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Comparative Effectiveness Research in the United States: The Failures And What Can Be Done To Fix It

By: John Barry*

I. Introduction

Each year over 750,000 vertebral fractures occur within the United States.¹ The preferred treatment for such injuries is vertebroplasty, the injection of acrylic bone cement into the affected vertebra.² Every year Medicare pays for 40,000 of these surgeries, each at a cost of \$3,000 or more.³ While a common and established procedure, there is actually no evidence that vertebroplasty or a number of related spinal procedures provide any benefit to patients above what they receive from conservative treatment options such as bed rest or physical therapy.⁴ Studies have shown that this surgery is no more effective than “fake,” or placebo, surgeries performed on those suffering from pain, and in fact, it can create additional risks for patients.⁵ This is but one example of a serious problem within the American medical system: many established medical treatments are performed or prescribed based on tradition, rather than clinical evidence.⁶ This often leads to wasted resources spent on treatments which provide little or no benefit.⁷ Comparative effectiveness research hopes to solve this problem.

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¹ David F. Kallmes et al., *A Randomized Trial of Vertebroplasty for Osteoporotic Spinal Fractures*, 361 NEW ENG. J. MED. 569, 570 (2009); Scott Kinkade & James Stevermer, *Vertebroplasty for Osteoporotic Fracture? Think Twice*, 58 J. FAM. PRAC. 654, 654 (2009).

² Kallmes, *supra* note 1, at 569.

³ Robert Langreth, *Common Spine Surgery Shows No Benefit*, FORBES (Aug. 5, 2009, 05:00 PM), <http://www.forbes.com/2009/08/05/vertebroplasty-healthcare-reform-business-healthcare-backpain.html>.

⁴ *Id.* (quoting David Kallmes, the leader of the study, who says “Vertebroplasty as currently practiced in this country and around the world doesn't seem to work”).

⁵ *Id.* (stating that patients who received the surgery had no increased functioning or decreased pain, while at the same time had been exposed to increased risks inherent in surgical procedures).

⁶ MEDICARE PAYMENT ADVISORY COMM'N, REPORT TO THE CONGRESS: REFORMING THE DELIVERY SYSTEM (2008), available at http://www.medpac.gov/documents/jun08_entirereport.pdf (describing the existence of large gaps in evidence between the way in which health care professionals treat patients and what clinical based evidence actually shows is effective); see also Jerome Groopman, *Why “Quality” Care Is Dangerous*, WALL ST. J. (Apr. 8, 2009),

Health care costs in the United States are increasing at an exponential rate.⁸ Total health expenditures in the United States have reached 2.5 trillion dollars per year.⁹ The United States surpasses every other country in the world in health care spending per capita.¹⁰ However, this vast spending has not led to a vastly healthier population.¹¹ While leading the world in costs, the United States ranks 27th in the world for life expectancy of its citizens.¹² This is emblematic of the fact that—no matter how hard a country may try to buy its way to health—increased spending does not directly correlate to better health outcomes.¹³

What is driving these extreme costs with low patient outcomes? While some might claim that Americans on a whole are to blame for their poor health,¹⁴ recent studies show that “health burdens” that Americans cause themselves account for only a small percentage of total health care costs.¹⁵ The real answer is that health care costs are a multifaceted problem, with

<http://online.wsj.com/article/SB123914878625199185.html> (describing an old adage reportedly told to medical students that “[h]alf of what we teach you is wrong – unfortunately we don’t know which half”).

⁷ See discussion *infra* Part V.

⁸ CTRS. FOR MEDICARE AND MEDICAID SERVS., NAT’L HEALTH EXPENDITURES 2010, *available at* <https://www.cms.gov/NationalHealthExpendData/downloads/highlights.pdf>. Health care spending rose 3.9% in 2010, following a 3.8% increase in 2009. *Id.*

⁹ *Id.* As of the last accounting by the Centers for Medicare and Medicaid Services, this \$2.6 trillion has accounted for nearly 18% of the gross national product of the United States. *Id.*

¹⁰ Uwe E. Reinhardt et al., *U.S. Health Care Spending In An International Context*, 23 HEALTH AFFAIRS 10, 11 (2004). The United States spends nearly double the funds of the next highest spending country, Switzerland. *Id.*

¹¹ *Id.*

¹² *Id.* The average life expectancy in the United States is just over seventy seven years of age. *Id.* at 13. Ranking directly behind the United States in 28th place for life expectancy is Cuba, which spends about 3% of what the United States spends on health care every year. *Id.*

¹³ See Reinhardt, *supra* note 10.

¹⁴ See, e.g., Catharine Paddock, *Obesity Healthcare Costs U.S. 147 Billion Dollars A Year, New Study*, MEDICAL NEWS TODAY, Jul. 28, 2009, <http://www.medicalnewstoday.com/articles/158948.php>; Nanci Hellmic, *Rising Obesity Will Cost U.S. Health Care \$344 Billion a Year*, USA TODAY, Nov. 17, 2011, http://www.usatoday.com/news/health/weightloss/2009-11-17-future-obesity-costs_N.htm; Patrica McBroom, *\$72.7 Billion: Smoking's Annual Health Care Cost*, THE BERKELEYAN, Sept. 16, 1998, <http://berkeley.edu/news/berkeleyan/1998/0916/smoking.html>.

¹⁵ Shubham Singhal et al., *How US Health Care Reform will Effect Employee Benefits*, MCKINSEY Q, June 2011, *available at* <http://www.scribd.com/doc/57371828/McKinsey>. This study states that while overall Americans are more obese than other populations, Americans also consume both less tobacco products and less alcohol than other economically developed countries. *Id.* The disease burden of the unhealthy American lifestyle is pegged at \$25 billion a year, accounting for only 1% of the total cost of health care in the United States. *Id.*

difficulties including availability, delivery, insurance coverage, and more.¹⁶ However, one approach that many developed nations have taken is to look closer at the pharmaceuticals and medical treatments that drive up health care costs in their systems.¹⁷ This Comment will focus on comparative effectiveness research, one way in which the United States has chosen to combat the rising costs seemingly inherent in pharmaceuticals and medical devices.

When the Food and Drug Administration (FDA) in the United States approves a drug or treatment, the administration does it based solely on the two factors of drug safety and drug efficacy.¹⁸ The traditional FDA approval process relies mainly on a comparison of a single treatment to a placebo.¹⁹ In contrast, what has gained great favor in many other countries around the globe is the use of comparative effectiveness research: the idea of evaluating treatments not only to see if they *work*, but to see if they *work better* than currently available treatments.²⁰ Fortunately, this concept is gaining ground in the United States.²¹ It holds the potential to have a great impact on the American health care system because at the foundation of comparative effectiveness research is the concept of providing better, clinically based treatments that in turn lead to lower health care costs.²²

¹⁶ *U.S. Health Care Costs*, KAISER FAMILY FOUND. (2011), available at <http://www.kaiseredu.org/Issue-Modules/US-Health-Care-Costs/Background-Brief.aspx>.

¹⁷ *Prescription Drug Costs*, KAISER FAMILY FOUND. (2011), available at <http://www.kaiseredu.org/Issue-Modules/Prescription-Drug-Costs/Background-Brief.aspx> (“The rise in costs of prescription medicines affects all sectors of the health care industry”).

¹⁸ 21 C.F.R. § 314.94 (2011).

¹⁹ CATHY SCHOEN ET AL., BENDING THE CURVE: OPTIONS FOR ACHIEVING SAVINGS AND IMPROVING VALUE IN U.S. HEALTH SPENDING, THE COMMONWEALTH FUND COMM’N ON A HIGH PERFORMANCE HEALTH SYSTEMS 19–21 (2007), available at <http://www.commonwealthfund.org/Content/Publications/Fund-Reports/2007/Dec/Bending-the-Curve--Options-for-Achieving-Savings-and-Improving-Value-in-U-S—Health-Spending.aspx>

²⁰ See discussion *infra* Part III.

²¹ SCHOEN, *supra* note 19.

²² *Id.* (“Better research leads to better treatments . . . which leads to healthier patients . . . and in turn a lower economic burden on the health care system”).

Behind comparative effectiveness research is the idea that “what is newest is not always best.”²³ By systemically comparing medications and medical devices, the hope is to find the best, evidenced-based care.²⁴ By finding the most effective clinically backed treatments, health care decision makers can treat their patients based on what actually works, without wasting time or funds on ineffective treatments. The potential benefit is thus that by knowing the best available treatment, care givers can provide better health outcomes, while at the same time save money by not wasting resources on ineffective or less effective treatments.²⁵

Part II of this Comment provides a brief background on comparative effectiveness research as it exists within the world of modern medical research. This part also provides a background on the history of comparative effectiveness research as used within the United States. It focuses on what the Patient Protection and Affordable Care Act,²⁶ the most recent overhaul of the American health care system, has authorized this research to be used for, in addition to what it may not be used for. Part III then explores the flaws contained in the implementation of comparative effectiveness research as it is now currently authorized in the United States. This Comment takes the position that as currently implemented, comparative effectiveness research will have little effect on either patient outcomes or cost savings in the American health care system. The current iteration of this program focuses on providing data from comparative effectiveness research to physicians in hopes that they will use the information in practice. This Comment takes the position that this use of information from comparative effectiveness research will not be effective.

²³ GRETCHEN JACOBSON, CONG. RESEARCH SERV., RL 31340, COMPARATIVE CLINICAL EFFECTIVENESS AND COST-EFFECTIVENESS RESEARCH: BACKGROUND, HISTORY, AND OVERVIEW 1 (2007).

²⁴ *Id.*

²⁵ *Id.* (stating the proposition that ineffective care is costly to the American health care system in many ways. Not only are ineffective treatments themselves a waste of funds, the use of ineffective treatments may lead to lower health outcomes by depriving patients of more beneficial treatments. Lower health outcomes in turn are costlier due to that fact that these patients continue to seek treatment within the health care system).

²⁶ Patient Protection and Affordable Care Act (PPACA) § 6301(a), Pub. L. No. 111-148, 124 Stat. 119, 727 (2010).

As a foil for what is being implemented in the United States, Part IV analyzes the health care system of the United Kingdom. The United Kingdom is among the most prominent leaders in implementation of comparative effectiveness research within a health care system. This Part will analyze the cost-saving measures within the context of this foreign health care system and will explain the benefits and downsides to the system.

Part V will explore the potential for integrating within the American system lessons learned from the United Kingdom. It will discuss the difficulties in creating an effective system of better care outcomes and cost savings. Both the social and political climate, which have created fears of severe cost cutting and health care rationing, in addition to the potential for real problems inherent in the use of comparative effectiveness research, create a difficult atmosphere for comparative effectiveness to actually take hold. This Comment proposes that it is possible to advance the current implementation of comparative effectiveness research in the United States, creating positive health care outcomes and real-world cost savings. However, it should start slow and pick the “low hanging fruit” of uncontroversial treatments, specifically avoiding end-of-life care, so as to garner acceptance within the patient population, society as a whole, and law makers.

II. Overview of Comparative Effectiveness Research within the United States

A. Comparative Effectiveness Research as a form of Health Technology Assessment

Comparative effectiveness research is one branch of a larger tree known as health technology assessment (HTA).²⁷ HTA is a field of study that looks to measure the value of medical technologies such as pharmaceuticals and medical devices in terms of both their medical and economic implications.²⁸ It serves to link the world of research-based findings to the world

²⁷ JACOBSON, *supra* note 22, at 3.

²⁸ *Id.* at 4.

of clinical, in-practice decision making.²⁹ There are three main branches of HTA prevalent in the world today: comparative effectiveness research, cost-effectiveness analysis, and cost-benefit analysis.³⁰

Comparative effectiveness research, although defined in many different ways,³¹ essentially compares the effectiveness of two or more health care services or treatments.³² It is important to note that effectiveness, as defined here, is different from efficacy. Effectiveness is the measure of the effect of a treatment in routine clinical practice.³³ In contrast, efficacy, the measurement used by the FDA when approving a treatment, is the effect of the treatment under optimal conditions.³⁴ By comparing competing treatments in real-world conditions, the hope is to find the most effective treatment that leads to the best outcomes for patients.³⁵

Cost-benefit analysis and cost-effectiveness analysis are two ways of building upon comparative effectiveness research by directly incorporating costs into the assessment of health care technologies.³⁶ These two approaches both compare the cost of services to the additional health benefits received.³⁷ They look to determine whether the additional health benefits, if any, serve to justify additional costs.³⁸ Where the two approaches differ is on how the health benefits are measured. In cost-benefit analysis, health benefits are valued in monetary terms, and the results of each assessment are stated in terms of the monetary difference between treatment costs

²⁹ *Id.*

³⁰ U.S. NATIONAL LIBRARY OF MEDICINE, HTA 101 (2011), available at <http://www.nlm.nih.gov/nichsr/hta101/ta10106.html>.

³¹ See, e.g. COST-EFFECTIVENESS IN HEALTH AND MEDICINE (Martha Gold et al. eds., 1996); PETER A. UBEL, PRICING LIFE: WHY IT'S TIME FOR HEALTH CARE RATIONING (1999).

³² JACOBSON, *supra* note 22, at 4.

³³ *Id.*

³⁴ *Id.* at 5.

³⁵ See SCHOEN, *supra* note 18.

³⁶ *Id.* at 6.

³⁷ *Id.*

³⁸ *Id.*

and health benefits.³⁹ In cost-effectiveness analysis, health benefits are measured in non-monetary units, with most systems using the unit of life years adjusted for quality, or quality adjusted life years (QALY).⁴⁰ What is calculated is a ratio of costs and benefits, a showing of the “cost-utility” of the treatment or pharmaceutical.⁴¹ QALY is seen as, and often criticized for, putting a spending cap on people’s lives.⁴²

This Comment will focus on comparative effectiveness research and its potential within the American health care system. Further, while other countries are implementing forms of cost-benefit analysis and cost-effectiveness analysis,⁴³ the social and political climate of America is likely not ready for these direct cost-savings measures.⁴⁴ And while there may come a time when the use of cost-benefit analysis or cost-effectiveness analysis need be further evaluated for use in our system, this Comment proposes that comparative effectiveness research is the way to garner greater acceptance for HTA use in every day clinical decision making.

B. A History of Comparative Effectiveness Research in the United States

Comparative effectiveness research is not completely new to the United States. The earliest government authorization of this form of research began at the state level with Oregon, which has used comparative effectiveness in allocating resources to Medicaid recipients.⁴⁵ Also, prior to this, private insurance companies and pharmaceutical manufacturers have used

³⁹ *Id.* at 7.

⁴⁰ *Id.*; see also *infra* Part IV.

⁴¹ SCHOEN, *supra* note 18, at 12.

⁴² See *infra* Part V. The harsh criticism of a QALY-based system will be explored with an examination of the United Kingdom’s health system in this section.

⁴³ See discussion *infra* Part V.

⁴⁴ See discussion *infra* Part V; see also John K. Iglehart, *The Political Fight Over Comparative Effectiveness Research*, 29 HEALTH AFF. 1757, 1758 (2010) (stating that comparative effectiveness is seen as akin to cost cutting and many Americans feel that it is simply another way for insurers to limit care benefits).

⁴⁵ OR. REV. STAT. § 442.589 (2011); see also Somnath Saha et al., *Giving Teeth to Comparative Effectiveness Research—The Oregon Experience*, 362 NEW ENG. J. MED. E18(1) (2010), available at <http://www.nejm.org/doi/pdf/10.1056/NEJMp0912938>.

comparative effectiveness research to analyze medications and allocate resources to patients.⁴⁶

There has been little oversight of these studies, however, and next to no transparency as to research methodologies.⁴⁷ Thus, these studies are viewed as skewed to the purely economic interests of the sponsors rather than towards providing economically efficient care.⁴⁸

On the federal level, the Agency for Healthcare Research and Quality (AHRQ)⁴⁹ had previously been given limited powers to undertake comparative effectiveness efforts. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003⁵⁰ provided a mere \$15 million per year in funding to AHRQ for research into comparative clinical effectiveness of certain health care items and services.⁵¹ Comparative effectiveness research finally gained real force in 2009 with the creation of the Federal Coordinating Council for Comparative Effectiveness Research.⁵² This was a government body created by the massive American Recovery and Reinvestment Act of 2009,⁵³ a bill which primarily focused on stimulating economic activity and job growth in the United States.⁵⁴ Over \$1 billion was earmarked in the legislation to go towards comparative effectiveness research within the United States.⁵⁵

This Federal Coordinating Council was short lived, however, as the sweeping health care reform of the Patient Protection and Affordable Care Act (PPACA) created the Patient-Centered Outcomes Research Institute (PCORI).⁵⁶ PCORI, unlike the Federal Coordinating Council

⁴⁶ Steven Pearson, *From Better Evidence to Better Care: Using Comparative Effectiveness Research to Guide Practice and Policy*, in BROOKINGS INST. IMPLEMENTING COMPARATIVE EFFECTIVENESS RESEARCH: PRIORITIES, METHODS AND IMPACT 55 (2009).

⁴⁷ *Id.* (explaining that private insurers often operate under a veil of secrecy with regards to their savings methodologies).

⁴⁸ *Id.* at 57.

⁴⁹ 42 U.S.C. § 299 (2006).

⁵⁰ Pub. L. No. 108-173, §1013(e), 117 Stat. 2066, 2438-41(2003) (codified at 42 U.S.C. §299b-7(e) (2006)).

⁵¹ *Id.*

⁵² American Recovery and Reinvestment Act of 2009 § 804, 42 U.S.C. § 299b-8 (2010).

⁵³ American Recovery and Reinvestment Act of 2009, Pub. L. 111-5, tit. VII, 123 Stat. 115.

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ Patient Protection and Affordable Care Act (PPACA) § 6301(a), Pub. L. No. 111-148, 124 Stat. 119, 727 (2010).

before it, is a non-governmental entity.⁵⁷ When PPACA becomes effective in 2014, this private non-profit organization will largely be comprised of private stakeholders: health care providers, pharmaceutical manufacturers, health insurers, and patient representatives.⁵⁸ There will also be a small number of government officials, such as representative from the National Institutes of Health, on the board.⁵⁹

While the Federal Coordinating Council defined the original iteration of comparative effectiveness research in use by the federal government,⁶⁰ the definition as applicable to this Comment comes from PPACA. 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 two or more medical treatments, services, and items.”⁶¹ These “medical treatments, services, and items” include health care interventions, protocols for treatment, care management, and delivery, procedures, medical devices, diagnostic tools, pharmaceuticals, 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.⁶² Though comparative effectiveness research as defined by PPACA may be seen as necessarily broad,⁶³ it also raises concerns with some that it

⁵⁷ *Id.* This form of comparative effectiveness research is actually slightly different than was originally proposed. The original House of Representatives version of the PPACA provided great strength to comparative effectiveness research and what the government was able to do with the data gained. Affordable Health Care for America Act, H.R. 3962, 111th Cong. §1401(a) (2009).

⁵⁸ § 6301(a).

⁵⁹ § 6301(a), § 1181(f), 42 U.S.C. § 1320e(f); see also Press Release, U.S. Gov’t Accountability Office, *GAO Announces Appointments to New Patient-Centered Outcomes Research Institute (PCORI) Board of Governors*, (Sept. 23, 2010), available at <http://www.gao.gov/press/pcori2010sep23.html>.

⁶⁰ 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/cerannualrpt.pdf>.

⁶¹ PPACA § 6302, 42 U.S.C. § 299b-8 (2012).

⁶² *Id.*

⁶³ Alan M. Garber & Harold C. Sox, *Analysis & Commentary: The Role of Costs in Comparative Effectiveness Research*, 29 HEALTH AFF. 1805, 1805 (2010) (stating the proposition that comparative effectiveness research should be defined broadly in order to give PCORI the proper discretion in creating an effective program).

is simply poorly defined and thus does not give proper structure and guidance for an effective clinical comparison system.⁶⁴

III. Comparative Effectiveness Research's Impact in United States

The main problem with the PPACA version of comparative effectiveness research, and the focus of this Comment, is that the legislation emphasizes collection of data from comparative effectiveness research as the end goal, rather than as a means to achieve cost-effective health care options.⁶⁵ While PPACA established the PCORI and allocates \$500 million in funding for research,⁶⁶ it explicitly prohibits PCORI from having any decision-making power in regards to “coverage, reimbursement or other policies for any public or private payer.”⁶⁷ Thus, though well funded, the PCORI cannot develop practice guidelines, let alone make coverage determinations.⁶⁸

Further, the legislation severely hampers what the Secretary of the Department of Health and Human Services may do with the findings of PCORI.⁶⁹ Findings may not be used in any way that may be construed as valuing the life of the young or non-disabled over the old or

⁶⁴ Richard Saver, *Health Care Reforms Wild Card: The Uncertain Effectiveness of Comparative Effectiveness Research*, 159 U. PA. L. REV. 2147, 2161 (2011) (“[I]mprecision creates considerable ambiguity during the critical rollout phase of the new legislation. It also enables law makers to avoid, perhaps indefinitely, directly addressing hard but critically important policy choices, such as whether comparative effectiveness research should look at treatment costs.”).

⁶⁵ Kevin D. Frick, *How Comparative Effectiveness Research Feeds into Cost-Benefit Analysis*, 13 AM. MED. ASS’N J. ETHICS 248, 249 (2011) (stating the proposition that collection of data alone from comparative effectiveness research is not enough to have a meaningful impact on the health care system).

⁶⁶ PPACA § 6301(e), 26 U.S.C. § 9511; *see also* AM. ASS’N OF MED. COLLS., SUMMARY OF PATIENT-CENTERED OUTCOMES RESEARCH PROVISIONS 11 (2010). This report contains a summary the PCORI provisions within the statute. *See id.*

⁶⁷ PPACA § 6301(a), 26 U.S.C. § 9511.

⁶⁸ *Id.*

⁶⁹ CEA Registry Team, *NICE Highlights Potential Cost-savings*, THE CEA REGISTRY BLOG (May 7, 2010, 4:37 PM) <https://research.tufts-nemc.org/cear4/Resources/CEARegistryBlog/tabid/69/EntryId/48/NICE-highlights-potential-cost-savings.aspx> (last visited Feb. 9, 2012) (“[L]anguage in the law places limitations on the types of evidence that can be used to evaluate health care technologies, hampering the potential to create a meaningful ‘bending’ of the healthcare cost-curve.”).

terminally ill.⁷⁰ While this Comment does not advocate devaluing the life of any person, this prohibition may be construed broadly to prohibit much of any cost savings.⁷¹ The statute also prohibits the Secretary from making Medicare coverage decisions based “solely” on data from comparative effectiveness research.⁷² In sum, these restrictions make it extremely hard for Medicare and other government health care entities to use the data obtained from comparative effectiveness studies in their care and coverage decisions.⁷³

Today, services and medications are approved for Medicare reimbursement so long as they are deemed “reasonable and necessary.”⁷⁴ Medicare does have a provision that *allows* for restricting payment to less costly alternative treatments but it goes unused.⁷⁵ At one time, Medicare did attempt to use this policy to limit reimbursement of a medication due to existence of a less-costly alternative, but it was struck down by the judiciary.⁷⁶ As such, Medicare has since stopped applying this policy when processing reimbursement for drugs covered under Medicare’s Part B insurance program.⁷⁷ Further, Medicare has been extremely hesitant to deny

⁷⁰ PPACA § 6301(a), 26 U.S.C. § 9511 (“[F]indings may not be used in such as manner that treats extending life of an elderly, disabled, or terminally ill individual as of lower value than extending the life or an individual who is younger, nondisabled or not terminally ill.”).

⁷¹ Saver, *supra* note 63, at 2153 (discussing how this prohibition will likely be a strong deterrence against attempts to limit many potentially ineffective care options primarily used by the elderly).

⁷² PPACA § 6301(c), § 1182(b)(2), 42 U.S.C. § 1320e-1(b)(2).

⁷³ Saver, *supra* note 63, at 2148 (“[L]awmakers have essentially defanged [comparative effectiveness research], deploying it under conditions that will leave it underpowered.”).

⁷⁴ 42 U.S.C. § 1395y(a)(1)(A)–(B).

⁷⁵ *Id.* (Medicare provides reimbursement for treatments only up to the price of their “reasonably feasible and medically appropriate” least costly alternatives.); *see also* MEDICARE PAYMENT ADVISORY COMM’N, REPORT TO THE CONGRESS: ALIGNING INCENTIVES IN MEDICARE 6–7 (2010).

⁷⁶ *Hays v. Sebelius*, 589 F.3d 1279, 1280, 1283 (D.C. Cir. 2009). This case involved Medicare’s denial of coverage for a treatment for chronic obstructive pulmonary disease. *Id.* The court found that Medicare’s restriction of reimbursement to an inexpensive medication rather than a more expensive alternative was unauthorized by that statute. *Id.*

⁷⁷ *CMS Instructs Contractors to Rescind All LCA Provisions in Current LCDs*, HEALTH POL’Y WKLY (AmerisourceBergen Specialty Grp., Wash., D.C.), Apr. 30, 2010, <https://www.iononline.com/app/Documents/Health%20Policy%20Weekly/2010/April%2030,%202010.pdf>.

coverage for medications, and even when the FDA has explicitly deemed a medication ineffective for treatment of a specific disease,⁷⁸ Medicare may still cover it for reimbursement.⁷⁹

Comparative effectiveness research that PPACA authorizes, in its current form, coupled with Medicare's current policies, likely ensures that the money spent to gather data from comparative effectiveness research will not save any Medicare funds.⁸⁰ It is worthy to note that while PCORI is primarily focused on the public payer side, it does show some attention to private health plans, but again fails to push any real innovation, as private health insurers have no obligation to follow any of the findings of PCORI and may do with the information as they see fit.⁸¹ The private insurers are unlikely to follow the findings of PCORI without Medicare also following suit.⁸²

Currently, the end result of the comparative effectiveness program that the PPACA authorizes is to make the information available to physicians and hope that they take the comparative effectiveness data into account when treating patients.⁸³ This use of the data faces many hurdles, as doctors are unlikely to change their practices of their own accord.⁸⁴ First, doctors, counter to what would commonly be assumed, do not base many of their practices on

⁷⁸ Andrew Pollock, *FDA Revokes Approval of Avastin for Use as Breast Cancer Drug*, N.Y. TIMES, Nov. 18, 2011, <http://www.nytimes.com/2011/11/19/business/fda-revokes-approval-of-avastin-as-breast-cancer-drug.html>

⁷⁹ Andrew Pollock, *Medicare Will Pay for Avastin in Treating Breast Cancer*, N.Y. TIMES, June 30, 2011, <http://prescriptions.blogs.nytimes.com/2011/06/30/medicare-will-pay-for-avastin-in-treating-breast-cancer/>. Avastin was a FDA approved medication for the treatment of breast cancer, but after new evidence came to light that the drug was ineffective for this treatment, the FDA removed its approval of the drug for breast cancer treatment. *Id.* Despite new evidence of ineffectiveness and removal of FDA approval, Medicare still agreed to pay for the drug to treat breast cancer. *Id.* The drug will cost Medicare \$8,000 per patient, per month of treatment. *Id.*

⁸⁰ Alexander K. Ommaya & Joel Kupersmith, *Challenges Facing the U.S. Patient-Centered Outcomes Research Institute*, 306 JAMA, 756, 756–66 (2011) (“[L]acking a substantial effort focused on implementation, the published results of comparative effectiveness research are unlikely to change medical practice on their own.”).

⁸¹ PPACA § 6301(a), § 1181(j), 42 U.S.C. § 1320e(j) (2006).

⁸² Ommaya, *supra* note 79, at 757.

⁸³ Saver, *supra* note 63, at 2150 (discussing how the information from the research will be made available to health care professionals in hopes that they will use it in practice).

⁸⁴ Ommaya, *supra* note 79, at 758 (explaining that physician care practices are extremely hard to change from within the physician community itself); *see also* Saver, *supra* note 63, at 2150 (“What will be done with the information? Not much. Many physicians seem unlikely to change clinical practice patterns, notwithstanding the outcomes of [comparative effectiveness research] studies.”).

data-driven evidence.⁸⁵ Access to better evidence relating to clinical practices does not necessarily translate into a change in real world practice.⁸⁶ For example, in 2007, the New England Journal of Medicine published the “COURAGE” (Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation) study.⁸⁷ The study showed that heart surgery using stents to unclog blocked arteries, a common procedure, was no more effective than treating the cardiac patients with drugs alone.⁸⁸ As a result of the study, it was thought there would be a significant decrease in stent use.⁸⁹ However, stent usage has not declined.⁹⁰

Secondly, many other factors besides available information or evidence effects the decisions that physicians make. Doctors often act based on how they are reimbursed for procedures.⁹¹ Marketing of pharmaceuticals and treatment options to physicians play a significant role in the care given to patients.⁹² Doctors also respond a great deal to patients’ requests for specific medications, which is in turn based on advertisements that patients see or hear.⁹³ In addition, another important factor driving physician treatment decisions is fear of

⁸⁵ See discussion *supra* note 6.

⁸⁶ See William E. Boden, *Optimal Medical Therapy With or Without PCI for Stable Coronary Disease*, 356 NEW ENG. J. MED. 1503 (2007).

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ Keith Winstein, *A Simple Health-Care Fix Fizzles Out*, WALL ST. J., Feb. 11, 2010, available at <http://online.wsj.com/article/SB10001424052748703652104574652401818092212.html> (discussing how stent implants “are now back at peak levels” and that such studies “have rarely altered medical practice”).

⁹⁰ *Id.* Part of the reluctance to change may be because physicians (and hospitals) receive better reimbursement for performing stent implants than for other treatments. *Id.*

⁹¹ David Hyman, *Follow the Money: Money Matters in Health Care, Just Like in Everything Else*, 36 AM. J.L. & MED. 370, 381 (2010) (“It is difficult to overstate the extent to which economic incentives explain the structure, performance, and pathologies of the American health care system.”).

⁹² ELIZABETH DOCTEUR, *How Will Comparative Effectiveness Research Affect the Quality of Health Care?: Timely Analysis of Immediate Health Policy Issues 5–6* (Urban Inst. 2010); see also MARCIA ANGEL, *THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT*, 3–9 (2004) (describing how hundreds of millions of dollars are spent bombarding doctors with targeted ads and in office pharmaceutical representatives and the tremendous impact this has on the prescribing practices.)

⁹³ See ANGEL, *supra* note 90. See also Ezekiel Emanuel, *The Perfect Storm of Overutilization*, 299 J. AM. MED. ASS. 2789, 2790 (2008) (discussing how part of the overutilization of health care can be causally linked to direct-to-consumer marketing); Thom Wilder, *Despite Doubts About CER's Impact, Studies Should Take Place, Researcher Says*, 9 MED. RES. L. & POL'Y REP 216 (2010) (Doctors were slow to abandon a traditionally accepted breast cancer treatment using a high-dose chemotherapy followed by bone marrow transplants in spite of mounting evidence of

malpractice liabilities.⁹⁴ One study involving over-utilization of treatments found a correlation between density of attorneys in a given area and the likelihood of over-prescription of medications.⁹⁵ Finally, doctors are hesitant to change their ways, and they value autonomy of decision making.⁹⁶

These factors coupled together demonstrate that the current state of comparative effectiveness research as authorized by the PPACA is likely to accomplish little in the way of care outcomes or cost savings. The program as it now exists will spend a great deal of money to provide a large amount of valuable data that, without proper implementation, will likely fall on deaf ears of health care professionals.

While comparative effectiveness research as currently implemented in the U.S. will likely have little impact, comparative research is being used widely abroad to provide better, more efficient care.⁹⁷ Part IV of this Comment will explore the United Kingdom's use of comparative effectiveness. The United Kingdom possesses one of the most established and longest running implementations of HTA. The United States can, and should, use the structuring of this system, its benefits, and its downsides to create a more beneficial system in America.

the treatment's ineffectiveness. This was attributed to patient demand, driven by anecdotal evidence of what patients had heard in support groups or from information disseminated from insurance companies.).

⁹⁴ Emanuel, *supra* note 91, at 2790 ("Medical malpractice laws and the resultant defensive medicine also contribute to overutilization [of health care]").

⁹⁵ George Sakoulas, *Relationship Between Population Density of Attorneys and Prevalence of Methicillin-Resistant Staphylococcus Aureus: Is Medical-Legal Pressure on Physicians a Driving Force Behind the Development of Antibiotic Resistance?*, 16 AM. J. OF THERAPEUTICS 1, 6 (Using attorney density in a area as a surrogate for medical malpractice likelihood, this study hypothesized that medications, in particular anti-biotics, are over-prescribed by physicians out of fear that if they fail to prescribe, they run a greater risk of being sued).

⁹⁶ Mark Miller, Remarks at the Public Meeting of the Medicare Payment Advisory Commission 107 (Sept. 17, 2009), available at <http://www.medpac.gov/transcripts/0909MedPAC.pdf>. A Medicare Payment Advisory Commission found that doctors do not like to change practice unless they have to. *Id.* "Personal experience" with a treatment was often enough to make treatment decisions. One physician was quoted as saying "We have our judgment, If we like something, if it works, great. If it doesn't, then we try something else." *Id.*

⁹⁷ See INTERNATIONAL PROFILES OF HEALTH CARE SYSTEMS, THE COMMONWEALTH FUND JUNE 2010, available at <http://www.commonwealthfund.org/Publications/Fund-Reports/2010/Jun/International-Profiles-of-Health-Care-Systems.aspx> (describing comparative effectiveness research system in use in such countries as the United Kingdom, France, Italy, Canada, Germany, and Australia).

IV. Comparative Effectiveness Research in the United Kingdom

Statutory authorization for the use of comparative effectiveness research in the approving of or paying for medical treatments is not new to Europe and other parts of the world.⁹⁸ The United Kingdom has a nationalized health care system where all people “ordinarily resident” in the country are entitled to predominantly free health care.⁹⁹ The United Kingdom National Health Service (NHS)¹⁰⁰ established the National Institute for Health and Clinical Excellence (NICE) for the purpose of making recommendations for coverage to the NHS in regards to new and existing medicines and treatments.¹⁰¹ The NHS is legally obligated to provide funding for pharmaceuticals recommended by the NICE.¹⁰²

The NICE’s focus when recommending treatments is not merely on clinical effectiveness but also factors in the cost of health care technologies.¹⁰³ This model uses a cost-benefit system of analysis,¹⁰⁴ relying heavily on cost analysis using quality-adjusted life years (QALY).¹⁰⁵ QALY is calculated by finding the current quality of life of a patient and examining any increase or decrease in quality of life and length of life that a new treatment may offer.¹⁰⁶ Although each drug or treatment is considered on a case-by case basis, generally “if a treatment costs more than £20,000 to £30,000 per QALY, it will not be considered cost effective.”¹⁰⁷

⁹⁸ *Id.*

⁹⁹ National Health Service Regulations, 1948, 15 & 16 Geo. 6, § 1483 (Eng.); *see also* INTERNATIONAL PROFILES OF HEALTH CARE SYSTEMS, THE COMMONWEALTH FUND JUNE 2010, *available at* <http://www.commonwealthfund.org/Publications/Fund-Reports/2010/Jun/International-Profiles-of-Health-Care-Systems.aspx>

¹⁰⁰ National Health Service, 1999, c. 220 (U.K.).

¹⁰¹ *Id.*; *see also* *Measuring Effectiveness and Cost effectiveness: the QALY*, NAT’L INST. FOR HEALTH AND CLINICAL EXCELLENCE, *available at* <http://www.nice.org.uk/newsroom/features/> (last updated Apr. 20, 2010). <http://www.nice.org.uk/newsroom/features/measuringeffectivenessandcosteffectivenesstheqaly.jsp>

¹⁰² National Health Service, 1999, c. 220 (U.K.).

¹⁰³ International Profiles of Health Care Systems, *supra* note 95.

¹⁰⁴ *See* discussion *supra* Part II.

¹⁰⁵ *Id.*

¹⁰⁶ *Measuring Effectiveness and Cost effectiveness: the QALY*, *supra* note 102.

¹⁰⁷ *Id.*

Many consider the NICE an international role model for the implementation of cost effectiveness in health care systems.¹⁰⁸ The belief is that the United Kingdom is an innovator, taking the steps to curb costs that most other health care systems will be forced to take in the future.¹⁰⁹ However, others have harshly criticized the NICE and its drastic use of QALY.¹¹⁰ Frequently, the NICE has issued guidance restricting the use of new medications that were found to be too expensive, based on a QALY analysis.¹¹¹ The system is criticized as being overly formulaic and rigid without allowing for adaptation to the clinical problem at hand.¹¹² Although used as a tool for health care systems to battle costs, some cite flaws, such as subjectivity and arbitrariness, inherent in a QALY-based system.¹¹³ In addition, because the most costly drugs are often the ones which are used to treat the sickest patients, the NICE's decisions are further thrust into the firing line. For example, the NICE has controversially rejected treatments for cancer patients because the costs were deemed too high.¹¹⁴ Cost-cutting care decisions such as these have led to a criticism that the United Kingdom has essentially instituted a system of "death panels" which sentence the sick to a lack of care simply due to costs.¹¹⁵ Thus, the duality

¹⁰⁸ *Id.* See generally CORINNA SORRENSEN ET AL., NICE: HOW DOES IT WORK AND WHAT ARE THE IMPLICATIONS FOR THE U.S.? (2008).

¹⁰⁹ Sorrenson, *supra* note 106.

¹¹⁰ Paul Eastman, *Does NICE have to be Cruel to be Kind?*, THE TELEGRAPH, Oct. 30, 2006, <http://www.telegraph.co.uk/health/3344366/Does-Nice-have-to-be-cruel-to-be-kind.html>; Emma Wilkinson, *Talk NICE around the Globe*, BBC NEWS, Feb. 16, 2009, <http://news.bbc.co.uk/2/hi/health/7830744.stm> (discussing how a series of controversial treatment denials led to outcry and protest from British citizens).

¹¹¹ See MICHAEL SCHLANDER, COMPARATIVE EFFECTIVENESS PROGRAMS: A GLOBAL PERSPECTIVE (GALEN INST. 2009).

¹¹² *Id.*

¹¹³ John Wyatt, *What's Wrong with Quality of Life as a Clinical Tool?*, 7 AM. MED. ASS'N J. ETHICS 2 (2005) (arguing that QALY measurements are not as internationally recognized and universally agreed upon as the United Kingdom would make them out to be).

¹¹⁴ Zosia Chustecka, *UK NICE Rejects 3 Drugs for Metastatic Colorectal Cancer*, MEDSCAPE.COM (Sept. 6, 2011), <http://www.medscape.com/viewarticle/749150>. Avastin, Erbitux and Vectibix, three medications for colorectal cancer, were rejected in 2011 because the cost, upwards of £150,000 per QALY gained, was deemed too high to justify the benefits. *Id.* Note that these medications are approved for payment by Medicare in the United States. *Id.*

¹¹⁵ See, e.g., Sophie Borland, *The Breast Cancer Patients TOO OLD To Save: Thousands Are Being Denied Surgery By 'Ageist' Doctors*, THE DAILY MAIL (June 16, 2011, 2:52PM), <http://www.dailymail.co.uk/health/article-2004040/Breast-cancer-Thousands-denied-life-saving-surgery-doctors-base-treatment-age.html#ixzz1kCuTcFir>

of the comparative effectiveness in the United Kingdom is striking: QALY has been used to save billions of pounds a year,¹¹⁶ but the controversy that the QALY system has brought with it has been great.¹¹⁷

V. Reforming Comparative Effectiveness Research in the United States: Meshing American Sensibilities with the Need for Change

As already discussed, the current implementation of comparative effectiveness research in the United States will likely produce little impact.¹¹⁸ Development of data is worthless without fostering a system that translates evidence into action.¹¹⁹ However all is not lost. By integrating what has been learned from the implementation of comparative effectiveness research in the United Kingdom with the needs of the American system, there is room to provide more clinically efficient care while still respecting the value of human life.

While the current implementation of comparative effectiveness research in the United States will likely produce little result, the solution is not to directly ration access to pharmaceuticals and treatments, as is being done in the United Kingdom, as this is likely not a proper fit for America.¹²⁰ Limiting access to pharmaceuticals, even minimally, is an extremely

(stating that 15,000 elderly die prematurely every year because cancer care on the NHS is not as good as that provided elsewhere in Europe and the United States); Denis Campbell, *Patients Denied Key Treatments Due To NHS Cost-cutting, Surgeons Warn*, THE GUARDIAN, Apr. 18, 2011, <http://www.guardian.co.uk/society/2011/apr/18/nhs-cost-cutting-surgeon-warning> (stating that surgeons in the United Kingdom worry that key procedures are unfairly being labeled as having limited clinical value due to cost-cutting measures).

¹¹⁶ Nicholas Timmons, *Letter From Britain: Across The Pond, Giant New Waves Of Health Reform*, 29 HEALTH AFFAIRS 12 (2010) (estimating that the QALY based system has been used to save the United Kingdom upwards of £20 billion a year).

¹¹⁷ *Id.* (noting that public protests in the United Kingdom against austerity measures, such as the use of QALY, are not an infrequent occurrence).

¹¹⁸ See *supra* Part IV.

¹¹⁹ Saver, *supra* note 63, at 2156.

¹²⁰ See, e.g., Peter Neumann & Dan Greenberg, *Is The United States Ready For QALYs?*, 5 Health Affairs 31 (“Strict adherence to a QALY approach is likely to prove unacceptable in the United States.”); *How the UK Rations Health Care*, PUBLIC RADIO INTERNATIONAL (Dec. 17, 2010, 9:24 AM), <http://www.pri.org/stories/health/how-the-uk-rations-health-care.html> (stating that rationing, even though controversial in the United Kingdom, would meet an exponentially colder reception in the United States. This is premised on the idea that in the United Kingdom “rationing [has] become a part of the national identity” due to the history of citizens sacrificing for the nation, reaching back to rationing of food and gasoline during World War II).

thorny issue in the United States that has already garnered much controversy.¹²¹ There are already rampant fears that comparative effectiveness research will lead to “death panels,”¹²² a somewhat Orwellian concept where the ill would be forced to go before tribunals in order to have funding approved or denied for their health care.¹²³

Even the short-lived Federal Council as established by the ARRA stimulus plan was maligned and often mischaracterized.¹²⁴ For example, the Wall Street Journal mischaracterized the plan as stipulating that certain medications “will no longer be prescribed.”¹²⁵ However, much of the fervor today is likely due to a misunderstanding of the complicated legislation or, unfortunately, an outright misstatement of what the PCORI is authorized to do.¹²⁶ Many have already confounded the NICE system of the United Kingdom with the legislation as enacted in the United States.¹²⁷

¹²¹ See, e.g., Alan S. Gerber et al., *A National Survey Reveals Public Skepticism About Research-Based Treatment Guidelines*, 29 HEALTH AFF. 1882 (2010).

¹²² *Id.*

¹²³ *Obama Embraces “Death Panel Concept in Medicare*, NEWSMAX (Dec. 26, 2010 6:41 PM), <http://www.newsmax.com/Headline/obama-death-panels-medicare/2010/12/26/id/381043>; Rachel Weiner, *Palin: Obama’s “Death Panel” Could Kill My Down Syndrome Baby*, THE HUFFINGTON POST, May 25, 2011, http://www.huffingtonpost.com/2009/08/07/palin-obamas-death-panel_n_254399.html (discussing how the once presidential hopeful Sarah Palin claimed that PPACA would institute “death panels.” Her claim was that those with illnesses such as down syndrome would be forced to “stand in front of Obama’s ‘death panel’ so his bureaucrats can decide, based on a subjective judgment of their ‘level of productivity in society,’ whether they are worthy of health care. Such a system is downright evil”).

¹²⁴ See, e.g., Alicia Mundy, *Drug Makers Fight Stimulus Provision*, WALL ST. J. (Feb. 10, 2009), <http://online.wsj.com/article/SB123423024203966081.html>

¹²⁵ *Id.* But see *WSJ Falsely Suggested That Comparative Effectiveness Research Provision in House Bill Dictates Certain Treatments “Will No Longer Be Prescribed”*, MEDIA MATTERS FOR AMERICA, Feb. 11, 2009, <http://mediamatters.org/research/200902110026> (correctly stating that the provision was not a part of the Federal Council authorization).

¹²⁶ Kativa Patel, *Health Reform’s Tortuous Route To The Patient-Centered Outcomes Research Institute*, 31 Health Affairs 1777, 1778 (stating that media overgeneralizations about PCORI and comparative effectiveness research have led some to distrust the system without actually understanding it).

¹²⁷ See David Catron, *How Much is a Year of Your Life Worth?*, AMERICAN SPECTATOR (July 24, 2009, 6:09 AM), <http://spectator.org/archives/2009/07/24/how-much-is-a-year-of-your-lif> (“This new bureaucracy . . . will assign a monetary value to your life and deny your care if you contract a malady whose cost-of-treatment exceeds that amount.”) In reality, the PCORI is not authorized to take into account QALY in any part of the legislation. Martin Feldstein, *ObamaCare Is All About Rationing*, WALL ST. J., Aug. 19, 2009, at A15 (“rationing health care is central” to the new strategy to reduce health care costs).

While the talk of “death panels” is vastly over-stated, it must be noted that to properly implement a working system of comparative effectiveness research there are valid concerns that must be addressed, as a system based on this type of research has the potential to contain great flaws. Of foremost importance is the concern that comparative effectiveness research by nature cannot adequately take into account individual patient differences.¹²⁸ There is also a risk of overbroad characterization of certain treatments or medications.¹²⁹ Treatments may be defined as “the same” when in fact the goals that they serve are different but in a nuanced way.¹³⁰ As such, an aggressive, rigid system such as that of the United Kingdom is not the best way to minimize these problems. What is best is a system which starts out based on conservative use comparative clinical effectiveness¹³¹ and then builds on the practical knowledge that is gained from real world use.

In order to assuage public fears and also limit potential complications from a rushed or improper implementation of a comparative effectiveness system, this Comment proposes that America start slow. For certain types of care, cost effectiveness included in comparative effectiveness research may not be the best fit. End-of-life care, while expensive,¹³² is the

¹²⁸ Saver, *supra* note 63, at 2155 (“[P]hysicians may rightly be concerned that a particular [comparative effectiveness research] study did not include subjects truly representative of their own patients.”).

¹²⁹ *Id.* at 2157.

¹³⁰ *Id.*

¹³¹ Miller, *supra* note 94 (quoting Thomas Dean, Medicare Payment Advisory Commissioner: “We are never going to have perfect data. There’s always going to be patients who have unique situations, and we have to make sure our policies allow for that, and that if we make good clinical decisions that don’t entirely follow [the results of comparative effectiveness research], there has to be an allowance for that”).

¹³² Centers for Medicare and Medicaid Services, *Decision Memo for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer*, June 30, 2011, available at <http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=247&ver=12&caName=Autologous+Cellular+Immunotherapy+Treatment+of+Metastatic+Prostate+Cancer&TimeFrame=7&DocType=All&bc=AgAAYAAAIAAA&>. Medicare approved Provenge, a treatment for prostate cancer that costs \$93,000 per patient. *Id.* See also Courtney Hutchinson, *Provenge Cancer Vaccine: Can You Put a Price on Delaying Death?*, ABC NEWS (July 29, 2010), <http://abcnews.go.com/Health/ProstateCancerNews/provenge-cancer-vaccine-months-life-worth-100k/story?id=11269159> (stating that while Provenge has been shown to extend the life of the patient for only four months, one reason for the expense of cancer treatments is that because they are traditionally covered by insurance and cost effectiveness is not taken into account by insurance companies, drug manufacturers can charge inflated

thorniest type of care to address. QALY analysis, as has been strictly applied in the United Kingdom is not as clear cut as it seems.¹³³ What constitutes the value or enjoyment of life is the subject of countless articles and books.¹³⁴ Even ignoring all moral grounds, from simply a strategic standpoint, attempting to tackle cost cutting by addressing end-of-life care would only give validity to the claims of “death panels” and care rationing that opponents of comparative effectiveness research have clamored over.¹³⁵ This would almost certainly sink the comparative effectiveness research ship before it even had a chance to leave port.

However, end-of-life care is but one portion of growing medical costs. The American health care system is ripe with the “low hanging fruit” of routine procedures and medications for non-life threatening illness that are not clinically proven but still routinely prescribed.¹³⁶ If the United States starts by addressing uncontroversial yet costly care, use of comparative effectiveness research has a chance of making a foothold in the United States.

A potential place to start would be by taking a closer look at certain types of “me-too” medications. A “me-too” medication is a class of drugs for which there are multiple variants, each containing a slightly modified version of the active ingredient.¹³⁷ Technically different molecules, the production of these medications is an easy way for drug manufacturers acquire

prices for treatments); Scott Hensley, *Debate Over Value of Provenge Boils over on Medicare Site*, NPR (Aug. 8, 2010), <http://www.npr.org/blogs/health/2010/08/02/128930253/provenge-medicare-coverage-comments> (discussing the battle between proponents for providing end-of-life care regardless of cost and those in favor of cutting end-of-life care that potentially adds little “value” to patients’ lives).

¹³³ See Wyatt, *supra* note 111.

¹³⁴ See, e.g., COST-EFFECTIVENESS IN HEALTH AND MEDICINE (Martha Gold et al. eds., 1996); PETER A. UBEL, PRICING LIFE: WHY IT’S TIME FOR HEALTH CARE RATIONING (1999); JOHN MCKIE, THE ALLOCATION OF HEALTH CARE RESOURCES: AN ETHICAL EVALUATION OF THE ‘QALY’ APPROACH (1998); ANDREW EDGAR ET AL., THE ETHICAL QALY: ETHICAL ISSUES IN HEALTHCARE RESOURCE ALLOCATIONS (1998).

¹³⁵ See discussion *supra* note 120.

¹³⁶ See *supra* notes 2–6; see also Alexandra Kirkley, *A Randomized Trial of Arthroscopic Surgery for Osteoarthritis of the Knee*, 359 NEW ENG. J. 1097 (2005) (finding that arthroscopic knee surgery failed to show any benefit to conventional physical therapy); R. Eugene Bailey, *Arthroscopic Surgery Ineffective for Osteoarthritis of the Knee*, 51 J. FAM. PRACTICE 10 (2006).

¹³⁷ Joshua Gange, *How Many “Me-too” Drugs is Too Many?*, 305 JAMA 152 (2011).

lucrative new patents.¹³⁸ For example, proton pump inhibitors (PPIs) are a category of drugs which are used to treat gastroesophageal reflux disease, commonly known as heartburn.¹³⁹ Nexium, a PPI, is in the top ten of all prescriptions within the United States¹⁴⁰ with sales topping \$8 billion in 2010.¹⁴¹ Nexium shares market space with many other PPIs, a group of drugs that are generally considered chemically equivalent.¹⁴² “Nexium is no more effective than Prilosec” said Sharon Levine, an executive with Kaiser Permanente, the largest health maintenance organization in the United States.¹⁴³ “I’m surprised anyone has ever written a prescription for Nexium.”¹⁴⁴ Nexium can cost over \$200 a month, but is the equivalent to Prilosec, a medication sold over the counter without need for a prescription.¹⁴⁵ Prilosec costs roughly \$15 a month.¹⁴⁶ They are both made by the same company, AstraZenica.¹⁴⁷

Starting with a small class of drugs, such as “me-too” drugs, and shining a light on the inefficiencies inherent in their use, has incredible potential for driving change. Not only will it save money directly by moving patients towards use of drugs that are still clinically effective but cheaper than others on the market, it has the potential to ease the public and health care providers into further acceptance of comparative effectiveness research. Even more, the money that is saved may help reduce the burden on the health care system, and thus foreclose the need to make

¹³⁸ *Id.*

¹³⁹ *Proton Pump Inhibitors*, HEARTBURN.COM, <http://www.heartburn.com/ReliefAndManagement/PPI.aspx>. (last visited Feb. 9, 2012).

¹⁴⁰ *Twenty Best Selling Drugs*, KNOL.COM, <http://knol.google.com/k/krishan-maggon/top-ten-twenty-best-selling-drugs-2010/3fy5eowy8suq3/141#> (last visited Feb. 9, 2012).

¹⁴¹ *Id.*

¹⁴² Stuart Elliot, *Prescription Drug Ads Come Under Criticism*, N.Y. TIMES, Oct. 13, 2004, <http://www.nytimes.com/2004/10/12/business/worldbusiness/12iht-drugs.html>.

¹⁴³ *Id.*

¹⁴⁴ *Id.*

¹⁴⁵ *Id.*

¹⁴⁶ *Id.*

¹⁴⁷ *Products A-Z*, ASTRAZENICA.COM, <http://www.astrazeneca.com/Medicines/Products-A-Z> (last visited Feb. 10, 2012).

difficult decisions about expensive end-of-life care in the future. This is directly counter to what people fear will happen with “death panels.”

This slow and easy start to using comparative effectiveness research in the United States further holds the potential to not only drive down health care costs but also to drive greater innovation. It is extremely expensive to produce innovative drugs, but much cheaper to produce “me-too” drugs.¹⁴⁸ In 2004, 75% of the drugs that the FDA approved were classified as similar to existing ones on the market in either chemical makeup or therapeutic value.¹⁴⁹ Marcia Angell, former editor-in-chief of the *New England Journal of Medicine*, stated that “over the past two decades [the drug industry] has moved very far from its original purpose of discovering and producing useful new drugs.”¹⁵⁰ She claims that the pharmaceutical companies are now “primarily . . . marketing machine(s) that sells drugs of dubious benefit.”¹⁵¹ By being able to produce profitable “me-too” medications, pharmaceutical companies have less incentive to invest in research and development for novel and potentially more needed drugs.¹⁵²

The FDA cannot take into account cost effectiveness when approving drugs to market.¹⁵³ With Medicare and PCORI hamstrung by legislation from effectively taking into account cost effectiveness or relative therapeutic value of drugs, pharmaceutical companies have little incentive not to spend money on marketing campaigns for recycled drugs rather than striving for

¹⁴⁸ Rosesanne Spector, *Me-Too Drugs: Sometimes They Are Just The Same Old, Same Old*, STANFORD MED. MAG. Summer 2005, available at <http://stanmed.stanford.edu/2005summer/drugs-metoo.html>.

¹⁴⁹ *Id.*

¹⁵⁰ See ANGELL, *supra* note 90.

¹⁵¹ Jake Whitney, *Pharmaceutical Sales 101: Me-Too Drugs*, GUERNICA MAG, Feb. 2006, available at http://www.guernicamag.com/features/111/me_too_drugs/ (discussing how many physicians and academics feel that pharmaceuticals have a tendency to look towards easy profits, not innovation. “Overall, the top U.S. pharmaceutical companies spend between two and two-and-a-half times as much on ‘marketing and administration’ as they do on research and development”).

¹⁵² AIDAN HOLLIS, *Me-Too Drugs: Is There A Problem?* (World Health Org. 2004), available at http://www.who.int/intellectualproperty/topics/ip/Me-tooDrugs_Hollis1.pdf (“The key problem with me-too drugs is that, to the extent that they are similar to pre-existing drugs, they diminish the incentives for innovation in pioneering drugs without adding therapeutic value. Me-too drugs also absorb [research and development] resources, which is wasteful if they are undifferentiated from pre-existing drugs”).

¹⁵³ 21 C.F.R. § 314.94.

new innovative treatments.¹⁵⁴ This Comment does not argue that the FDA should ban safe and effective drugs from authorization in the United States simply because they might not be cost-effective.¹⁵⁵ However, by having Medicare, the largest insurance payer in the United States, look closely at the relative clinical effectiveness of medications, drug manufacturers will maintain incentives to spend their funds on new drug innovation. By moving manufacturers away from recycling drugs with new patents, the benefits for approving a new drug for payment in the same medication class become less and less.¹⁵⁶

By having Medicare take into account comparative clinical effectiveness, an added incentive is that it will not only legitimize the practice for additional use by private insurance companies, it will actually push them to use it. Medicare makes decisions that “profoundly affect . . . the cost-benefit calculations and policy decisions of . . . [private] insurers.”¹⁵⁷

Medicare provides health coverage to one out of every seven Americans.¹⁵⁸ Its reimbursement and coverage policies are widely adopted by private insurers and other public programs.¹⁵⁹ Since private insurers are driven by Medicare as the first mover, mandating that for certain procedures or medications Medicare must take into account cost effectiveness will push the private side to do the same.¹⁶⁰

¹⁵⁴ Gange, *supra* note 132 (discussing how different variations of the same statin class have been patented over a 25-year period with little showing of difference in effectiveness for patient populations).

¹⁵⁵ Scott Hensley, *Should FDA Hold ‘Me-Too’ Drugs To A Higher Standard?*, NPR HEALTH BLOG (Feb. 15, 2011), <http://www.npr.org/blogs/health/2011/02/17/133784085/should-fda-hold-me-too-drugs-to-a-higher-standard>.

¹⁵⁶ See Gange, *supra* note 132.

¹⁵⁷ RICK MAYES, MEDICARE PROSPECTIVE PAYMENT AND THE SHAPING OF U.S. HEALTH CARE (2006).

¹⁵⁸ *Id.*

¹⁵⁹ Center On Budget and Policy Priority Decisions, *Medicare Changes Can Complement Health Reform* (July 31, 2008), <http://www.cbpp.org/cms/index.cfm?fa=view&id=563>.

¹⁶⁰ OFFICE OF TECHNOLOGY ASSESSMENT, US CONGRESS, MEDICAL TECHNOLOGY AND COSTS OF THE MEDICARE PROGRAM (1984).

VII. Conclusion

“No publically funded health care system . . . can possibly pay for every new medical treatment . . . choices have to be made.”¹⁶¹ While it may be somewhat unsettling to envision a system where health care choices are made with view towards economy, this statement bluntly describes the realities that health care systems, both public and private, face in countries across the globe. With health care costs rising every year,¹⁶² something must be done to curb spending.

Comparative effectiveness research is unique in that it holds the promise of cutting costs while actually increasing health outcomes.¹⁶³ While some countries like the United Kingdom have used comparative effectiveness to ration care,¹⁶⁴ comparative effectiveness research is more accurately framed in a different light. At its foundation is not the rationing of care, but actually the providing of better care.¹⁶⁵ The best promise for comparative effectiveness research to make a difference in America is to use it to weed out expensive, redundant, or unfruitful treatments so patients can get the right treatment. Cost effectiveness is an added benefit to, and inherently flows from, providing proper, effective treatments to patients. If you provide people with the proper care, not just the newest or most expensive care, people will be healthier, use less of the resources of the health care system, and in turn the system will save money.

Although comparative effectiveness research has been maligned due to fear of care rationing and “death panels,”¹⁶⁶ if the United States implements the system the right way, it can foster a better understanding of what comparative effectiveness research actually means.

¹⁶¹ *Measuring Effectiveness and Cost effectiveness: the QALY*, *supra* note 102.

¹⁶² *U.S. Health Care Costs*, KAISER FAMILY FOUND. (2011), <http://www.kaiseredu.org/Issue-Modules/US-Health-Care-Costs/Background-Brief.aspx> (citing that health care costs in the United States have risen every year and total costs tripled between 1990 and 1998).

¹⁶³ Saver, *supra* note 63, at 2147 (“If [comparative effectiveness research] works as planned, it may be one of the few reform measures in the final health care legislation that could flatten the cost curve while also improving quality”).

¹⁶⁴ See discussion *supra* Part V.

¹⁶⁵ See discussion *supra* Part V.

¹⁶⁶ See text accompanying *supra* notes 106, 109.

Garnering doctor, patient, and political support for this system is essential if a difference is to be made in the health care system. While comparative effectiveness research carries with it very real potential downsides, if implemented with an eye towards caution, these downsides can be avoided.¹⁶⁷

Thus, the translation of research data to clinical outcomes should start slowly. Treatments that involve end-of-life care or lifesaving procedures are undoubtedly expensive, but starting a comparative effectiveness program that attacks this end of the health care cost spectrum is unwise. There is much to be saved on the other end of the spectrum, by starting to take action with routine, everyday medications and procedures. By starting with low-level medications that treat non-life threatening illnesses, we can make a smart, sensible change in the way medications and treatments are prescribed. This will garner support for comparative effectiveness research, lower health care cost, drive pharmaceutical innovation and create a healthier populace.

¹⁶⁷ See discussion *supra* Part VI.

