

4 See Garber & Tunis, supra note 3, at 1926 (“Perhaps the most important goal of CER is to broaden and deepen . . . information [about which patients are most likely to benefit from a clinical strategy], providing tools for matching medical care much more precisely to individual patients.”); see also Robert Epstein & J. Russell Teagarden, Comparative Effectiveness and Personalized Medicine: Evolving Together or Apart?, 29 HEALTH AFF. 1783, 1786 (2010) (“Comparative effectiveness research can . . . extend the potential applications of personalized medicine.”); John K. Iglehart, The Political Fight over Comparative Effectiveness Research, 29 HEALTH AFF. 1757, 1759 (2010) (quoting the president of Friends of Cancer Research as saying that it has become “clear that [comparative effectiveness research] could be a step toward ‘personalized’ medicine”).

5 See infra Part I.A (providing an array of definitions on what the term “comparative effectiveness” encompasses).
treatment is actually just one of many benefits that can be derived from increased use of CER.

Comparative effectiveness research also has the ability to save lives and generate tremendous savings in the health care system, rendering it a critical “game-changer” of the newly passed U.S. federal health reform law. In fact, Francis Collins, the director of the National Institutes of Health, calls the support for comparative effectiveness research embedded in the Patient Protection and Affordable Care Act its “most significant” component, and CER has been touted as the new “headwind for the health-care industry” due to its ability to discern which drugs, treatments, and devices work best.

Comparative effectiveness research already plays an important role in the health care systems of many industrialized nations, including those of the United Kingdom, France, Germany, and Australia.

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6 Mark McClellan, Dir., Brookings Inst. Engelberg Ctr. for Health Care Reform, Welcome Address at the Brookings Institution Event: Implementing Comparative Effectiveness Research: Priorities, Methods, and Impact 6 (June 9, 2009), available at http://www.brookings.edu/~/media/Files/events/2009/0609_health_care_cer/20090609_health_care_cer.pdf [hereinafter Brookings Institution, Implementing Comparative Effectiveness]; see Rachel Saslow, NIH Director Sees Hits and Misses in Health Care, WASH. POST, Mar. 24, 2010, at A15 (describing an interview with the Director of the National Institutes of Health in which he states that the “most significant” aspect of the new health care bill is the inclusion of comparative effectiveness research); see also Alex Nussbaum & Meg Tirrell, Health Care Bill’s Small Detail to Have Big Outcome: $500M Institute to Increase Scrutiny of Drug Studies, STAR-LEDGER (Newark, N.J.), Mar. 28, 2010, at B1 (noting that despite being tucked into page 1,617 of the new 2,400 page health care law and sparking minimal debate, the section on comparative effectiveness research is perhaps “the most sweeping change to health care in 45 years”). The article also indicated that comparative effectiveness research would be used to help “pry savings from the [health care] system.” Id.

7 Saslow, supra note 6, at A15.

8 Nussbaum & Tirrell, supra note 6, at B1.

9 In the United Kingdom, for instance, the National Institute for Health and Clinical Excellence (NICE), which is an independent committee of health professionals, academics, industry and lay representatives, has been established. KALIPSO CHALKIDOU, THE COMMONWEALTH FUND, COMPARATIVE EFFECTIVE REVIEW WITHIN THE U.K.’S NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXPERIENCE 1–2 (2009), http://www.commonwealthfund.org/~/media/Pubs/Publications/Issue%20Brief/2009/Jul/Chalkidou/1296_Chalkidou_UK_CER_issue_brief_717.pdf (discussing the composition of NICE). NICE was originally created to “reduce[] unwarranted variation in medical practice,” facilitate quick “diffusion of high-value new technologies,” and ensure that taxpayers’ funds were invested so as to maximize health benefit. Id. at 1. “NICE committees consider comparative clinical and . . . social values . . . and U.K. and European Union legislation when making their decisions.” CHALKIDOU, supra at 2. England recently decided to stop considering costs in these decisions. See Ed Silverman, U.K.’s NICE Loses Decision-Making Powers, PHARMA L (Nov. 2, 2010, 7:36 AM) http://www.pharmalot.com/2010/11/02/uk-nicesoses-decision-making-powers. A variety of mechanisms have been undertaken by the U.K. government to ensure compliance with NICE-issued guidelines. See id. at 2 (“Local purchasers of care . . . are required to fund newly recommended technologies and hospitals to make them available when requested
Some CER studies have been undertaken in the United States.\(^\text{13}\) In fact, the state of Oregon has been successfully using CER to pri-

by a patient and his or her physician; compliance is increasingly considered as part of provider accreditation, and a new NHS Constitution makes access to NICE-recommended treatments a right for everyone in England.”). France created the National Authority for Health (Haute Autorité de Santé, or HAS) in 2005 “with the goals of optimizing the basket of reimbursable goods and services and helping health care professionals continuously improve their clinical practice by defining best-care standards and identifying relevant tools and methods.” Lise Rocheix & Bertrand Xerri, The Commonwealth Fund, National Authority for Health: France 1 (2009), http://www.commonwealthfund.org/-/media/Files/Publications/Issue%20Brief/2009/Jul/Chalkidou/1295_Rocheix_CER_France_issue_brief_724.pdf. HAS is an independent public authority with financial independence and a “unique legal identity.” Id. at 1.

Germany evaluates comparative effectiveness research through its Institute for Quality and Efficiency in Health Care (IQWiG). See Mona Nasser & Peter Sawicki, The Commonwealth Fund, Institute for Quality and Efficiency in Health Care: Germany, 1 (2009), http://www.commonwealthfund.org/-/media/Files/Publications/Issue%20Brief/2009/Jul/Chalkidou/1294_Nasser_CER_Germany_issue_brief_724.pdf (providing background on IQWiG). The majority of Germans obtain health coverage via the Statutory Health Insurance (SHI) system of sickness funds. Id. at 1. Decisions regarding coverage under this system are made by a Federal Joint Committee, which is comprised of a provider, insurer, and patient representatives. Id. at 2. Established in 2004, IQWiG functions in an advisory role to review available evidence and develop recommendations regarding the costs and benefits of various health services. Id. at 2. IQWiG has created processes to allow “public and stakeholder comment” on its “preliminary reports.” Id. at 6. While the involvement of these participants furthers the transparency of the process, it has also caused “debate, criticisms, and discussion,” and has resulted in substantial media attention focusing on these reports. Id. at 8. These recommendations are reviewed by the German Joint Commission, which issues coverage and payment directives. See id. at 1 (affording an explanation of the role of Germany’s Federal Joint Committee). Since German law requires insurance funds to cover medically necessary services, “cost-effectiveness analysis can only be used to exclude a treatment from coverage if at least one equivalent alternative exists.” Id. at 2.

In Australia, the majority of “prescriptions drugs are subsidized through the Pharmaceutical Benefits Scheme (PBS).” Ruth Lopert, The Commonwealth Fund, Evidence-Based Decision-Making Within Australia’s Pharmaceutical Benefits Scheme 1 (2009), http://www.commonwealthfund.org/-/media/Files/Publications/Issue%20Brief/2009/Jul/Chalkidou/1297_Lopert_CER_Australia_issue_brief_724.pdf. Drugs are recommended for inclusion on this list by the Pharmaceutical Benefits Advisory Committee (PBAC), an independent statutory committee, which considers both the comparative effectiveness and the comparative cost-effectiveness of the drugs it reviews. Id. at 1–2. Despite cost-effectiveness considerations, the PBS processes are not considered a cost-containment mechanism but rather a way to ensure the best value for Australian taxpayers’ money and equal access to affordable prescription drugs. Id. at 3. The PBS maintains significant public support, despite some controversial decisions. Id. at 9.

See Richard S. Saver, Health Care Reform’s Wild Card: The Uncertain Effectiveness of Comparative Effectiveness Research, 159 U. Pa. L. Rev. (forthcoming 2011) (noting that some government agencies, such as the Agency for Healthcare Research and Quality, have previously provided support for CER activities, and that some private entities, including health insurance companies and drug and device companies, have also previously undertaken CER studies).
oritize services for its Medicaid recipients since the mid-1990s. Yet the potentially substantial benefits of widespread use of CER have only recently begun to garner significant attention in the United States.

The current buzz in the U.S. media over comparative effectiveness research perhaps began in earnest on February 17, 2009, when CER was thrust to center stage as President Obama signed into law the American Recovery and Reinvestment Act of 2009 (ARRA), “a nationwide effort to . . . transform our economy to compete in the 21st century.” The Act included provisions creating jobs and providing relief to working-and middle-class families. Perhaps less well known, it also set aside a substantial grant of $1.1 billion for comparative effectiveness research.

Following on the heels of the ARRA, Americans saw the enactment of health care reform on March 23, 2010. The Patient Protection and Affordable Care Act (PPACA) provides additional support for CER by establishing a new non-governmental organization, the Patient-Centered Outcomes Research Institute, whose primary pur-

15 See Conway & Clancy, supra note 3, at 985 (“The concept of CE research is not new . . . [w]hat is new is the recognition of and substantial public support for research that is essential for delivering care that is consistently patient centered and an important accelerator for achieving the promise of personalized medicine.”); James M. Stubenrauch, Comparative Effectiveness Research: It Could Change the Way Health Care Decisions Are Made, AM. J. NURSING, Oct. 2009, at 26, 27 (relaying a quote by the director of the National Institute for Nursing Research that “[c]omparative effectiveness research has garnered increased attention as an area of science that can have a significant impact upon the future health care of the American people” (internal quotation marks omitted)).
18 See Agency for Healthcare Research & Quality, AHRQ and the Recovery Act, U.S. DEPARTMENT HEALTn & Hum. Services (June 2010), http://www.ahrq.gov/fund/cefarra.htm (elaborating on the funding provided to AHRQ through the ARRA for comparative effectiveness research); see also FED. COORDINATING COUNCIL FOR COMPARATIVE EFFECTIVENESS RESEARCH, REPORT TO THE PRESIDENT AND THE CONGRESS 11 (2009), available at http://www.hhs.gov/recovery/programs/cer/ceannualrpt.pdf (“The ARRA funding reflects the heightened interest in CER among the nation’s clinicians, patients, policy makers and researchers and broader recognition of its potential to improve outcomes that matter to patients, including morbidity, mortality, and quality of life.”).
pose is to facilitate comparative effectiveness research. These successive, massive grants of federal dollars for CER raise the question, “What is comparative effectiveness research, and why is the government pouring so much money into it?”

A. What Is Comparative Effectiveness Research?

The definition of CER continues to evolve. Thus, different sources offer slightly varying definitions of what comparative effectiveness research encompasses. After the enactment of the ARRA, two different entities—the Federal Coordinating Council for Comparative Effectiveness Research and the Institute of Medicine—were charged with creating priorities for comparative effectiveness research. Each entity proposed its own definitions of comparative effectiveness research.

In its report to the President and Congress, the Federal Coordinating Council for Comparative Effectiveness Research defines comparative effectiveness research as follows:

Comparative effectiveness research is 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.

- To provide this information, comparative effectiveness research must assess a comprehensive array of health-related outcomes for diverse patient populations and subgroups.
- Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, diagnostic testing, behavioral change, and delivery system strategies.

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21 See infra notes 22–25 and accompanying text.
This research necessitates the development, expansion, and use of a variety of data sources and methods to assess comparative effectiveness and actively disseminate the results.\footnote{22}

An alternative definition of comparative effective research has been proposed by the Institute of Medicine (IOM). According to the IOM, CER is 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.\footnote{23}

The IOM notes that “CER can take many forms.”\footnote{24} These forms can include reviews of literature, established databases such as electronic medical records, or prospective registries. They can also include research done through cohort studies and randomized control trials.\footnote{25}

Another important definition of CER is found in the Patient Protection and Affordable Care Act (PPACA). The PPACA defines comparative effectiveness research as follows: “The term[] ‘comparative clinical effectiveness research’ . . . mean[s] research evaluating and comparing health outcomes and the clinical effectiveness, risks, and benefits of 2 or more medical treatments, services, and items.” These “medical treatments, services, and items” include:

- health care interventions, protocols for treatment, care management, and delivery, procedures, medical devices, diagnostic tools, pharmaceuticals (include drugs and biologicals), integrative health practices, and any other strategies or items being used in the treatment, management, and diagnosis of, or prevention of illness or injury in, individuals.\footnote{26}

The PPACA’s definition of CER indicates that the scope of CER which will be funded by the federal government is quite broad.\footnote{27} The PPACA eliminated the Federal Coordinating Council on Comparative Effectiveness, which was created by the Recovery and Reinvestment Act, and established a new Patient-Centered Outcomes Research Institute to develop and help implement a CER project.

\begin{footnotes}
\footnote{22}{Fed. Coordinating Council for Comparative Effectiveness Research, \textit{supra} note 18, at 5.}


\footnote{24}{Id. at 1.}

\footnote{25}{Id. at 1–2.}

\footnote{26}{See Patient Protection and Affordable Care Act (PPACA) \textsection 6301(a), Pub. L. No. 111-148, 124 Stat. 119, 727 (2010) (to be codified at 42 U.S.C. \textsection 1320e).}

\footnote{27}{Alan M. Garber & Harold C. Sox, \textit{Analysis \\& Commentary: The Role of Costs in Comparative Effectiveness Research}, 29 Health Aff. 1805, 1805 (2010).}
\end{footnotes}
The Institute is charged with assisting patient, physician, purchaser, and policy makers in healthcare-related decisions by making better evidence available to them through CER studies. The Institute’s purpose is to “disseminat[e] . . . research findings with respect to the relative outcomes, clinical effectiveness, and appropriateness of . . . medical treatments, services and items.”

B. Why Is the U.S. Government Interested in Utilizing Comparative Effectiveness Research Findings?

The new focus on comparative effectiveness clinical research in the United States stems from a growing recognition that rising American health care costs constitute a significant challenge in the quest for successful health care reform. Proliferating health care services, increases in the volume and intensity of services, the provision of unnecessary care, professional liability, advances in medical technology, and an aging population are just some of the reasons cited for the current health care cost crisis. While various strategies have been employed to reduce these costs, better information, obtained through comparative effectiveness research, regarding the costs and benefits of health care treatment options has more recently been

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28 Patient Protection and Affordable Care Act § 6302 (terminating the Federal Coordinating Council); Patient Protection and Affordable Care Act § 6301 (establishing the Patient-Centered Outcomes Research Institute).

29 Patient Protection and Affordable Care Act § 6301.

30 See Patient Protection and Affordable Care Act § 6301(a) (specifying the purpose of the Patient-Centered Outcomes Research Institute).

31 See Shailagh Murray & Lori Montgomery, Affordability Is Major Challenge for Reform—Burden on Middle Class Is a Top Concern, WASH. POST, Sept. 18, 2009, at A1 (“Democrats and Republicans alike worry that a [health care] bill intended to address one source of financial hardship—the skyrocketing cost of health care—could lead to another, in the form of hefty premiums.”); Karen Davis, Why Health Reform Must Counter the Rising Costs of Health Insurance Premiums, COMMONWEALTH FUND BLOG (Aug. 18, 2009), http://www.commonwealthfund.org/-/media/Files/Publications/Blog/Davis_Blog_Aug ust_09_rev.pdf (“As health reform advanced through congressional committees this summer, much attention was given to trimming the federal budget cost and slowing the growth in Medicare outlays. . . . Health system reform will be effective only if the legislation considers the financial well-being of all participants, not just that of the federal government.”).


touted as the key to reducing health care spending without adversely impacting the quality of health care provided in the United States. 34

In light of the belief that CER can help to reduce health care spending, references to cost-effectiveness are noticeably absent from the PPACA’s CER definition. Cost-effectiveness analysis is a component of CER in some other countries. 35 However, largely due to fears of rationing, cost-effectiveness analysis as a component of CER in the United States is limited in the PPACA. 36

Cost-effectiveness, which has been defined as “a method . . . to assess the comparative impacts of expenditures on different health interventions,” is actually frequently conflated with CER. 37

[People confuse cost-effectiveness analysis with [CER] because the denominator of the incremental cost-effectiveness ratio is often derived directly from the results of a study of . . . comparative effectiveness. If the

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34 See CONG. BUDGET OFFICE, supra note 3, at 1–2 (discussing how comparative effectiveness research may enable our health care system to save money without compromising the quality of care); Tobias Loddenkemper et al., Fears and Promises of Comparative Effectiveness Research, 99 ACTA PÆDIATRICA 1311, 1312 (2010) (“CER . . . suggests opportunities for reduced spending when it identifies what is inefficient or ineffective. An additional benefit would be the avoidance of adverse side effects of unneeded tests and therapies, and the reduced occurrence of false positive results and their consequences.”); see also Ellen-Marie Whelan & Sonia Sekhar, Better Health Through Better Information: Comparative Effectiveness Research Will Help Deliver Better Medical Care, CENTER FOR AM. PROGRESS (Sept. 29, 2009), http://www.americanprogress.org/issues/2009/09/cer_brief.html (explaining how comparative effectiveness could improve the current American health care system, in which “[i]t’s estimated that one-third of procedures and treatments administered in the United States have no proven benefit and account for up to $700 billion annually in current spending. Moreover, some of these treatments can have harmful side effects, produce worse health outcomes, and then, as a result, add to the soaring costs of medical care”).


36 See Patient Protection and Affordable Care Act (PPACA) § 6301(a), Pub. L. No. 111-148, 124 Stat 119, 741 (2010) (to be codified at 42 U.S.C. § 1320e-1) (“The Patient-Centered Outcomes Research Institute . . . shall not develop or employ 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. The Secretary shall not utilize such an adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs under title XVIII.”).

37 See Garber & Sox, supra note 27, at 1808 (quoting A.M. Garber et al., Theoretical Foundations of Cost-Effectiveness Analysis, in COST-EFFECTIVENESS IN HEALTH AND MEDICINE (Marthe R. Gold et al. eds. 1996)) (internal quotation marks omitted) (defining cost-effectiveness according to the Federal Panel on Cost-Effectiveness in Health and Medicine).
study outcomes and the analysis are expressed in the same units, . . . the two quantities will ordinarily be identical.\textsuperscript{38}

The PPACA’s limitation on cost-effectiveness analyses may, at first, seem incongruous with the desire to use CER to improve the value of American health care. However, health care experts contend that these diverging interests are reconciled by the fact that private parties, such as health insurance companies, physician groups, and hospitals, will use the federal government’s CER to conduct their own cost-analyses and distribute this cost information. By funding CER that does not contain a cost-effectiveness component, the federal government can avoid the backlash that would likely stem from directly financing cost-effectiveness analysis while simultaneously facilitating such analyses.\textsuperscript{39}

A variety of factors suggest that the U.S. government is likely to seek some way to utilize comparative effectiveness research to bend the health care cost curve. First and foremost, the fact that substantial savings could be generated by using such information was recently acknowledged by Peter Orszag,\textsuperscript{40} the former head of the Congressional Budget Office and a key player in the passage of Obama’s health reform plan.\textsuperscript{41} Other health care and economics experts are also beginning to tout the manner in which comparative effectiveness research could help the government achieve savings in publicly funded health care programs.\textsuperscript{42} Furthermore, many other major world powers have already acknowledged the benefits of CER and integrated such research into their health care systems, suggesting that

\textsuperscript{38} Id.
\textsuperscript{39} See id. at 1810; see also Robert Wood Johnson Found., Health Policy Brief, Updated: Comparative Effectiveness Research, HEALTH AFF., http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=28 (describing how the government and the Patient-Centered Outcomes Research Institute cannot use a cost-effectiveness measure as a “threshold” for establishing coverage of health care treatment options, but researchers undertaking federally funded CER can incorporate a cost-effectiveness component in their analysis).
\textsuperscript{40} See Key Players: Health Care Reform, PBS NEWSHOUR, http://www.pbs.org/newshour/updates/health/jan-june09/healthprofiles_0648.html (listing the critical players in the health reform debates); see also Michael D. Shear & Ed O’Keefe, Orszag to Resign as White House Budget Director, Source Says, WASH. POST, June 22, 2010, at A4 (indicating that Orszag announced his resignation from the Office of Management and Budget in June 2010).
\textsuperscript{41} See Steven D. Pearson & Peter B. Bach, How Medicare Could Use Comparative Effectiveness Research in Deciding on New Coverage and Reimbursement, 29 HEALTH AFF. 1796, 1797 (2010) (noting that “comparative effectiveness research may be able to play a role in Medicare, particularly if a clear vision can be developed for the program’s use of research data to help contain costs without restricting access to services”).
the United States is lagging behind the times on this issue.\textsuperscript{43} Finally, there is growing recognition that health care in the United States is rationed even when no decision is explicitly made to do so. The suggestion has been put forth that allowing the government to ration care directly might be more beneficial to the general U.S. population than allowing indirect rationing to continue.\textsuperscript{44}

C. Political Opposition to Comparative Effectiveness Research

History has shown that federal “agencies whose central mission is research on such practical matters as the cost, quality, use and outcomes of health services perennially struggle” in U.S. politics to find support.\textsuperscript{45} Since CER seeks to achieve similar goals, it is perhaps not surprising that certain factions have been strongly opposed to providing federal support for such research. Some sectors of the health care industry, for instance, “fear that a truly efficient and effective healthcare system would cripple their profit margins.”\textsuperscript{46} Other CER opponents contend that it will create government interference in the doctor-patient relationship and fail to account for individual patient

\textsuperscript{43} See sources cited \textit{supra} notes 9–12 (indicating that countries such as the United Kingdom, Germany, France, and Australia have all incorporated comparative effectiveness research into their health care decision making).

\textsuperscript{44} See Peter Singer, \textit{Why We Must Ration Health Care}, N.Y. TIMES, July 19, 2009, at MM38 (discussing how health care is rationed even when no explicit decision is made to do so); see also Jessica Dunsay Silver, \textit{From Baby Doe to Grandpa Doe: The Impact of the Federal Age Discrimination Act on the “Hidden” Rationing of Medical Care}, 37 CATH. U. L. REV. 993, 1004–11 (1988) (providing further background on health care rationing).

\textsuperscript{45} See Bradford H. Gray et al., \textit{AHCPR and the Changing Politics of Health Services Research}, HEALTH AFF. 2 (June 25, 2003), available at http://content.healthaffairs.org/content/early/2003/06/25/hlthaff.w3.283.full.pdf.

differences in medical decision making.47 Some argue that treatment guidelines could be impacted by “corruption and abuse” and that these guidelines might be unable to keep pace with medical innovation.48

Whether the new health reform legislation should include support for comparative effectiveness research was a “fierce debate” in Congress in the summer of 2009, when rumors were rampant that comparative effectiveness research would lead to government rationing of health care and “death panels.”49 During the 2009 legislative session, the Patient-Centered Outcomes Research Act was introduced in the Senate but ultimately did not pass, largely as a result of these various stakeholder concerns.50 Other attempts have also been made

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47 See Iglehart, supra note 20, at 327 (enumerating concerns that some health care stakeholders have regarding the use of comparative effectiveness research); Loddenkemper, supra note 34, at 1312 (discussing concerns about physicians becoming “gatekeepers” of health care access and about rationing of care, delays in treatment, and a reduction in available treatment options); see also Jeffrey Bernstein, U.S. PUB. INTEREST RESEARCH GRP., THE FACTS ABOUT COMPARATIVE EFFECTIVENESS RESEARCH 3 (2009), available at http://www.uspirg.org/home/reports/report-archives/health-care/health-care/the-facts-about-comparative-effectiveness-research (noting that comparative effectiveness research has recently emerged in the health care reform debate as an area of controversy); Tony Coelho, A Patient Advocate’s Perspective on Patient-Centered Comparative Effectiveness Research, 29 HEALTH AFF. 1885, 1888 (2010) (discussing how “many Americans still misinterpret the intent of [comparative effectiveness] research”); Stubenrauch, supra note 15, at 27 (“Despite the clear need for CER and its obvious benefits, it has recently become a matter of heated debate within the struggle over health care reform. Just as some opponents of current reform plans have misrepresented a proposal to fund optional end-of-life counseling for Medicare patients as ‘death panels’ that would ‘pull the plug on Grandma,’ they have also tried to raise fears that CER could be used to deny specific treatments to deserving patients and to ‘ration’ health care.”); Whelan & Sekhar, supra note 34 (“Comparative effectiveness research is now under fire despite its critical importance as objective research. Critics worry about the government’s role in determining best practices. They assert that the research will not account for variations in patient health statuses and backgrounds. And they are concerned that the findings will be used to make coverage determinations.”).


49 Susan Dentzer, Comparative Effectiveness: Coherent Health Care at Last?, 29 HEALTH AFF. 1756, 1756 (2010). For a more analytical view of the potential harms of Medicare using comparative effectiveness research to guide its reimbursement decisions, see Anirban Basu & Tomas J. Philipson, The Impact of Comparative Effectiveness Research on Health and Health Care Spending (Nat’l Bureau of Econ. Research, Working Paper No. 15633, 2010), available at http://www.nber.org/papers/w15633 (“The main conclusion of our analysis is that simplistic thinking about the impact of traditionally perceived CER may have adverse effects.”).

50 See Patient-Centered Outcomes Research Act of 2009, S. 1213, 111th Cong. (1st Sess. 2009); See generally Paul Keckley & Barbara B. Frink, Comparative Effectiveness: A Strategic Perspective on What It Is and What It May Mean for the United States, 3 J. HEALTH & LIFE SCI.
to prevent the government from funding comparative effectiveness research, though these efforts have received little attention in the media. Ultimately, support for comparative effectiveness research was incorporated into the Patient Protection and Affordable Care Act, but the initiative is said to have been “so controversial . . . that it spent weeks in surgery before materializing in the final reform package.”

While CER has already “dodged a barrage of well-coordinated bullets[,] . . . the debate is bound to continue.” Comparative effectiveness research is potentially poised to play a tremendous role in health reform with respect to “bending the health care cost curve.” However, if its use is significantly obstructed by opponents, the ability of health care reform to succeed could be severely undermined.

The U.S. government could choose to harness comparative effectiveness research findings in a variety of ways. The government could use CER findings to ban outright all U.S. citizens from accessing certain treatment options. Alternatively, the government could use CER results to ban a certain classification of individuals, such as a specific racial group or gender, from accessing a given treatment option.

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51 See Avorn, supra note 46, at 1927 (“The proposal to include $1.1 billion for comparative-effectiveness research (CER) in the federal stimulus package encountered a vigorous and well-coordinated backlash. The campaign to gut this funding ultimately failed, but the debate it engendered and the resonance of the opposition’s arguments in both lay and policy circles reveal much about the issues that will surround such research and its application in the coming years.”).

52 See Bob Moffit & Julius Chen, Senate Committee Blocks Anti-Rationing Amendments, FOUNDATION: CONSERVATIVE POLICY NEWS (July 10, 2009), http://blog.heritage.org/2009/07/10/senate-committee-blocks-anti-rationing-amendments/ (highlighting that the media has largely ignored attempts to block funding for comparative effectiveness research).

53 Iglehart, supra note 4, at 1757.

54 Avorn, supra note 46, at 1929; see also Iglehart, supra note 4, at 1760 (“[T]he debate over the role of comparative effectiveness research in US health care is clearly far from over.”).

55 See Brookings Institution, Implementing Comparative Effectiveness, supra note 6, at 6.

56 See Consensus Statement on the Critical Importance of Comparative Effectiveness Research, PAC. BUS. GROUP ON HEALTH (Dec. 2, 2009), http://www.phgh.org/news/pubs/documents/CER-StatementtoSenate.pdf (providing a public consensus statement on behalf of forty-four organizations representing business, labor, consumers, researchers, health plans, physicians, nurses, and other providers that “comparative effectiveness research [is] a critical component of health reform” and should be “retained in any reform legislation”); see also Mark McClellan & Joshua Benner, Comparative Effectiveness Research: Will It Bend the Health Care Cost Curve and Improve Quality?, in IMPLEMENTING COMPARATIVE EFFECTIVENESS RESEARCH: PRIORITIES, METHODS, AND IMPACT 7, 14 (2009) (indicating that implementing CER properly may “be challenging, but doing so could enable CER to play an essential role in achieving the goal of bending the cost curve while improving health in America”).
The government could also use CER findings to alter procedural requirements so as to render more difficult obtaining a treatment option that has been deemed less desirable on the basis of CER results. The government could also deny public funding for certain medical treatment options on the basis of CER findings.

In the near future, the U.S. Department of Health and Human Services is likely to resort to at least some of these means of banning or limiting access to health care treatment options on the basis of CER results in order to rein in escalating health care costs. Legal commentators believe that such government rationing of health care will raise constitutional challenges.

Thus, Parts II through IV of this Comment explore whether each of these potential ways in which the U.S. government may seek to use comparative effectiveness research findings to ban or limit access to health treatment options would withstand constitutional challenge. Part VI considers the relevant procedural due process concerns raised when the government deprives an individual of a health care treatment option without adequate procedural protections. Finally, Part VII explores whether the government could constitutionally use certificate-of-need standards or licensing requirements to restrict health care investments by private actors on the basis of CER findings. Ultimately, this Comment affords an in-depth assessment of potential constitutional hurdles to a national health care system that harnesses comparative effectiveness research findings to ban or limit access to certain health care treatment options. In light of the major investments and support provided for CER in recent federal legisla-

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57 Health care experts already emphatically advocate for a cost-effectiveness component to be incorporated into the government’s CER research. See, e.g., Garber & Sox, supra note 27, at 1809 (“[T]he Patient-Center Outcomes Research Institute and other sponsors of the research should demand that it include data on use and costs, for several reasons.”); see also Pearson & Bach, supra note 42, at 1797 (“[T]he best way for Medicare to benefit from the nation’s new investment in comparative effectiveness research is to use it as a bridge—a conceptual and practical tool to link positive coverage decisions with evidence-based reimbursement levels.”). Note that constitutional challenges to PPACA have already occurred. See, for instance, Florida v. U.S. Dep’t of Health & Human Servs., No. 3:10-cv-91-RV/EMT, 2011 WL 285683 (N.D. Fla. Jan. 31, 2011). However, at the time this Comment went to press, the challenges had only focused on the act’s mandate to purchase health care coverage and not the use of CER results.

58 See Maxwell J. Mehlman, Rationing Expensive Lifesaving Medical Treatments, 1985 WIS. L. REV. 239, 285–86 (surmising that constitutional challenges would likely be raised if expensive lifesaving medical treatments were rationed by the government); see also Kelli D. Back, Rationing Health Care: Naturally Unjust?, 12 HAMLINE J. PUB. L. & POL’Y 245, 255 (1991) (explaining that “[t]he Supreme Court has not yet addressed a case of explicit health care rationing. Still the issue is alive,” so health care rationing may be subject to constitutional challenge).
tion and the growing emphasis on finding ways that the government can rely on CER findings to help reduce costs in the U.S. health care system, this issue is critically relevant to current legal debates.  

II. COMPARATIVE EFFECTIVENESS RESEARCH AND THE PATIENT PROTECTION AND AFFORDABLE CARE ACT

In 2009, a bill about using CER findings made its way through the House but ultimately failed to succeed in the Senate. However, CER research was later a prominent feature of the Senate’s version of health care reform legislation, known as the Patient Protection and Affordable Care Act (PPACA), that was enacted into law after being passed by the House and signed by the President. A detailed look at the language of the PPACA, as amended by the Health Care and Education Reconciliation Act of 2010, reveals explicit language regarding how CER findings may be utilized by the U.S. government.

Section 6301(a) of the PPACA prohibits the newly established Patient-Centered Outcomes Research Institute, established to develop and implement a CER project agenda, from mandating “coverage, reimbursement, or other policies for any public or private payer.” Section 6301(a) provides that “[t]he [Department of Health and Human Services’] Secretary may only use evidence and findings from research conducted under section 1181 [of the Social Security Act]..."
amended] to make a determination regarding Title XVIII if such use is through an iterative and transparent process which includes public comment and considers the effect on subpopulations. The legislation further specifies that CER findings should not be construed as permitting the Secretary to deny Medicare coverage for items or services "solely" on the basis of such research. The Secretary is also prohibited from using such 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, nondisabled, or not terminally ill." However, the Secretary may utilize such findings when they would help extend the lives of such individuals.

While this newly enacted health care law specifies some limitations on the use of comparative effectiveness research findings, the Act does leave room for the Department of Health and Human Services to use comparative effectiveness research findings to guide its determinations about Medicare coverage for certain health care treatment options. The PPACA explicitly states that such changes can occur through "an iterative and transparent process which includes public comment and considers the effect on subpopulations" (and as long as the findings do not value extending the life of an elderly, disabled, or terminally ill individual less than extending the life of younger, nondisabled or non-terminally ill individuals). A final rule issued by the Department of Health and Human Services with new provisions banning or limiting access to health care treatment options on the basis of comparative effectiveness research findings, even if enacted through proper administrative procedures, could of course still be challenged on constitutional grounds. As more CER results become

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66 See id. Note that Title XVIII refers to Medicare coverage, which is public health insurance for the aged and disabled. See Compilation of the Social Security Laws, Title XVIII: Health Insurance for the Aged and Disabled, http://www.ssa.gov/OP_Home/ssact/title18/1800.htm. The PPACA does include a parallel provision for Medicaid.

67 See Patient Protection and Affordable Care Act § 6301(a) (specifying limitations on the Secretary of the Department of Health and Human Services with respect to uses of comparative effectiveness research).

68 See id.

69 See id. (specifying permissible uses of comparative effectiveness research). It is perhaps interesting to note that this language only references how to value "extending" life. The Act is silent with respect to how the quality of life of an elderly, disabled, or terminally ill individual should be valued when weighed against extending the life, or the quality of life, of an individual who is younger, nondisabled, or not terminally ill.

70 See id.

71 See, e.g., Initiative & Referendum Inst. v. U.S. Postal Serv., 417 F.3d 1299, 1312 (D.C. Cir. 2005) (holding that a Postal Service regulation prohibiting solicitation of signatures on
available, the government may seek to utilize these findings to achieve health care savings. The next sections of this Comment contemplate the ways in which the U.S. government could attempt to use new comparative effectiveness research findings to impact access to health care treatment options. This Comment will also consider whether those intended uses could withstand constitutional challenge.

III. THE CONSTITUTIONALITY OF ABSOLUTE GOVERNMENT BANS ON MEDICAL TREATMENT OPTIONS

The U.S. government has the capacity to use comparative effectiveness research findings directly in a number of ways. One conceivable way is to impose an absolute ban on access to a certain medical treatment option. Such a scenario could unfold if CER results show a particular medical treatment option is substantially better than a competing treatment option. For instance, CER findings could reveal that Drug A, which is used to treat leukemia, has markedly better patient outcomes and fewer side effects than Drug B, a competitor. While both drugs may be approved by the FDA, the Department of Health and Human Services could, on the basis of these CER findings, promulgate a rule which would ban all Americans from accessing Drug B. Would such an absolute government ban withstand constitutional challenge?

In order to assess the constitutionality of the government denying access to certain health care treatment options, the substantive aspects of the due process provisions of the Fifth and Fourteenth Amendments must be considered. The U.S. Constitution grants and restricts government power, but does not directly control the activi-

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72 See supra note 57.
ties of private individuals or organizations. Thus, a constitutional claim cannot stand unless the alleged harm stems from government wrongdoing. The state action inquiry occurs before the merits of the constitutional claim are considered.

In this inquiry, courts will examine the specific conduct about which the plaintiff is complaining and whether the decision making regarding that conduct implicates the government in any way. Where the government makes a decision to deny an individual access to a certain health care treatment option, the state action doctrine would clearly be implicated. The next stage of constitutional analysis would proceed differently depending on the type of medical treatment option at issue. In order to explore these differences more clearly, the next portion of analysis will focus on the following two common medical treatment options and the constitutional implications of denying access to each of them: new drugs and medical procedures.

A. Absolute Bans on Drugs

A constitutional challenge could be brought if the U.S. government imposes an absolute ban on certain drugs. This section explains why a constitutional challenge a ban on a drug not yet approved by the Food and Drug Administration is unlikely to succeed. It also describes why a constitutional challenge to an absolute ban on a drug approved by the FDA could be more successful.

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76 See Cole, supra note 74, at 327 ("Purely ‘private’ action cannot violate these provisions.").

77 See John Fee, *The Formal State Action Doctrine and Free Speech Analysis*, 83 N.C. L. Rev. 569, 578 (2005) ("[T]he state action inquiry occurs prior to, and separate from, the merits of a constitutional claim.").

78 See id. at 577–78 (explaining the basic structure of state action analysis).

79 See supra notes 74–78 and accompanying text (discussing when the state action doctrine is implicated).

80 See Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 Va. L. Rev. 1753, 1753 (1996) ("Before a new therapeutic drug or medical device can be commercialized in the United States, it must meet the safety and effectiveness requirements of the Food and Drug Administration (FDA)." ); cf. David A. Grimes, Commentary, *Technology Follies: The Uncritical Acceptance of Medical Innovation*, 269 JAMA 3030, 3032 (1993) ("A double standard in tests and treatments prevails. While new medicines must have rigorous proof of efficacy and safety before clinical use, tests and operations do not.").
The modern day Food, Drug, and Cosmetic Act was enacted in 1938, giving rise to our current system of Food and Drug Administration (FDA) premarket approval for new drugs that enter the U.S. marketplace. While the Act initially only allowed the FDA to establish that new drugs were safe, the 1962 amendments to the Act led to the current requirement that new drugs be found not only safe but also effective in order to be approved by the FDA and permitted to enter the market. Thus, presently, the U.S. government has the power to forbid individuals from obtaining drugs which do not meet necessary safety and efficacy standards.

Cases such as *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach* have tested the constitutionality of forbidding access to new drugs that have not yet met all of the FDA’s safety and efficacy standards for market approval. In *Abigail Alliance*, the Court of Appeals for the District of Columbia applied the test outlined in *Washington v. Glucksberg* to determine whether terminally ill patients have a fundamental right to access experimental drugs that have completed Phase I clinical testing for safety but have not yet been evaluated for effectiveness. The court first determined that such a right could not be considered fundamental, as our nation’s history demon-

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81 *See Merrill, supra note 80, at 1761 (noting that the 1938 Food, Drug, and Cosmetic Act was passed after the “Elixir Sulfanilamide disaster” resulted in more than one hundred Tennessee residents being poisoned by a recklessly produced new drug (internal quotation marks omitted)).*

82 *See id. at 1762 (“This was the beginning of the modern system of premarket approval which now covers practically all drugs . . . .”).*

83 *See id. at 1765 (“[T]he Amendments . . . raised the standard that a new drug had to satisfy by explicitly directing FDA to confirm its effectiveness as well as its safety.”); *see also* Charles J. Walsh & Alissa Pyrich, *Rationalizing the Regulation of Prescription Drugs and Medical Devices: Perspectives on Private Certification and Tort Reform*, 48 RUTGERS L. REV. 883, 890–914 (1996) (providing an overview of modern regulation of drugs by the FDA).


85 *See Washington v. Glucksberg, 521 U.S. 702, 720–21 (1997) (establishing that, in order for a right to be protected by the Due Process Clause, the right must be a fundamental right or liberty that is “deeply rooted in this Nation’s history and tradition,” . . . and ‘implicit in the concept of ordered liberty,’ such that ‘neither liberty nor justice would exist if they were sacrificed,’” and that a “careful description” of the asserted fundamental liberty interest” must be provided (citations omitted) (quoting *Palko v. Connecticut*, 302 U.S. 319, 325, 326 (1937))).

86 *See Abigail Alliance*, 495 F.3d at 699 (discussing how Abigail Alliance requested that the FDA promulgate new regulations to permit the marketing of experimental drugs in certain circumstances after Phase I trials were completed).
strates increasing regulation of drugs. Furthermore, the court determined that the country’s legal traditions of allowing a necessity defense, prohibiting intentional interference with rescue, and recognizing a right of self-defense did not justify creating a constitutional right for an individual to assume any level of risk with respect to the drugs they ingest. Since the right of access to experimental drugs was ultimately not deemed fundamental, government restrictions on access to these drugs were subject to mere rational basis review. The court held that the “FDA’s policy of limiting access to investigational drugs” that have only completed Phase I testing was “rationally related to the legitimate state interest of protecting patients, including the terminally ill, from potentially unsafe drugs with unknown therapeutic effects.”

The Supreme Court declined certiorari.

This case reveals that the FDA can constitutionally ban access to drugs that it has not yet approved. This holding is also supported by United States v. Cannabis Cultivator’s Club, in which the U.S. District Court for the Northern District of California determined that the patients did not have a fundamental right of access to a different drug, medical marijuana. The court opinion cited to Carnohan v. United States and Rutherford v. United States, both of which rejected claims that individuals had substantive due process rights to a drug believed to treat cancer, but unapproved by the FDA.

87 See id. at 707 (“[C]reating constitutional rights to be free from regulation based solely upon a prior lack of regulation would undermine much of the modern administrative state, which, like drug regulation, has increased in scope as changing conditions have warranted.”).
88 See id. at 707–10 (discussing why Alliance’s arguments fail to establish the requested right as fundamental).
89 See id. at 712 (“Because the Alliance’s claimed right is not fundamental, the Alliance’s claim of a right of access to experimental drugs is subject only to rational basis scrutiny.”).
90 Id. at 713.
91 See Robert Barnes, Supreme Court Lets Stand Experimental-Drug Ruling, WASH. POST, Jan. 15, 2008, at A2 (discussing the Supreme Court’s decision to let stand the circuit court’s determination that the terminally ill do not have a constitutional right to access experimental drugs).
93 616 F.2d 1129, 1122 (9th Cir. 1980) (declining to find a constitutional right for the plaintiff to treat himself with a drug not yet approved by the FDA).
94 442 U.S. 544, 559 (1979) (holding that patients do not have a constitutional right to access drugs unapproved by the FDA).
The same District Court ruling in **Cannabis Buyers’ Cooperative** reached the same conclusion again a few years later in **Raich v. Ashcroft**. In **Raich**, the court rejected patients’ claims to medicinal marijuana, again finding that access to medicinal marijuana did not constitute a fundamental due process right. This determination was upheld by the Ninth Circuit.

These cases show that American courts generally do not believe that the Constitution provides for a fundamental right of access to a drug that has not been approved by the FDA, even where the patients requesting the drug are terminally ill. As a result, if the government decides on the basis of CER findings to impose an absolute ban on access to a non-FDA-approved drug, a constitutional challenge to this decision would likely be reviewed by courts under rational basis review. The court would likely uphold the decision. This review of the case law shows that a new drug must already be approved by the FDA as both safe and effective before comparative effectiveness research findings could impact Americans’ access to the drug.

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96 Raich v. Ashcroft, 248 F. Supp. 2d 918, 931 (N.D. Cal. 2003) (holding that the Controlled Substances Act does not violate the Ninth or Tenth Amendments), **rev’d on other grounds**, 352 F.3d 1222 (9th Cir. 2003), **vacated sub nom.**, Gonzales v. Raich, 545 U.S. 1 (2005), **aff’d on remand**, 500 F.3d 850 (9th Cir. 2007). This case would later reach the Supreme Court as **Gonzales v. Raich**, where the Court addressed whether the federal Controlled Substances Act, which conflicted with California’s Compassionate Use Act permitting the use of medicinal marijuana, fell within Congress’ commerce powers. However, the issue of whether patients had a substantive due process right to marijuana was never considered by the Supreme Court; it was first raised at the district court level. **See Gonzales v. Raich**, 545 U.S. 1, 28-29 (2005) (permitting Congress to ban the use of marijuana even where states have approved its use for medicinal purposes).

97 **See Raich**, 248 F. Supp. 2d at 928 (addressing whether access to medicinal marijuana constitutes a fundamental right).

98 **See Raich v. Gonzales**, 500 F.3d 850, 869 (9th Cir. 2007) (affirming the district court’s determination that access to medicinal marijuana does not constitute a fundamental right under the Constitution).

99 **See** Linda Katherine Leibfarth, *Giving the Terminally Ill Their Due (Process): A Case for Expanded Access to Experimental Drugs Through the Political Process*, 61 VAND. L. REV. 1281, 1293 (2008) (discussing how the courts have found no fundamental right of access to experimental drugs). But see id. at 1288–90 (noting that the FDA has actually promulgated a Compassionate Use exemption for terminal illness, though only to access certain drugs undergoing Phase III trials, and has made efforts to expedite access to drugs to treat AIDS and other serious illnesses).

100 **See** Williamson v. Lee Optical., Inc., 348 U.S. 483, 491 (1955) (“We cannot say that the regulation has no rational relation to that objective and therefore is beyond constitutional bounds.”); **see also** Gayle Lynn Pettinga, Note, *Rational Basis with Bite: Intermediate Scrutiny by Any Other Name*, 62 IND. L.J. 779, 779 (describing how, traditionally, rational basis review involves substantial deference to the government).

101 **See** Leibfarth, supra note 99, at 1282 (noting that new drugs must meet the FDA’s safety and efficacy standards before they can enter the United States marketplace).
As comparative effectiveness research becomes more widely available, Congress could alter the FDA’s drug approval standards so that it will only approve a drug to enter the marketplace when comparative effectiveness research shows that it is the safest or most effective of an array of drugs available to treat a given medical condition.\textsuperscript{102} Alternatively, the Secretary of the Department of Health and Human Services could promulgate a rule which bans an FDA-approved drug that is deemed less effective or safe than a competitor on the basis of CER. A constitutional challenge could be raised in either of these contexts. However, since no such laws exist today, our courts have not previously been confronted with a similar challenge. The outcome of such a constitutional challenge is interesting to consider, but also extremely difficult to predict. Furthermore, it seems far more likely that the government would seek to discourage use of FDA-approved drugs that have been deemed less safe or effective than competitors on the basis of CER before they would altogether ban such drugs. For these reasons, this issue remains beyond the scope of this Comment.

\textbf{B. Absolute Bans on Medical Procedures}

In contrast to drugs—few of which ever make it to the American marketplace because they must be found both safe and effective by the FDA before Americans can access them—medical procedures are “subject to little formal control or regulation.”\textsuperscript{103} Medical procedures, such as surgical techniques, are generally only governed “by guidelines, promulgated by national consensus organizations, which entail neither enforcement nor penalty.”\textsuperscript{104} Some informal protocols are also in place to help control medical procedures. These controls consist of “state licensure committees for medical practitioners, the fear of malpractice liability, physician profile databases, and hospital review boards,” and they “are beset with significant problems.”\textsuperscript{105} Thus, most medical procedures could be affected by a government decision to ban medical procedures deemed less safe or effective than competitors on the basis of CER results. Most, but not all, government decisions to ban a medical procedure would probably be reviewed by the

\textsuperscript{102} Medicare and Medicaid could also deny coverage for the drug, but this section is focused on absolute bans of access, rather than issues of coverage.

\textsuperscript{103} Amer S. Ahmed, Note, The Last Twist of the Knife: Encouraging the Regulation of Innovative Surgical Procedures, 105 COLUM. L. REV. 1529, 1536 (2005) (analyzing the disparity between administrative regulation of pharmaceuticals and surgical procedures).

\textsuperscript{104} \textit{id} at 1530.

\textsuperscript{105} \textit{id}.
courts using a mere rational basis standard, a very low threshold, and upheld.\footnote{See Williamson v. Lee Optical Co., 348 U.S. 483, 491 (1955) (“We cannot say that the regulation has no rational relation to that objective and therefore is beyond constitutional bounds.”); Pettinga, supra note 100, 779.}

However, the government’s ability to deny access to certain medical procedures on the basis of comparative effectiveness research is not entirely unrestricted. Medical treatment options which have been deemed fundamental rights by the courts cannot be easily denied by the federal government, even if comparative effectiveness research findings suggest that they should be denied.\footnote{See Roe v. Wade, 410 U.S. 113, 152–56 (1973) (establishing a fundamental right to abortion).} An examination of the case law pertaining to a woman’s right to an abortion elucidates this idea.

A woman’s right to abortion has its roots in the 1965 Supreme Court decision in Griswold v. Connecticut, in which the Court first explicitly recognized a constitutionally protected right to privacy.\footnote{See Griswold v. Connecticut, 381 U.S. 479, 499 (1965) (establishing that “the right of privacy in the marital relation is fundamental and basic” and “protected by the Fourteenth Amendment from infringement by the States”).} The Court concluded that a zone of privacy encompasses the rights specified in the Bill of Rights in order to give them full effect.\footnote{See id. at 485 (“The present case . . . concerns a relationship lying within the zone of privacy created by several fundamental constitutional guarantees.”).} The Supreme Court further pursued this linkage of privacy rights to family-related decision making in Roe v. Wade, where the Supreme Court held that a woman has a fundamental right to abort her pregnancy for any reason, up until the “point at which the fetus becomes ‘viable.’”\footnote{Roe, 410 U.S. at 160.} The Court held that an abortion must be available when needed to protect a woman’s health, and rested its conclusions on the substantive due process provision embedded in the Fourteenth Amendment.\footnote{See id. at 152–56 (establishing a fundamental right to abortion).} Roe’s holding supported the notion that the government may be more limited in its ability to deny access to medical treatment options deemed fundamental by the courts.\footnote{See Shannon L. Pedersen, Comment, When Congress Practices Medicine: How Congressional Legislation of Medical Judgment May Infringe a Fundamental Right, 24 Touro L. Rev. 791, 808–09 (2008) (discussing the medical treatments that have been recognized by the courts as fundamental rights, including “contraceptives, abortion, and the right to refuse medical treatment”).} While elements of Roe, including the trimester framework, were overturned by Planned Parenthood of Southeastern Pennsylvania v. Casey, Roe’s essential holding—that a woman has a right to an abortion during the pre-
viability portion of her pregnancy—was upheld in *Casey*. Thus, *Casey* left intact the notion that there are limitations on the government’s ability to deny access to medical treatment options deemed fundamental by the courts.

Government use of comparative effectiveness research to deny access to medical procedures such as abortion would likely be viewed by the courts as infringing on fundamental rights protected by the Constitution’s substantive due process protections. Such government action is also likely to be subject to strict scrutiny and struck down by the courts. Thus, *Casey* suggests that access to medical procedures which constitute fundamental rights could not be denied by the government on the basis of comparative effectiveness research findings.

However, the courts may allow the government to prohibit certain means of achieving these fundamental rights, as demonstrated by *Gonzales v. Carhart*. While the *Carhart* Court acknowledged that “a woman has the right to choose to have an abortion before fetal viability and to obtain it without undue interference from the State,” the Court viewed the Partial Birth Abortion Ban Act at issue in the case as “[r]egulations which do no more than create structural mechanisms by which the State . . . may express profound respect for the life of the unborn are permitted, if they are not a substantial obstacle to the woman’s exercise of the right to choose.” Since the Act did not prohibit the standard dilation and extraction form of abortion, once the Act was implemented, women would still have some means by which to obtain a partial-birth abortion; only the intact dilation and extraction form of partial-birth abortions was prohibited. Since women still had access to some procedure that would help protect their fundamental right to an abortion, the Court, despite applying a


114 See Gonzales v. Carhart, 550 U.S. 124, 158–66 (2007) (upholding a statute that permitted one form of partial-birth abortion procedures, intact dilation and extraction, but not another form of partial-birth abortion procedures, known as standard dilation and extraction).


116 See *Carhart*, 550 U.S. at 154 (“[I]nterpreting the Act so that it does not prohibit standard [dilation and extraction] is the most reasonable reading and understanding of its terms.”).
heightened form of scrutiny, did not view the Act as an “undue burden from any overbreadth” on women seeking an abortion.\footnote{Id. at 147; see also David L. Faigman et al., Amicus Brief of Constitutional Law Professors David L. Faigman and Ashutosh A. Bhagwat, et al. in the Case of Gonzales v. Carhart, 34 HASTINGS CONST. L.Q. 69, 99 (2006) (stating “[t]he undue burden test constitutes a form of heightened judicial scrutiny” and “[t]he right to choose an abortion is a core constitutional right, which triggers heightened scrutiny” (capitalization in original omitted)).}

Generally, individual rights deemed fundamental under the Constitution receive extra protection in the courts in the form of strict scrutiny review.\footnote{See Adam Winkler, Fundamentally Wrong About Fundamental Rights, 25 CONST. COMMENT. 227, 227 (2006) (discussing how an infringement on fundamental rights triggers strict scrutiny analysis, which requires the government to show a compelling purpose for its actions as well as that no other, less restrictive alternative is available).} Since abortions have been designated a fundamental right by the courts,\footnote{See Roe v. Wade, 410 U.S. 113, 152–56 (1973) (establishing a fundamental right to abortion).} the courts must apply a form of heightened scrutiny when the government attempts to interfere with this right.\footnote{See Winkler, supra note 118, at 227 (indicating that strict scrutiny analysis applies in the context of fundamental rights).}

Yet the Court’s ultimate determination in \textit{Carhart} serves as a reminder that, while fundamental rights are subject to heightened scrutiny,\footnote{See Faigman et al., supra note 117, at 83 (“[T]he undue burden test remains a form of strict scrutiny.”).} there may nevertheless be limits on the protections these fundamental rights receive.

The holding of \textit{Carhart} can be extended to the comparative effectiveness research context. \textit{Carhart} serves as a reminder that, in at least some circumstances, it is constitutionally permissible for the government to ban a medical procedure associated with a fundamental right. This conclusion, in turn, suggests that the government could ban, on the basis of CER findings, a certain medical procedure that enables an individual to exercise a fundamental right. The courts may uphold the government’s decision as long as a compelling interest, narrowly tailored to meet government objectives, can be shown.\footnote{See Gonzales v. Carhart, 550 U.S. 124, 158–166 (2007) (upholding intact dilation and extraction partial-birth abortion procedures but not standard dilation and extraction, an alternative form of partial birth abortion procedure); see also id. at 157–61 (discussing how a ban on standard dilation and extraction procedures achieves legitimate governmental interests, including protecting both “the integrity and ethics of the medical profession” and unborn life (quoting Washington v. Glucksberg, 521 U.S. 702, 731 (1997)) (internal quotation marks omitted)).} Notably, it is difficult to imagine another medical procedure which the courts would deem to be a fundamental right. Abortion procedures may be \textit{sui generis} among medical procedures in terms of the protection that they receive from the courts, meaning a ban on other

\footnote{Id. at 147; see also David L. Faigman et al., Amicus Brief of Constitutional Law Professors David L. Faigman and Ashutosh A. Bhagwat, et al. in the Case of Gonzales v. Carhart, 34 HASTINGS CONST. L.Q. 69, 99 (2006) (stating “[t]he undue burden test constitutes a form of heightened judicial scrutiny” and “[t]he right to choose an abortion is a core constitutional right, which triggers heightened scrutiny” (capitalization in original omitted)).}

\footnote{See Adam Winkler, Fundamentally Wrong About Fundamental Rights, 25 CONST. COMMENT. 227, 227 (2006) (discussing how an infringement on fundamental rights triggers strict scrutiny analysis, which requires the government to show a compelling purpose for its actions as well as that no other, less restrictive alternative is available).}

\footnote{See Roe v. Wade, 410 U.S. 113, 152–56 (1973) (establishing a fundamental right to abortion).}

\footnote{See Winkler, supra note 118, at 227 (indicating that strict scrutiny analysis applies in the context of fundamental rights).}

\footnote{See Faigman et al., supra note 117, at 83 (“[T]he undue burden test remains a form of strict scrutiny.”).}

\footnote{See Gonzales v. Carhart, 550 U.S. 124, 158–166 (2007) (upholding intact dilation and extraction partial-birth abortion procedures but not standard dilation and extraction, an alternative form of partial birth abortion procedure); see also id. at 157–61 (discussing how a ban on standard dilation and extraction procedures achieves legitimate governmental interests, including protecting both “the integrity and ethics of the medical profession” and unborn life (quoting Washington v. Glucksberg, 521 U.S. 702, 731 (1997)) (internal quotation marks omitted)).}
medical procedures would perhaps never be subject to the type of heightened scrutiny employed to review bans on abortion procedures. Thus, it seems that there are few, if any, constitutional barriers to government efforts to deny access to a medical procedure on the basis of CER research findings.

IV. THE CONSTITUTIONALITY OF GOVERNMENT BANS ON MEDICAL TREATMENT OPTIONS ON THE BASIS OF RACE, GENDER, OR AGE

This Comment has addressed the constitutional implications of attempts by the U.S. government to use CER results to impose an absolute ban on access to a certain medical treatment option. The next section of this Comment explores the constitutional effects of banning certain classifications of individuals, such as women, African-Americans, the elderly, or those with disabilities, from accessing a medical treatment option on the basis of CER findings. For instance, CER results might show that FDA-approved Drug A has substantially better patient outcomes and fewer side effects than FDA-approved Drug B, a competitor, for African-Americans. However, the two drugs might provide similar patient outcomes and side effects among Caucasians. On the basis of these CER findings, the government could choose to promulgate a rule banning all African-Americans from using Drug B while continuing to permit Caucasians to use both Drug A and Drug B. State action would clearly be implicated in this case, since the government would be making a decision to ban a class of individuals from accessing a certain health care treatment option. Thus, the next step in this analysis involves considering the merits of a constitutional challenge to such a ban.

A. Banning Treatment Options on the Basis of Race

The Federal Coordinating Council (FCC) for Comparative Effectiveness, in a 2009 report to the President and Congress outlining comparative effectiveness research priorities, indicated that more studies addressing the needs of individuals often underrepresented in

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123 See Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach, 495 F.3d 695, 707–10 (D.C. Cir. 2007) (applying the Glucksberg test for establishing a fundamental right); see also Carhart, 550 U.S. at 156–68 (upholding regulations prohibiting a certain procedure for a partial-birth abortion).

124 See generally Cole, supra note 74 (contrasting federal and state constitutional state action doctrine); Gardbaum, supra note 75 (discussing applicability of individual constitutional rights only to state action).
clinical studies should be an important CER priority for the U.S. government. The FCC indicated that more CER at the sub-group level could facilitate greater personalization of medicine.\(^\text{125}\) While the goal of such specialized research may be to improve treatment options for these sub-group populations, it is possible that this research could have unintended consequences. For instance, if studies suggest that an FDA-approved drug is very safe and highly effective for Caucasians but that it is substantially less safe and effective for African-Americans, the Secretary of the Department of Health and Human Services could technically use this information to issue a rule which bans African-Americans from accessing the drug. This section considers the likely success of a constitutional challenge to such a ban.

The notion of treatment options geared toward certain races first came to light in 2005, when the Food and Drug Administration approved a heart failure therapy drug called BiDil, which was only intended for use by African-Americans. Controversy surrounded the announcement; while some geneticists feared that the FDA was “using race as a crude shortcut for genetic typing,” certain prominent black politicians and scientists “embraced BiDil . . . as a way to redress years of inequality in medical treatment and outcomes.”\(^\text{126}\) However, evidence suggests that the drug might also work in individuals who are not black, and off-label prescribing to non-blacks allows the drug’s manufacturer to reach these other markets.\(^\text{127}\)

In the BiDil situation, the government created an overt racial classification with arguably benign effects on majority racial classifications, since the FDA technically only approved the drugs for blacks but other racial groups can still obtain access through off-label prescribing. This scenario seems to find a parallel in affirmative action cases. The appropriate level of scrutiny in such circumstances re-

\(^{125}\) See Fed. Coordinating Council for Comparative Effectiveness Research, supra note 18, at 6 (“The priority populations specifically include, but are not limited to, racial and ethnic minorities, persons with disabilities, children, the elderly, and patients with multiple chronic conditions. These groups have been traditionally under-represented in medical research.”).

\(^{126}\) Stephanie Saul, F.D.A. Approves a Heart Drug for African-Americans, N.Y. Times, June 24, 2005, at C2, available at http://www.nytimes.com/2005/06/24/health/24drugs.html?_r=1&ref=bidil_drug (describing reactions to FDA’s approval of BiDil for blacks); see also Pamela Sankar & Jonathan Kahn, BiDil: Race Medicine or Race Marketing?, Health Aff., W5-455 (2005), http://content.healthaffairs.org/cgi/reprint/hlthaff.w5.455v1 (discussing whether the FDA’s approval of BiDil for just one race should be viewed as an advancement or a setback for blacks).

\(^{127}\) See Sankar & Kahn, supra note 126, at W5-461 (discussing the ways in which BiDil’s manufacturer could reap the benefits of market exclusivity for several years after the drug was first approved for blacks by the FDA).
mains subject to litigation. While some Supreme Court cases suggest strict scrutiny is warranted in parallel affirmative-action circumstances, others suggest more of a “strict scrutiny minus” or “strict in theory but not fatal in fact” standard. The BiDil situation can be distinguished from typical affirmative action cases because whites and other races presumably can still access the drug through off-label prescribing. Thus, they probably would not satisfy the requirements for standing to sue, which include “injury in fact.”

But consider what would happen if the BiDil scenario was adjusted in two ways. Imagine, first, that African-Americans are the only classification of individuals that cannot access the drug. Then imagine that African-Americans are actually prohibited from accessing the drug (the drug cannot be obtained via off-label prescribing). It is theoretically possible that, on the basis of CER findings which suggest that a medical treatment is safe and effective except when used by African-Americans, the government could attempt to ban only African-Americans from accessing the drug. The government’s decision would most likely be reviewed under a strict scrutiny standard. This standard requires that a regulation serve compelling governmental interests and be essential to those interests. Under this standard the burden would shift to the government to prove that it has a compelling interest and that the means of achieving this interest is narrowly tailored so as not to have a disadvantageous effect on a minority group.

The Supreme Court, writing in Korematsu, indicated that “[p]ressing public necessity may sometimes justify the existence of such restrictions.” However, if the government is enacting such regulations as a means to cut down on health care costs, it seems extraordinarily unlikely that the courts would find this rationale sufficient to constitute “[p]ressing public necessity,” since, in practice, disadvantaging racial classifications have nearly always been struck

128 See Regents of the Univ. of Cal. v. Bakke, 438 U.S. 265, 287–88 (1978) (addressing, for the first time, the appropriate level of scrutiny for benign racial classifications); see also Adarand Constructors, Inc. v. Pena, 515 U.S. 200, 224 (1995) (finding that all racial classifications, whether imposed by federal, state or local governments, are subject to strict scrutiny).
130 See Lujan v. Defenders of Wildlife, 504 U.S. 555, 560–61 (1992) (discussing the three requirements of standing to sue, which include injury in fact, causation, and redressability).
131 See Korematsu v. United States, 323 U.S. 214, 216 (1944) (“[A]ll legal restrictions which curtail the civil rights of a single racial group are immediately suspect.”).
132 Id.
Thus, it seems that strong legal safeguards are available to prevent the federal government from banning only certain minorities from accessing a given medical treatment option.

B. Banning Treatment Options on the Basis of Gender

In its report to the President and Congress, the Federal Coordinating Council highlighted the need for greater representation of women in clinical trials in an effort to ensure that medical advancements are responsive to their unique needs.134 If CER studies show that a given medical treatment is much safer and more effective for men than for women, the U.S. federal government could potentially seek to prohibit only women from accessing these treatments. Such state action would likely be evaluated under the intermediate scrutiny test, whereby statutory “classifications by gender must serve important government objectives and be substantially related to achievement of those objectives” in order to remain constitutionally permissible.135 “The burden of justification is demanding and it rests entirely on the State.”136 The state must show an “exceedingly persuasive justification for [the] action.”137 The state cannot use “inherent differences” as grounds for a sex-based classification.138

Judicial precedent suggests that the court will probably strike down a law based on differences that are mere social constructs.139 However, the courts may be willing to uphold a law that benefits women when CER suggests that the differences are real.140 Yet it is difficult

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133 See Thomas W. Joo, Presumed Disloyal: Executive Power, Judicial Deference, and the Construction of Race Before and After September 11, 34 COLUM. HUM. RTS. L. REV. 1, 23 (2002) (“In every subsequent application of Korematsu’s “rigid scrutiny” . . . the Court has struck down harmful government racial classifications. As a result, most commentators came to believe that government racial discrimination would never survive strict scrutiny again.”). But see Korematsu, 323 U.S. at 219 (“We uphold the exclusion order as of the time it was made and when the petitioner violated it.”).
134 FED. COORDINATING COUNCIL FOR COMPARATIVE EFFECTIVENESS RESEARCH, supra note 18, at 17 (recognizing that the underrepresentation of women in clinical studies “presents a major challenge in applying the results” of those studies to women).
137 Id. at 531.
138 Id. at 533.
139 See, e.g., Orr v. Orr, 440 U.S. 268, 283 (1979) (striking down a state gender-based statutory scheme requiring husbands to pay alimony after a divorce but not wives); Weinberger v. Weisenfeld, 420 U.S. 636, 653 (1975) (striking down a gender-based statutory scheme in which Social Security benefits are paid to a widow and her children if a husband dies, but which gives such benefits only to the children when the deceased parent is the mother).
to imagine how limiting access to medical treatment options would benefit women. It remains to be seen whether courts would find constitutional a ban on women’s access to a medical treatment option which is not beneficial to women. The government would probably seek to justify its actions by indicating that the treatment option is not sufficiently safe or effective for women. Yet it is unclear if this justification would be “exceedingly persuasive” to the court. Thus, it seems that some legal safeguards exist to protect women from being categorically denied access to certain medical treatment options on the basis of CER findings, but this safeguard should perhaps be strengthened.

C. Banning Treatment Options on the Basis of Age

Opponents of comparative effectiveness research have often expressed concern that the results of such research would be used to disadvantage the elderly. These fears may be warranted, since courts have generally applied a mere rational basis test when reviewing laws that are disadvantageous for the elderly. Historically, laws subject to rational basis review have been upheld, though they may be struck down in rare circumstances if they express animus or prejudice toward a particular group. If the government decides to use comparative effectiveness research findings to deny the elderly access to certain treatment options, impacted individuals have little option for recourse on the basis of judicial precedent alone.

Some might argue that protections for the elderly are provided by explicit language in the Patient Protection and Affordable Care Act stating that “[t]he Secretary shall not use evidence or findings from comparative clinical effectiveness research . . . in a manner that treats extending the life of an elderly . . . individual as of lower value than


142 See Mass. Bd. of Ret. v. Murgia, 427 U.S. 307, 314–15 (1976) (applying rational basis review and upholding a mandatory retirement law for state police officers because people over fifty years of age have neither experienced a history of purposeful unequal treatment nor been subjected to unique disabilities on the basis of stereotyped characteristics not truly indicative of their abilities).

143 See e.g., Williamson v. Lee Optical Co., 348 U.S. 483, 491 (1955) (applying rational basis review to uphold a state regulation).

144 See City of Cleburne v. Cleburne Living Ctr., Inc., 473 U.S. 432, 440 (1985) (noting that a law subject to rational basis review may be found invalid if the law is driven by prejudice or animosity).
extending the life of an individual who is younger." \(^{145}\) However, these protections only relate to “determining coverage, reimbursement, or incentive programs.” \(^{146}\)

These provisions seem to have a few loopholes. They do not provide guidelines for how the quality of life of an elderly individual should be valued when weighed against extending the life of or the quality of life of an individual who is younger, nor do they provide guidelines regarding government decisions about access to certain treatment options. The Act seems to allow the government to choose not to provide financial coverage for a certain treatment option to anyone while simultaneously making it legal for non-elderly individuals to access the treatment option and illegal for elderly individuals to access the treatment option. Such a ruling would likely be scrutinized by the courts using a standard of rational basis review, which means the ruling is likely to be upheld. \(^{147}\) Of course, if the courts view the regulation as being created with animus or prejudice toward the elderly, they will sometimes strike it down, using more of a “rational basis with bite” standard. \(^{148}\) The elderly could potentially be banned from accessing a certain treatment option on the basis of CER results. The courts would likely invoke this “rational basis with bite” standard of review to strike down the statute, as such a scenario would seem to involve prejudice toward the elderly. \(^{149}\)

However, if the government bans the elderly from accessing a certain FDA-approved drug because CER shows that this drug is significantly less effective among the elderly, the government could argue that its decision does not involve animus or prejudice toward the elderly. Rather, the government would claim that its decision is grounded in real differences between the elderly and younger individuals. Such real differences would likely pass the weak rational basis standard that would be applied by the courts, and the ban would likely be upheld. Since regulations which disadvantage individuals on

\(^{145}\) See Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6301(a), 124 Stat. 119, 740 (2010) (to be codified at 42 U.S.C. 1301e-1). For the purposes of the Act, the life of a disabled person also cannot be treated as having lower value than the life of an individual who is not disabled. The way in which this provision interacts with the Americans with Disabilities Act of 1990 (ADA), 42 U.S.C. §§ 12101-12213 (2006 & Supp. II 2008), would be an interesting topic for further research and discussion, but it is beyond the scope of this Comment.

\(^{146}\) Id.

\(^{147}\) See supra note 143.

\(^{148}\) Pettina, supra note 100, at 780.

\(^{149}\) Id. at 779–80 (internal quotation marks omitted) (discussing the emergence of the “rational basis with bite” standard of review).
the basis of age historically do not receive any form of heightened judicial scrutiny, it seems that the government could, guided by CER findings, successfully prevent access to certain treatment options on the basis of age.

V. GOVERNMENT ALTERING OF PROCEDURAL REQUIREMENTS TO IMPede ACCESS TO CERTAIN MEDICAL TREATMENT OPTIONS

The federal government may indeed be able, constitutionally, to deny access to drugs and the vast majority of medical procedures, but such outright denial of access is likely to be viewed by the public unfavorably and as a rather drastic measure. It seems more likely that the federal government will attempt to use CER results simply to discourage use of certain medical treatment options that it deems less safe or effective than competitors. One way in which the government can seek to discourage use of a given medical treatment option is by imposing procedural barriers that impede access to that option.

The federal and state governments have, in fact, sought to use a variety of procedural barriers to impede access to abortion procedures, and an examination of this line of cases illuminates the implications of the government seeking to extend such procedural barriers to comparative effectiveness research. These cases demonstrate that the federal government is limited in its ability to use procedural barriers to impede access to medical treatments associated with fundamental rights, but medical treatments that are not


associated with fundamental rights are unlikely to be subject to such limitations.

If the government seeks to use procedural barriers to impede access to a medical treatment option associated with a fundamental right, a claim alleging a violation of substantive due process rights is likely to be raised. The first element of a substantive due process claim, the state action requirement, would clearly be met.\(^\text{154}\) In order to assess the constitutional merits of such a claim, it may be helpful to consider the case of *Carey v. Population Services International*.

In *Carey*, the Supreme Court held that "where a decision as fundamental as that whether to bear or beget a child is involved, regulations imposing a burden on it may be justified only by compelling state interests, and must be narrowly drawn to express only those interests."\(^\text{155}\) The Court then struck down a state statute prohibiting distribution of non-medical contraceptives to individuals sixteen years of age or older, except through licensed pharmacists, on the grounds that the law was not justified by a sufficiently compelling governmental interest.\(^\text{156}\)

While *Carey* involved access to contraceptives, a number of cases relating to abortion also demonstrate that when a state attempts to prevent access to a fundamental right through additional, unduly burdensome procedural requirements, the courts generally have not found the state interest to be narrowly tailored and have struck down these state-imposed requirements as unconstitutional.\(^\text{157}\) In *Doe v. Bolton*, portions of an abortion law in Georgia that sought to regulate medical procedures were deemed an unconstitutional infringement on substantive due process rights to an abortion.\(^\text{158}\) The Supreme Court invalidated provisions requiring that abortions be performed in a Joint Commission-accredited\(^\text{159}\) hospital, that the abortion be approved by a hospital staff abortion committee, and that the performing physician’s judgment be confirmed by two independent examina-


\(^{156}\) *Id.* at 697–99.


\(^{158}\) *Id.* at 201.

\(^{159}\) Until 2007, the Joint Commission was known as the Joint Commission on Accreditation of Hospital Organizations. *See The Joint Commission’s Brand Identity*, JOINT COMMISSION, http://www.jointcommission.org/AboutUs/brand.htm (last visited Feb. 18, 2011).
tions of the patient by two other licensed physicians. The state claimed that it was imposing these requirements to protect the woman’s health and the potential human life of the unborn child, but the Court determined that the state’s means of achieving its compelling interests were not narrowly tailored.

Another case in which the Court struck down overly burdensome procedural regulations of abortions was Akron v. Akron Center for Reproductive Health (Akron I). In this case, the Supreme Court invalidated a requirement that abortions performed after the first trimester be performed in a hospital rather than in outpatient facilities, which were typically less expensive, as well as a twenty-four-hour waiting period before a woman could undergo her abortion. In Planned Parenthood of Central Missouri v. Danforth, the Court struck down a state requirement that a woman obtain consent from her spouse prior to obtaining an abortion. In Planned Parenthood Ass’n of Kansas City v. Ashcroft, the Court held that a state could involve a parent in a minor’s abortion decision if it also provided an alternative judicial bypass procedure so that the parental involvement would not amount to a potentially arbitrary and absolute veto. This holding built on the Court’s earlier finding that a parental consent requirement was unconstitutional only if it “unduly burdens the right to seek an abortion.”

The outcome of these cases is applicable to concerns about potential government use of comparative effectiveness research findings. If comparative effectiveness research findings indicate that certain medical treatment options are less desirable than others on the basis of quality or safety, the aforementioned cases suggest that, where the treatment option pertains to a right deemed fundamental by the courts, the government may be limited in imposing procedural barriers. Of course, given that the Courts have only found an affirmative right to medical treatment involving contraceptives, abortion, and medical care for prisoners, as well as refusal of medical treatment,

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160 Bolton, 410 U.S. at 201.
161 Id. at 187.
163 Id. at 452.
167 See Pedersen, supra note 112, at 808–09 (discussing the medical treatments that have been recognized by the courts as “constitutionally-protected”).
the vast majority of medical treatment options for which procedural barriers are erected would likely be subject to mere rational basis review. While fundamental rights are subject to strict scrutiny and require the government to show that its action is necessary to achieve a compelling state interest, rational basis review requires the minimum level of scrutiny.\textsuperscript{168} When rational basis review is employed, the burden of proof is on the complainant and that standard requires only that the government action be “rationally related to a legitimate state interest.”\textsuperscript{169} Thus, the government may indeed have substantial flexibility in using procedural barriers to hinder access to medical treatment options unassociated with fundamental rights (which are the majority of medical treatments) if CER findings suggest these treatment options are inferior to other comparable forms of treatment.

A. Government Restrictions on Financial Assistance for Medical Treatments

There is one potential barrier to treatment in which courts have fairly consistently upheld government decisions that impede access, even where a fundamental interest such as abortion is implicated. This unique barrier is restrictions on public subsidies.\textsuperscript{170} The relevant line of cases confirms the notion that the Constitution embodies primarily negative, rather than positive, liberties.\textsuperscript{171} These cases also indicate that the government may constitutionally use a restriction on public subsidies to impede access to seemingly any medical treatment option deemed less desirable on the basis of CER findings, even if such medical treatment options are considered fundamental rights.

Several cases have raised due process challenges to restrictions on public subsidies in the context of medical treatment options deemed fundamental, such as abortion.\textsuperscript{172} In \textit{Harris v. McRae}, for instance, the claimants sought to enjoin enforcement of the Hyde Amendment.\textsuperscript{173}

\textsuperscript{168} See Neelum J. Wadhwani, Note, Rational Reviews, Irrational Results, 84 TEX. L. REV. 801, 805–06 (2006) (discussing the differences between strict scrutiny and rational basis review with respect to due process).

\textsuperscript{169} Id. at 806 (emphasis omitted).

\textsuperscript{170} See Maher v. Roe, 432 U.S. 464, 469–470 (1977) (holding that there was no constitutional requirement that the government fund abortions for indigent women).

\textsuperscript{171} See Gary A. Winters, Unconstitutional Conditions as “Nonsubsidies”: When Is Defe

\textsuperscript{172} See Roe v. Wade, 410 U.S. 113, 154 (1973) (recognizing that the right to privacy encompasses a woman’s right to an abortion).

\textsuperscript{173} Omnibus Appropriations Act, 2009 (Hyde Amendment), Pub. L. No. 111-8, §§ 507-08, 123 Stat. 524, 802-03 (providing that state funds may not be used to fund abortion procedures except if the mother’s life would be endangered were the fetus carried to term or
on the grounds that it violated the Due Process Clause of the Fifth Amendment. The plaintiffs argued that a state participating in Medicaid ought to be obligated on constitutional grounds to fund all medically necessary abortions. The Supreme Court ultimately held that "the Hyde Amendment does not impinge on the due process liberty recognized in [Roe]." The Court noted that the amendment did not place any governmental obstacle in the path of a woman seeking an abortion but simply encouraged alternative activity deemed in the public interest. The Court added that, despite the fact that Roe recognized abortion as a fundamental right embedded in the due process guarantees of the Constitution:

[I]t simply does not follow that a woman’s freedom of choice carries with it a constitutional entitlement to the financial resources to avail herself of the full range of protected choices . . . . [A]lthough government may not place obstacles in the path of a woman’s exercise of her freedom of choice, it need not remove those not of its own creation. Indigency falls in the latter category.

The Supreme Court re-affirmed this holding in subsequent cases. In Webster v. Reproductive Health Services, for instance, the Court upheld provisions of Missouri law barring the use of public employees and facilities for non-therapeutic abortions, even where the patient paid for the abortion herself. The Supreme Court re-iterated its previously indicated stance that “the Due Process Clause[ ] generally confer[s] no affirmative right to governmental aid, even where such aid may be necessary to secure life, liberty, or property interests of which the government itself may not deprive the individual.”

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174 Harris v. McRae, 448 U.S. 297, 301 (1980) (“The constitutional question . . . is whether the Hyde Amendment, by denying public funding for certain medically necessary abortions, contravenes the liberty or equal protection guarantees of the Due Process Clause of the Fifth Amendment . . . .”).
175 Id. at 307–08.
176 Id. at 318.
177 Id. at 315.
178 See id. at 316 (citing Maher v. Roe, 432 U.S. 464 (1977)).
180 Id. at 507 (quoting DeShaney v. Winnebago Cnty. Dep’t of Soc. Servs., 489 U.S. 189, 196 (1989)).
The Supreme Court upheld similar financial restrictions in *Rust v. Sullivan*. In this case, the Department of Health and Human Services’ practice of only granting family planning projects funding under Title X to entities that agreed not to provide information on abortions was challenged. The Court noted that “[t]he financial constraints that restrict an indigent woman’s ability to enjoy the full range of constitutionally protected freedom of choice are the product not of governmental restrictions on access to abortion, but rather of her indigency.”

Despite the Court’s seemingly consistent determinations that the Constitution does not impose an obligation on states to pay the medical expenses of indigents, even with respect to medical treatment options deemed fundamental rights, there is at least one population that has been granted an affirmative right to health care treatment by the state: prisoners.

When a “special custodial or other relationship” between an individual and the state exists, as occurs when the state or municipality exercises custody, control, coercion, dominion, or restraint over an individual, a constitutional duty arises for that state or municipality to grant a general right to the provision of medical care and treatment by the state. *Estelle v. Gamble* held that prisoners have an affirmative right to such care. When the government fails to provide health care to prisoners, it acts in violation of the Eighth Amendment.

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182 See id. at 177–78, 181 (discussing petitioners’ reasons for bringing suit).

183 Id. at 203 (quoting *Harris*, 448 U.S. at 316).

184 See *Estelle v. Gamble*, 429 U.S. 97, 103 (1976) (holding that the government has an obligation to provide medical care for the incarcerated, as “[a]n inmate must rely on prison authorities to treat his medical needs”).

185 See Ralph M. Rivera, *Note, The Mentally Ill Offender: A Brighter Tomorrow Through the Eyes of the Mentally Ill Offender Treatment and Crime Reduction Act of 2004*, 19 J.L. & HEALTH 107, 111–12 (2004-05) (discussing how, when the government has a special or custodial relationship with individuals such as prisoners, the government has a constitutional obligation to provide such individuals with necessary medical services).

186 See *Estelle*, 429 U.S. at 103 (establishing that prisoners have an affirmative right to medical care).

187 See Comment, *Actionability of Negligence Under Section 1983 and the Eighth Amendment*, 127 U. PA. L. REV. 533, 561 (1978) (“It is thus well settled that the government has a constitutional duty to provide for those whom it is punishing by incarceration. When the government fails to fulfill this duty it violates the [E]ighth [A]mendment.” (footnotes omitted)). Unfortunately for prisoners, while they technically have an affirmative right to health care, in reality, this right is difficult to enforce. When a prison patient is treated negligently or experiences malpractice, the prisoner must prove that there was “deliberate indifference to [his or her] serious medical needs,” which is challenging legal stan-
These cases indicate that, at least from the substantive due process perspective, opponents of the use of comparative effectiveness research findings are unlikely to be successful in challenging the government should it choose to use such findings as guidelines for restricting public subsidies for certain forms of treatment. The only limitation on the government if it wishes to restrict access in this manner might be in a scenario where a prisoner requires a subsidy for treatment.

While challenges to restrictions on public funding for a certain medical treatment option will generally prove unsuccessful, an attempt could still be made to challenge such restrictions on Medicare or Medicaid funding on equal protection grounds. The alleged classification would be on the basis of wealth. In cases such as *San Antonio Independent School District v. Rodriguez*, the Supreme Court has determined that classifications on the basis of wealth do not trigger strict scrutiny. Strict scrutiny analysis is also employed in cases that involve a right deemed by the courts to be fundamental, but as has been discussed, the Court has determined that U.S. citizens do not have a fundamental right to health care. Thus, the vast majority of equal protection claims to a certain health care treatment would be viewed under the rational basis test, the lowest level of judicial scrutiny. This minimal level of scrutiny would most likely be applied to an equal protection challenge of a law which restricts public subsidies for a health care treatment deemed less safe or effective than competitors on the basis of CER. Since it is not difficult for the government to overcome this low threshold of judicial scrutiny, the court would likely uphold most government laws or policies that restrict public


189 See *San Antonio Indep. Sch. Dist. v. Rodriguez*, 411 U.S. 1, 28 (1973) (declining to apply a judicial strict scrutiny standard in a case involving a classification on the basis of wealth); *see also* Dandridge v. Williams, 397 U.S. 471, 519–21 (1970) (Marshall, J., dissenting) (noting that courts are generally unwilling to apply a strict scrutiny standard to classifications on the basis of wealth); Back, *supra* note 58, at 255–56 (providing support for the notion that courts are generally unwilling to apply the strict scrutiny standard where a wealth classification is at issue).

190 See Mariner, *supra* note 189, at 360 (discussing how the Supreme Court has been reluctant to categorize health care as a fundamental right).

191 See Back, *supra* note 58, at 256–57 (discussing the minimum rationality test for equal protection analysis).
subsidies for certain health care treatments on the basis of CER findings.

An examination of the case law regarding this issue helps to elucidate how these issues are generally viewed by the courts. In *Maher v. Roe*, for instance, the claimants challenged a Connecticut regulation granting Medicaid benefits for childbirth but not for medically unnecessary abortions, claiming this law violated the Equal Protection Clause of the Fourteenth Amendment.\(^\text{192}\) The Court ultimately upheld the regulation, stating that the law did not violate the Equal Protection Clause.\(^\text{193}\) The Court determined that the regulation did not create an undue burden on a woman’s right to have an abortion and noted that “this Court has never held that financial need alone identifies a suspect class for purposes of equal protection analysis.”\(^\text{194}\) The Court also determined that it was unnecessary for a state to show a compelling interest in favoring normal childbirth over abortion in order for the law to be upheld. The fact that the state had at least a legitimate interest in encouraging normal childbirth satisfied the Court that the law should be upheld.\(^\text{195}\)

As noted previously, the Supreme Court rejected a due process violation claim in *Harris v. McRae*.\(^\text{196}\) In this case, the Court also rejected a claim that the federal funding limitations of the Hyde Amendment constituted a violation of the equal protection component of the Fifth Amendment’s Due Process Clause.\(^\text{197}\) The Court noted that the Hyde Amendment, which disproportionately impacted the poor, was not predicated on a constitutionally suspect classification.\(^\text{198}\) “[P]overty, standing alone, is not a suspect classification.”\(^\text{199}\) Thus, the rational basis test was applied, and the court found that the law was indeed rationally related to a legitimate government interest

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\(^\text{193}\) Id. at 470.

\(^\text{194}\) Id. at 471.

\(^\text{195}\) See id. at 469-70 (explaining why the state may constitutionally subsidize the costs of childbirth while declining to subsidize the costs of abortion); see also LYNN D. WARDLE, THE ABORTION PRIVACY DOCTRINE: A COMPENDIUM AND CRITIQUE OF FEDERAL COURT ABORTION CASES 261 (1981) (discussing the Supreme Court’s decision in *Maher*).

\(^\text{196}\) See *Harris v. McRae*, 448 U.S. 297, 317–18 (1980) (“Although the liberty protected by the Due Process Clause affords protection against unwarranted government interferences with freedom of choice in the context of certain personal decisions, it does not confer an entitlement to such funds as may be necessary to realize all the advantages of that freedom.”).

\(^\text{197}\) See id. at 324 (finding the government regulation to withstand equal protection analysis).

\(^\text{198}\) See id. at 323 (finding that the poor women impacted by the regulation did not constitute a suspect class).

\(^\text{199}\) Id.
since “the Hyde Amendment bears a rational relationship to its legitimate interest in protecting the potential life of the fetus.”

Despite the general failure of equal protection economic rights claims in federal courts when alleging a violation of the federal constitutional right to equal protection, those who oppose such funding restrictions on medical treatments deemed fundamental rights may find success in certain state courts when alleging a violation of a state constitutional right to equal protection. While not all state constitutions have explicit equal protection language as provided in the U.S. Constitution’s Fourteenth Amendment, all of the U.S. state constitutions have been interpreted as requiring equal protection of the laws. In some states cases, “broad guarantees of individual rights have been interpreted to require equal protection of the laws.” In other states, “multiple provisions” have been interpreted as “collectively providing equal protection” of the laws. While some challenges to abortion funding restrictions have been successful when alleging a violation of a state constitution’s equal protection guarantee, it is perhaps worth noting that no state court has found a right to public funding for abortions when the state does not provide public funding for pregnancy-related services.

A number of recent challenges to such regulations have argued that funding restrictions on abortions burden equal protection guarantees of state constitutions. California, Connecticut, Massachusetts, New Jersey, and West Virginia have held that the state government’s refusal to provide funding for abortions while opting to provide funding for other medical procedures burdens the fundamental right to have an abortion as established in Roe. The courts in these states grounded their decision in the “neutrality doctrine,” under which, “once the government acts in a particular area, it must

200 Id. at 324.
201 See id. (dismissing a claim that a federal law violated equal protection rights of the U.S. Constitution); see also Maher v. Roe, 432 U.S. 464, 470 (1977) (dismissing a claim that a state abortion law violated equal protection rights of the U.S. Constitution).
204 Id.
205 Jeffrey, supra note 203, at 283.
206 Id.
207 Id. at 282.
In the context of public funding for abortion, these courts concluded that once the state makes a decision to provide Medicaid funding for pregnancy-related health care, the state cannot then restrict funding for abortions, as the state would not be acting in a neutral manner.

Oregon has determined that state funding restrictions on abortions constitute a violation of equal protection of Oregon’s constitution. The Oregon court considering this issue acknowledged that Roe protects the right to an abortion. The court determined that providing Medicaid funding for abortions only for women who required the abortion for medical reasons was a form of discrimination that required the court to weigh the harm to individuals affected by the state action against the state’s justification. Upon implementing this balancing test, the Oregon court concluded that the state’s justification, which included cost savings and safeguarding potential life, did not outweigh the potentially harmful effects to women’s health. Thus, the court determined that state funding restrictions on abortions violated the Oregon Constitution’s Equal Protection Clause.

However, four states—Michigan, New York, North Carolina, and Pennsylvania—have held that a state government’s abortion funding restrictions do not burden the fundamental right to have an abortion. These courts applied mere rational basis review in determining whether to uphold the state’s abortion funding restrictions. They determined that the state interests in “protecting potential life, promoting childbirth, and promoting infant health” afforded sufficient justification for the states’ restrictions. These courts also concluded that their respective states’ restrictions were indeed “rationally related” to these objectives.

These cases suggest that the federal government cannot generally be prevented on substantive due process grounds or equal protection grounds from restricting public subsidies for medical treatment options based on CER findings. However, opponents of such funding

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208 Id. at 283.
209 Id.
210 See id. at 282 (discussing the unique stance adopted by the Oregon courts).
211 Id.
212 Id. 285–86.
213 Id.
214 Id. at 286.
215 Id.
216 Id. at 286–87.
217 Id.
restrictions may have success in challenging state-initiated funding restrictions, at least with respect to medical treatment options deemed fundamental rights, on the grounds that such restrictions violate equal protection provisions of a given state’s constitution.

Additionally, opponents of government funding restrictions based on CER findings can undoubtedly use to their advantage any restrictions that, in some manner, also create classifications on the basis of race or gender. For instance, acquired immune deficiency syndrome (AIDS) disproportionately impacts the black community.\footnote{See Fighting HIV Among African Americans: A Heightened National Response, CENTERS FOR DISEASE CONTROL & PREVENTION, (2007). http://www.cdc.gov/hiv/topics/aa/resources/factsheets/pdf/AA_response_media_fact.pdf (stating that while blacks account for approximately 13% of the U.S. population, they account for roughly half of the people who suffer from HIV/AIDS).} If the government decides, on the basis of comparative effectiveness research findings, to stop providing reimbursement through Medicaid or Medicare for a particular AIDS treatment, an equal protection claim could be brought on the grounds that the decision makes a classification based not only on wealth but also on race. In light of the indirect racial classification associated with the direct classification based on wealth, an argument could be advanced that the government’s decision to restrict public subsidies for this treatment option should be subject to the strict scrutiny standard.\footnote{See Michael A. Helfand, How the Diversity Rationale Lays the Groundwork for New Discrimination: Examining the Trajectory of Equal Protection Doctrine, 17 WM. & MARY BILL RTS. J. 607, 618–19 (2009) (stating that a party does need not demonstrate “invidious discriminatory intent against a racial class” to “trigger strict scrutiny”); see also Washington v. Davis, 426 U.S. 229, 242 (1976) (noting that “an invidious discriminatory purpose may often be inferred from the totality of the relevant facts, including . . . that the law bears more heavily on one race than another”); Richard H. Fallon, Jr., Strict Judicial Scrutiny, 54 UCLA L. REV. 1267, 1268 (2007) (describing the judicial strict scrutiny standard).} The courts would have to find the government’s reasoning for this classification to be compelling and the means of achieving this goal to be “narrowly tailored” to the government’s legitimate interest, which is a very high burden for the government.\footnote{See Roozbeh B. Baker, Balancing Competing Priorities: Affirmative Action in the United States and Canada, 18 TRANSNAT’L L. & CONTEMP. PROBS. 527, 530–32 (2009) (discussing the rational basis, intermediate scrutiny, and strict scrutiny standards for equal protection claims).} The government would probably have to argue that its interest pertained to safety, effectiveness, or saving money. It is difficult to say with certainty whether the courts would consider these interests to be sufficiently compelling and whether the government could narrowly tailor its means of achieving these interests, but, historically, the government has very rarely been able to meet the burden of proof required in strict scrutiny cases.
Thus, courts are less likely to uphold a government regulation prohibiting public subsidies for medical treatments that disproportionately impact a certain racial group or suspect class.

Presumably, a heightened scrutiny standard of intermediate scrutiny, which applies to regulations that discriminate on the basis of gender, would also apply to government restrictions on public subsidies that disproportionately affect one gender. However, in practice, courts have declined to apply a heightened intermediate scrutiny standard in equal protection claims in at least one area of medical treatment: abortion. It remains unclear whether there is a unique aspect of the abortion context that warrants this diversion from general equal protection analysis or whether such holdings signal the courts' reluctance, more broadly, to view government determinations about public subsidies for medical treatment options under heightened forms of scrutiny.

VI. PROCEDURAL DUE PROCESS CONCERNS

A new government rule that deprives an individual of certain health benefits without appropriate procedures, as required by the procedural due process guarantees of the Constitution, may also be found unconstitutional. In *Perry v. Sindermann*, the Court found that individuals deprived of liberty or property are entitled to certain due process procedural protections. If a U.S. citizen has regularly had a certain treatment subsidized by Medicare or Medicaid and the Secretary of the Department of Health and Human Services promulgates a rule prohibiting future access to that treatment, the affected individual could attempt to claim a deprivation of property.

If a court agrees that such a rule deprives the individual of liberty or property interests, the entitlement threshold for procedural due process is met, and the court must establish what process is due or, rather, what procedural protections must be afforded to protect the

221 See id. at 530 (“Courts review legislation that classifies people on the basis of gender...for the purposes of treating them differently under the intermediate scrutiny test.”).

222 See Mary Catherine Wilcox, *Why the Equal Protection Clause Cannot “Fix” Abortion Law*, 7 Ave Maria L. Rev. 307, 313–14 (2008) (“The Court has refused to apply intermediate scrutiny in cases of restrictions on public funding of abortion and abortion clinic regulations, repeatedly holding that such restrictions and regulations do not violate the Equal Protection Clause.”); see also Tucson Woman’s Clinic v. Eden, 379 F.3d 531, 547–48 (9th Cir. 2004) (holding a statutory and regulatory scheme covering abortion to be gender-neutral on its face and thus not subject to intermediate scrutiny).

individual’s interests.\textsuperscript{224} The \textit{Mathews v. Eldridge} “balancing test” will then be applied. This test considers three distinct factors: (1) “the private interest . . . affected by the official action”; (2) “the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional . . . procedural safeguards”; and (3) “the Government’s interest, including the function involved and the fiscal and administrative burdens that the additional . . . procedural requirement would entail.”\textsuperscript{225}

\textit{Goldberg v. Kelly} established that the Procedural Due Process Clause requires an evidentiary hearing before the termination of certain benefits, such as welfare benefits.\textsuperscript{226} However, the Court in \textit{Mathews} found that an evidentiary hearing prior to termination of social security disability benefit payments was not required by the Constitution’s Due Process Clause.\textsuperscript{227} The Court in \textit{Mathews} distinguished \textit{Goldberg} by noting that the entitlement decision in \textit{Mathews} was derived from the physician, who could provide unbiased medical reports and communicate effectively, rather than through the individual, as was the case in \textit{Goldberg}. If the government issues new rules, based on CER findings, which leave the determination of whether someone is eligible for a given treatment in the hands of a physician, \textit{Mathews} suggests that a physician’s decision that the patient no longer requires the treatment may be upheld by the courts; no further procedural protections need be afforded to protect the individual’s interests.

However, decisions by the government to exclude certain categories of individuals, on the basis of CER findings, from access to health care treatment options would perhaps be more similar to the scenario in \textit{Heckler v. Campbell}, in which medical-vocational guidelines were promulgated to help systematically determine an individual’s capacity for work in the national economy once the applicant’s age, work experience, education, and physical condition were established. The Supreme Court upheld the issuance and use of the medical-vocational guidelines in \textit{Heckler}, since the determination of whether jobs existed for a particular claimant was not unique to each claimant.\textsuperscript{228}

\textsuperscript{225} Id. at 335.
\textsuperscript{227} Mathews, 424 U.S. at 339–40.
\textsuperscript{228} Heckler v. Campbell, 461 U.S. 458, 468 (1983) (“To require the Secretary to relitigate the existence of jobs in the national economy at each hearing would hinder needlessly an already overburdened agency. We conclude that the Secretary [of the Department of Health and Human Services]’s use of medical-vocational guidelines does not conflict with
Similarly, the government might be able to argue that CER findings clearly show that a certain treatment never works for some category of individuals, such as all individuals over age sixty-five. The government could then issue guidelines specifying that individuals over age sixty-five cannot have access to the treatment, and the court might be willing to uphold the guidelines. The court would presumably uphold the guidelines on the theory that a unique hearing need not be held for each individual over age sixty-five who wishes to relitigate this issue where the scientific evidence is clear-cut.

However, regulations that incorporate general guidelines are not always upheld. The Supreme Court in Sullivan v. Zerbly, for instance, overturned the Social Security Administration’s reliance on children’s disability regulations to deny, without an adjudicatory hearing, benefits to a child claimant under a Supplemental Security Income program. The Court found that the guidelines did not sufficiently account for all the conditions that could prevent a child from undertaking normal activities. This case suggests that courts may overturn government guidelines that do not sufficiently account for all of the variables that should factor into whether an individual may have access to a given treatment.

VII. GOVERNMENT INFLUENCE AND PRIVATE ACTORS

The aforementioned scenarios pertain to direct government regulations to deny access or render more difficult to obtain certain medical treatment options on the basis of CER findings. Analysis of the case law suggests that such governmental action will generally be constitutionally permissible. However, the question remains whether there are any constitutional limitations on government efforts to influence private actors to utilize CER findings to help reduce health care costs. The next portion of this Comment will explore this question in the context of government restrictions on health care investments by private entities and health care licensing mandates.

230 Ideas for the general issues to be discussed in this portion of this Comment were drawn substantially from James F. Blumstein’s *Rationing Medical Resources: A Constitutional, Legal, and Policy Analysis*, 59 Tex. L. Rev. 1345, 1386–90 (1981) (discussing restrictions on the use of private funds, including Certificate of Need (CON) laws and licensing requirements).
A. Government Restrictions on Health Care Investments by Private Entities

In an effort to control health care costs and render more equitable distribution of health care resources, many states at one point adopted Certificate of Need (CON) legislation, mandated by Congress in the National Health Planning and Resources Development Act (NHPDRA) of 1974. Under this Act, when a health care facility wished to begin providing a new service that would entail acquiring medical equipment exceeding $400,000, capital expenditures exceeding $600,000 (indexed for inflation), or certain other particularly costly endeavors, the facility had to request a CON statement. Such a statement, issued by a state agency, served as a formal acknowledgment by the state that the additional service or equipment was “needed.”

The NHPDRA was repealed fewer than ten years after it was enacted. As a result, the national CON law requirements no longer exist. However, a number of states continue to manage their own CON law programs, though CON law requirements are certainly less common than they once were. State governments could seek to utilize certificate-of-need requests as a means of limiting certain services within private facilities that are deemed less desirable on the basis CER findings. Affected individuals could bring suits alleging violations of their due process or equal protection rights. However, the relevant case law suggests that such restrictions would most likely pass constitutional muster on both due process and equal protection grounds.

For instance, in Madarang v. Bermudes, a group of dentists brought a suit alleging a violation of their substantive due process rights to protest a CON law prohibiting them from building a dental clinic. Acknowledging the U.S. Supreme Court’s pattern of upholding eco-

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231 See Lowell M. Zeta, Note, Fundamental First Steps Along the Road to Health Care Reform, 41 CREIGHTON L. REV. 727, 748 (2008) (discussing the impact of CON regulations on health care costs); see also Blumstein, supra note 231, at 1386 (discussing provider investment and revenue restrictions).


233 Id. at 491.


235 See Madarang v. Bermudes, 889 F.2d 251, 253–54 (9th Cir. 1989) (upholding the CON regulation on equal protection, procedural due process, and substantive due process grounds).

236 See id. at 252–53 (applying Fourteenth Amendment due process analysis).
nomic regulations, the court of appeals determined that the CON law did not constitute a violation of substantive due process. The court of appeals also concluded that the law satisfied the applicable rational basis test, as “the Commonwealth [had] a legitimate interest in preventing the establishment of unneeded facilities,” and “the CON regulations [were] rationally related to” that end. The Supreme Court of New Jersey upheld the constitutionality of the state’s CON laws on similar grounds in In re Certificate of Need Granted to the Harborage. These cases suggest that if states attempt to make use of CER research through their CON requirements, lawsuits by affected individuals alleging violations of their substantive due process or equal protection rights are unlikely to succeed.

B. The Government, Private Actors, and Licensing Requirements

Constitutional challenges have previously been brought against government licensing requirements. In Moose Lodge No. 107 v. Irvis, the plaintiff alleged that a state act affirmatively facilitated, encouraged, or authorized private discrimination. The Court held that state alcohol licensing of a private club that refused to serve black guests does not constitute sufficient state action to render such licensing a violation of Fourteenth Amendment prohibitions against discrimination. The Court noted that the distinction between private and public entities would become meaningless if the Fourteenth Amendment was held to apply to a private entity whenever such an entity received any sort of benefit or service from the state or was subject to any state regulation.

237 See id. at 253–54 (establishing that there was no violation of substantive or procedural due process).
239 See In re Certificate of Need Granted to the Harborage, 693 A.2d 133, 146 (N.J. Super. Ct. App. Div. 1997) (“[T]he administrative regulation challenged on this appeal is rationally related to the legislative goal, and we will not declare it unconstitutional.”).
241 See id. at 178–79 (holding that the state alcohol license of a private club which discriminates against its members does not constitute a violation of the Fourteenth Amendment).
242 See id. at 173 (“The Court has never held, of course, that discrimination by a[] . . . private entity would be violative of the Equal Protection Clause if the private entity receives any sort of benefit or service at all from the State, or if it is subject to state regulation in any degree whatever. . . . [s]uch a holding would utterly emasculate the distinction between private as distinguished from state conduct. . . .”).
Government licensing can be used in the medical context to discourage a particular activity or use of a particular type of provider deemed less beneficial on the basis of CER results. For instance, if CER results show that deliveries are more successful when performed by a physician rather than a midwife,\textsuperscript{243} the government could promulgate a rule which says that it is unlawful for deliveries to be overseen by anyone other than a physician (except, perhaps, in exceptional circumstances). At some point, CER findings may indicate that the ability to exercise a certain fundamental right, such as the right to an abortion, is best done in a certain facility, such as a hospital. The relevant case law suggests that, so long as the government can show it has a compelling interest and has narrowly tailored its means of achieving that interest, licensing restrictions that prohibit other facilities from providing abortion services could potentially be upheld.\textsuperscript{249}

Lawsuits alleging violations of substantive due process may not be brought against private individuals unless state action is implicated.\textsuperscript{245} Yet, echoing the Moose Lodge holding, hospitals generally may not be deemed state actors merely because they receive Medicare and Medicaid funds and are subject to state regulations, such as licensing requirements.\textsuperscript{246} Similarly, nursing homes cannot be deemed state actors merely because they receive funding from the state and are subject to state regulations.\textsuperscript{247} Health care facilities that received Hill-Burton funds are also not automatically deemed state actors on that basis.\textsuperscript{248}
Kottmyer v. Maas serves as an example of this judicial stance. In Kottmyer, an infant was born with severe brain damage in a hospital that was operating pursuant to licensing and authority of state and federal governments.\(^\text{249}\) The infant’s parents alleged that the hospital and a hospital social worker were state actors at the time the harm occurred, and therefore subject to constitutional constraints.\(^\text{250}\) However, the court held that the fact that the hospital was operating pursuant to government licensing requirements did not establish that it was a state actor.\(^\text{251}\) Thus, the parents could not claim any constitutional violation.\(^\text{252}\) Similarly, in American Manufacturers Mutual Insurance Co. v. Sullivan, the Court found that there was no state action in private insurers’ decisions to withhold payment pursuant to a state regulatory scheme because the ultimate insurance decisions could not be attributed to the state.\(^\text{253}\)

If the government uses comparative effectiveness research findings to guide its licensing restrictions, the cases examined in this section suggest that such use of CER results would not be unconstitutional. These cases also suggest that it is constitutionally permissible for the government to infringe on access to health care treatment options, at least to a certain extent, through the use of licensing restrictions. Thus, the government may be successful in using licensing requirements to constrain health care practices and the actions of private parties so as to conform with CER findings, even where government licensing requirements infringe to some extent on fundamental rights.

VIII. CONCLUSION

Comparative effectiveness research has emerged at the frontlines of the health care debate as perhaps the most important component of the new Patient Protection and Affordable Care Act.\(^\text{254}\) It is be-

\(^{249}\) See Kottmyer v. Maas, 436 F.3d 684, 687 (6th Cir. 2006) (describing the circumstances of the daughter’s death).

\(^{250}\) See id. at 688 (indicating the parents’ argument for considering the hospital and its employees to be state actors).

\(^{251}\) See id. (holding that neither the hospital nor its employees should be considered state actors).

\(^{252}\) See id. (indicating that the fact that the hospital and social worker operate pursuant to government licensing requirements was insufficient to establish that their actions constituted state action).


\(^{254}\) See supra notes 7–8.
lieved that new CER results will contribute substantially to the goal of personalizing medicine by elucidating which health care treatment options are safest and most effective for patients with varying genetic makeup. CER also has the potential to help rein in escalating health care costs. In the immediate future, CER can contribute to this goal by affording private entities a wealth of safety and effectiveness information that can be plugged into their own cost-effectiveness analyses and utilized. At some point in the future, the U.S. government may also seek to incorporate a cost-effectiveness component directly into the comparative effectiveness research that it presently sponsors, which could help wring further savings from our health care system.

While proponents of CER tout its ability to save money while ensuring safe and effective care, opponents argue its use will disincentivize innovation, allow government intrusion into patient-provider relationships, and signal the beginning of health care rationing.

This Comment has examined whether government use of comparative effectiveness research findings to influence Americans’ access to various health care treatment options would be found constitutional by the courts. This issue is of critical importance in light of the newly passed health care reform legislation, which includes provisions focused on CER, and the funding cordoned off for CER in the American Recovery and Reinvestment Act. It is also important because there remain strong opponents of CER who are likely to raise constitutional challenges to government efforts to utilize CER findings.

The discussion presented indicates that such opponents will have very few constitutional claims on which to protect health services, practices, facilities, and stakeholders from government decisions to ban or restrict access to health care treatment options on the basis of CER findings. However, some legal protections do exist if the government attempts to deny access to certain treatment options on the basis of race or gender, and some protections for individuals on the basis of age have been incorporated into the Patient Protection and Affordable Care Act. Yet overall, the conclusion that the government will have fairly broad authority to utilize CER findings without fear of constitutional challenge will undoubtedly be viewed by CER proponents as a major victory for health care reform.

This Comment has discussed how the government could attempt to ban or restrict access to health treatment options on the basis of

255 See supra note 5 and accompanying text (describing how comparative effectiveness research is expected to save money in the health care system).

256 See Keckley & Frink, supra note 50, at 73-78 (describing why some stakeholders oppose the use of comparative effectiveness research).
CER findings. While an outright government ban on certain health treatment options may seem unlikely, imposition of Medicare or Medicaid restrictions on reimbursement for certain health treatment options deemed less safe or effective on the basis of comparative effectiveness research is a real possibility in the near future. For some Americans, a restriction on coverage will effectively be a denial of access. And it is of course critical to bear in mind that government decisions about health care coverage will influence what private insurers are willing to cover.\footnote{257 Editorial, Is Newer Better? Not Always, N.Y. TIMES, Sept. 12, 2010, at WK10.}

In a country that values freedom of choice, the question remains whether the American public will be ready for the government to exercise greater control over access to health care treatment options. Given the massive impact that use of these findings could have on access to various medical treatment options, the government may be well-advised to consider whether additional protections surrounding the use of CER findings are warranted. For instance, if certain medical treatment options can be identified as particularly valuable to or desired by many Americans, such as mammograms for women under age fifty,\footnote{258 See Gina Kolata, Panel Urges Mammograms at 50, Not 40, N.Y. TIMES, Nov. 16, 2009, http://www.nytimes.com/2009/11/17/health/17cancer.html (discussing the debate over whether to heed new mammography guidelines as provided by the U.S. Preventive Services Task Force).} state or federal legislatures may wish to consider acting preemptively to afford these treatment options special protections through new legislation. While guidelines would need to be carefully constructed to ensure that such a system is not abused and that it reflects important underlying policy goals, such a system could play an important role in ensuring that the benefits of harnessing CER findings for health care decision making are maximized, while the potential harms are kept at bay.