University of Cincinnati Law Review

Volume 79 | Issue 1 Article 1

10-17-2011

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I. INTRODUCTION

The Patient Protection and Affordable Care Act,[1] signed into law on March 23, 2010, promises to increase access to health care for millions of Americans, but does not entirely resolve the continuing problem of cost. The new law will swiftly and dramatically alter the market dynamics for people who need health insurance, making it much easier for them to purchase coverage; yet, it fails to create any mechanism to absolutely curtail government or private sector spending. The cost of the healthcare system presents legal and social challenges requiring the attention of legal scholars, particularly in a manner tailored to address the challenges that the changing system presents.

The U.S. economy has absorbed escalating healthcare costs for decades, even as the country has historically failed to provide access to necessary care for many of its citizens, doing far worse than many countries that spend far less.[2] In 2009, the cost of the healthcare system in the United States was about $2.5 trillion, up 5.7% from the previous year[3]—17.3% of the entire Gross Domestic Product.[4] By 2019, this cost is projected to reach $4.5 trillion,[5] 19.3% of the Gross Domestic Product.[6] Costs continue to rise far above what any other country spends per capita.[7] Lack of access to health care can be lethal,[8] and

1. Pub. L. No. 111-148, 124 Stat. 119 (2010).

2. According to the United States Census Bureau, 15% of Americans did not have health insurance in 2008, more than 46 million people. Press Release, U.S. Census Bureau, Income, Poverty and Health Insurance Coverage in the United States: 2008 (Sept. 10, 2009), *available at* http://www.census.gov/newsroom/releases/archives/income_wealth/cb09-141.html. *See also* CARMEN DENAVAS-WALT ET AL., U.S. CENSUS BUREAU, INCOME, POVERTY, AND HEALTH INSURANCE COVERAGE IN THE UNITED STATES: 2008, 57–67 (2009), *available at* http://www.census.gov/prod/2009pubs/p60-236.pdf.

3. CTRS. FOR MEDICARE & MEDICAID SERVS., U.S. DEP'T OF HEALTH & HUMAN SERVS., NATIONAL HEALTH EXPENDITURE PROJECTIONS 2009–2019 (2009), *available at* https://www.cms.gov/NationalHealthExpendData/downloads/proj2009.pdf [hereinafter NHEP].

4. *Id.* In 2008, healthcare expenditures were 16.2% of gross domestic products (GDP). *Id.* This 1.1% increase in percentage of GDP spent on health care is the greatest single year increase in U.S. history. *Id.*

5. *Id.* tbl.3.

6. *Id.*

7. Press Release, World Health Org., World Health Organization Assesses the World's Health Systems (2010), http://www.who.int/whr/2000/media_centre/press_release/en/index.html. *See also* WORLD HEALTH ORG., THE WORLD HEALTH REPORT 2000: HEALTH SYSTEMS: IMPROVING PERFORMANCE 155 (2000), *available at* http://www.who.int/whr/2000/en/whr00_en.pdf (ranking the United States first in spending per capita among 191 countries) [hereinafter WHO REPORT]. As one can easily imagine, the WHO 2000 ranking is subject to criticism. *See* Carl Bialik, *Ill-Conceived Ranking Makes for Unhealthy Debate*: *In the Wrangle Over Health Care, a Low Rating for the U.S. System*

there is cause for hope that the increased access promised by the Patient Protection Act will go a long way toward reducing these preventable harms. However, while increased access will improve many aspects of the current system, including the overall value it acquires for dollars spent, the Patient Protection Act is not likely, by itself, to end current cost concerns.

Costs place an extraordinary, distorting pressure on the healthcare system. While the political system dictates the content of laws, cost often shapes how these laws are implemented. This Article looks closely at this dynamic in the Medicare system, but also attempts to create a blueprint for further critical study of the broader problem's effect on the institutions that health law seeks to regulate. This is especially important as the United States creates a massive regulatory framework to implement the new healthcare laws. There are flaws in the current healthcare system, driven into being by unspoken cost concerns, which have long gone unremarked upon by legal scholars. A new regulatory framework that fails to take this dynamic into account risks entrenching the same problems—its authors carrying the sins of this generation into the next.

A driving force in increasing medical expenditures is the cost of new medical technologies, drugs, and procedures provided to persons who have health insurance.[9] People with insurance consume an extraordinary amount of healthcare resources per person, far more than is reflected in the simple per capita cost of health care, which averages costs across all persons, insured and uninsured alike. This needs to be limited. Nevertheless, the clamorous public debate over health care leading to passage of the new healthcare legislation beyond calling for increased studies about efficacy and waste was silent about setting limits

Keeps Emerging Despite Evident Shortcomings in Study, WALL ST. J., Oct. 21, 2009, at A19, *available at* http://online.wsj.com/article/SB125608054324397621.html.

8. The Institute of Medicine, in a report from 2002, found that lack of health insurance caused at least 18,000 deaths each year. INST. OF MED., INSURING AMERICA'S HEALTH: PRINCIPLES AND RECOMMENDATIONS 8 (2004). While this study was based on data collected in 1993, an academic study from 2009 found that "lack of health insurance is associated with as many as 44,789 deaths per year in the United States." Andrew P. Wilper et al., *Health Insurance and Mortality in US Adults*, 99 AM. J. PUB. HEALTH 2289, 2295 (2009).

9. The Henry J. Kaiser Family Found., U.S. Health Care Costs, http://www.kaiseredu.org/Issue-Modules/US-Health-Care-Costs/Background-Brief.aspx (last visited Aug. 26, 2010) (citing *Growth in Health Care Costs: Before the Comm. on the Budget U.S. Senate* (2008) (statement of Peter R. Orszag, Dir., Cong. Budget Office)). *See also id.* ("[S]pending on prescription drugs has decelerated. Some analysts state that the availability of more expensive, state-of-the-art technological services and new drugs fuel healthcare spending not only because the development costs of these products must be recouped by industry but also because they generate consumer demand for more intense, costly services even if they are not necessarily cost-effective." (citing CONG. BUDGET OFFICE, TECHNOLOGICAL CHANGE AND THE GROWTH OF HEALTH CARE SPENDING (2008))).

on spending for expensive new medical treatments, particularly for those covered by Medicare.

The normative implications of rationing health care have been exhaustively discussed in academic literature from many disciplines, including health policy, law, philosophy, and bioethics. While no clear consensus has emerged as to what the proper goals of a just system are (or how a society goes about achieving such a system), and while substantive work remains to be done in this field, there are looming problems in the non-ideal world that beg for the legal academy to begin focusing its energy in a different direction. Given the escalating cost of new medical technologies, for example, the question emerges as to how current payment structures grapple with cost pressures in the context of the laws that govern them. This form of critical analysis has a twofold focus, assessing both whether current laws can be utilized to reduce cost and whether any resulting cost reductions are legitimately achieved.

Medicare is the single largest health care benefits provider in the country,[10] and its decisions have a broad effect on the entire United States healthcare system. In 2009, Medicare spent $507 billion,[11] covering 46 million people.[12] While more than 150 million Americans have private insurance[13] spread across many insurers, and another 33.2 million are enrolled in Medicaid programs,[14] no other single insurance plan covers as many people—or spends as many dollars—as Medicare.

As Medicare's costs spin out of control, a hidden rationing problem has developed where Medicare considers the cost of new treatments when deciding whether to cover them, but does so in an undemocratic way that is not transparent nor subject to direct public response. While Medicare is under enormous pressure to control costs, it resorts to hidden rationing, because Congress has refused to give it statutory power to consider costs in deciding whether to cover expensive new medical technologies. These important coverage decisions are made by the Centers for Medicare and Medicaid Services (CMS), a federal

10. Medicare is the federal program that provides medical benefits to people over the age of sixty-five and to the disabled. Health Insurance for the Aged Act (Medicare Act), Pub. L. No. 89-97, 79 Stat. 286 (1965).

11. *See* NHEP, *supra* note 3, at 1.

12. THE HENRY J. KAISER FAMILY FOUND., MEDICARE: MEDICARE AT A GLANCE 1 (2010), http://www.kff.org/medicare/upload/1066-12.pdf.

13. JOHN HOLAHAN & ALLISON COOK, THE HENRY J. KAISER FAMILY FOUND., CHANGES IN HEALTH INSURANCE COVERAGE, 2007–2008: EARLY IMPACT OF THE RECESSION 2 fig.1 (2009), *available at* http://www.kff.org/uninsured/upload/8004.pdf.

14. *Id*. fig.2. Medicaid is the combined federal and state program that provides health benefits for those with low incomes. *See* Medicaid Act of 1965, Pub. L. No. 89-97, § 121(a), 79 Stat. 343 (2008).

agency in the Department of Health and Human Services (HHS). Funding for CMS comes from two politically sensitive sources—payroll tax revenues allocated by Congress and premiums paid by Medicare recipients.

CMS has a process by which it makes National Coverage Determinations (NCDs) to decide whether to cover particularly expensive new technologies, and the problem discussed in this Article occurs here. Even as the potential cost-benefit ratio of technology can legally justify the issuance of an NCD, the Medicare Act prohibits cost to shape the actual NCD issued by CMS. CMS often flatly denies that cost impacts its specific decisions,[15] yet its management continually stresses the importance of cost control.[16] As a result of these conflicting messages, and in light of CMS's actual decisions, it has become an "open secret" in health policy that CMS considers cost when issuing NCDs.[17]

This Article argues that Medicare needs to be changed, giving CMS the power and obligation to openly consider the cost of new medical treatments before covering them. Doing so will yield two distinct benefits. First, such a change will give CMS legitimate power to more effectively lower Medicare's costs. Unless CMS is formally empowered to consider costs as well as benefits of new medical treatments in its NCDs, the costs of Medicare undoubtedly will continue to escalate, which would be highly problematic for the nation. Current projections reveal that without some change, Medicare alone will cost the nation nearly $1 trillion by 2019.[18]

15. "[T]he cost of a particular technology is not relevant in the determination of whether the technology improves health outcomes or should be covered for the Medicare population through an NCD." CTRS. FOR MEDICARE & MEDICAID, DEP'T OF HEALTH & HUMAN SERVS., GUIDANCE FOR THE PUBLIC, INDUSTRY AND CMS STAFF: FACTORS CMS CONSIDERS IN OPENING A NATIONAL COVERAGE DETERMINATION (2006), *available at* http://www.cms.hhs.gov/mcd/ncpc_view_document.asp?id=6. *See also* Ruth Faden & Sean Tunis, *Virtual Colonoscopy: A Window Into the Challenges of Health Care Reform*, HEALTH CARE COST MONITOR, Aug. 6, 2009, *available at* http://healthcarecostmonitor.thehastingscenter.org/ruthfaden/virtual-colonoscopy-a-window-into-the-challenges-of-health-carereform/ ("Medicare also addressed the question of whether the higher cost . . . factored into its decision; it said that the costs were considered but emphasized that its decision was based on uncertainty about the clinical benefits."). The cost effectiveness of the colonoscopy at issue in this case was discussed extensively by people outside of CMS in response to the CMS decision, making CMS's denial particularly interesting. One is left wondering whether CMS was ignoring important cost implications or refusing to admit it had done so.

16. *See infra* notes 125–127 and accompanying text.

17. *See, e.g.*, Philip R. Alper, Commentary, *Kids' Shoes and Death Panels: Deciding Between Needs and Wants is Health Care's Impossible Task*, WASH. TIMES, Feb. 10, 2010, at B04, *available at* http://www.washingtontimes.com/news/2010/feb/10/kids-shoes-and-death-panels/ ("It is an open secret, however, that the more costly the claim, the more intense the scrutiny.").

18. NHEP, *supra* note 3, at tbl.3 (predicting $978 billion by 2019).

The second benefit from directing CMS to openly consider these types of costs is that, by putting cost-benefit balancing on the table, the public will have an opportunity to participate in the difficult, cost-driven decisions CMS already makes *sub rosa*.[19] There are distinct advantages to this form of public participation. Without open debate in the face of the rapid increase of healthcare costs, the United States remains blind as to what its societal value system requires from difficult cost and access decisions about health care.[20] To fix this, the nation must clarify the kinds of medical care that it believes are most fundamentally important. Yet, before it can do this, the nation needs to put in place effective forms of democratic deliberation for use in defining the values the nation wants its healthcare system to reflect. Medicare is uniquely situated as the place to begin identifying national values regarding the costs of health care, both because of its sheer size and because its administrator, CMS, has a platform from which it can generate public discussion about its proposed rules through its NCD process.

The most significant challenge in directing Medicare explicitly to consider the costs of particular medical treatment is the fear of revealing the frightening fact that Medicare is actually rationing health care in America and that healthcare rationing will only increase in the years ahead. It may be that politicians' fears of negative public perception could lead to limited political support for changing Medicare in the manner proposed here. On the other hand, experience has shown that some politicians appear to have benefited from frankly addressing medical rationing. Putting aside the politics of the matter, it is critically necessary to control the overall costs of the Medicare program. Without a more forthright approach to rationing, the healthcare system's massive projected cost increases could actually destroy the country's economy. Changes in the law that effectively stop this from occurring are clearly in the public interest.

Part II of this Article describes the CMS process for issuing NCDs and uses a case study to show how cost concerns affect the NCDs it issues. This Part describes the history of the Medicare Act, particularly why costs were not addressed in the language of the Act, and explains the legal structure of the Medicare Act in the context of this history by focusing on the language of the Act and how it can be interpreted

19. Public participation takes place during the public comment period in the Medicare coverage process, described in Part V.B, *infra*.

20. *See* Allan S. Brett, *"American Values" – A Smoke Screen in the Debate on Health Care Reform*, 361 NEW ENG. J. MED. 5, 440 (2009) (an excellent discussion on both the constant use of the concept of "American Values" in healthcare debates and how little we truly know of what these values are).

regarding cost.

Part II then examines the evolving process for making NCDs. While CMS has made a series of failed attempts to explicitly incorporate cost into this process, more recently it has focused almost entirely on the quality of evidence it requires from applicants to justify coverage. This focus, in turn, has created new cost-control problems for CMS. Under the current scheme, applicants have the financial incentive to design studies that will receive coverage for the broadest possible population. Yet, CMS has the financial incentive to interpret the same data so as to narrow the population for which it approves coverage. CMS's cost-driven interpretations of data to deny coverage are difficult to justify when the data are of a high quality and clearly support the applicants' coverage position. Part II concludes with a case study of the NCDs issued for implantable cardiac defibrillators to illustrate how the prohibition against considering cost distorts the NCD process.

Part III of the Article considers the relationship between Medicare's hidden rationing problem and the recent creation and dissolution of the Federal Coordinating Council for Comparative Effectiveness Research (the Coordinating Council), coupled with substantial funding recently directed towards cost effectiveness research (CER), arguing that CER is both vulnerable to being distorted by CMS for cost purposes and that CER's potential value to society will be greatly increased by amending Medicare in the manner this Article suggests. To enable people to pursue greater value for their healthcare purchases, provisions of the Patient Protection and Affordable Care Act strengthen the federal government's commitment to funding comparative effectiveness research. The value-enhancing use of this information is left almost entirely to consumers as the laws governing federal funding of comparative effectiveness research make it clear that the results of the research cannot be used by government agencies to create coverage policies for the purpose of saving money. Part III explains how CER results are vulnerable to being manipulated for cost-saving purposes. Given the absence of a formal process for using CER for cost-saving purposes and how much trust is required for the public to actually adopt CER findings as guidance for their own medical choices, CER's success depends almost entirely on transparently separating its findings from cost concerns, something that Medicare is currently unable to do while still protecting its fiscal stability.

Part IV of the Article explores the heart of the political problem—the explicit rationing of health care—and argues that, counterintuitively, politicians should be able to survive promoting rationing and that the nation will benefit, therefrom. The implementation of the Oregon

rationing structure provides an example of post-rationing political viability and public approval. Part V offers a proposal for amending the Medicare Act allowing the cost of new medical treatments to be addressed openly and directly.

II. THE MEDICARE PROBLEM: HIDING COST IN COVERAGE CONSIDERATIONS

CMS is the federal agency that administers the Medicare program (Medicare), which provides health insurance for those over sixty-five years of age and for the disabled receiving Social Security benefits. It is responsible for providing healthcare benefits to roughly 45 million people, the majority of whom are over sixty-five.[21] Medicare spent $507 billion in 2009, which is 13% of the federal budget for that year.[22]

Medicare is an expensive program, and CMS's relationship with cost-based rationing of health care within Medicare is complex. CMS does not have legislative power to refuse coverage for medical treatments because of how much they cost, but functions within a budget set by Congress. Congress, in turn, raises revenue to pay for what Medicare covers. Raising revenue creates its own set of problems, such as the political cost of raising taxes. This situation creates an incentive for CMS to control cost without appearing to violate the law, and provides Congress with an incentive to loosely examine CMS's cost-saving decisions.

CMS has championed efficacy studies and demanded evidence of the highest probative value to support its coverage decisions.[23] CMS supports using a "gold standard"[24] of medical evidence. To do this, CMS ranks the quality of clinical studies based on numerous, coherent, and sensible criteria that help assess the reliability of the data generated.[25] For example, studies where doctors do not know which

21. BARBARA S. KLEES ET AL., DEP'T OF HEALTH & HUMAN SERVS., BRIEF SUMMARIES OF MEDICARE & MEDICAID 7 (2009), *available at* http://www.cms.gov/MedicareMedicaidStatSupp/downloads/2009BriefSummaries.pdf.

22. THE HENRY J. KAISER FAMILY FOUND., MEDICARE: A PRIMER 13 (2009), *available at* http://www.kff.org/medicare/upload/7615-02.pdf [hereinafter PRIMER] (citing OFFICE OF MGMT. & BUDGET, EXECUTIVE OFFICE OF THE PRESIDENT, FISCAL YEAR 2009 MID-SESSION REVIEW: BUDGET OF THE U.S. GOVERNMENT (2008)).

23. *See* Medicare Program: Criteria for Making Coverage Decisions, 65 Fed. Reg. 31,124 (May 16, 2000).

24. *See generally* STEFAN TIMMERMANS & MARC BERG, THE GOLD STANDARD: THE CHALLENGE OF EVIDENCE-BASED MEDICINE AND STANDARDIZATION IN HEALTH CARE (2003).

25. CTRS. FOR MEDICARE & MEDICAID SERVS., U.S. DEP'T OF HEALTH & HUMAN SERVS., MEDICARE COVERAGE ADVISORY COMMITTEE OPERATIONS AND METHODOLOGY SUBCOMMITTEE; PROCESS FOR EVALUATION OF EFFECTIVENESS AND COMMITTEE OPERATIONS 3–6 (2006), *available at*

patient is taking a placebo and which is taking a new medicine are considered more reliable than anecdotal reports of one doctor's experience with a patient.

However, when faced with applications for coverage of new and expensive medical treatments, CMS's need to control cost makes it difficult for it to rely entirely on the highest quality data when making its decisions. Medical costs continue to rise at an astonishing rate[26] with new treatments driving this increase.[27] CMS must somehow take cost into account, and when this problem arises, it is actually the high quality evidence in support of expensive treatments presenting the biggest problem. Since CMS cannot explicitly consider cost-based criteria when making coverage decisions, it can only control cost by interpreting data in a manner that supports a cost-limiting coverage decision. This leads to CMS making decisions where the role of cost is hidden and its interpretations of applicants' data are suspect.

It may appear harsh to claim that CMS's NCDs are unreliable because of hidden cost concerns that may influence their ultimate decisions. In light of CMS's support of high quality data, particularly in the current, highly sensitive political environment, such a claim must be made cautiously. This Article justifies doing so by explaining how the law and regulations governing Medicare constrain how CMS makes coverage decisions, supported by concrete, specific examples of how those constraints have led to this result. This Article does not seek to portray a government agency that is corrupt or malicious. Rather, CMS is an agency motivated by stewardship of the Medicare program and protection of its members. The problem lies in the legal and political conditions within which CMS must function, and which directly promote data manipulation. These structures and conditions must change.

A. A Short History of Medicare and Cost

The United States is far behind most other developed countries in terms of developing a system of universal health care.[28] In truth, our

http://www.cms.hhs.gov/FACA/Downloads/recommendations.pdf.

26. NHEP, *supra* note 3, at 1 (indicating that the average rate of healthcare spending is expected to increase by 6.1% a year into the foreseeable future, while growth in the overall economy is expected to be 4.4% per year).

27. *See* The Henry J. Kaiser Family Found., *supra* note 9.

28. An excellent comparison of different countries' systems can be found in HEALTH CARE COVERAGE DETERMINATIONS: AN INTERNATIONAL COMPARATIVE STUDY (Timothy Jost ed., 2004). *See also* The Henry J. Kaiser Family Found., *supra* note 9.

"system" is a series of imperfect safety nets.[29] Medicare, enacted in 1965, was one of the first healthcare safety nets created by the federal government.

Before the passage of Medicare, people over the age of sixty-five found it difficult to acquire private health insurance.[30] The poverty rate for the elderly was quite high, and without insurance, illness was often financially devastating.[31] Medicare sought to address this problem and has been very successful in doing so. More than 99% of those over sixty-five are currently insured in the United States.[32] The poverty rate for the elderly has been reduced from 35.2 % in 1959 to 10.2% in 2003.[33]

While successful in increasing access to health care for the elderly, Medicare was the result of numerous compromises among the various interested parties and those compromises resulted in some structural problems that have contributed to out-of-control spending.[34] The cost of Medicare now threatens to undermine the increased access that the original program provided so successfully. The compromises in Medicare were meant to address stakeholder concerns that: (1) government, rather than physicians, would control healthcare choices; (2) hospitals and doctors would be forced to accept low payments due to government bargaining power; and (3) the elderly would be refused treatment or provided a lower level of care due to their status as Medicare beneficiaries.[35] Cost does not appear to have been a pressing concern, which makes sense when one considers that total national expenditures for health care, as measured by the federal government in

29. Medicare Act, 42 U.S.C. §§ 1395 *et seq*. (2006) (providing coverage for those over 65 and the disabled); Medicaid Act, 42 U.S.C. §§ 1396 *et seq*. (2006) (providing coverage for the poor); Emergency Medical Treatment & Active Labor Act (EMTALA), 42 U.S.C. § 1395dd (2006) (requiring emergency departments to stabilize patients in emergency situations, though the patients bear financial responsibility for the care provided).

30. PRIMER, *supra* note 22, at 1 ("Prior to 1965, roughly half of all seniors lacked medical insurance.").

31. *See* Press Release, Patrick Leahy, Statement of Senator Patrick Leahy on the Motion to Proceed to H.R. 3590, The "Patient Protection and Affordable Care Act" (November 21, 2009), *available at* http://leahy.senate.gov/press/press_releases/release/?id=62ef39d7-76f2-4621-b7b8-f1d959433ef3 (stating that more than one in three elderly people lived in poverty prior to the passage of Medicare).

32. James W. Mold et al., *Who Are the Uninsured Elderly in the United States*, 52 J. AM. GERIATRICS SOC'Y 601, 601–06 (2004) (publishing the results of a 2000 study which found 350,000 uninsured people over the age of sixty-five).

33. DENAVAS-WALT ET AL., *supra* note 2, at 50 tbl.B-2.

34. *See* Jacqueline Fox, *Medicare Should, but Cannot, Consider Cost: Legal Impediments to a Sound Policy*, 53 BUFF. L. REV. 577, 586–96 (2005); *see also* THEODORE R. MARMOR, THE POLITICS OF MEDICARE (2d ed. 2000).

35. Fox, *supra* note 34, at 595.

1965, were $42 billion, compared with expenditures of $2.57 trillion projected for 2010.[36]

In order to satisfy critics and, primarily, to gain the support of the American Medical Association and similar lobbying groups, Medicare was designed to encourage providers to treat the elderly to protect both the pricing structure for the provision of medical care in effect at the time and the right of physicians to make decisions for their individual patients.[37] Whatever the merits of these choices, they are now widely understood to have created a payment system that had an inflationary impact on the cost of the United States healthcare system.[38]

B. How the "Reasonable and Necessary" Language of Medicare Prevents CMS from Considering Costs

Medicare is administered by CMS, which is an arm of the Department of Health and Human Services (HHS), which itself is an agency in the executive branch. CMS gets its legal power from the Medicare enabling act, entitled The Medicare Act, passed by Congress in 1965 and amended numerous times in subsequent years.[39] The language of the original Medicare Act specifies Medicare's scope of coverage: "No payment may be made under [Medicare] for any expense incurred for items or services which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."[40] This language has remained unchanged since 1965 and is the language that dictates how Medicare evaluates expensive new medical technologies and procedures.

The meaning of Medicare's "reasonable and necessary" language is extremely important. Because this language has never been amended, it is the meaning *in 1965* that matters. "Reasonable and necessary" is not included in any printed official legislative history related to that section of the Act. The absence of reported debate is not surprising since the language was inserted in Medicare only as the final work was done

36. Ctrs. for Medicare & Medicaid Servs., National Health Expenditures Historical and Projections 1965–2019, *available at* http://www.cms.hhs.gov/nationalhealthexpenddata/03_nationalhealthaccountsprojected.asp (follow "NHE Historical and projections, 1965–2019 (ZIP, 32 KB)" hyperlink) (last visited Aug. 29, 2010). *See also* Christopher Chantrill, Total Budgeted Government Spending Expenditure, http://www.usgovernmentspending.com/year1965_0.html (last visited Aug. 26, 2009) (showing that the entire federal budget for 1965 was $118 billion and thus suggesting that the cost of health care was not as worrisome then as it is now).

37. Fox, *supra* note 34, at 595.

38. *Id.* at 596–97.

39. Medicare Act, 42 U.S.C. §§ 1395 *et seq*. (2006).

40. 42 U.S.C. § 1395y(a)(1)(A) (2006) ("Exclusions from coverage").

drafting the law for this extensively negotiated program.[41] The language was taken from a health insurance policy that AETNA offered to federal government employees at that time.[42] The only change in language from the AETNA policy was that AETNA refused payment for services not "reasonable or necessary," whereas the Medicare program specified coverage for services that were "reasonable and necessary."[43]

In the 1960s, state courts heard numerous cases requiring judges to interpret close variants of the statutory language, as it was the typical language of fee-for-service health insurance contracts at that time.[44] These courts consistently interpreted the health insurance contract language as giving broad discretion to the recommendation of the covered person's treating physician.[45] If the treating physician determined that a course of treatment was necessary, it appeared to the courts to be presumptively reasonable that the insurance company should pay for it.[46] Courts were reluctant to enter into physician's decision-making, and they saw nothing in the contracts that allowed insurance companies to participate in that process either.[47]

Soon after passage of the Medicare Act, escalating medical costs became a national concern.[48] When Medicare was originally written, these costs were still relatively low, in part due to a limited range of available medical treatments. As modern science expanded treatment options, it became clear that medical spending could be theoretically limitless.[49] In addition, Medicare's initial reimbursement rates had an inflationary effect, leading to an explosion of spending for hospital infrastructures.[50] Medicare's initial cost projections quickly proved to be significantly underestimated. In 1965, it projected that the program would cost $3.1 billion (in 1965 dollars) to administer for 1970.[51] By 1969, that estimate was revised to $5 billion (in 1969 dollars), an increase of projected cost in raw dollars of more than 60% in four

41. Fox, *supra* note 34, at 591–93.

42. *Id.* at 594.

43. *Id.*

44. *Id.* at 594–95.

45. *Id.*

46. *Id.*

47. *Id.*

48. *Id.* at 596.

49. *Id.*

50. S. REP. NO. 89-404, at 36 (1965), *as reprinted in* 1965 U.S.C.C.A.N. 1943, 1977. In an effort to garner political support from hospitals, the Medicare Act included generous hospital reimbursement rates that were meant to include infrastructure costs.

51. S. REP. NO. 91-1431, at 138 (1970).

years.[52] This rapid increase in spending for medical care was not limited to spending on Medicare recipients, and new structures for providing health insurance in the United States were created in response to the problem.[53] Some form of managed care gradually became the norm for most types of medical insurance while Medicare remained bound to the language of traditional contracts of a different era.[54]

In addition to rising costs, a significant part of changing the health insurance culture apart from Medicare was the enactment of the Employee Retirement Income Security Act (ERISA), which became law in 1974.[55] ERISA is an employee benefit law that regulates employer-based pension and health plans. Most importantly here, ERISA pre-empts most state lawsuits related to such plans,[56] requires benefit law suits to be brought in federal court, and does not allow any damages to be awarded to patients beyond the value of the medical care in dispute.[57] Due to ERISA preemption, the majority of health insurance contracts are administered without fear of significant liability exposure because most people in this country receive their health insurance through employer-sponsored ERISA plans.[58] This allows plan administrators to take an aggressive, cost-saving stance in benefits decisions without the risk of being held responsible for any damages that a wrongful denial might cause. The state courts from the 1960s, discussed *supra*, protected the right of the doctor to determine what a patient needed, and ERISA has excluded these courts from most health insurance coverage disputes. Arguably, ERISA preemption is one of the few significant healthcare cost-reducing components of our healthcare system.[59]

As the health insurance industry broadly adopted concepts from managed care, insurers changed the language in their contracts to reflect this, reserving for themselves increasing authority to decide which

52. *Id.*

53. The federal government enacted the Health Maintenance Organization (HMO) Act in 1973, which encouraged the creation of these new forms of health insurance. Health Maintenance Organization Act of 1973, 42 U.S.C. §§ 300e *et seq.* (2006).

54. Gail A. Jensen et al., *The New Dominance of Managed Care: Insurance Trends in the 1990s*, 16 HEALTH AFF. 125 (1997).

55. Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. §§ 1001 *et seq*. (2006).

56. 29 U.S.C. § 1144(a) (2006).

57. § 1001.

58. *See* THE HENRY J. KAISER FAMILY FOUND. & HEALTH RES. & EDUC. TRUST, EMPLOYER HEALTH BENEFITS: 2009 SUMMARY OF FINDINGS 1 (2009), *available at* http://ehbs.kff.org/pdf/2009/7937.pdf (reporting that 159 million people are covered by employer-sponsored plans as of 2009).

59. Jacqueline R. Fox, *Will Health Care Reform Increase Litigation Over Denied Claims?*, HEALTH CARE COST MONITOR, Oct. 29, 2009, *available at* http://healthcarecostmonitor.thehastingscenter.org/jacquelinefox/will-health-care-reform-increase-litigation-over-denied-claims/.

expenditures were appropriate for individual patients.[60] Adoption and exercise of this "gate-keeping" role by the insurance companies represented a change from the "hands off" approach to doctors' decisions previously sanctioned by the courts. This change has not been smooth and the transition from fee-for-service to managed care has been contentious, but managed care has become ubiquitous outside of Medicare.

Given the structure of the Medicare Act, where coverage decisions are still limited to determining what is "reasonable and necessary," CMS has not had the power to follow the private sector in changing its decision-making process to take cost into account. Absent specific legislative authority to make such resource allocation decisions, the legality of CMS doing so is questionable. Moreover, without any statutory changes that explicitly give it this power, CMS has little political legitimacy to make this type of decision, which is particularly important since decisions about access to health care have powerful normative implications. As Jerry Mashaw has addressed in the context of other administrative actions, the perception of fairness and legitimacy in a life-altering, decision-making process can be extraordinarily important to people impacted by the decision.[61]

However, even while constrained by its statutory language, it is impossible for CMS to ignore the cost of new medical treatments. CMS must protect the fiscal security of the Medicare program. If it fails to do so, it jeopardizes the provision of health care to its members and risks angering Congress, who, after all, must raise the money to pay the bulk of Medicare's costs. Medicare is already one of the single most expensive government programs in the federal budget,[62] with costs projected to rise into the foreseeable future.[63] Medicare's funding comes from both payroll taxes and premiums paid by its recipients.[64] These sources of funding are heavily constrained by political pressure on Congress, this pressure coming from both taxpayers and the elderly.[65] If CMS were to ignore its decision's cost implications, Medicare's massive cost could become even more problematic.

60. Glen P. Mays et al., *Market Watch: Managed Care Rebound? Recent Changes in Health Plans' Cost Containment Strategies*, HEALTH AFFAIRS, Aug. 2004, *available at* http://content.healthaffairs.org/cgi/content/full/hlthaff.w4.427/DC1.

61. Jerry L. Mashaw, *Small Things Like Reason Are Put in a Jar: Reason and Legitimacy in the Administrative State*, 70 FORDHAM L. REV. 17, 35 (2001).

62. PRIMER, *supra* note 22, at 1, 13.

63. *Id.*

64. *Id.* at 16.

65. *See* discussion *infra* Part IV.

C. National Coverage Determinations

Structurally, Medicare faces two challenges in evaluating expensive new medical treatments. The first is how to shape NCDs to encourage or compel Medicare recipients to make the most cost-effective decisions. The second is how to limit or deny coverage for new technologies or treatments that are too expensive for the program to support, even if they are effective. As shown above, it has no power to transparently achieve either result, which gives it very few avenues for pursuing these goals. The NCD process affords CMS discretion as it determines which new medical treatments to cover, and it is within these discretionary acts that cost concerns have found a home.

1. NCDs and the FDA: How CMS Determines Whether it Should Issue an NCD, and How This Relates to FDA Approval

New medical technologies face a series of hurdles before being adopted for use in the United States marketplace. The first hurdle is approval by the Food and Drug Administration (FDA), which medical device and drug manufacturers must secure in order to get their products into the marketplace.[66] A second, and equally important, hurdle is approval by CMS for coverage by the Medicare program. Developers of medical technology know that, without approval from the CMS, their products will have no market among the elderly population. Furthermore, it is highly unlikely that private insurers will pay for coverage without CMS approval.[67]

The decision by CMS to consider the issuance of a formal NCD is primarily based on the potential high cost of a new technology for Medicare, but it may also be considered if it appears difficult to assess whether the technology is appropriate for use by Medicare recipients.[68] Potential applicants can also request that CMS consider issuing an NCD if they believe it will clarify the coverage of a new technology.[69] In the absence of an NCD, local Medicare administrators throughout the country make coverage decisions by applying the broad standards of the

66. *See* 21 C.F.R. §§ 814.1 *et seq*. (2010) (premarket approval of medical devices).

67. *See* PAUL N. VAN DE WATER, CTR. ON BUDGET & POLICY PRIORITIES, MEDICARE CHANGES CAN COMPLEMENT HEALTH REFORM (2008), *available at* http://www.cbpp.org/files/7-31-08health.pdf (discussing the dynamics in the healthcare industry that lead to Medicare having such a dominant role in coverage decisions).

68. *See* Medicare Program; Revised Process for Making Medicare National Coverage Decisions, 68 Fed. Reg. 55,634, 55,634-55,641 (Sept. 26, 2003).

69. *Id.* at 55,638.

program.[70] These local decisions need not be consistent with each other. Once an NCD is made, all Medicare coverage must be consistent with it.[71] It is far more efficient for CMS to undertake NCDs in appropriate circumstances than for this type of decision to be made countless times in individual cases.

The current CMS process for approval of new technologies or treatments requires three steps. First, the care that the technology or treatment is to provide must fit within a general area that Medicare covers under the Medicare Act.[72] Second, the specific treatment or technology must be found to be reasonable and necessary.[73] Third, Medicare must determine how much it will pay for the proposed treatment. The Medicare Act requires that this last determination be kept entirely separate from the first two and made only after they are completed.[74]

Apart from the regulatory process itself, CMS encourages a collaborative process between persons applying for NCDs and CMS.[75] CMS has said that it wishes collaboration to begin long before a formal application for an NCD is filed, particularly for new technologies that have not been approved by the FDA for any use whatsoever. An application for an NCD can be submitted to CMS at the same time as an application is presented to the FDA for the same device or pharmaceutical, if the device or pharmaceutical has already received FDA approval for any other use.[76] However, a formal application for an NCD is generally not accepted by CMS until a device or pharmaceutical has received FDA approval for some type of use.[77]

For entirely new technologies, the applicant would first apply for an initial approval from the FDA, wait for the approval, and then apply for an NCD.[78] To shorten the time involved in this process, as FDA approval is pending, CMS will collaborate with an applicant on the design of the studies to be submitted so that the eventual NCD can proceed quickly after FDA marketing approval is given.[79]

FDA approval alone, does not qualify a technology or pharmaceutical

70. 42 U.S.C.A. § 1395x(v)(l) (West 2010).

71. *Id.*

72. *Id.*; 68 Fed. Reg. at 55,635.

73. 42 U.S.C. § 1395y(a)(1) (West 2010).

74. The Secretary of HHS determines payment amounts under § 1395(g)(a) for benefits provided under Part A of Medicare, and under § 13951(a) for benefits provided under Part B of Medicare.

75. 68 Fed. Reg. at 55,636.

76. *Id.*

77. *Id.*

78. *Id.*

79. *Id.*

for NCD approval. CMS has stated that the data sufficient for FDA approval does not give CMS the type or degree of information it needs to make the decision required by the "reasonable and necessary" language.[80] The FDA only decides if a device or pharmaceutical is "safe and effective," a phrase with a precise statutory and regulatory meaning.[81] Simply put, the FDA assesses data about a drug or device to ensure that it works as claimed and that the health benefits of its use outweigh the risks.[82] FDA approval is limited in scope: the FDA only examines the specific use for which the sponsor applies. Because the basis for FDA approval does not currently involve comparing the drug or device to any other available treatment, the new drug or device does not need to function as well or better than other ones and it does not need to be safer than existing protocols.[83] Furthermore, because of numerous factors, such as the small number of study participants in FDA trials, the poor after-approval market analysis of adverse events, and the wide-spread "off-label" use of what is approved,[84] FDA approval, by itself, gives limited information about how well a drug or device will actually function in the Medicare patient population.[85] This approval is of limited use to CMS in making its own NCD.

2. The Cost Control Potential of NCDs

CMS's NCDs have implications beyond the health care provided to Medicare recipients and have the potential to control costs for the entire United States healthcare system. Once an NCD about a new medical technology is made, most health insurance companies follow that decision for their own members,[86] affecting approximately 150 million people in private plans and another 33.3 million people who are covered by Medicaid.[87] Consequently, the effect of these coverage decisions and

80. *Id.*

81. 21 U.S.C.A. § 321(p)(1), (v)(1) (West 2010) (defining "safe & effective").

82. *Id.*

83. This, too, may be changing, though it is too soon to know what role the FDA will eventually have in assessing the comparative quality of new drugs and devices.

84. Off-label usage means that drugs or devices are free to be used by healthcare practitioners however they see fit once a single reason for use has been approved of by the FDA. When such drugs or devices are used in any way besides what the FDA has approved, it is referred to as off-label.

85. Bruce Patsner, *CMS Review Could Act as a Check on FDA Shortcomings*, HEALTH L. PERSPECTIVES, at 1–3, Sept. 24, 2008, *available at* http://www.law.uh.edu/Healthlaw/perspectives/2008/(BP)%20cms2.pdf.

86. JACOB S. HACKER, INST. FOR AM. FUTURE, THE CASE FOR PUBLIC PLAN CHOICE IN NATIONAL HEALTH REFORM: KEY TO COST CONTROL AND QUALITY COVERAGE 14 (2009), *available at* http://institute.ourfuture.org/files/Jacob_Hacker_Public_Plan_Choice.pdf.

87. HOLAHAN & COOK, *supra* note 13, at 2 fig.1.

the importance of what CMS considers when making them are magnified far beyond the number of Medicare recipients.

Consider what happens if this process has to incorporate CMS's unspoken concerns about cost. From the perspective of the sophisticated device manufacturer, the Medicare NCD approval process is clearly important and any concerns CMS has should be satisfied. The manufacturer must address and challenge these concerns subtly and indirectly because there is no step in the process where they can do it forthrightly. The resulting NCD process risks distorting the scientific and practical conversations concerning the efficacy and general usefulness of the new technology that ostensibly occur in a regulatory environment. As CMS increasingly focuses on the principles of evidence-based medicine, requiring vigorous proof of efficacy, its constant concern about cost creates an equally constant risk that the interpretation of this same evidence will be distorted in order to justify cost-saving choices. For those generating the data, the risk of distortion, in turn, creates incentives for them to collect data in a way that is more resistant to any interpretations influenced by cost that they may face. A more direct, open, and explicit conversation about the cost of the new technology would make much more sense from a practical standpoint. The lack of transparency in the current system undermines the legitimacy of the public program and creates a ripple effect, distorting private market decisions.

Furthermore, once coverage has been decided in steps one and two, reimbursement rates are difficult for Medicare to use as a cost-saving device. When CMS has agreed to cover a treatment or a technology, the companies that proposed the technologies or treatments have very little to lose in battling for generous reimbursement rates. By legally separating the questions of what a new technology or treatment accomplishes and what it is worth to Medicare financially, the process makes bargaining between CMS and the manufacturers extremely difficult, if not impossible, by removing the coverage decision as leverage.

It is in the second step of the process, determining what is "reasonable and necessary," where centralized gate keeping of expensive medical technologies, with the concurrent cost saving, occurs for Medicare.

3. Attempts to Define and Expand the Scope of the NCD Process

While managed care spread throughout the private sector, CMS engaged in a series of unsuccessful attempts to bring concepts from managed care into its NCD process. CMS published proposed

regulations in 1989, 1999, and 2000 to incorporate some features of managed care programs into the Medicare program.[88] Given the limited scope of the "reasonable and necessary" language, the detailed plans contained in the proposed regulations likely exceeded CMS's power to adopt them. This would have adversely affected their enforceability under general principles of administrative law.[89] In 2003, CMS took a different approach and published notices of the procedures it would follow in making NCDs that did not seek to include a role for cost.

The stated intent of all of the proposed regulations was to define the criteria to be considered when deciding if a new technology or treatment was "reasonable and necessary," and additionally, what would trigger an NCD process.[90] A variety of ideas were included in the 1989, 1999, and 2000 proposals. In response, CMS received tens of thousands of negative comments[91] and did not adopt any of the proposals as final rules. CMS did not provide a reason for those decisions.[92]

In the 1989 proposal, CMS suggested using cost effectiveness to analyze new technology.[93] That suggestion was not adopted as a specific criterion for NCDs. Cost effectiveness, popularly understood to mean determining if a new treatment or technology is "as effective as an alternative but less expensive,"[94] was used in the proposed rule to describe a process of comparing the benefits and risks offered by a new technology or treatment against existing ones, while also considering the comparative financial costs of both. Benefits and risks are construed narrowly, meaning those that occur to the patient either in the treatment of a short-term problem or over the course of an illness.[95]

88. *See* Medicare Program; Criteria and Procedures for Making Medical Services Coverage Decisions That Relate to Health Care Technology, 54 Fed. Reg. 4302, 4302–4318 (Jan. 30, 1989); Medicare Program; Procedures for Making National Coverage Decisions, 64 Fed. Reg. 22,619 (Apr. 27, 1999); Medicare Program; Criteria for Making Coverage Decisions, 65 Fed. Reg. 31,124 (May 16, 2000).

89. *See* Administrative Procedures Act, 5 U.S.C § 553(b)(3)(A) (2006).

90. Medicare Program; Revised Process for Making Medicare National Coverage Decisions, 68 Fed. Reg. 55,634, 55,634 (Sept. 26, 2003).

91. Fox, *supra* note 34, at 612.

92. 5 U.S.C. § 557(b) (2006) (clarifying that when an agency does not adopt a rule, there is no requirement that a reason be given.).

93. Medicare Program; Criteria and Procedures for Making Medical Services Coverage Decisions That Relate to Health Care Technology, 54 Fed. Reg. 4302, 4302–4318 (Jan. 30, 1989).

94. Paul E. Kalb, *Controlling Health Care Costs by Controlling Technology: A Private Contractual Approach*, 99 YALE L.J. 1109, 1112 (1990).

95. An example of this type of study is the recent work that comparing the use of medicated with non-medicated coronary artery stents for risks, benefits, cost and outcomes of each. *See* Patrick W. Serruys et al., *Percutaneous Coronary Intervention versus Coronary-Artery Bypass Grafting for Severe Coronary Artery Disease*, 360 NEW ENG. J. MED. 961, 961–72 (2009); *see also* Kathy Hardy, *Angioplasty vs. CABG—A Look at Comparative Effectiveness Research*, RADIOLOGY TODAY, June 15,

The 1999 proposed rule provided for consideration of a cost-benefit analysis for new technologies or treatments.[96] This type of analysis requires a society-wide assessment that is broader than the assessment in a cost-effectiveness analysis and can be a far more problematic undertaking. A cost-benefit analysis requires numerous value judgments; the decision maker must determine the worth of a medical intervention to society, in part by comparing its benefit to those provided by other, unrelated expenditures.[97]

A relatively simple example of a cost-benefit analysis would be an examination of whether people over the age of fifty should have organ transplant surgery. Assuming, for purposes of this example, that organ transplants can be physically beneficial and life extending for individual patients, they are arguably cost effective in individual cases.[98] A cost-benefit analysis requires additional assessment, particularly in light of the limited number of organs available for transplant into all potential patients, many of them far younger and healthier than patients over fifty.[99] The classic question that arises in this example is whether we should use a scarce organ for a young person, offering society more healthy, productive years, or use the organ for an older patient, who has already given many productive years to the society and so, from that perspective, might be more deserving.

Contemplation of a refusal of coverage for an individually beneficial medical procedure represents an extraordinarily challenging decision for persons in healthcare management. Advising sick people that they cannot have access to medical care because society does not value their lives sufficiently to pay for that care creates high emotional and psychological costs. It certainly raises both moral and normative issues.[100] This is what is at stake in a cost-benefit analysis of decisions of resource allocation.

4. Using Evidence of Effectiveness in NCDs

Since 2001, CMS has generally abandoned its effort to explicitly consider cost when making NCDs. Instead, it has moved toward using

2009, at 10 (article discussing the results of the study).

96. Medicare Program; Procedures for Making National Coverage Decisions, 64 Fed. Reg. 22,619, 22,619–22,625 (Apr. 27, 1999).

97. *Id.*

98. Fox, *supra* note 34, at 580–82 (discussing the cost-benefit analysis process in the context of Heart Transplantation).

99. *Id.*

100. *See generally* D.J. Hunter, *Rationing Health Care: The Political Perspective*, 51 BR. MED. BULL. 876, 876–84 (1995).

the concepts of evidence-based medicine and comparative effectiveness to assess what a new technology or treatment offers Medicare recipients. In 2003, CMS published a notice of a proposal to revise the process for making NCDs.[101] The purpose was to "clarify the decision-making process and increase the opportunity for public participation."[102] Furthermore, the proposal embodied a new system intended to create a process that would be as efficient as possible, while ensuring that CMS had access to all relevant information for making its decisions.[103] The notice described three types of information to be considered as a basis for NCDs: descriptive information, scientific evidence, and clinical evidence.[104]

CMS determined that, in order to most efficiently generate data of the quality it intends to use for NCDs, it needs to work with the scientific and medical community early in the process of developing a technology for the marketplace.[105] It did this with Implantable Cardiac Defibrillators (ICDs), as described in the case study in Part II.D. The goal to secure the highest quality data also led CMS to seek to clarify the types of evidence it values, the best practices for study design, and the manner in which it ranks the quality of evidence supporting the technology or treatment it is evaluating.[106] CMS plays an active role in the design of studies and collects data from its recipients regarding technology or procedures for which it does not yet have adequate evidence.[107] This active role will likely be enhanced in the future because CMS appears to have been given a role in allocating federal funding for comparative effectiveness research.[108] This funding source is useful because once a new treatment has been approved by CMS, little incentive remains for a manufacturer to finance further studies.

Oddly, CMS has not explicitly stated an intention to undergo comparative effectiveness analysis as part of its own NCDs even though it supports studies that generate the necessary information for doing so. This intention, however, may be implied from language in the 2003

101. Medicare Program; Revised Process for Making Medicare National Coverage Decisions, 68 Fed. Reg. 55,634, 55,634–55,641 (Sept. 26, 2003).

102. *Id.* at 55,634.

103. *Id.*

104. *Id.*

105. *Id.*

106. MEDICARE COVERAGE ADVISORY COMM. OPERATIONS & METHODOLOGY SUBCOMM., CTRS. FOR MEDICARE & MEDICAID SERVS. PROCESS FOR EVALUATION OF EFFECTIVENESS AND COMMITTEE OPERATIONS (2006), *available at* http://www.cms.hhs.gov/FACA/Downloads/recommendations.pdf.

107. *Id.* at 6.

108. FED. COORDINATING COUNCIL FOR COMPARATIVE EFFECTIVENESS RES., DEP'T OF HEALTH & HUMAN SERVS., REPORT TO THE PRESIDENT AND THE CONGRESS 4 (2009) [hereinafter CER REPORT].

notice regarding what type of information CMS considers in making NCDs. CMS specifically asks for evidence showing the magnitude of the medical benefit that is, how "coverage of the item or service will help improve the medical benefit to the target population."[109] If a different treatment were already in use with Medicare recipients for the same diagnosis, the approval of a new treatment, arguably, would only improve the medical benefit for those recipients if it provided something better than what was already available.

By focusing on the quality of evidence concerning new technologies and treatments in making NCDs, CMS enhances the possibility of providing health care that is most helpful to the target population but still has done nothing to rein in out-of-control healthcare spending. CMS puts itself in a position to filter out those expenses for technologies and treatments that are not useful but does nothing to resolve the problem of what to do when a technology or treatment is correctly identified as useful but unreasonable to provide due to cost.

5. How the NCD Process Creates Financial Incentives for Both the Applicants and CMS to Distort Scientific Data

The way CMS uses scientific data, as clarified in the 2003 notice, should have a significant impact on the research goals for those who would seek an NCD approval. First, CMS reserved the right to withhold approval of a proposed treatment or technology based on inadequate evidence. "In the absence of adequate evidence, we may conclude that the item or service is not reasonable and necessary."[110] Given that most medical procedures currently in use have little or no evidence to support their efficacy, such a determination could impose a significantly higher standard for approval of new technologies or treatments than the previous standard. This higher standard, in turn, creates genuine opportunities for CMS to bring about cultural changes regarding adoption of new medical technologies or treatments.[111] This standard makes it imperative for companies seeking approval to provide evidence of efficacy at a level high enough to be considered "adequate" by CMS.

Given the economic importance of a positive NCD to those seeking CMS approval, the new language clarifies the risk calculus for them. While testing beyond what the FDA requires for marketing approval

109. Medicare Program; Revised Process for Making Medicare National Coverage Decisions, 68 Fed. Reg. 55,634, 55,637 (Sept. 26, 2003).

110. *Id.* at 55,636.

111. Peter J. Neumann & Sean R. Tunis, *Medicare and Medical Technology – The Growing Demand for Relevant Outcomes*, 362 NEW ENG. J. MED. 377 (2010).

may expose weaknesses in safety or efficacy of a technology or pharmaceutical, failure to perform the testing may preclude CMS approval altogether. Meaningful comparisons of the efficacy of one treatment or technology with another are difficult without data that does just that, derived from studies designed to make such comparisons. Studies do not routinely compare "apples with apples." For FDA approval, a study is far more likely to compare an apple with no apple at all. The standard tests to show benefit are measured against a baseline of a placebo, which is the most straightforward method for testing a new drug.[112] Such studies are not designed to show the comparative value of the technology or treatment with other technologies or treatments that are available. If one looks at the risks and costs faced by an applicant, there is no reason for a manufacturer to sponsor studies that pit its product against accepted or alternate ones without a specific demand from CMS for such comparative data. On the other hand, proof of cost effectiveness or increased efficacy over current treatments would be highly valuable in addressing cost concerns.

CMS's desire to use accurate evidence for its NCDs is problematic because of cost. Evidence could be presented as part of an application that justifies spending more money than CMS can easily absorb. The higher the standards of scientific integrity CMS claims to follow, the more difficult it becomes to justify its interpretations of data that are not consistent with those standards.

Another problem with the hidden role of cost in this regulatory scheme is that the FDA and CMS approval criteria create an attractive opportunity for applicants to maximize profitability at the cost of patient quality of care. From a profit-maximizing perspective, the ideal study would present just enough evidence to satisfy both the FDA and Medicare standards, but nothing more. The applicant would provide evidence to give proof of efficacy across a broad population, even if the measure of efficacy was somewhat low, rather than designing a study that would pinpoint the smaller number of those for whom the device would be most efficacious. There are no absolute numeric values of efficacy that automatically count as satisfying the "reasonable and necessary" standard of the Medicare Act. An applicant can design a study that is likely to find the amount of effectiveness in a given population that is required to show a technology is reasonable and necessary, while keeping the class of possible users as broadly defined as possible.

This problematic dynamic may well be playing out with some

112. *See* 21 C.F.R. § 314.126 (2010) (describing the acceptable study designs for FDA submissions).

regularity in the NCD process. On the surface, CMS values evidence of a high standard and vigorously promotes its collection. The applicants listen to and work with CMS, and they move together to engage in an efficient approval process. Below the surface, the applicants can design studies calculated to secure approval of the broadest, most profit-generating scope. CMS can then interpret this data so that it appears to justify artificially narrowing its approval, thus saving money. This Article hypothesizes that this is exactly how the process occurs. CMS has developed a way of controlling some aspects of the cost problem, with the most difficult decisions and negotiations being made almost entirely below the surface.

6. Coverage with Limitations: The Current Compromise Between Cost and Evidence

Rather than outright denying applications for NCDs, CMS has a pattern of approving coverage with limitations. Doing this allows CMS to consider the evidence, decide that a new treatment is both reasonable and necessary, and limit the cost of the treatment to the program by giving it to fewer patients than the applicant had hoped. A recent study examined sixty-nine CMS NCDs issued between 1999 and 2003 to assess if CMS decisions were consistent with the quality of the evidence then available.[113] This study concluded that most CMS decisions to cover a technology or treatment were consistent with the quality of the evidence.[114] The more troubling finding (though not noted as such by the authors) was that 61% of all CMS decisions that agreed to cover the technologies or treatments were limited in scope. These NCDs provided coverage with substantial conditions or limiting factors.[115] Even though the study found that the broad decision, whether or not to cover at all, was consistent with the evidence before CMS, it did not examine whether the conditions or limitations were consistent with the evidence.

Given the extraordinary cost of new medical treatments, is it implausible that 61% of all NCDs over a four-year span were limited in scope to save money? It is a significant possibility that this occurs, and evidence of this is presented in the case study discussed in Part II.D. By refraining from denying coverage outright and by remaining flexible in the face of new data, Medicare manages to stave off political problems likely created by an outright denial. To accomplish all of this, CMS

113. Peter J. Neumann et al., *Medicare's National Coverage Decisions, 1999–2003: Quality of Evidence and Review Times*, 24 HEALTH AFF. 243, 243–54 (2005).

114. *Id.* at 243.

115. *Id.* at 246, 252–53.

must behave in a manner that is not transparent, that contravenes its enabling act, and that perpetuates a system distorting the healthcare system by generating suspect NCDs. Given the pressure on CMS to manage cost in this hidden manner, the Medicare Act should be amended to require explicit consideration of cost in making NCDs so that this is no longer even a theoretical risk.

D. A Case Study: High Quality Evidence and Implantable Cardiac Defibrillators

CMS coverage of the Implantable Cardiac Defibrillators (ICD) is a case study that gives concrete examples of how the incentives described *supra* for both CMS and applicants distort the NCD process. It also shows how the current NCD process cannot be used to adequately address the problem of extraordinarily expensive new medical treatments.

An ICD is a small electronic device implanted in a person's body and designed to restart the heart if it fails, much as an external defibrillator does.[116] Simply put, the benefits of the implantable device over the external machine are that it: (1) provides constant monitoring; (2) does not require trained personnel to be operated; and (3) fires immediately when there is a problem, thereby protecting the user from damage caused by any delay in restarting his or her heart. The device became well known when former Vice President Cheney had one implanted during his first term in office.[117]

Initially, CMS approved coverage of ICDs for people who had already suffered a "sudden death" cardiac episode and had been successfully resuscitated.[118] While purchasing and implanting the device was expensive, the covered population was small and the total cost to the Medicare program by 2001 was $1 billion a year, roughly 1%

116. MOSBY'S MEDICAL DICTIONARY (8th ed. 2009) ("[I]mplantable cardioverter-defibrillator (ICD), a surgically implanted electric device that automatically terminates lethal ventricular arrhythmias by delivering low-energy shocks to the heart, restoring proper rhythm when the heart begins beating rapidly or erratically. About the size of an audiotape cassette, the device can be implanted without thoracotomy in many cases. It is attached to the abdomen or chest wall with a wire link to the heart.").

117. Abigail Trafford, *Second Opinion: Implantable Defibrillators*, WASH. POST, July 31, 2001, *available at* http://www.washingtonpost.com/wp-srv/liveonline/01/health/health0731.htm.

118. This was an accepted treatment for these patients, particularly after 1997, when the *New England Journal of Medicine* published a study showing that ICDs worked better than the drugs available at that time. *See* AVID Clinical Trial Ctr., *A Comparison of Antiarrhythmic-Drug Therapy with Implantable Defibrillators in Patients Resuscitated from Near-Fatal Ventricular Arrhythmias*: *The Antiarrhythmics Versus Implantable Defibrillators (AVID) Investigators*, 337 NEW ENG. J. MED. 1576, 1576–83 (1997) (a comparison of antiarrhythmic drug therapy with implantable defibrillators in patients resuscitated from near-fatal ventricular arrhythmias).

of the Medicare annual budget at that time.[119]

By November 2001, CMS was aware that studies sponsored by manufacturers of ICDs were showing that a far broader patient population could benefit from implanting the device and that it would be extremely expensive for Medicare to provide it to such a population. These new potential patients were people who suffered from heart problems but who had not yet suffered a sudden death cardiac episode. The MADIT II trial was a large-scale, multi-hospital study of ICDs sponsored by Guidant, an ICD manufacturer, which included this expanded class of potential patients.[120] It was halted in November 2001 because the data safety monitoring board that oversaw the trial found a large positive effect of the ICD. This made it potentially unethical not to offer the device to all of the people enrolled in both arms of the trial, including those receiving the ICD and those receiving only medications. The positive results of the MADIT II trial were published in the *New England Journal of Medicine* on March 11, 2002.[121] On July 18, 2002, the FDA expanded its approval of the Guidant ICD so that it covered the types of patients identified in the MADIT II study.

By mid-2003, CMS had not expanded its coverage of ICDs to cover patients fitting within the MADIT II criteria. This generated controversy, especially in light of the overall positive reception the trial results had received.[122] Following on the heels of the rapid FDA approval action in July 2002, the American Heart Association consensus guidelines that guide cardiology practice recommended that cardiac surgeons follow the MADIT II criteria when assessing who should have an ICD implanted.[123] In February 2003, the Medicare Coverage Advisory Committee that convened to assist CMS in making the ICD-coverage decision voted unanimously in favor of coverage for the

119. Stephen C. Hammill, *Influence of the Medicare Reimbursement System on ICD Implantation*, 5 CARDIAC ELECTROPHYSIOLOGY REV. 133, 135 (2001).

120. Medscape CRM, *Medicare Panel Recommends Expanded Coverage for ICDs*, MEDSCAPE TODAY, Mar. 21, 2003, http://www.medscape.com/viewarticle/451046 (explaining in detail the structure of the Second Multicenter Automated Defibrillator Implantation Trial).

121. Arthur J. Moss et al., *Prophylactic Implantation on a Defibrillator in Patients with Myocardial Infarction and Reduced Ejection Fraction*, 346 NEW ENG. J. MED. 877, 877, 882 (2002) (for the Multicenter Automatic Defibrillator Implantation Trial II Investigators).

122. Medscape CRM, *CMS Draws Heat as Coverage of MADIT II ICD Decision Draws Near*, MEDSCAPE TODAY, May 23, 2003, http://www.medscape.com/viewarticle/456391 [hereinafter *Medscape Heat*].

123. The full title of the guidelines is the American Heart Association/American College of Cardiology/North American Society of Pacing and Electrophysiology (AHA/ACC/NASPE) Consensus Guidelines. *See* Matthew R. Reynolds & Mark E. Josephson, *MADIT II (Second Multicenter Automated Defibrillator Implantation Trial) Debate: Risk Stratification, Costs, and Public Policy*, 108 AM. HEALTH ASS'N 1779, 1780 (2003).

MADIT II criteria.[124]

On May 15, 2003, Sean Tunis, CMS's medical director at that time, spoke at a public meeting on the subject of CMS's delay in approval for expanded ICD coverage.[125] While he listed some scientific concerns regarding coverage, he clearly stated that the overwhelming problem was "about the money," and that CMS had to "draw a line in the sand" because there is "no wiggle room in the Medicare budget."[126] In a forthright explanation of the problems Medicare faced with new and expensive medical treatments, he said:

> As money goes to higher tech services and newer benefits, we are led in [the] direction of under compensating for primary care, home health care, [and] skilled nursing care. Medicare must avoid this tendency so that these worthwhile services don't get starved as more and more resources are applied to newer, high tech services, especially those that are very expensive and have [only] modest benefits.[127]

Clearly the main point of this speech was that CMS must control the costs of new and expensive medical treatments so that other Medicare programs do not suffer underfunding. When examined in light of Medicare's legal structure, it is unclear what power CMS has to legitimately address any of these concerns. The ICD presented sufficient financial risk to Medicare to make line drawing necessary, if at all possible for it to accomplish. The cost implications of the MADIT II trial were astonishing.[128] If all existing patients with the implicated heart conditions had use for an ICD, it could include an estimated 3 to 5 million patients.[129] Many of these patients were Medicare recipients, and, in addition to the initial cost, an estimated 300,000 additional Medicare patients would require the ICD each year.[130] At a cost of $30,000 a patient for the surgery and device, the initial outlay could

124. *Id.* at 1779.

125. *Medscape Heat*, *supra* note 122.

126. *Id.*

127. *Id.* ("At a free-wheeling CMS issues session at the North American Society of Pacing and Electrophysiology (NASPE) 24th Annual Scientific Sessions, Tunis bluntly told attendees that 'it is about the money.' There is no wiggle room in the Medicare budget, he said, so CMS has drawn a clear line in the sand.").

128. Helen S. Barold, *Using the MADIT II Criteria for Implantable Cardioverter Defibrillators—What is the Role of the Food and Drug Administration Approval?*, 7 CARDIO ELECTROPHYSIOLOGY REV. 443, 446 (2004) ("The results of the MADIT II study have generated a great deal of controversy in the world of electrophysiology. Much of the controversy appears related to the sheer numbers of potential Implantable Cardioverter Defibrillator (ICD) implants and their potential cost to the healthcare system.").

129. *Medscape Heat*, *supra* note 122 (including those with serious coronary heart disease and advanced left ventricular dysfunction).

130. *Id.* (explaining the structure of this study in some detail).

have been as much as $150 billion, more than the entire 2002 Medicare budget, as well as future annual costs of $8 billion a year, 8% of Medicare's annual budget.[131]

Even as CMS expressed concern about cost and delayed issuing an NCD, it was in an awkward position regarding any criticism it could make about the MADIT II trial. CMS had already made clear that it valued evidence of a high caliber and that it preferred to work with potential applicants early in the process, so that it could help ensure that the studies submitted to it were well designed. Consistent with this commitment, CMS and the FDA advised Guidant on how to collect data on safety and efficacy during the MADIT II trial that would serve to satisfy CMS's and the FDA's different approval requirements.[132] Given CMS's early role in the study and the otherwise positive reception for its results, CMS's challenges to the quality of the data were going to be difficult to justify.

From CMS's perspective, one could argue that the overwhelming flaw in the study was that it failed to identify who was most likely to truly benefit from the ICD. The study showed solid evidence of benefit in a small percentage of a broad population when all of the population used the device, but did not give enough information to assess which specific people needed it.[133] Put another way, the data as presented by Guidant showed that a small percentage of a large population would get a positive benefit from having these devices.[134] The data did not give a clear picture of how to identify, in advance, which patients would benefit. If CMS could accurately identify these people, it would save money as well as prevent unnecessary and risky medical procedures for its recipients. Furthermore, the question of how coverage could be structured had been left open until more information had been collected to assist CMS in narrowing the target population. MADIT II did not, by itself, answer this query because it provided insufficient data about subgroups within its subjects.[135]

While it would be unfair to expect a single study to answer all questions one could have, the contemporaneous criticisms of Guidant's study appear to substantiate a claim that it was meant to give little information to guide those making stratification decisions. The clear

131. *Id.*

132. Moss et al., *supra* note 121.

133. *Medscape Heat*, *supra* note 122.

134. Reynolds & Josephson, *supra* note 123, at 1781.

135. *Id.* ("From the outset, there has been concern that compared with current risk-stratification strategies, less selective criteria for ICD implantation could result in many patients receiving ICDs who do not stand to benefit from them, exposing some patients to unnecessary risks and using societal resources less efficiently.").

financial incentive for applicants in the NCD process is to show enough benefit to have coverage be "reasonable and necessary" in the broadest possible group of people. Guidant succeeded in this to such an extraordinary degree with MADIT II as to push CMS into a financial corner.

As an example of study design choices that are consistent with the incentives described here, MADIT II enrolled people with both inducible and noninducible ventricular arrhythmias, but did not test them or sort them into different groups because of this difference. Prior studies had shown that ICDs were effective for people with inducible arrhythmias, but, by lumping both types of patients together, the study did not give clear answers as to ICD usefulness in those with noninducible arrhythmias.[136] This data was also never collected for the control group of the study, that is, the people who did not receive the ICD.[137] CMS wanted this data to help shape its NCD and so both Guidant and CMS tried to interpret the MADIT II data for this purpose.[138] It is difficult to analyze data after a study has been completed and these post hoc studies are not as statistically relevant as the results of the study itself.[139] The two post hoc analyses reached different conclusions, and neither was as valid as other forms of statistical data could be.[140]

CMS issued its NCD for ICDs on June 6, 2003. It expanded the scope of coverage from what it had covered before, but coverage was substantially narrower than the MADIT II criteria. It did not follow its own advisory board recommendation or the FDA marketing approval. Instead, it conducted a post hoc analysis of the MADIT II data and created a stratification strategy that sharply limited the number of potential patients who would qualify for ICDs. The validity of this post hoc analysis was strongly criticized when the NCD was issued. A typical criticism of the coverage policy claimed that it was dependant on CMS's "controversial interpretation [of the MADIT II data] that was widely viewed by the medical community as an arbitrary attempt to reduce the coverage population."[141] Although cost was a problem

136. *Id.* at 1779–80.

137. *Id.* at 1780.

138. *Id.*

139. *Id.*

140. *Id.* ("That these analyses even became necessary in our opinion simply illustrates that the most crucial clinical question to arise from MADIT II (is EP testing necessary?) was inadequately addressed by the design of the study. In retrospect, a study enrolling only noninducible patients might have generated less controversy.").

141. Michael O. Sweeny et al., *Rules of Evidence: CMS and the Primary Prevention of Sudden Cardiac Death in Systolic Heart Failure*, 28 PACE 81, 83 (2005).

openly discussed by Medicare officials, "the internal technology assessment conducted by CMS on MADIT II specifically excluded cost effectiveness studies."[142] This CMS claim, that cost played no factor in its decision, was not credible.[143]

Is it necessary, in light of this history of how the ICD-NCD process occurred, for CMS to change? CMS saved money, protecting Medicare from financial ruin. It has been flexible in its coverage of ICDs since 2003, issuing new, modified NCDs as better data about ideal patient populations has been collected.[144] Patients have access to ICDs, and the United States is doing well in providing access compared to other countries.[145] As described above, the problem is with the process CMS used. The purpose of this case study is to show how the cost of new medical treatments can influence CMS's coverage decisions and the harm that results. There was no transparent, public debate about how much money should be spent on ICDs, nor was there an open discussion about the quality of evidence that should be required before expanding the use of this treatment or to justify paying for it. Instead, the existence of questions about the quality of the evidence was used as an opportunity to justify cost savings for Medicare.

III. COMPARATIVE-EFFECTIVENESS RESEARCH

A discussion about cost and Medicare would be incomplete without some consideration of Comparative Effectiveness Research (CER). CER has been promoted as a way to control the cost of the healthcare system, particularly Medicare,[146] but in truth it is not likely to control cost unless it is coupled with some form of programmatic rationing. On its own, CER can be directly used to guide patient decision-making, without regard for cost. Coupled with policy decisions regarding

142. Reynolds & Josephson, *supra* note 123, at 1783 (referencing Ctrs. for Medicare & Medicaid Services, Decision Memorandum: Implantable Cardioverter Defibrillators, # 00157N (2003)).

143. *Id.* at 1781 ("The result is awkward, with CMS publicly pretending that their decisions are not driven in part by financial motives, and nobody really believing them.").

144. Sweeny et al., *supra* note 141, at 81 (discussing CMS's continuing efforts to correctly identify appropriate ICD recipients).

145. Christopher S. Simpson, *Implantable Cardioverter Defibrillators Work—So Why Aren't We Using Them*?, 177 CAN. MED. ASS'N J. 49, 49 (2007) (discussing utilization).

146. *See, e.g.*, Robert, Steinbrook, *Health Care and the American Recovery and Reinvestment Act*, 360 NEW ENG. J. MED. 1057, 1057 (2009) ("[C]omparative effectiveness studies that directly compare the risks and benefits of different treatments for a particular condition are essential for improving practice and slowing cost escalation."); THE HENRY J. KAISER FAMILY FOUND., EXPLAINING HEALTH REFORM: WHAT IS COMPARATIVE EFFECTIVENESS RESEARCH? 1 (2009), *available at* http://www.kff.org/healthreform/upload/7946.pdf ("Identifying the most effective and efficient interventions has the potential to reduce unnecessary treatments, which in turn, may help lower costs.").

rationing, CER can be used to guide resource allocations, thus allowing finite resources to be spent in a manner that secures the best outcomes for patients in the aggregate. Given the current problems with hidden rationing in Medicare, CER results are at risk of being distorted relied upon as scientific support for what are, in truth, political and societal decisions about healthcare rationing.[147]

Additionally, the usefulness of CER is significantly compromised due to persistent public distrust of its ultimate goals.[148] Currently, the public does not trust healthcare research about effectiveness generated by both private enterprise and the government.[149] There is no clear reason for this public distrust except, perhaps, due to the fear that the research will be used to justify rationing without any public debate.[150] CER is not the same as the rationing decisions that may be made in its name, but this fact is poorly understood. If future CER findings are manipulated by CMS, this will only serve to confirm people's fears and undermine the ability of CER to improve the quality of the healthcare system.

Important for this discussion is the increase in federal funding for CER, and the structure for conducting it. The Federal Coordinating

147. For an excellent discussion of this vulnerability in the context of politics, the healthcare industry and CER, see Susan Bartlett Foote, *How Comparative Effectiveness Can Save Money*, HEALTH CARE COST MONITOR, July 7, 2009, *available at* http://healthcarecostmonitor.thehastingscenter.org/suasanbartlettfoote/how-comparative-effectiveness-research-can-save-money/ ("Comparative effectiveness will not save money unless supporters of value-based care stand up and say—let's not just gather evidence, let's be sure we do not pay for care that is inconsistent with it.").

148. Consider, for example, the November 2009 recommendations about the frequency of mammograms by the United States Preventive Services Task Force and the public response. These recommendations called for mammograms to start at a later age and take place less frequently than had been called for by its previous recommendation from 2002. The new recommendations unleashed a public controversy, with the Secretary of Health and Human Services finally assuring voters that the federal government policies about mammograms would not change as a result of these recommendations. *See* Editorial, *Sebelius: Mammogram Policies Unchanged*, UPI.COM, Nov. 18, 2009, http://www.upi.com/Top_News/US/2009/11/18/Sebelius-Mammogram-policies-unchanged/UPI-18271258591793/ (notably failing to address whether the panel recommendations were actually correct or appropriate); *see also* Roni Caryn Rabin, *Doctor-Patient Divide on Mammograms*, N.Y. TIMES, Feb. 10, 2010, at D7. According to an editorial in the Annals of Internal Medicine from February 2010, doctors are more inclined to accept the new recommendations, implying, arguably, that there is at least some scientific merit to the new recommendations. Editorial, *When Evidence Collides with Anecdote, Politics, and Emotion: Breast Cancer Screening*, 152 ANNALS INTERNAL MED. 531 (2010).

149. NAT'L PUBLIC RADIO ET AL., THE PUBLIC AND THE HEALTH CARE DELIVERY SYSTEM 2 (2009), http://www.npr.org/documents/2009/apr/nprpoll_charts.pdf (reporting poll results showing 72% of Americans think there is insufficient scientific research to show what will work best for patients, and only 55% would trust an independent panel of experts to help make these determinations, with the percentage trusting this panel dropping to 41% if the federal government plays a role in appointing these experts and, even in the face of evidence that a treatment is not as effective as another, 56% think private insurers should be compelled to pay for the less effective treatment).

150. Rush Limbaugh, Transcript, The March to Socialized Medicine Starts in Obama's Porkulus Bill, Feb. 9, 2009, http://www.rushlimbaugh.com/home/daily/site_020909/content/01125111.guest.html (consistently expressing the idea that the purpose of CER is to ration health care).

Council for CER (the Council) was created by federal law in 2009. The Council was terminated under the Patient Protection and Affordable Care Act of 2010,[151] replaced by the Patient Centered Outcomes Research Trust Fund[152] for the support of the Patient Centered Outcomes Research Institute (the Institute). The goals of this Institute appear to be the same as the earlier Council, though the new legislation is far less detailed than the original. The Council appears to have been "the source for the 'death panel' uproar,"[153] which perhaps led to its demise and reconfiguration. The original law creating the Council was explicit with regard to excluding cost from the recommendations the Council could issue based on CER studies as well as severely limiting the force these recommendations could carry. While prohibiting discussion of cost, which one might assume will carry over to the newly formed Institute, may serve to protect CER from political turmoil, it also severely limits CER's ability to reduce the cost of the healthcare system. Part III.B describes the problems of, and limitations with, CER. Finally, Part III.C describes the sources for the high level of public distrust of CER that has become evident since this new language was passed.

A. Federal Law and CER Funding

In February 2009, $1.1 billion in funding for CER was included in the American Recovery and Reinvestment Act of 2009 (ARRA).[154] ARRA also included legislation creating the Federal Coordinating Council for CER (the Coordinating Council), which was meant to oversee the distribution of much of the funding.[155] The proposal to fund CER met some resistance, which continued throughout the debate over the healthcare reform, resulting in the Council being terminated in the new Act and replaced by the Institute. The publically stated concern expressed by some commentators is that CER is a code word for rationing health care, and that the federal government will use CER to dictate the medical care to which people have access.[156] The language

151. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6302, 124 Stat. 119 (2010).

152. § 6301(e)(1), (e)(2), (f).

153. *See* 1 CCH, CCH'S LAW, EXPLANATION AND ANALYSIS OF THE PATIENT PROTECTION AND AFFORDABLE CARE ACT 850 (2010).

154. American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115. *See also* CER REPORT, *supra* note 108, at 11.

155. 42 U.S.C.A. § 299b-8 (West 2010).

156. *See* Colin Hanna, *Rationing Wolves in Public Servants' Clothing*, ROLL CALL, July 6, 2009, *available at* http://www.rollcall.com/news/36488-1.html; *see also* Peter Singer, *Why We Must Ration Health Care*, N.Y. TIMES, July 15, 2009, at MM38, *available at* http://www.nytimes.com/2009/07/19/

of ARRA, as well as subsequent communications from the Coordinating Council, does not substantiate these claims and, in fact, goes to great pains to defuse this type of concern.[157] The Coordinating Council released a report on June 30, 2009, explaining that "[t]he purpose of [CER] is to provide information that helps clinicians and patients choose which option best fits an individual patient's needs and preferences."[158] This information is necessary, the Coordinating Council said, due to "astonishing achievements in biomedical science," leading doctors and patients to a "plethora of choices" when it is often "unclear which therapeutic choices work best for whom, when and in what circumstances."[159]

While the results of CER can be used to justify cost-based decisions, there is nothing in CER itself that directly leads to rationing. Certainly benefits and problems have the potential to arise through the interpretation and use of CER. Perhaps CER and its uses have been conflated in the public's eye, or, of more interest here, perhaps prior use of CER by private and public sector healthcare payers to justify decisions that are motivated by unspoken cost concerns has poisoned the public trust.

Whatever its source, public worry about CER has been expressed in graphic terms. One of the more colorful was the accusation that funding for CER was part of a government goal to create "death panels," where elderly patients would have to appear individually and where a government committee would then vote on their right to continued treatment.[160] There have also been accusations that the Coordinating Council would use newly compelled electronic medical records to track the individual care decisions made by doctors in the country, with power to override any single treatment decision and many other similar claims.[161] No language in ARRA supports any of these claims. In fact,

magazine/19healthcare-t.html?_r=2.

157. CER REPORT, *supra* note 108, at 16 (CER has been defined by the Coordinating Council as "the conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in 'real world' settings. The purpose of this research is to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances.").

158. *Id.* at 3 (containing part of a longer definition of the purpose of the Council's work).

159. *Id.*

160. Limbaugh, *supra* note 150 (quoting Betsy McCaughey, former Lt. Governor of N.Y.).

161. *Id. See also* Kurt Nimmo, *Barney Frank, Eugenics Death Panels, and a Dining Room Table*, FREE REPUBLIC, Aug. 19, 2009, http://www.freerepublic.com/focus/news/2320327/posts (The Council's "purpose is to empower an unelected bureaucracy to make decisions about healthcare rationing that elected politicians are politically unable to make."); Rich Lowery & Robert Costa, *The Rogue, on the Record*, NAT'L REV. ONLINE, Nov. 17, 2009, http://article.nationalreview.com/414954/the-rogue-on-the-

the Coordinating Council went to excessive lengths to make clear that its purpose is to enhance the quality of information that a doctor and patient consider when making individual, patient care decisions.[162] Yet, as of September 2009, 41% of Americans believed that healthcare reform included a panel that would prevent the elderly from obtaining necessary medical care, as described by critics of CER and the Coordinating Council.[163]

CER is especially important because the healthcare system does not currently include any centralized resource allocation system. While there are benefits to allowing autonomous decisions regarding individual healthcare choices, the responsibility for demanding value, minimizing waste, and being responsible about resource uses now rests heavily upon individual patients, the medical establishment, and insurance companies. The information presented by high quality CER is a resource that can guide these individual decisions if the conclusions are trusted. As described below, this trust is not currently assured, and failure to change the system to allow it to flourish may cripple many of the goals of healthcare reform. Medicare, as currently constructed, is a part of this problem, but it can readily become part of its resolution.

B. Problems with CER

CER can be useful, but it is extremely complex and potentially problematic to implement recommendations based on its results. CER's usefulness depends on a fairly sophisticated level of understanding regarding the meaning of its results and how to use that information. It may be that this complexity is what raises such significant public concerns. If so, it is essential to have trusted resources for both

record/rich-lowry-and-robert-costa?page=3 (Sarah Palin describing why she referred to the Council as a "death panel": "While reading that section of the bill, it became so evident that there would be a panel of bureaucrats who would decide on levels of health care, decide on those who are worthy or not worthy of receiving some government-controlled coverage," which would, in turn "lead to harm.").

162. CER REPORT, *supra* note 108, at 59. In its response to the negative public outcries, an interesting notation appears in the minutes of the Coordinating Council's second meeting: "Council members also noted that they had heard, loud and clear, that the Council's governance and processes must be transparent, and that the Council must incorporate input from all stakeholders to gain credibility and build trust." *Id.* This comment makes it clear that trust and credibility are problems here.

163. Opinion Res. Corp., CNN Opinion Research Poll, at 7, Sept. 13, 2009, *available at* http://i2.cdn.turner.com/cnn/2009/images/09/14/rel14b2.pdf. Typical of the incoherency within this debate, the argument has been that the Council, as created in February 2009, would lead to death panels whereas the Poll, given in September 2009, was asking about people's concerns with proposals for future healthcare reform, specifically: "If Obama's plan became law, do you think senior citizens or seriously-ill patients would die because government panels would prevent them from getting the medical treatment they needed?" *Id.* One could argue, then, that it is unclear what, exactly, these fears are even peripherally related to.

communicating and educating. For a sick person, the availability of reliable and unbiased information comparing the available treatments is useful, and, so, from that perspective, it seems strange that the collection of such information would become a lightning rod for political debate. As one conservative commentator put it, "CER is obviously a valuable and time-honored endeavor, and for anyone (conservatives or anyone else) to come out against it would be akin to coming out against babies, or bunnies."[164]

An example of CER's usefulness is a study from 2009 that offered guidance to patients making decisions about heart surgery. This study compared two treatments available for people with serious heart disease: an invasive type of heart surgery as compared to a less invasive implantation of cardiac stents.[165] Comparing the two procedures across a large population of patients, it appeared that if a patient had a stent implanted, she would have a greater risk of needing further surgery.[166] If, on the other hand, the patient had the more invasive heart surgery, she would have a greater risk of suffering serious strokes.[167] Closer analysis of the data implied that if a patient had a more serious form of heart disease, she might not benefit from the stents as much as she would from the surgical procedure.[168] Such information did not present an easy or obvious choice for patients and necessarily required close communication with the treating physician to ascertain the best approach.[169] The CER, however, did add significant information to the decision-making process.

There are limitations to what a healthcare study can be expected to accomplish. Statistics about the efficacy of medical care provide percentages of success, failure, and the risk of side effects in the study population. Because efficacy is rarely proven in 100% of cases, patients who go forward with medical treatment do so with foreknowledge of some risk. The statistics show that the healthcare system consistently both under- and over-treat. A certain number of patients will be given a

164. Posting of DrRich to Better Health, http://www.getbetterhealth.com/who's-against-comparative-effectiveness-research/2009.05.15 (May 15, 2009).

165. *See* Patrick W. Serruys et al., *Percutaneous Coronary Intervention versus Coronary-Artery Bypass Grafting for Severe Coronary Artery Disease*, 360 NEW ENG. J. MED. 961, 961–72 (2009).

166. *Id.* (specifically, an increased risk of needing "revascularization").

167. *Id.*

168. *Id.*

169. Roni Caryn Rabin, *Heart Stents Found as Effective as Bypass for Many Patients*, N.Y. TIMES, Feb. 19, 2009, *available at* http://www.nytimes.com/2009/02/20/health/20heart.html?_r=1&ref=health ("'What they're telling us is that these procedures are similar in many respects,' he added. 'For individual patients, one is often better than the other. For a patient who can have either one, there are pluses or minuses to each one.'" (quoting Dr. L. David Hillis, Chairman of the Dep't of Med. at the Univ. of Tex. Med. Sch. in San Antonio)).

treatment and not benefit and a certain number of patients will suffer side effects. Some unfortunate patients will not have positive effects and will suffer side effects. When research predicts a percentage of "winners" from an intervention, it is known that the balance of that 100% will be "losers" of some sort.

For an example of winners and losers, consider a hypothetical—a simple study of effectiveness for a new antibiotic. If the new antibiotic *A* is 80% effective in a sample population for curing a specific bacterial infection *Z*, then if the same ratio holds true for the general population outside of the study, 20% of the people given the antibiotic will not benefit from it. Since all medical treatment has some risk of a negative side effect or allergy, that 20% will be exposed to this risk of harm without receiving any benefits.

A comparison of the effectiveness of two antibiotics, as is performed in CER, becomes more complex. If research shows that Antibiotic *B* is effective in 20% of a similar sample population for a similar problem as in the original study about *A*, new problems emerge. A simple response to this comparison would be to use *A* and not use *B*, since *B*'s efficacy is much lower than *A*'s. But what if some of the 20% for whom *B* works are the same people who do not receive a benefit from *A*? Presuming CER has not generated a method for absolutely identifying which group a patient belongs in, the risk of using the wrong antibiotic remains.

From a societal perspective, CER presents a different problem. Because of the research, it is known that a predictable amount of waste and some unnecessary exposure to the risks of negative effects will occur when using either antibiotic. Across a population, an antibiotic that has an 80% success rate is clearly better than one with a 20% success rate. Putting that conclusion into a specific policy and choosing *A* over *B*, deprives 20% of the population of a treatment that might work for them. A policy could also be implemented that would provide both *A* and *B*, letting patients decide, but that risks curing far fewer people if many choose what is known, statistically, to be the wrong choice for the population as a whole. Using a broad protocol for all patients based on CER, entrenches the numbers of losers and winners. Failure to continue research in an area after adopting a protocol risks stifling research into new protocols that could improve outcomes. Such a result would not be risked in the absence of a CER-supported protocol. The challenge with the information available from CER is to resist over-simplifying, that is, reaching for an easy decision about medical treatments when the data alone does not justify that response.

The political implications become greater when one adds a cost component to this discussion. Add to the complexity of the decision

about antibiotics *A* and *B* the fact that *B* costs ten, or even one hundred times, more than *A*. Again, the instinct is to choose *A*, but the same problems remain. The cost difference could make a difference in how society views *B*, since it has both a low efficacy across the population and a high overall cost, but it does not change what happens to the 20% for whom *B* would work. This is the point where hidden-cost concerns can be most damaging to the usefulness of CER. The temptation to maximize the dollar value of interventions, while at the same time avoiding the appearance of making difficult allocation decisions, could prevent the system from further probing the potential usefulness of *B*. This can be accomplished by saying that *B* is simply not good enough because it only works in 20% of the patients. While reliable information can be generated by CER, it can then be used to make rigid decisions based on both CER and cost, without a public airing of how cost considerations are taken into account. This appears to be the fear behind the criticisms of CER and is a problem likely to arise in Medicare.

C. Why the Public Mistrusts Data

The difficulties with CER as described above, while challenging, are likely only one reason for the public debate. Those who control data can easily manipulate it, as the public has seen in various contexts in recent years. It would be sensible for this to lead to suspicions about study results. The subtle distortion of data that occurs in the CMS approval process is not likely to be widely understood, and it is hardly fair to place the blame on CMS for the strong opposition to CER.

A significant reason for the public's mistrust lies with the pharmaceutical industry. Research into the efficacy of drugs and medical devices is widely considered unreliable and riddled with scandal, and, as a result, people do not trust pharmaceutical companies or those who regulate them.[170] Proof of "safety and efficacy," as certified by the FDA, is a promise to patients, but it is also a necessary

170. *See* News Release, Harris Interactive, Large Numbers of People Do Not Trust the Institutions They Identify as Most Responsible for Drug Safety (Apr. 25, 2007), http://www.harrisinteractive.com/news/allnewsbydate.asp?NewsID=1216. The poll data on this issue shows, repeatedly, that this distrust is quite strong. A Harris Interactive poll of United States adults, for example, found that

> only 45 percent of people somewhat trust or very strongly trust the U.S. FDA. Only 27 percent of people somewhat or very strongly trust pharmaceutical companies. Only 20 percent of people somewhat or very strongly trust Congress. However, many more people, a 58 percent majority, somewhat or very strongly trust doctors or other professionals who prescribe drugs.

Id. The same poll found that most people do not believe that drug companies will ever release any data about adverse reactions to their drugs.

tool to open the door to the marketplace for drug and device companies. This marketplace focus appears to have influenced both the collection of data and how it is presented to the public.[171] Efficacy, as a concept, is currently tainted in the public's eye by its association with the pharmaceutical industry and the FDA approval process.[172]

The public has seen a number of examples in the press of unreliable behavior by drug companies and researchers relating to the development and use of effectiveness data. One extensively reported story concerned a physician-scientist named Dr. Timothy Kuklo, a military surgeon at Walter Reed Hospital. According to press reports, during his time at the hospital, Dr. Kuklo was alleged to have received payments of more than $850,000 from Medtronic, which manufactures Infuse, a bioengineered bone-growth protein.[173] In addition, he appears to have falsified study results to show that Infuse worked well, published the falsified results in a prestigious journal,[174] listed another researcher as a co-author who had never heard of the project, and failed to disclose his financial conflict of interest to the journal prior to publication.[175] The manufacturers of Celebrex used positive data to support a positive article that was published in the *Journal of the American Medical Association* (JAMA), although they did not include the data from the same study that had less positive results.[176] The manufacturer then submitted the full set of data to the FDA, who found significant problems.[177] The ensuing problems led to a class action securities fraud lawsuit against the manufacturer, as its behavior had caused the price of its securities to decline.[178]

The list of publicly reported types of drug company behavior that reduce public trust is quite extensive. There has been public exposure of "ghost-writing," a practice in which highly regarded scientists sign their

171. MARCIA ANGELL, THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT (2005), *available at* http://www.nybooks.com/articles/archives/2004/jul/15/the-truth-about-the-drug-companies/.

172. Harlan M. Krumholz & Joseph S. Ross, *Relationships with the Drug Industry: More Regulation, Greater Transparency*, 338 BMJ b211 (2009), *available at* http://www.bmj.com/cgi/content/full/338/feb03_2/b211 (analyzing Harris Interactive poll, *supra* note 170, and other studies showing both the distrust and vulnerability of consumers and patients).

173. Barry Meier & Duff Wilson, *Medical School Says Former Army Surgeon Hid Ties to Medtronic*, N.Y. TIMES, July 15, 2009, at B3, *available at* http://www.nytimes.com/2009/07/15/business/15device.html.

174. *Id. See also* Timothy Kuklo, *Recombinant Human Bone Morphogenetic Protein-2 for Grade III Open Segmental Tibial Fractures from Combat Injuries in Iraq*, 90-B J. BONE & JOINT SURG. 1068 (2008) (withdrawn by: J. Scott, *Withdrawal of a Paper*, 91-B J. BONE & JOINT SURG. 285, 286 (2009)).

175. Meier & Wilson, *supra* note 173.

176. Alaska Elec. Pension Fund v. Pharmacia Corp., 554 F.3d 342, 344 (3d Cir. 2009), *cert. denied*, 130 S. Ct. 2401 (2010).

177. *Id.* at 345.

178. *Id.* (discussing at length the data manipulation surrounding Celebrex).

names to articles in medical journals without participating in the studies or writing the articles later attributed to them.[179] Additionally, researchers have not been consistently forthcoming about financial conflicts of interest regarding the subject they are writing about, even when journals require such disclosure as a condition for publication.[180]

With CER, people are frightened by the possibility of the manipulation of effectiveness data to justify rationing health care, but it is the many known and widely publicized instances of data manipulation that have led to this environment of distrust and presumptive illegitimacy. Creating a system for collecting CER that ostensibly protects it from the explicit consideration of cost, as the Coordinating Council legislation does, will not make people trust CER. It will add to the climate of distrust, because people assume cost is an unspoken and powerful part of CER conclusions and recommendations. The current CER system has the potential to create additional layers of opaque, cost-based decision-making that can be added to the current NCD process.

IV. POLITICAL SELF-INTEREST AND MEDICARE

There is a widespread belief that it is politically damaging for government to explicitly limit access to health care in order to save money.[181] This belief may contribute to Congress' tolerance of the current NCD process, where CMS improperly takes cost into account when determining the scope of coverage and does so without transparency.

Congressional tolerance for the current NCD system, though harmful, persists. Given the importance of health care to society[182] and given that

179. Joseph S. Ross et al., *Guest Authorship and Ghostwriting in Publications Related to Rofecoxib: A Case Study of Industry Documents From Rofecoxib Litigation*, 299 JAMA 1800 (2008), *available at* http://jama.ama-assn.org/cgi/content/abstract/299/15/1800 (examining documents that were produced during discovery for a products liability case concerning rofecoxiband that showed the prevalence of ghost writing along with a pattern of keeping this hidden).

180. *See* MERRILL GOOZNER, CTR. FOR SCI. IN THE PUB. INTEREST, UNREVEALED: NON-DISCLOSURE OF CONFLICTS OF INTEREST IN FOUR LEADING MEDICAL AND SCIENTIFIC JOURNALS 2 (2004), *available at* http://www.cspinet.org/new/pdf/unrevealed_final.pdf.

181. In support of this belief, a national poll from October 2009 found that nearly 80% of people polled said they oppose restrictions on access to health care if treatments will not be covered because they are too costly, not essential or have too little chance of success. *See* Gary Langer, *Growing Health Care Concerns Fuel Cautious Support for Change*, ABCNEWS, Oct. 29, 2003, http://abcnews.go.com/images/pdf/935a3HealthCare.pdf.

182. In support of this assertion, a recent poll found that 93% of Americans polled said it was extremely or very important that their healthcare plan cover tests and treatments that they or their doctor thought were necessary. Jeffrey M. Jones, *Majority in U.S. Favors Healthcare Reform This Year*, GALLUP, July 14, 2009, http://www.gallup.com/poll/121664/majority-favors-healthcare-reform-this-year.aspx.

healthcare spending is widely considered to be out of control,[183] it is striking that a more aggressive system for defining public values and allocating spending accordingly in Medicare has not been implemented. Congress should demand that Medicare justify the cost of new medical treatments that it wishes to provide its recipients. The health of the Medicare population should be of paramount concern, and in the face of finite resources, any change in how Medicare funding is allocated should require an explanation as to how the change improves the program. Political self-interest theory presumes that a government official will make choices that maximize the goods he seeks and minimize his harms.[184] Under this theory, Congress must be acting under the belief that advocating for reduced healthcare expenditures would harm this self-interest, and so the underlying truth of the matter needs to be examined. There is substantial criticism of the political self-interest theory that calls into question how accurate the theory is at predicting or describing Congressional decision-making.[185] But, assuming for the sake of argument that the theory is correct, the Oregon healthcare system presents a counter-argument as to the effect of rationing on political support. Oregon has transparent healthcare rationing that is subject to public debate, and supporters of that system do not appear to suffer political penalties.

A. Political Self-Interest: Is Rationing Risky?

In *The Politics of Health Legislation: An Economic Perspective*,[186] Paul Feldstein discusses in detail a theory of how political self-interest functions in healthcare legislation. Feldstein posits that legislators are essentially interested in their own self-interest and that if one can ascertain the relevant types of legislative actions that are good or bad for that self-interest, one can predict how Congress will behave. Central to this premise is that legislators are only concerned with a narrow cost-benefit analysis that pertains to their re-election, rather than a concern over the costs and benefits of legislation to society.[187] This self-interest functions within a political marketplace where political support (campaign contributions, votes and volunteers) is traded for the benefits

183. *Id.* In this same poll, 52% of Americans polled said that controlling cost was the most important goal of healthcare reform. *Id.*

184. *See* discussion *infra* notes 186–187 and accompanying text.

185. *See infra* notes 200–205 and accompanying text.

186. PAUL J. FELDSTEIN, THE POLITICS OF HEALTH LEGISLATION: AN ECONOMIC PERSPECTIVE (3d ed. 2006).

187. *Id.* at 10.

of legislation.[188]

There are two main groups of people who seek to benefit from legislation in this marketplace. Population groups seek wealth transfers.[189] Private sector corporations and industries seek legislation that increases and protects their profitability, and protects them from intrusive regulation.[190] A group needs to be motivated to act, and, if the group is rational, this will occur when the effect of potential legislation is great enough to justify the costs of organizing and participating in the political process.[191] When a situation gives a group a rational motivation to act, the group has developed a "concentrated interest" in the political process.[192] Concentrated interests can be created by both benefits and burdens of legislation and, because of this, a politician must create benefits for the intended group without putting substantial burdens on a different group who would then organize in opposition.[193] Thus, the ideal legislative action creates a highly visible benefit for at least one group and a diffuse set of burdens that do not motivate any other group to oppose it.[194]

Using this theory, Medicare, as currently constructed, can be described as an ideal legislative action because it generates substantial political benefit with minimal risk. First, it provides a large, highly visible benefit to its participants, many of whom would be foreclosed from participation in the private market due to age or pre-existing conditions,[195] and so would otherwise not have health insurance. Second, it provides a benefit to the healthcare industry, whose revenues have increased due to Medicare.[196] The funding of the program is relatively diffuse. Money is primarily provided by people who work and pay taxes,[197] and there are roughly 160 million employed people in the

188. *Id.*

189. *Id.* at 11. For example, the elderly seek the financial benefit from Medicare. *Id.*

190. *Id.*

191. *Id.* Cost is a broad term that includes financial contributions, volunteer efforts, protests, *etc*. The term is used to encompass all of the things one can do to influence the process that requires expending one's resources: time, money, influence, energy, *etc*.

192. *Id.*

193. *Id.* Funding allocations to one program that require taking money from another program can also risk creating a concentrated interest in the group that is losing the benefit of financing. This happens "[w]hen the financial commitments imposed on it [or demanded from it] require cutbacks in other politically popular programs or necessitate a tax increase." *Id.* at 154.

194. *Id.* at 11. The preference for creating diffuse burdens would explain why legislators would rather borrow to fund a program than tax current constituents. The cost is shifted to the distant future.

195. Before Medicare was enacted, people over sixty-five were mostly shut out of the private market for health insurance. Fox, *supra* note 34, at 585.

196. FELDSTEIN, *supra* note 186, at 3.

197. *Id.*

United States sharing this burden.[198] The program shifts resources from these workers to the two groups that benefit. The workers funding Medicare receive a promise that they will benefit in the future as a Medicare beneficiary. The risk of any substantial increase in the cost of this future care is shifted to future generations, who will pay for it with their payroll taxes.[199]

Medicare's structure creates an incentive for Congress to maintain or increase the cost of the program, up to a certain point. The large base of taxpayers who support Medicare can absorb a small rise in the payroll tax without experiencing enough discomfort to justify opposing the program. If this same amount was cut directly from Medicare, both its participants and the companies that benefit from providing healthcare services would be more likely to have a concentrated interest in the legislation, justifying political action. Overt cost control over Medicare will only become politically necessary when the payroll tax is raised high enough to create an incentive for organized political opposition to Medicare. If CMS's current efforts to control costs are sufficient to keep Medicare funding below this level, the efforts successfully protect congressional self-interest. Congress would lack motivation to intrude on CMS's NCD process, even if not properly conducted under the Medicare Act.

The narrow view of Congressional self-interest described here has been challenged,[200] both in terms of the accuracy of its descriptive or predictive claims and in the underlying soundness of its central theme. This theory of self-interest is essentially meant to be descriptive, yet fails to take into account numerous political actions that do not fit its model.[201] For example, there are a number of regulatory regimes for public health and safety that exist, yet, under this theory, they should not because they provide diffuse benefits and concentrated costs.[202] Furthermore, this self-interest theory fails to account for the consistent impact of personal ideology on legislators' voting behavior.[203] Second, there is substantial support for a contrary view of the political system,

198. SOC. SEC. ADMIN., SOCIAL SECURITY: UNDERSTANDING THE BENEFITS 4 (2010), *available at* http://ssa.gov/pubs/10024.html.

199. FELDSTEIN, *supra* note 186, at 154.

200. Jerry L. Mashaw, *Public Law and Public Choice: Critique and Rapprochement, in* RESEARCH HANDBOOK ON PUBLIC CHOICE AND PUBLIC LAW 19 (Daniel A. Farber eds. et al., 2010) (fully discussing political self-interest and its flaws). Repeating here the arguments against the narrow view of Congressional self-interest would be outside the scope of this Article, yet the topic, in all detail, is of great importance to the debate about how to ration health care in the United States system.

201. *Id.* at 25.

202. *Id.*

203. *Id.* (as empirical studies have shown).

one where the shared, communal goal of the political process is to create a collective definition of public values and where Congress is a willing participant.[204] In this view, the work that voters undertake to participate in the system, such as political organization and education, are actually perceived as benefits that people seek, rather than burdens or costs that are only reluctantly undertaken.[205] Increasing public participation in healthcare resource-allocation decisions would increase the opportunity for voters to have this benefit.

B. Oregon: An Example of Political Viability[206]

In 1987, Neil Goldschmidt, the governor of Oregon, appointed a working group to determine what Oregon's Medicaid program should cover.[207] This group made a series of findings,[208] the first being that all Oregon citizens should have access to a basic level of care. Second, it found that there must be a process to define what the basic level of care is, and, further, that this "process must be based on criteria that are publicly debated, reflect a consensus of social values, and consider the good of society as a whole."[209]

The Oregon Health Services Commission (the Commission) was created in 1989[210] to create a list of medical benefits to be included in the "basic" level of care. The Commission crafts this list through a biennial process that "represent[s] an unusual marriage of health services research and deliberative democracy,"[211] including holding an extensive series of public meetings, as well as analyzing scientific

204. *Id.* (citing Arthur Maas, CONGRESS AND THE COMMON GOOD (1983); Cass R. Sunstein, *Interest Groups in American Public Law*, 38 STAN. L. REV. 29 (1985); Cass R. Sunstein, *Legal Interference with Private Preferences*, U. CHI. L. REV. 1129 (1986)).

205. *Id.*

206. Oregon's approach to health care and cost is described in this Article only for the purpose of providing an example of sustained electorate support of a government healthcare system that directly addresses cost. Much more can, and has, been said about Oregon. For an in-depth discussion, see Leonard M. Fleck, *Just Caring: Oregon, Health Care Rationing, and Informed Democratic Deliberation*, 19 J. MED. & PHIL. 367 (1994); Somnath Saha et al., *Giving Teeth to Comparative-Effectiveness Research—The Oregon Experience*, 362 NEW ENG. J. MED. e18 (2010). *See also* RATIONING AMERICA'S MEDICAL CARE: THE OREGON PLAN AND BEYOND (Martin A. Strosberg et al. eds., 1992). For a particularly critical analysis, see Jonathan Oberlander et al., *Rationing Medical Care: Rhetoric and Reality in the Oregon Health Plan*, 164 CAN. MED. ASS'N J. 1583 (2001).

207. OFFICE OF MED. ASSISTANCE PROGRAMS, OR. DEP'T OF HUMAN SERVS., OREGON HEALTH PLAN: A HISTORICAL OVERVIEW 1 (2006), *available at* http://www.oregon.gov/DHS/healthplan/data_pubs/ohpoverview0706.pdf.

208. *Id.*

209. *Id.* at 2.

210. *Id.* at 4.

211. Oberlander et al., *supra* note 206, at 1586.

studies. The Commission's list, and the subsequent limitations on care provided to Oregon Medicaid recipients, has led to substantial controversy on a number of occasions since the first list was implemented in 1993, and yet the system is still intact. For example, the list specifically does not cover diagnostic or curative care for patients who have a 5% or less chance of survival for five years (though it covers palliative care).[212] This means that Oregon does not provide all possible treatment choices to people who are dying and have very little chance to live, which has attracted intense criticism.

This exclusion garnered extensive attention during the illness of Barbara Wagner. Wagner, suffering from a recurrence of her lung cancer in August 2008, was denied coverage for a cancer treatment because it was not included on the list as she had less than a 5% chance of surviving for more than five years. Wagner was offered coverage for palliative care, including, by implication, access to physician-assisted suicide.[213] This struck some as being exceptionally cruel. The decision resulted in immense criticism, particularly on the Internet, where the authors of the list were accused of preferring to kill patients rather than treating them.[214] Shortly after coverage was denied, Wagner received the treatment as a donation from the drug manufacturer.[215] The treatment failed, and Wagner died in October 2008.

Even in the face of this controversy regarding the Commission's specific choices, the process Oregon uses to determine the health care it will cover is tolerated, and perhaps approved of, by its citizens. In 2008, 54% of Oregon residents felt that Oregon was doing a good job in assuring access to health care, an increase of 11% from 2006.[216] There is also evidence that promoting healthcare rationing is not harming political futures there. John Kitzhaber, an emergency medicine specialist and Oregon state senator in 1987, was the person who originally proposed that Oregon ration health care in order to provide basic care to more people. He became Oregon's governor in 1995, after

212. OR. HEALTH SERVS. COMM'N, PRIORITIZED LIST OF HEALTH SERVICES SI-1 (2008), *available at* http://www.oregon.gov/OHPPR/HSC/docs/Jan08Plist_B.pdf.

213. Susan Donaldson James, *Death Drugs Cause Uproar in Oregon: Terminally Ill Denied Drugs for Life, but Can Opt for Suicide*, ABCNEWS, Aug. 6, 2008, http://abcnews.go.com/Health/story?id=5517492&page=1.

214. Jeffrey Lord, *The Ultimate Cost Saver*, THE AM. SPECTATOR, Aug. 18, 2009, http://spectator.org/archives/2009/08/18/the-ultimate-cost-saver.

215. Rick Attig, *Sensationalizing a Sad Case Cheats the Public of Sound Debate*, THE OREGONIAN, Nov. 29, 2008, http://www.oregonlive.com/opinion/index.ssf/2008/11/sensationalizing_a_sad_case_ch.html.

216. Press Release, Or. Dep't of Admin. Servs., State Releases 2008 Population Survey, Feb. 23, 2009, *available at* http://www.oregon.gov/DAS/OPB/docs/PopSurv/2008OPS/OPS_2008_Press_Release.pdf.

the first Oregon list of covered services had been implemented. He served from 1995 to 2003.[217]

V. CHANGING MEDICARE

This Part contains a proposal for congressional amendment of the Medicare Act to allow CMS to explicitly consider cost when making NCDs. This proposal will give CMS both the power to better control cost and the obligation to be forthright as it does so. This change will increase transparency, allow for open debate and hopefully lead to a more mature, informed process that will ultimately be successful in controlling healthcare costs throughout the United States. CMS and Congress have created a process for making NCDs that allows for a high degree of public participation. Cost-based rationing of a new treatment should be debated within this existing process, which only requires minor changes to ensure that the debate takes place in a timely and informed manner.

A. Changing "Reasonable and Necessary"

The original Medicare Act requires CMS to make no payment "for any expenses which are incurred for items and services which are not reasonable and necessary for the diagnosis or treatment of illness or injury."[218] In *Hays v. Sibelius*, a recent federal appellate decision interpreting this language, Judge Tatel, writing for the majority, read this language to mean that "reasonable" is used here as a modifier of "items and services," and not of "expenses."[219] This reading is consistent with the legislative history of the Medicare Act.

Consider the following way of changing this language to allow Medicare to consider cost: "for any expenses *which are unreasonable* and which are incurred for items and services which are not reasonable and necessary for the diagnosis or treatment of illness or injury." The purpose of adding the language "which are unreasonable" as a modifier of "expenses" is to allow CMS to make a full inquiry as to the

217. *See* John Kitzhaber, http://www.johnkitzhaber.com/ (last visited Aug. 30, 2010).

218. 42 U.S.C. § 1395 (2006).

219. Hays v. Sebelius, 589 F.3d 1279, 1282–83 (3d Cir. 2009). This recent appellate decision in the DC Circuit analyzes the language of this section of the Medicare Act. The language of the relevant section of the Medicare Act reads: "no payment may be made . . . for any expenses which are incurred for items and services . . . which are not reasonable and necessary for the diagnosis or treatment of illness or injury." *Id.* at 1280 (quoting § 1395y(a)(1)(A)). The Court stated that Congress could have inserted the word "and" after "services," but chose not to, and thus did not have reasonable as a modifier of "expenses" but instead as a modifier for "items and services." *Id.* at 1282.

reasonableness of an expense in terms of its effect on the cost of Medicare, without impairing its ability to consider whether an item or treatment is reasonable and necessary for the diagnosis or treatment of illness or injury. It is important to restate that, to some degree, CMS already makes the inquiries about reasonable cost envisioned here, and it is impossible to imagine a political situation that would not generate pressure on it to continue doing so. The goal of the statutory change is to empower CMS to create a more transparent, rational, and fair process.

The case study in Part II.D of this Article presents an example of how the proposed statutory change would alter the NCD process. Prior to CMS issuing a new NCD for implantable cardiac defibrillators (ICD), after it received the results of the study calling for an expansion of ICD coverage, the worst-case cost scenario for funding this new NCD was an initial outlay of $150 billion for Medicare, with annual costs of up to $8 billion each year thereafter. Under the proposed Medicare language, this great expense would present a question as to whether it was reasonable for Medicare to spend this money, even if the ICD was "reasonable and necessary for the diagnosis or treatment of illness or injury." The language does not dictate the answer, but rather, allows for the question to be asked openly.

It has been argued that the word "reasonable" in the current Medicare Act should be interpreted to already include what it is reasonable to pay for, at least going so far as to allow CMS the right to consider cost effectiveness of a new treatment.[220] The legislative history discussed in Part II makes it clear that Congress did not envision this. The cost of the healthcare system was not a problem in 1965, and as a result, controlling cost was not a pressing concern that needed to be considered in Medicare's language. Furthermore, it was an anathema to the medical establishment to give the federal government the power to determine cost-worthiness of physician-prescribed treatments.[221] It would not have supported the law without having its autonomy protected, which is what the Medicare Act clearly did.[222]

220. *See* Michael S. Kolber, *Opacity and Cost Effectiveness Analysis in Medicare Coverage Decisions: Health Policy Encounters Administrative Law*, 64 FOOD & DRUG L.J. 515 (2009) (Kolber argues that the language is broad enough to encompass a cost effectiveness analysis). *But see supra* Part II; *Hays*, 589 F.3d at 1282–83 (declining to address the issue of whether CMS may consider cost in its coverage decisions, but making clear that coverage and cost are two separate steps of the coverage process).

221. *Supra* Part II.

222. The language of the law made this position clear. 42 U.S.C. § 1395 (2006) ("Prohibition against any Federal interference . . . Nothing in this subchapter [42 U.S.C. § 1395 *et seq.*] shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided . . . .").

Even if a strained reading of the language could justify allowing a narrow cost effectiveness analysis to be part of an NCD process,[223] this consideration will be insufficient to solve Medicare's problems of cost and lack of transparency. Cost effectiveness analysis is not, by itself, going to stop out-of-control spending on health care. Two questions remain persistently unanswered with even the best cost effectiveness data. First, when is something effective enough to justify paying for it? Second, if inflation of medical costs is controlled, there will be finite resources for Medicare. In the face of finite resources, when are existing medical costs important enough to continue funding, rather than shifting resources to a new, effective treatment? The new language proposed here is meant to encompass the power to answer both of these questions. Furthermore, merely allowing CMS to narrowly consider cost as would occur in this scenario does nothing to compel it to disclose when it has done so, thus failing to improve transparency. If there is political pressure on CMS to hide its cost-based decision-making from the public, only a strong public commitment to transparency will lead to any meaningful change.

B. Changing the NCD Process to Ensure Transparency and Public Debate About Cost

The NCD process was created through a combination of federal law and CMS actions. If Medicare is amended as suggested, minor changes need to be made in the federal law governing this process to incorporate the new role of cost, and to protect the transparency of any cost-based decisions that are made.

The NCD process is controlled by its own federal law, 42 U.S.C. § 1395y(l). The process is exempt from the notice and comment process of the Administrative Procedures Act that would ordinarily apply to a similar agency undertaking.[224] Furthermore, an NCD is not reviewable

223. In Kolber's reading of the Medicare Act, this is as broad a role for cost as he is able to find in the language. While it is debatable as to whether the modern concept of "cost effectiveness," as embodied in the CMS regulations discussed in Part II, even existed in 1965, it may be fair to read "reasonable" to include some ability to exclude wasteful procedures from coverage. The source of the Medicare language, however, is the typical health care insurance policy language of 1965, and, as described in Part II, there are no contemporaneous judicial interpretations of this contract language that support reading this power into this language. In *Dynamic Statutory Interpretation*, Eskridge has a theory that would allow for a changing interpretation of a durable statute like Medicare, and it is persuasive. Problems of legitimacy and transparency still need to be addressed, and that, in turn, seems to call for a more explicit statutory framework for this undertaking than somehow finding that this power has developed, organically, in the Medicare Act.

224. *See* 42 U.S.C. § 1395hh(a)(2) (2006); 42 U.S.C. § 1395ff(f)(1)(A) (2006) (exempting the NCD process from the Administrative Procedure Act, 5 U.S.C. § 553(b)(3)(A) (2006)).

by administrative law judges, who ordinarily have jurisdiction to review individual Medicare coverage denials.[225]

Under 42 U.S.C. § 1395y(l), the language of the first subsection, entitled "(1) Factors and evidence used in making national coverage determinations," states: "The Secretary shall make available to the public the factors considered in making national coverage determinations of whether an item or service is reasonable and necessary."[226] Currently, specific factors are not enumerated in this subsection. This language should be changed to compel the disclosure of cost concerns, thereby encouraging the transparent process called for in this Article, when such concerns are a factor in making an NCD. The first subsection quoted above should be entitled (A) and a new subsection (B) should be inserted, stating: "When cost of a proposed medical treatment is a factor in making a national coverage determination, the Secretary shall, in a timely manner, disclose that this factor is being considered, and, after a national coverage determination is issued, any effect it had on that determination."

Section (l) further delineates certain procedures that must be followed when issuing NCDs, including when CMS must explain its reasoning. The timing of this process could create barriers to encouraging robust public debate about the role cost plays in an NCD. Subsections 3(A) and (B) of Section (l) require that a proposed NCD be made available for a public comment period lasting thirty days.[227] These comments must then be addressed in the final NCD, which must be issued within sixty days of the end of the public comment period.[228] It is only as CMS issues its final decision that Subsection 3(C) requires CMS to "make available to the public the clinical evidence and other data used in making such a decision when the decision differs from the recommendations of the Medicare Coverage Advisory Committee."[229]

Prior to the public comment period, it may be impossible for CMS to know exactly how, or if, its NCD will differ from an Advisory Committee recommendation. However, if the recommendation has already been issued, CMS should know if it intends to re-examine it. If a factor in considering re-examining a recommendation is cost concerns created by the scope of the coverage recommendation, this needs to be made clear in the public notice posted about the proposed NCD. In the case study described in Part II of this Article, the NCD for ICDs was

225. 42 C.F.R. §§ 405.732, 405.860 (2010).

226. 42 U.S.C.A. § 1395y(l)(1) (West 2010).

227. § 1395y(l)(B).

228. § 1395y(l)(C).

229. § 1395y(l)(3)(C)(iii).

issued after the Medicare Coverage Advisory Committee recommended coverage consistent with the FDA marketing approval, and, subsequently, CMS declined to follow this recommendation. It is likely that the difference between the coverage recommended by the Medicare Coverage Advisory Committee and the coverage embodied in the NCD was substantially influenced by cost concerns. The change proposed here would allow the public to comment on cost concerns created by the scope of the recommendation before the final NCD is issued.

Furthermore, before or as the public comment period begins, the public needs access to more information about CMS's decision-making process than may be contained in the text of a proposed NCD. The current language of subsections (3)(A) and (B) call for a public comment period that is triggered by publication of a draft of the proposed NCD. This should be amended to include substantive guidance for CMS as to the type of information it must release in addition to the actual content of the proposed NCD itself so that the public can make informed comments in response to the role cost has played in the draft NCD.

The United States has not grappled with open rationing of health care in this way, and it would be unrealistic to expect the process to occur without error. It should be expected that mistakes and injustices will occur, especially concerning technologies whose future usefulness and cost are fluid and difficult to predict. In anticipation of these problems, Congress should require CMS to revisit NCDs when substantial evidence of error or injustice is presented. To some degree, CMS has shown itself to be open to this, as can be seen from its willingness to modify of its original NCD about ICDs.[230]

VI. CONCLUSION

Nearly a half-century has passed since America created Medicare. Since that time, the cost of medical care has emerged as one of the most challenging problems facing this nation. When Medicare was created, it was structured to protect the physician's power to decide what was in the best interests of the patient, without regard to the potentially ruinous cost to the nation this would create. The nature and culture of the healthcare system has changed dramatically since 1965, yet the Medicare Act has remained chained to an outmoded premise that aggregate medical costs should not be considered when making coverage decisions. This dangerous statutory prohibition has forced the

230. *See supra* Part II.D.

contemporary Medicare program to consider cost as best it can, but in a closeted manner, without the benefit of public debate.

This Article proposed reforming the Medicare Act so that regulators are not only empowered but also compelled to consider the cost of new medical treatments when they make program-wide coverage decisions, and that they be required to disclose how cost factored into these decisions. Consistent with the goals of healthcare reform, these changes will allow Medicare to improve the quality of care its recipients receive, reduce the out-of-control costs of the program, and increase the public's ability to participate in making these difficult decisions. These changes are likely to be politically difficult to achieve, yet the current healthcare crisis and the extraordinary future financial problems require bold change.

The problem of cost does not rest solely within Medicare, and is, instead, widespread throughout the healthcare system. Given the strain on resources created by the ever-increasing cost of funding the system, how could pressure not be widespread? In particular, cost creates powerful pressure on the legal structures that regulate this industry, a pressure that can distort everything from insurance company benefit decisions to recommendations regarding preventive testing. Legal scholars need to do more to analyze the effects of this pressure and to help devise regulatory structures for the new healthcare laws that will enable a more honest, transparent, and effective system. Cost will not disappear, but it needs to be addressed directly. Precedence for this undertaking can be found in the legal literature concerning ERISA preemption from the 1990s, where the cost-saving motives of the insurance industry were openly discussed. This discussion contributed to widespread legal change, including the creation of external review boards and state ombudsman offices as well as the development of patient-protecting Department of Labor regulations for employer-based health insurance benefit disputes. The goal could never be forcing third-party payers to make benefit decisions without an eye on potential costs, but rather to enable patients to have access to the rights guaranteed to them in coverage contracts and the changes focused on this form of empowerment.

The work of academics searching for the North Star to serve as a guide to an ethical, just, and affordable healthcare system is important, and it justifiably occupies much energy. However, the current environment is one where incremental change is likely to remain the norm, and where problems of cost, access, and quality are unlikely to be resolved in one fell swoop. It is in this non-ideal world that the values of transparency, maturity, and honesty need to be defended as these

values are constantly threatened by the problem of cost.