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# Medicare Should, but Cannot, Consider Cost: Legal Impediments to a Sound Policy

JACQUELINE FOX†

## INTRODUCTION

There is much discussion of the political, philosophical and economic issues surrounding how and when to control the cost of Medicare. However, most people are unaware that there are profound legal impediments that must be addressed before any other steps are taken.

Under the enabling statute for Medicare passed in 1965, and all subsequent amendments, it seems clear that Medicare cannot consider the cost of medical care when deciding if a particular treatment will be paid for by Medicare. The Center for Medicare and Medicaid Services (CMS) has historically controlled cost by issuing coverage decisions that have used cost in a covert manner to limit the care provided. The motive for this covert activity can perhaps best be explained by recognizing that CMS functions in a dangerous landscape, one littered with political landmines likely to explode if care is rationed and economic landmines just as likely to explode if care is paid for.

This article discusses in depth the legal issues that CMS, and its reformists, must resolve before any meaningful change is possible. It further suggests that legislative change should come from Congress in two ways. The first is with an explicit statutory grant of power to

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CMS to consider cost-effectiveness of medical technology when making coverage decisions.

It is tempting to follow the lead of many in the area of agency law and argue that CMS should have the power to expand its regulatory reach as circumstances require without need of legislative intervention. As is discussed later in this article, CMS has tried and failed to adopt regulations to accomplish this. While Eskridge and others believe in the theory of expanding agency power and the need for a flexible reading of agency enabling statutes, in the case of Medicare that theory is a poor fit. An agency right that is premised on a strained reading of its statutory enabling language and is in direct conflict with its legislative history is not going to be perceived as politically legitimate in an area as fundamentally complex and morally contested as rationing of healthcare.

The second call for legislative change is to address a more difficult problem than mere cost-effectiveness. Recognizing that some medical technology is both effective and extremely expensive, a system needs to be created for deciding when something is simply too expensive to pay for. Congress once created a process for deciding when to close military bases.<sup>1</sup> A commission was appointed with a grant of power allowing it to determine which bases required closing. That process was created in recognition of the political impossibility of managing these difficult cost-saving measures through the traditional budget process. A similar and ongoing structure should be created for considering Medicare coverage of medical technologies whose projected or actual cost will have a significant impact on the Medicare budget overall.<sup>2</sup>

Health insurance companies in this country have historically applied CMS coverage decisions to their own members. When CMS limits access to care for the elderly, it is in effect limited for all Americans whose insurance

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1. Defense Authorization Amendments and Base Closure and Realignment Act, Pub. L. No. 100-526 §§ 200-209, 102 Stat. 2623 (codified at 10 U.S.C. § 2689 (1988)). This law created a commission to oversee base closings. The commission expired in 1995. See also Edwin R. Render, *The Privatization of A Military Installation: A Misapplication of The Base Closure and Realignment Act*, 44 NAVAL L. REV. 245 (1997) (giving a description of this program).

2. This process would, by definition, be reserved for those technologies that do not create net cost-saving opportunities by replacing current treatments.

companies follow Medicare coverage decisions. This means CMS is currently making broad-reaching resource allocation decisions. It is to everyone's benefit to have a more rational, politically transparent and explicit decision-making process to allocate our resources. Without change to the Medicare statute, that process cannot be developed.

The legal analysis of the Medicare cost issue requires a multifaceted approach. This article considers both the official and unofficial legislative history of the relevant language of the original Medicare Act of 1965. It further examines changes in both medicine and the healthcare system since 1965, attempts made by Congress and Medicare to tackle the problem of cost head on and what courts have done in interpreting the relevant statutory language. Furthermore, the article contains an analysis of what the Supreme Court is likely to do in light of its recent decisions if faced with this issue and what it should do in the same circumstances. Finally, the question as to whether CMS is qualified to make this sort of decision for our society is examined.

Looming over all of this is the question of how best to deal with particularly thorny resource allocation issues in our society. Is this an area where Madisonian democratic principles that would encourage a public and spirited legislative debate simply fail us? It would appear at first glance that this is so. Must agencies move beyond powers expressly given them by Congress because these are areas in which we cannot manage to legislate properly? The author would argue that we must simply try harder to develop imaginative and socially palatable solutions that have a firmer base of political legitimacy. The risk of not doing so is that rationing will continue to occur in an irrational and imprecise way and we will continue to risk waste of scarce resources.

Buried in the recently enacted Medicare Prescription Drug Plan is a small paragraph directing the Secretary of Health and Human Services ("HHS") to make available to the public the factors considered in making national coverage determinations for coverage of Medicare benefits.<sup>3</sup> These determinations are how Medicare often decides the

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3. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 731, 117 Stat. 2066, 2349 (2003).

scope of coverage for expensive new medical technologies. For almost twenty years the Medicare Program has tried to promulgate criteria for these determinations that would include the cost of medical technology when deciding if Medicare will provide coverage for the care.

What Congress has directed HHS to do raises a breadth of issues that need to be critically examined in hopes that HHS can develop criteria that both protect Medicare's financial stability and provide the broadest possible access to health care technology. The effect of this small paragraph in the law should be felt not only by those concerned with health law but also those in agency law, constitutional law and those more broadly concerned with how our government should properly determine how or if we should ration health care and other scarce resources.

By ordering HHS to promulgate explicit criteria, Congress has opened a Pandora's Box. It is likely that HHS cannot promulgate criteria that accurately reflect how they decide about coverage of expensive medical technology or how they should make these decisions. They implicitly consider cost in shaping the coverage of many expensive technologies. This law has the potential to force into the open this implicit process, exposing a problem that has been simmering under cover almost since the beginning of the Medicare program. With this action, Congress may have actually deprived Medicare of the way it has coped with the challenge of cost until now. Once Medicare commits to explicit factors, its decisions will be analyzed to see if it complies with those factors. Litigation challenging the use of those factors will be a logical next step. Implicit cost factors could then be exposed and a Medicare coverage decision overturned by the courts because of them.

#### I. HEART TRANSPLANT COVERAGE: AN EXAMPLE OF THE ROLE OF COST IN COVERAGE DECISIONS

What follows is an example of the use of implicit or covert cost considerations in a Medicare coverage decision. In 1980, Medicare's national office discovered that a local Medicare administrator had been paying for heart transplants performed at Stanford University's medical center in California. The Medicare program was then

administered by the Health Care Financing Administration ("HCFA").<sup>4</sup> HCFA published a notice in the *Federal Register* announcing it would no longer cover heart transplants until further studies produced appropriate criteria. The issues HCFA was concerned about included "patient selection and potential social and economic implications."<sup>5</sup>

Lurking over HCFA's concerns was the previous decade's introduction of the End Stage Renal Disease Program, under which Medicare extended benefits to all Americans suffering from kidney disease who required dialysis or kidney transplants. This program faced rapidly growing costs. Patricia Harris, at this time the Secretary of the Department of Health and Human Services ("DHHS") expressly said cost effectiveness would be taken into consideration by Medicare in making its coverage decision about heart transplants.<sup>6</sup> HCFA paid for a study whose purpose was to assess the criteria described in the *Federal Register* notice. Secretary Harris wanted new technologies generally to be assessed for their social consequences, among other factors.<sup>7</sup> The contract to conduct the study assessing heart transplants was awarded in September of 1981 for the purpose of analyzing "the scientific, economic and ethical consequences of Medicare coverage for heart transplants."<sup>8</sup>

HCFA had every reason to worry about the possible costs of heart transplants. Prior to contracting for this study, its own internal studies had predicted enormous potential costs for heart transplants if they were provided to all potential recipients. Organ transplant recipients require continual care to prevent organ rejection throughout their lifetimes. HCFA generated estimated continuing costs for recipients ranging from \$2500 a year to

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4. Medicare has been administered by a number of different federal offices, the current one being the Centers for Medicare and Medicaid Services, known as "CMS." HCFA was the immediate predecessor of CMS.

5. Exclusion of Heart Transplantation Procedures From Medicare Coverage, 45 Fed.Reg. 52,296, 52,297 (Aug.6, 1980).

6. See Ward Casscells, M.D., *Heart Transplantation: Recent Policy Developments*, 315 NEW ENG. J. MED. 1365 (1986).

7. See R.W. Evans, *Coverage and Reimbursement for Heart Transplantation*, 2 INT'L J. TECH. ASSESSMENT IN HEALTH CARE 425, 425 (1986).

8. *Id.* at 425.

\$15,000 a year per person after surgery costs. The total cost estimate for the program ranged from \$150 million to \$4.5 billion in 1979 dollars.<sup>9</sup>

The HCFA funded study, completed in 1985, revealed a number of possible money-saving features of heart transplants. The lack of suitable organs for transplantation was going to severely limit the hearts available, thus limiting the number of recipients. The lead investigator of the study, Roger Evans, in light of his charge to consider economics, ethics and science, recommended a series of limiting criteria for HCFA's approval for the stated purpose of saving money.<sup>10</sup> His recommendations included difficult criteria for hospitals to meet in order to be considered qualified to perform heart transplants. Criteria for patient selection could almost entirely exclude the Medicare population from access to the procedure by limiting it to people less than sixty-five years of age, among other things.<sup>11</sup> These criteria would serve to minimize the "economic implications of Medicare coverage,"<sup>12</sup> according to Dr. Evans.

After the publication of this study and before Medicare adopted a coverage guideline for heart transplants, Dr. Evans worried that coverage decisions were "under pressure to be converted to allocation and rationing decisions."<sup>13</sup> Meanwhile, there had been a change in presidential administrations and a change in the language used by those at Medicare making these decisions. Retreating from statements of explicit economic concerns, William Roper, director of Medicare in 1986, stated that safety and efficacy were the major concerns for heart transplant coverage and that the "decision was not a cost-driven decision."<sup>14</sup> He also said that cost was an implicit part of every decision Medicare makes, and, in the same interview, spoke of Medicare fears of a repeat of the cost

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9. *See id.* at 430.

10. *See id.* at 435.

11. Medicare coverage begins at age 65 for those who do not qualify earlier because of a disability.

12. Evans, *supra* note 7, at 435.

13. *Id.* at 446.

14. Julie Kosterlitz, *Picking Up The Tab: Medicare Coverage of Heart Transplants*, NAT'L J. 18:30 at 1825, 1827 (1986).

explosion in the End Stage Renal Disease program. This program was by then facing projected annual costs thirty-five times higher than originally estimated.<sup>15</sup> He thought Congress needed to address how Medicare should consider cost.<sup>16</sup>

Ronald Milhorn, a senior administrator with Medicare at that time, interviewed during the research for this paper, made it clear that designing a coverage policy for heart transplants that limited potential costs was a primary goal for Medicare. He also said this directive came from the White House as well as from senior Medicare employees.<sup>17</sup>

By focusing on developing a policy that built on the limited number of hearts available for transplant, the problem becomes a blameless tragedy of access to a scarce resource. This is not to imply that Medicare could have changed the amount of available organs for donation, but rather that they embraced this as a money-saving aspect of organ transplant coverage. With no further explicit mention of economics or cost-effectiveness concerns, HCFA published a notice in the *Federal Register* in April of 1987 that said heart transplants are reasonable and necessary when specific criteria are met.<sup>18</sup> The criteria were the ones recommended by Dr. Evans in 1985 as the best from an economic standpoint, including limiting criteria for transplant center approval and age limits that kept most Medicare recipients from qualifying. The idea is to provide organs to those most likely to receive the greatest benefit from them. It is not based on a finding that heart transplants would be of no benefit to those over age sixty-five.

Recently, Medicare has been in the process of determining coverage criteria for a medical device called a left-ventricle assist device ("L-VAD"). The L-VAD has been in use for some time as a device that helps potential heart transplant recipients survive long enough to receive a

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15. *Id.*

16. *See id.*

17. Interview with Ronald Milhorn in Baltimore, Md. (July 2, 2002). This is one of a series of interviews conducted by the author during the summer of 2002 with people involved in the earliest days of Medicare implementation.

18. Medicare Program; Criteria for Medicare Coverage of Heart Transplants 52 Fed. Reg. 10,935 (Apr. 6, 1987).



heart. This use is known as a “bridge to transplant.” The new approval is for the L-VAD to be used as an end stage therapy, meaning as a treatment for those who do not qualify for a heart transplant. This has the potential to re-open the door to all of the people over age sixty-five who could benefit from some form of a new heart, whether a donated organ or an artificial component, but had been shut out by earlier criteria for heart transplants.

L-VAD technology is merely one example of the expensive technologies on the near horizon. There are other technologies with enormous financial implications that Medicare has to grapple with. Implantable defibrillators, for example, have the potential to cost far more for Medicare than it can easily absorb.<sup>19</sup> As the heart transplant story shows, CMS has not had a consistent perspective on what role cost is allowed to play in Medicare coverage decisions about new or existing medical technology or how that role of cost is implemented. What has occurred in the past is a finagling of coverage decisions by Medicare officials who are implicitly or explicitly concerned with saving money. Cost has and continues to play a significant role, poorly defined and perhaps poorly implemented, and we now have rationing of healthcare by Medicare based solely or in part on the cost of a procedure. This is done by shaping coverage decisions so that medical criteria for when Medicare will pay for a procedure are determined at least in part by a desire to minimize the number of procedures performed, thus saving money.

## II. THE PASSAGE OF THE MEDICARE ACT AND THE ORIGINAL MEANING OF “REASONABLE AND NECESSARY”

This section of this article analyzes the circumstances of the passage of the Medicare Act of 1965 as it relates to the issue of what Medicare covers, specifically the official and unofficial history of the phrase “reasonable and necessary.” That phrase is the statutory language that must be interpreted for all Medicare coverage decisions. It was put in the Medicare Act at the last minute, lifted from an Aetna policy for government employees. This section of

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19. See Mark B. McClellan, M.D. & Sean R. Tunis, M.D., *Medicare Coverage of ICDs*, 352 *NEW ENG. J. MED.* 222 (2005), where the authors discuss how CMS should frame coverage of implantable defibrillators.

this article also describes drafters' concerns about cost, concerns about interference with physicians' rights to practice, and other issues which serve to illuminate what was meant by reasonable and necessary at that time.

This history, both legislative and political, is necessary for the discussion here. It is not widely known and has importance for two reasons. The first is that the relevant language has not changed since the Act was passed in 1965, making its original context important for assessing what it was meant to accomplish. The second is because this history illuminates the political pitfalls still operating for those who would modify Medicare.

The Medicare Act was passed in 1965. This brought health care insurance to Americans over the age of 65. Prior to its passage, most Americans received health insurance from their employers, paid for healthcare themselves or received charity care. Insurers did not want to insure the elderly, who then found it extremely difficult to handle the expenses of any serious illness. The passage of the law was the result of a complex alignment of political forces that had taken almost eighty years to bring together. In 1883, Germany created a universal health plan and was the first modern western society to do so. In the United States there were attempts to have Congress pass legislation providing for universal health coverage as early as 1902. Legislation calling for national health insurance was formally proposed every year from 1939 until 1965.<sup>20</sup> This idea was a plank in numerous political platforms for decades.

There were clear opponents, spearheaded by the American Medical Association.<sup>21</sup> Their primary concern was that government-funded healthcare would become government controlled healthcare. The AMA, reflecting their worry of potential involvement far beyond payment, labeled President Truman's proposals for national health insurance "socialized medicine."<sup>22</sup>

While universal healthcare seemed unlikely to pass, the creation of the social security program opened a door to the

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20. See THEODORE R. MARMOR, *THE POLITICS OF MEDICARE* (2d ed. 2000).

21. See FRANK D. CAMPION, *THE AMA AND US HEALTH POLICY SINCE 1940* 256 (1984).

22. MARMOR, *supra* note 20, at 9.

government providing some sort of health coverage for the elderly, paid for by the social security tax. Older Americans were an easily definable group whose reasons for requiring assistance were straightforward and not related to any personal failure. On average, they had less health insurance coverage, lower incomes and poorer health than younger groups.<sup>23</sup> Another draw for selecting the elderly for a proposed plan was the fact that the group was the one all Americans could look forward to joining. Rather than being a question of us versus them, this presented a plan for the inevitable time when us became them.<sup>24</sup>

President John F. Kennedy ran for election in the late 1950s on a platform that included a Medicare-type program for the elderly. After his election, he failed to move his legislation on this issue through Congress. The AMA had put its considerable weight behind blocking him in this area. His proposal of 1961 was known as the King-Anderson bill. It was narrow in its focus and provided for coverage of ninety days of hospital care and no physician services.

Still trying to move the issue forward, Kennedy gave a speech from Madison Square Garden on the evening of May 20, 1962 on this Medicare-type proposal. It was televised nationally. The AMA responded by renting Madison Square Garden that same night, filing a rebuttal speech among the left over debris of posters, balloons and colored tissue paper. It then purchased time for the next night on NBC and aired their rebuttal nationally at 8 p.m., May 21.<sup>25</sup>

The King-Anderson bill focused on relieving the elderly of specific financial burdens. While the underlying issue was access to healthcare, the bill as proposed did very little to ensure this, with no coverage for the day-to-day expenses of healthcare.<sup>26</sup>

The constant hammering by the AMA was effective in two ways. First, Congress was passing no legislation.

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23. See *id.* at 15. See also Madison Powers, *The Future of Medicare: Some Ethical Reflections on Its Social Purpose*, in *THE ETHICS OF MEDICARE REFORM*, at 6 (2002).

24. See Powers, *supra* note 23, at 10.

25. CAMPION, *supra* note 21, at 264.

26. MARMOR, *supra* note 20, at 49.

Second, relevant here, all proposals were being carefully drafted to avoid the appearance of government interfering in physicians' decisions regarding their patients' care.<sup>27</sup> Wilbur Mills, Chairman of the House of Representatives Ways and Means Committee, was opposed to the King-Anderson bill. He was also a powerful southern Democrat. This gave him the power to prevent the bill from making it out of his committee and it never came to a vote.<sup>28</sup>

Kennedy was assassinated in 1963, bringing his vice-president, Lyndon Baines Johnson, into office as President. President Johnson was an experienced legislator and known for being highly capable in moving legislation through Congress from his time there.<sup>29</sup> He embarked on a plan to pass Kennedy's legislative agenda and used all of his considerable skills and power to get Congress to seriously consider issues they had rejected before.<sup>30</sup> Chairman Mills changed his stance on the King-Anderson bill, allowing extensive hearings to be held in Congress on the issue. There was a presidential election looming and no action was taken on the bill prior to that. Johnson's overwhelming win, garnering two out of every three votes, sent a strong signal to Congress about the popularity of his agenda for social programs.<sup>31</sup>

By early 1965, the King-Anderson bill had enough votes to pass. The issue in both the House and Senate was what the final bill would look like. In December of 1964, (after

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27. The idea of patient autonomy was not a dominant one in the 1950s and 1960s. It would not emerge as such until the 1970s and would then only increase in influence. The concern in this earlier time was protecting the physician's autonomy to practice medicine as he saw fit, without government interference.

28. See MARMOR, *supra* note 20, at 51, 53.

29. See Interview by Joe B. Frantz with Wilbur Mills (Nov. 2, 1971), Wilbur Mills Oral History Interview I (transcript available in the Lyndon Baines Johnson Library and Museum) available at <http://www.lbjlib.utexas.edu/johnson/archives.hom/oralhistory.hom/Mills-w/mills1.pdf> (last visited Apr. 25, 2005) [hereinafter Interview I]; Interview by Michael L. Gillette with Wilbur Mills (Mar. 25, 1987), Wilbur Mills Oral History Interview II (transcript available in the Lyndon Baines Johnson Library and Museum), available at <http://www.lbjlib.utexas.edu/johnson/archives.hom/oralhistory.hom/Mills-w/mills2.pdf> (last visited Apr. 25, 2005).

30. See *id.*

31. See *id.*

the presidential election and Johnson's resounding victory) Mills gave a speech where he worried that there were "discrepancies between popular conceptions of Medicare" and the proposal embodied in the bill still on the table.<sup>32</sup> In an interview given a decade later, Mills explained that Medicare, as initially proposed, would only provide coverage for 25% of a person's medical expenses due to the lack of coverage for physician services and care given outside of a strictly hospital setting. Mills worried that the elderly would do the math and realize there had been a false promise made.<sup>33</sup>

While it appeared that passage of some form of Medicare bill was inevitable, there was an intense debate in Congress. The Republicans and the AMA headed the opposition. Rather than continuing to oppose all coverage, they now proposed a bill for a program that would be means tested, administered by the states and would provide a far richer benefit plan than the King-Anderson proposal.<sup>34</sup> This transformed the debate into one about the scope of coverage Medicare would provide and who would receive the care. This was the problem that Mills was referring to in his speech, how to craft a program that would not disappoint the recipients.

The proposal on the table provided for a catastrophic hospital plan, and closely resembles what became Medicare Part A. But there was the desire to provide a fuller plan, one that would do a "complete job"<sup>35</sup> of providing medical care. This concern led much of the public debate, as recorded in the press and the published legislative history.<sup>36</sup> This is where the power of the AMA strangely impacted on the Medicare program. The AMA worried that providing a minimum of care to all the elderly would not fix the worst problems of the worst off.<sup>37</sup> It was in favor of providing full access to medical care to the truly needy, and

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32. MARMOR, *supra* note 20, at 56.

33. See Interview I, *supra* note 29, at 11. Note the similarity between this concern and arguments made during the recent debate over a Medicare prescription drug benefit.

34. See CAMPION, *supra* note 21, at 257.

35. *Id.*

36. See S. REP. NO. 89-404 (1965), *reprinted in* 1965 U.S.C.C.A.N. 1943.

37. See CAMPION, *supra* note 21, at 53-258.

in its efforts to show how Medicare failed to provide this it highlighted the troubling gaps in the Medicare proposal it opposed. It isn't clear that the AMA actually wanted a program to provide government-sponsored healthcare to anybody, but in its efforts to show the logical flaws in the Medicare bill, the AMA helped turn it into a far more generous entitlement.

Much of Johnson's success in passing Kennedy's legislative agenda came from his ability to utilize the existing power structure in Congress. Mills was a crucial ally in orchestrating how the House dealt with this legislation, particularly when it became a fluid and dramatic drafting and negotiating session.<sup>38</sup> The structure of Congress in the mid-1960s was very different from what it is now in that Congress did not have the expert staff available on its own payroll that it does now. The President tended to allow Congress to have access to the expertise of the different executive branch agencies when relevant legislation was being proposed and drafted. Johnson was extremely generous in this area. He made outright loans of staff. Social Security Administration ("SSA") staffers were assigned to assist Congressional staffers in drafting various Medicare versions and were told that for the duration of the project, their duty would be entirely to Congress.<sup>39</sup>

The last forty-eight hours of the Medicare debate brought together the different concerns of House members in a form also palatable to the Senate.<sup>40</sup> The fundamental change was in adding the benefits that became Medicare Part B. This was the physician services section. Part B would make Medicare a more complete plan, less of an "empty promise." The hospital coverage became Part A. There was no provision made for coverage of preventive care and the premise of Part B, as with A, was to be there for cases of emergency and high costs. The annual deductible for Part B was fifty dollars, which was thought to be enough to pay for four doctor's office visits in any given year. At the time, this was the average cost and

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38. Milhorn Interview, *supra* note 17.

39. *See id.* Milhorn was one of the people assigned by Johnson to draft the Medicare Act and related this story.

40. *See generally* Interview I, *supra* note 29 and MARMOR, *supra* note 20.

average number of office visits in the country.<sup>41</sup> To legislators at that time, the typical office visit was a low-technology encounter involving limited or no tests.<sup>42</sup>

To quiet the AMA and others worried about socialized medicine, the statute was to include a strict statement that government would not interfere with the doctor-patient relationship.<sup>43</sup> The concerns about cost were focused on unscrupulous over-utilization of services and were addressed with provisions for a limited utilization review of the same physician decisions meant to be protected by the statute's language described in the previous paragraph. These provisions for cost control were not the subjects of much debate. They were weak in their structure, conducted by hospital panels made up of the admitting physicians. The fear of government intrusion through this mechanism was minimal.<sup>44</sup>

Part B was introduced with a different financing mechanism than Part A, altering the payment structure of Medicare at the last minute. Part A is financed through a payroll tax, whereas Part B is paid for by the individuals who receive it, usually as a deduction from their social security checks.

Medicare was thus clearly limited by design as to what types of care it provided coverage for. For example, as described above, Medicare did not cover preventive care, such as yearly examinations, and also did not cover eyeglasses.<sup>45</sup>

Within the broad areas that were covered, the specific limitation is as follows: "No payment may be made under part A or part B for any expenses incurred for items or services which . . . are not reasonable and necessary for the

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41. Milhorn, *supra* note 17.

42. See Interview I, *supra* note 29.

43. See 42 U.S.C. §1395 (2002) ("Prohibition against any Federal interference"). "Nothing in this title [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." *Id.*

44. Interview with Marty Svolos, employee of SSA who served on the original Medicare Implementation Task Force, in Baltimore, Md. (July 2, 2002).

45. See Milhorn, *supra* note 17.

diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”<sup>46</sup>

This language remains essentially unchanged from when it was first passed in 1965. It represents the standards that the Centers for Medicare and Medicaid Services (“CMS”), the agency that now administers Medicare, considers when deciding whether or not to cover any given procedure or technology. There has been much written about the history of the Medicare Act but almost nothing has been written about this particular section. A review of the published formal legislative history reveals little about its substantive meaning, but it is enlightening as to meanings it was not meant to convey.

The overriding concerns in the legislative history were to make sure the elderly received a high quality of medical care and that providers were paid generously for providing it. The most striking statement in the legislative history as regards cost and coverage is the statement that the goal of Medicare is to “encourage participating institutions, agencies, and individuals to make the best of modern medicine more readily available to the aged.”<sup>47</sup>

Neither reasonable nor necessary appear in the legislative history in relation to the statute section quoted above. The word “reasonable” was discussed almost entirely as it related to reimbursement rates that Medicare would pay. These were discussed within the context that the rates had to be generous enough. For example, “reasonable” was discussed with regard to physician reimbursement, which, it was said, would be reasonable if rates were aligned with customary charges for similar services by that doctor or other doctors in the community.<sup>48</sup>

At another place in the debate, “reasonable” was used in the context of setting reimbursements to hospitals at the “adequate, normal, reasonable amount so hospitals are not discouraged from treating people with Medicare coverage.”<sup>49</sup> The focus, again, was on a full scope of benefits

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46. 42 U.S.C. § 1395y(a)(1)(A) (2002) (“Exclusions from coverage”).

47. S. REP. NO. 89-404, at 24 (1965), *reprinted in* 1965 U.S.C.C.A.N. 1943, 1965.

48. *Id.* at 7.

49. *Id.* at 27. This concern resulted in vast overpayments to hospitals in the



being available to Medicare beneficiaries. Reimbursement rates for hospitals were to be set to take into account necessary and proper expenses incurred in rendering services, including normal standby costs of equipment. Reasonable costs also included depreciation of buildings and equipment and necessary and proper interest on capital indebtedness.<sup>50</sup>

It was noted that Medicare's payment structure was not intended to reimburse hospitals for charity work, or for treating the uninsured. The understanding was that Medicare and its new companion, Medicaid, would already be taking a large burden of charity care off of hospitals by providing coverage for many of the people who previously required charity and so further financing would be unnecessary.<sup>51</sup> The only language that could be interpreted as functioning to limit what care a Medicare patient could get was in a brief discussion of reasonable and necessary. There, it was stated that Medicare would pay for care "only if it were a reasonable and necessary part of a sick person's treatment," and costs would only be covered "where they contribute meaningfully to the treatment of an illness or injury."<sup>52</sup> The language was not defined or debated further. Finally, it was noted that an assumption underlying the cost estimates of Medicare in 1965 and into the future was that there would be "development of new medical techniques and procedures, with the resultant increased expense."<sup>53</sup>

Because Johnson loaned SSA personnel to Congress to assist in drafting the legislation, these people have a unique perspective on what considerations went into the language that was eventually chosen. After Medicare became a law, it was implemented as part of SSA. Many of those involved in drafting the legislation from SSA then became part of the

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first years of the Medicare program, something that was of great interest during the Carter presidency, see CONGRESSIONAL QUARTERLY, INC., PRESIDENT CARTER: 1978 47 (1979).

50. S. REP. NO. 89-404, at 36, *reprinted in* 1965 U.S.C.C.A.N. 1943, 1977. This payment theory contributed to an enormous boom in hospital building. The reimbursement for standby costs of equipment certainly encouraged hospitals to purchase their own, often underutilized, expensive diagnostic equipment.

51. *See* S. REP. NO. 89-404, at 27, *reprinted in* 1965 U.S.C.C.A.N. 1943, 1978.

52. S. REP. NO. 89-404, at 48, *reprinted in* 1965 U.S.C.C.A.N. 1943, 1989.

53. S. REP. NO. 89-404, at 59, *reprinted in* 1965 U.S.C.C.A.N. 1943, 1999.

original Medicare staff. From recent interviews and correspondence with three of these SSA employees, it has been possible to piece together some of what remained unspoken by Congress on the public record at that time. The three were Marty Svolos, a member of the original Medicare Implementation Task Force, Robert Hoyer, one of the primary drafters of Medicare, and Ronald Milhorn, involved then and also active in national coverage decisions made by Medicare through the 1990s.

From these interviews it is clear that there were concerns about the potential costs of Medicare when it was drafted. The primary concern was that a broadly worded entitlement would lead to abuse in utilization, and this is reflected in parts of the original statute as described earlier. What quickly became the dominant concern after passage of the Medicare Act was the real cost of the care it was promising to cover. In the five years leading up to the passage of the Medicare Act, medical costs had increased at a rate greater than inflation.<sup>54</sup> Yet in the legislative history, in the discussion of the probable cost of the proposed Medicare program, the assumption was made that this rate of increase would not continue.<sup>55</sup> This assumption was not supported by any evidence, but was integral to the funding estimates as to the predicted cost of the program over the first five years of coverage.<sup>56</sup>

Robert Hoyer's recollections about drafting the Medicare Act are illuminating with regard to the use of the "reasonable and necessary" language.

When Chairman Mills surprised everyone and asked us to add physician benefits to the King-Anderson Bill, we wrote the new medical insurance provisions in a new Part B ... As I recall it, the reasonable and necessary provision and other exclusions in §1862 were taken from an Aetna policy that was available to federal employees at the time . . . .<sup>57</sup> It is my impression that [in 1965] neither . . . commercial [insurance companies] or the Blue [Cross Blue Shield plans] paid much attention to the reasonable and necessary exclusions written into their policies. However, the proponents of Medicare were always being called to show that the

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54. See Milhorn Interview, *supra* note 17.

55. See S. REP. NO. 89-404, at 24, *reprinted* in 1965 U.S.C.C.A.N. 1943, 1999.

56. See S. REP. NO. 89-404, at 24, *reprinted* in 1965 U.S.C.C.A.N. 1943, 1999.

57. See also Svolos, *supra* note 44.

program would not flood hospitals with healthy elderly patients and our intention was to provide credible utilization safeguards.<sup>58</sup>

This language was taken from an Aetna policy that the federal government provided for its employees at that time. The relevant passage in the Aetna policy is in the section entitled “Exclusions” and states: “Charges listed on this and the following page are *not allowable*: Charges for services and supplies . . . [n]ot reasonably necessary for treatment of pregnancy, illness, or injury, or to improve the functioning of a malformed body member.”<sup>59</sup>

There was a shift in the language from the Aetna policy to the Medicare Act. Rather than having reasonable be a modifier of necessary (reasonably necessary), it became its own, independent, limiting criteria.<sup>60</sup> The item or service under Medicare must be reasonable as well as necessary, whereas in the Aetna policy it had to be reasonably necessary. This structure has since been used by Medicare to justify some criteria to be considered in making their coverage assessments, as discussed in Part six of this article.

Given that this language came from an Aetna policy, the meaning of reasonable and necessary in the context of private insurance plans at that time is relevant. For Aetna and other insurance companies (including the Blue Cross and Blue Shield plans) “reasonably necessary” was not an effective cost-saving feature of health plans and was not used as one. This can be illustrated by a fairly typical case from that era, *Aetna Life Insurance Company v. Sanders*.<sup>61</sup> In that case, involving surgery as a treatment of obesity, the court was called upon to decide if surgery had been reasonably necessary and whether it was covered under an Aetna health insurance policy. It found the treating

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58. E-mail from Robert Hoyer to Jacqueline Fox (July 2, 2002) (on file with author).

59. Aetna Life & Casualty, Government-Wide Indemnity Benefit Plan: United States Civil Service Commission (as revised January 1, 1966) (on file with author).

60. As described by Robert Hoyer when asked about the difference between the two paragraphs. See e-mail from Robert Hoyer to Jacqueline Fox (Mar. 3, 2003) (on file with author).

61. See *Aetna Life Ins. Co. v. Sanders*, 193 S.E. 2d 173, 127 Ga. App. 352 (1972).

physician's determination of this issue to be dispositive. To quote from the opinion, "The operation in question was recommended and approved by a physician attending the Plaintiff, who determined that it was necessary for the treatment of the disease concerned, as required by the contract."<sup>62</sup>

The courts at the time of the passage of the Medicare Act were very likely to find that a medical treatment that was recommended by a treating physician was presumptively reasonably necessary because the treating physician said it was. The inclusion in the Medicare Act of language strictly prohibiting the government from intruding in the physician/patient relationship<sup>63</sup> could easily be read to encourage and support this judicial line of reasoning and interpretation being applied to the Medicare Act. Since 1965, this situation has dramatically changed in the private sector. The typical health insurance policy now has language that reserves to Aetna (and most other major insurers) the right to be the sole interpreter of what constitutes reasonably necessary (though the term often used now is "medical necessity") and also has language that states this in no way is meant to give an opinion on what is the best medical treatment plan for a patient.

Medicare was drafted to quiet the concerns of those who worried it would not provide high quality care to the elderly, those who worried that physicians would refuse to treat Medicare patients and those who worried that the government would begin to control physicians' treatment decisions. It did a fairly proficient job of calming these worries and, almost immediately after implementation, cost of these generously promised benefits became a constant concern of those running the program.

### III. CHANGES IN MEDICARE AND THE HEALTHCARE MARKETPLACE GENERALLY SINCE 1965

Daniel Callahan, writing in the *New England Journal of Medicine* in 1996, said "[w]e ought to be able to see already that government-provided health care for the elderly cannot remain what it has been in the latter part of

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62. *Id.* at 356.

63.42 U.S.C. § 1395 (2005) ("Prohibition against any Federal interference").

the twentieth century—an open-ended entitlement, provided without regard to cost. Those days are gone forever.”<sup>64</sup> Callahan was writing about the projected increases in the cost of the Medicare program, and whether overt or covert rationing would be the best approach to controlling cost. As this paper has shown, covert rationing has been a part of Medicare’s coverage decisions for some time, but his point still stands.

This section describes the dramatic changes in the health care arena since 1965 and how they impact on Medicare and cost. The marketplace changes have been in the areas of cost, market structure, legal issues and related areas. There have also been substantial changes in the tools we can use to improve a person’s health.<sup>65</sup> What we have the ability to do and what we choose to do are very different and access to health care is a constant, pressing concern.

When Medicare began it quickly became clear that there appeared to be no limit on what you could spend on medical care.<sup>66</sup> The original actuarial projections made in 1965 for the cost of providing Medicare’s benefit package to its members assumed the program would cost \$3.1 billion in 1970. In 1967, the estimate was revised to \$4.4 billion and in 1969, it was revised to \$5 billion.<sup>67</sup> Medicare has continued to increase in cost. With the retirement of the baby-boomer generation, the Medicare population is expected to increase substantially, placing further financial burdens on the system.<sup>68</sup>

From 1966 to 1971, the goal of Medicare was accommodation with American medicine.<sup>69</sup> Many parts of the Medicare statute ended up having an inflationary

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64. Daniel Callahan, *Controlling the Costs of Health Care for the Elderly—Fair Means and Foul*, 335 NEW ENG. J. MED. 744, 746 (1996).

65. See Lawrence O. Gostin, *Securing Health or Just Health Care? The Effect of the Health Care System on the Health of America*, 39 ST. LOUIS U. L.J. 7 (1994-95).

66. Milhorn Interview, *supra* note 17. See also COLLEEN M. FLOOD, INTERNATIONAL HEALTH CARE REFORM: A LEGAL, ECONOMIC AND POLITICAL ANALYSIS 55 (2000).

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

68. See Powers, *supra* note 23, at 9.

69. Theodore R. Marmor & Gary J. McKissick, *Medicare’s Future: Fact, Fiction and Folly*, 26 AM. J.L. & MED. 225, 230 (2000).

impact on medical costs. "Reasonable" costs paid to hospitals, "customary charges" paid to physicians, and the consideration of depreciation and capital costs for development of new medical infrastructure, all encouraged the medical establishment to charge as much as it could and develop as much as it could be reimbursed for.<sup>70</sup> Even after these unintended inflationary reimbursement rules were changed, costs have continued to rise. New technology plays a significant role in increased costs. First, the new is often more expensive than what came before. Second, the new increases treatment options, meaning more things can be done, and billed for, for a patient.

One interesting point is that there is tension between the Food and Drug Administration (the "FDA") and Medicare about new technology. The FDA is responsible for determining if new medical technology is safe and effective. Once the FDA has made a positive determination, CMS faces significant pressure from device manufacturers to find immediately the technology to be reasonable and necessary. A complex battle has been underway for years among the various stakeholders in this system to decide what impact FDA approval should have on Medicare coverage decisions.<sup>71</sup>

CMS has not been consistent about this problem. In various communications to the regional carriers who make the individual coverage decisions and in other public documents, the language "safe and effective" has been used variously as a synonym for "reasonable and necessary" and as part of a definition of the same.<sup>72</sup> An example of this confusion can be found in a notice published in the *Federal Register* in 1987. CMS (then HCFA) stated that a coverage assessment about an item or service would ascertain its safety and effectiveness.<sup>73</sup> In the same publication, CMS said current Medicare manuals provided for coverage of

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70. *Id.* See also FLOOD, *supra* note 66, at 49.

71. Medicare Program; Procedures for Medical Services Coverage Decisions; Request for Comments, 52 Fed. Reg. 15,560 (Apr. 29, 1987).

72. *Id.* For example, see Enclosure 2 to Intermediary Letters 77-4 and 77-5, CCH MEDICARE AND MEDICAID GUIDE, ¶ 28,152, at 10,601 (1976). See also Evans, *supra* note 7, at 428 (describing these criteria in HCFA publications).

73. Medicare Program; Procedures for Medical Services Coverage Decisions; Request for Comments, 52 Fed. Reg. at 15,562.

drugs and biologicals approved by the FDA unless it was designated as not covered by a CMS national decision.<sup>74</sup> This would appear to reserve a right to CMS to come to a contrary decision from the FDA. It would also appear that the standard for their decision would be the same one the FDA had just applied.

In another publication in the *Federal Register*, this one from 1989, CMS said that historically, “reasonable and necessary” had been translated into a test of “whether the service in question is ‘safe’ and ‘effective’ and not ‘experimental,’” quoting from Intermediary Letters sent to regional carriers as guidance for their coverage decisions.<sup>75</sup>

FDA’s positive determination only means that a minimal amount of efficacy has been found. “Safe and effective” does not set a standard for how effective, and does not compare it to other available treatments. An approved drug could be substantially less effective and less safe than one currently on the market and still be approved. There is room for difference in the two standards. If the two processes were conflated, it would make the role of cost in CMS decisions moot, since the FDA’s would be the final word.

A different issue concerns the private sector of health care payers. Private, non-governmental health care payers have undergone substantial structural changes that need to be considered when making generalizations about what needs to be done or what works in controlling health care costs. Two federal laws passed in the early 1970s related to this. The Health Maintenance Organization Act of 1973 (the “HMO Act”)<sup>76</sup> and the Employee Retirement Income Security Act of 1974 (“ERISA”)<sup>77</sup> changed the relationship between the payer and the patient. As described earlier, insurance companies used to have a deferential approach to physician decisions regarding patient care, as did courts.

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74. Medicare Program; Procedures for Medical Services Coverage Decisions; Request for Comments, 52 Fed. Reg. at 15,561.

75. Medicare Program; Criteria and Procedures for Making Medical Services Coverage Decisions that Relate to Health Care Technology, 54 Fed. Reg. 4302, 4304 (Jan. 30, 1989) (quoting from Part A Intermediary Letter 77-4 and Part B Intermediary Letter 77-5 (Jan. 1977)).

76. 42 U.S.C. §§ 300e *et seq.* (2004).

77. 29 U.S.C. §§ 1001 *et seq.* (2004).

Perhaps in part due to this deference, care costs increased. With the steady and expensive surge in care, payers looked for ways to reign in utilization of health care services. These two laws made that easier. The HMO Act “allowed the formation of HMOs that assume financial risks for the provision of health care services.”<sup>78</sup> A key aspect of HMOs is that “there must be rationing and an inducement to ration” to function properly.<sup>79</sup> Contracts between HMOs and their physician employees offer incentives to ensure limited utilization of expensive procedures.

The second law, ERISA, was written in large part to protect employees’ pensions and other benefits from unethical employers. It imposes a limited fiduciary obligation on employers in their role as protectors or managers of benefits, including pension funds. Employees have a right to sue employers under ERISA in federal court for benefits they are being denied, such as disability or pension funds. They can receive attorney’s fees and the benefit being sought.<sup>80</sup> Most state laws that regulate ERISA benefits are preempted by the federal law and regulations, as are state causes of action against employers for their actions regarding ERISA benefits.<sup>81</sup> Health benefits provided by employers are included under ERISA.

The preemption of state law and the limits of recovery under a federal ERISA action shifted the financial risk for health care payers. Plaintiffs cannot recover damages for any harm caused by a denial of benefits in an ERISA plan. At most they can recover the cost of the denied benefit.

A classic example of the ERISA preemption at work is the case of Florence Corcoran.<sup>82</sup> Corcoran was a pregnant woman in Louisiana in 1989. She received health benefits through her employer. Near her delivery date, her doctor ordered her hospitalization in order to provide twenty-four hour monitoring for her distressed fetus. Coverage for this was denied and instead she was approved for ten hours of daily monitoring at home. She accepted the ten hours of

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78. *Pegram v. Herdrich*, 530 U.S. 211, 233 (2000).

79. *Id.* at 221.

80. 29 U.S.C. § 1001.

81. 29 U.S.C. § 1144(a).

82. *Corcoran v. United Healthcare, Inc.*, 965 F.2d 1321 (5th Cir. 1992).



monitoring. The fetus then died during the other fourteen hours of the day. Corcoran's earlier pregnancy required the exact same monitoring; she was hospitalized that time and the baby was delivered by emergency caesarian section after suffering fetal distress. That baby survived.

These facts appear to assert a straightforward claim for liability against the payer, but for ERISA. The court in *Corcoran* interpreted the ERISA preemption broadly, as the Supreme Court had instructed in an ERISA case from 1990 that said, "[t]he preemption clause is conspicuous for its breadth."<sup>83</sup> The *Corcoran* court conceded "[t]he acknowledged absence of a remedy under ERISA's civil enforcement scheme for medical malpractice committed in connection with a plan benefit determination."<sup>84</sup> Absent Congressional action, the absence of a remedy remains. For a payer in an ERISA plan and/or an HMO, the financial risk of denying coverage is often less than the financial risk of paying for a treatment. While CMS is also not vulnerable to malpractice suits for its decisions, there are differences between Medicare and non-governmental payers that make this type of risk assessment practical for private sector payers and not for CMS.

When care is denied, there is a risk that a problem might develop as a result of the denied care that would prove to be more expensive to treat, resulting in a net loss for the insurer. One risk that needs to be balanced, then, is the eventual cost of foregoing needed medical care. Non-governmental payers rarely have to shoulder this for two reasons. First, there is a constant migration of members among different health care plans. It would be rare for a person to have one company's coverage throughout his or her working life.<sup>85</sup> Second, due to the existence of Medicare, these payers do not have to bear the risk of problems that arise in later life. At age sixty-five, their member population will leave them, taking along any possible costs of their increased ill health due to earlier denied care.<sup>86</sup>

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83. *FMC Corp. v. Holliday*, 498 U.S. 52, 58 (1990).

84. 965 F.2d at 1333.

85. See Madison Powers, *Managed Care: How Economic Incentive Reforms Went Wrong*, KENNEDY INST. ETHICS J. 353, 355-57 (1997).

86. *Id.* at 358-59.

The long-term benefits of interventions are not realized predictably by non-government payers. The benefits of early interventions that impact the quality of later life accrue to Medicare, not to the company paying for them. These interventions are a poor investment from the perspective of an organization's assessment of its expected risks and benefits. The benefits of intervention that might become clear in a decade are also not necessarily going to accrue to the non-government payer.

For payers who are for-profit corporations whose stock is publicly traded, the risk-benefit analysis is even further removed from Medicare's. Quarterly reports, required to be filed under securities laws, need to list salient details about cash reserves and other numbers indicative of a company's financial performance. These reports often have a direct impact on stock market values of a company's shares. This creates an entirely different incentive structure for these corporations, as they need to gage the impact of payments and denials on their quarterly reports. This creates a motive to deny coverage of an expensive procedure late in a quarter in order to increase the cash on hand, while the same procedure might be approved at a better time in the fiscal year.

The point of these comparisons between Medicare and non-government plans is not to condemn either side. The point is, rather, that techniques used by these payers are not readily transferable to the Medicare system. The risk-benefit analysis is different and needs to be taken into account when assessing the usefulness of a given scheme.

Managed care is a structure for providing health care where an insurer "attempts to influence the cost, volume, and quality of health services supplied and/or recommended by health care providers."<sup>87</sup> As managed care flooded the American marketplace in the 1990s, there appeared to be great cost-saving benefits. The rate of medical inflation slowed from 1990-1995, but then began to rise again.<sup>88</sup> At the same time, the public reacted strongly against the more draconian limits of managed care. During the late 1990s, numerous bills were introduced in Congress to prohibit insurance companies from making specific types of

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87. FLOOD, *supra* note 66, at 8.

88. *Id.* at 59.

denials.<sup>89</sup> Mandatory coverage for two days of hospitalization for a mother after a vaginal delivery was put in place after some HMOs were reported to have been sending mothers home within eight hours of giving birth. Mandatory coverage for breast reconstruction after mastectomy was another example of a federal limit on trends in managed care.

There has been a retreat away from managed care in the first half of this decade. The Federal Department of Labor created regulations under ERISA that have given plan members significant powers to appeal denials in a timely and effective manner. Consumers are reported to have gotten increasingly sophisticated about the importance of appeals in health care determinations. All of this increases the already high costs of administering managed care plans.

Medicare has also had an impact on changes in the non-government payer arena. Generally, other payers follow CMS's coverage decisions. If a procedure or technology is paid for by Medicare, or denied by Medicare, that usually represents the final word for non-governmental payers in the country.<sup>90</sup> The importance of CMS coverage decisions is hard to exaggerate, as they have the de facto power to deny access to most Americans. Thus the criteria used to make these decisions resonate beyond the Medicare population, making it immediately relevant to everyone else. Was Medicare to deny coverage of an effective new technology due in large part to its cost, that same denial, judging by past patterns, would most likely result in members of for-profit insurance plans being denied access to the same, no matter how much they pay for coverage. In other words, due to the influence of CMS coverage decisions on other insurers, there is a risk of cost-based rationing being implemented across the entire American population with no or limited benefit to the overall population.

An example of CMS-influenced rationing of health care happened in the heart transplant case described earlier in this article. Medicare took a long time to develop coverage criteria. During that time, non-governmental payers began to cover heart transplants with generous benefits. Once

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89. *Id.*

90. Evans, *supra* note 7, at 438.

Medicare implemented its criteria, that criteria became the standard applied by other payers. A hospital's transplant center that was not certified by Medicare to perform heart transplants was highly unlikely to be reimbursed by any other payer for performing a heart transplant on one of their beneficiaries. The cost criteria hidden within Medicare's decision controlled much of the country's access to heart transplants.<sup>91</sup>

#### IV. CONGRESSIONAL ATTEMPTS TO CONTROL MEDICARE COSTS

The issue facing Medicare is whether it may consider cost in making coverage decisions, absent any direct guidance from Congress. Given the increase in Medicare's cost since the program's inception, it is important to consider what Congress has already done about it and why it hasn't given CMS explicit guidance about cost.

This section examines different legislative proposals in an effort both to explicate the dynamics of this issue and to show more broadly what Congress has done here. An overriding principle to keep in mind while considering this is in a quote from a former long-term CMS employee: "The third rail of Medicare politics was limiting necessary care. Touch it and die."<sup>92</sup>

The first Congressional action examined here is a Senate Finance Committee Report on Medicare costs from 1970 (the "Finance Committee").<sup>93</sup> This report proposed legislation to control Medicare costs. The proposed legislation is then compared with the enacted legislation to see which cost controls were politically palatable at that time. The second concerns legislation proposed by President Carter for the purpose of limiting the inflation rate of hospital costs. Congress reacted vehemently against this. The third is the prospective payment legislation that was passed in the 1980s.

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91. See M.F. Baldwin, *Heart Transplant Centers Must Meet Volume Criteria*, MODERN HEALTHCARE, Nov. 7, 1986, at 36-37 (discussion about implementation of Medicare's coverage criteria).

92. Milhorn Interview, *supra* note 17.

93. STAFF OF SENATE FINANCE COMMITTEE, REPORT ON MEDICARE PROBLEMS, S. REP. NO. 91-1431, at 46 (1970).

In 1970, the Senate Finance Committee released a report on Medicare costs. The report was based on information gathered during extensive hearings on this issue conducted by the Senate Subcommittee on Medicare and Medicaid. In the report, the increase in Medicare costs was attributed to two problems. The first was the cost of each separate unit of covered care. The second was the increase in the number of services provided to members of Medicare. The Finance Committee observed that as Medicare was then structured, there was little incentive for providers to contain costs or to produce services in the most efficient or effective manner.<sup>94</sup> To fix this, the Finance Committee proposed a prospective payment system, with rates set in advance of treatment.

The second problem was approached differently. The concern was caused by a number of witnesses who "testified that a significant number of the health services provided under Medicare . . . are in excess of those which would be found medically necessary."<sup>95</sup> The unnecessary care was considered problematic both because of its cost and its predictable negative effect on those receiving it.

The report based all of its recommendations on the underlying premise that to rid the system of care that was not necessary would solve the financial problem of Medicare's increasing cost. In fact, studies have since shown that increased utilization, by itself, has "played a small role in driving up Medicare's costs."<sup>96</sup> Nevertheless, at the time, the recommendation was for a much more rigorous utilization review process and for a restructuring of Medicare to make it more closely resemble HMOs then popular in California. As discussed earlier in this paper, it is now commonly accepted that one principle reason for having increased management of care, including with HMOs, is to ration care, but that was not expressly stated by the Senate Finance Committee.

To increase the effectiveness of utilization review, the Senate Finance Committee proposed the creation of Professional Standards Review Organizations ("PSROs").

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94. *Id.* at 118.

95. *Id.* at 150.

96. MARMOR, *supra* note 20, at 108 (citation omitted).

Ideally, these groups would develop adequate regional norms of care and would apply them in assessing utilization in individual circumstances. PSROs would determine medical necessity of a treatment and would encourage the use of least costly treatments and least costly sites for care for a particular patient.<sup>97</sup> PSROs would review provider records to see where patterns of inappropriate care were occurring. The success of PSROs would be based, in some part, on whether their denial rates were as high as other PSROs. PSROs would be vulnerable to financial penalties if they were not maintaining adequate denial rates.<sup>98</sup> Under this proposal, physicians who treated Medicare patients could be liable for varying degrees of sanctions for routinely exceeding the PSRO norms of care. There was also a proposal for a demonstration project where a PSRO would underwrite all care for the Medicare population in its geographic area. It would be paid on a capitated basis. That is, it would be paid a set amount per person to provide all necessary care.

The goal of all of these proposals was to create an environment where “physicians involved would have economic incentives to practice efficiently and effectively.”<sup>99</sup>

The merits of different parts of this proposal can be argued with substantial merits on either side. The point here, however, is to compare this proposal with what became the actual PSRO law.<sup>100</sup> The PSRO law gave PSROs responsibility for determining medical necessity of care. This included determining whether the care could be given in a less expensive environment.<sup>101</sup> It did not include the power to determine whether there was a less expensive treatment available, as had been proposed by the Senate Finance Committee. The PSROs had no financial incentives to deny care and had no role in determining norms of care. They were given an additional role not envisioned by the Senate Finance Committee, which was to ensure the

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97. S. REP. NO. 91-1431, at 157.

98. *Id.*

99. *Id.* at 164.

100. Professional Standards Review, Pub. L. No. 92-603, 86 Stat. 1329, 1429-30 (1972) (amending Title XI, § 1151 of the Social Security Act).

101. 42 U.S.C. § 1320c-3(a)(1)(A) and (C) (2005).

quality of care provided to beneficiaries met "professionally recognized standards of health care."<sup>102</sup>

The proposed demonstration project did not occur. The PSRO law, as finally enacted, did not result in savings.<sup>103</sup> It is not clear from the legislative history what led to the changes from the proposed law to the one that passed, but it isn't hard to guess what the concerns of Congress were.

The pressure on Congress to stay away from certain forms of health care reform is illustrated in an event from the Carter presidency in the late 1970s. According to the Congressional Research Service, from the period of 1950 to 1978, health care costs in the United States had increased eleven fold, had increased four fold since 1963, and had doubled since 1972.<sup>104</sup>

President Carter assessed the health care system as a failure on many levels. In his book *Keeping Faith*, published in 1982, he described it this way: "Although American medical skill is among the best in the world, we have an abominable system in this country for the delivery of health care, with gross inequities . . . and profiteering by many hospitals . . ." <sup>105</sup> His analysis was that the system created numerous inefficiencies, particularly in the area of unnecessary hospital facilities and underutilized equipment.<sup>106</sup> In fact, the breadth of Medicare benefits and the "reasonable cost" reimbursements had combined to eliminate price competition to control hospital costs, causing inflation.<sup>107</sup> In 1977 the Carter Administration proposed guidelines for the purpose of eliminating the underused beds and facilities. This proposal "set off an

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102. 42 U.S.C. § 1320c-3(a)(1)(B).

103. See Stuart H. Altman & Harvey M. Sapolsky, *Preface*, in *FEDERAL HEALTH PROGRAMS: PROBLEMS AND PROSPECTS* at vii, xiv (Stuart H. Altman & Harvey M. Sapolsky, eds., 1981). See also David E. Berman & Paul M. Gertman, *Cost Containment and Quality Assurance: The Potential and Performance of the Professional Standard Review Organization Program*, in *FEDERAL HEALTH PROGRAMS*, *supra*, at 42.

104. CONGRESSIONAL QUARTERLY, INC., *supra* note 49, at 47.

105. JIMMY CARTER, *KEEPING FAITH* 85 (1982).

106. *Id.*

107. Stephen M. Weiner, *Paying for Hospital Services under Medicare: Can We Control Hospital Costs?*, in *FEDERAL HEALTH PROGRAMS*, *supra* note 103, at 135, 137-39.

avalanche of protests."<sup>108</sup> The protest letters sent to Congress had a substantial impact. These letters were apparently orchestrated by the hospital industry, but still reflected enough public concern to be effective.

In 1979, Carter proposed a hospital cost containment bill.<sup>109</sup> It suffered a resounding defeat. The rhetoric in Congress was sharp, including by prominent Democrats, those in the President's own party. Industry executives and physicians testified that Carter's plan would lead to rationing and would inhibit the development of life-saving technology. During the House debates, Representative Phil Gramm (then a Democrat from Texas) said "[p]eople are going to die" if the bill was enacted. According to the *Congressional Quarterly*, this "touched perhaps on the most controversial, underlying issue."<sup>110</sup> Carter, observing gross inequities and inefficiencies, wanted to increase access to health care. He proposed legislation to accomplish some of this and did not succeed due to the perception that he was taking access away from the people, threatening both their lives and the future of American medicine. Clearly, he had trod upon dangerous ground in American politics.

In 1983, Congress created a prospective payment system.<sup>111</sup> An independent commission was established as part of this system. The Commission, known as the Prospective Payment Assessment Commission, was given the explicit authority to consider and assess safety, efficacy and cost-effectiveness of new and currently in use medical procedures and technology. This was to be done as part of making recommendations as to how much should be paid for various procedures.<sup>112</sup> The prospective payment system is not a part of a medical necessity decision-making process. Instead, Congress created a two-step approach still in effect today. The first step is coverage, determining whether

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108. CONGRESSIONAL QUARTERLY, INC., *supra* note 49, at 47.

109. H.R. 2626, 96th Cong. (1979).

110. CONGRESSIONAL QUARTERLY, INC., PRESIDENT CARTER: 1979 75 (1980) (rejection by House of Representatives of President Carter's Hospital Control Plan).

111. Social Security Amendments of 1983, Pub. L. No. 98-21, 97 Stat. 65 (1983).

112. Institute of Medicine, *The Scope of U.S. Medical Technology Assessment*, 2 ASSESSING MED. TECH. 42 (1985).



something is reasonable and necessary. The second step is to determine the reimbursement rate, that is, how much Medicare will pay for the care to be provided to patients.

A focus on reducing costs by challenging provider reimbursement is a safer political tack to take.<sup>113</sup> There is still a risk of patients arguing that payment can cause a reduction in care, but it is a more attenuated argument to make. The program was based on diagnosis-related groups ("DRGs"). Medicare would pay fixed rates based on the diagnosis rather than on what actually occurred in the treatment of a specific patient.<sup>114</sup> This type of payment method was first used for hospitals and was extended to physician services in 1989. It was couched in "technocratic garb" to "keep disputes over cost control out of the political process."<sup>115</sup>

In effect, DRGs put a cap on treatment costs for a specific diagnosis putting pressure on the provider to use resources efficiently. This shift to a two-part system (coverage then cost) with CMS exerting tremendous control over what the cost would be introduced what could be considered a "new regulatory regime" into Medicare.<sup>116</sup> From 1985 to 1990, Medicare's share of national hospital expenditures was reduced by 2.8% and Medicare expenses per member grew more slowly than private insurers during the same time period.<sup>117</sup> This would imply some success, and of course one cannot know what would have happened in the absence of this program's enactment.

There have been other proposals debated. One, the disastrous Medicare Catastrophic Coverage Act of 1988 ("MCCA") was passed and repealed in the time between the passage of the prospective payment system for hospitals and the one for physician services. This Act greatly expanded Medicare's coverage, with added benefits for prescription drugs and preventive care. It did not cover extended nursing home stays. It also incorporated a higher Part B premium for those with greater wealth, introducing

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113. See generally FEDERAL HEALTH PROGRAMS, *supra* note 103.

114. MARMOR, *supra* note 20, at 109.

115. *Id.*

116. *Id.* at 108.

117. *Id.* at 110.

a progressive payment structure not seen in Medicare before. MCCA was reviled by organizations representing the elderly and the law was repealed within two years of its passage.<sup>118</sup>

Congress has tried different approaches to controlling Medicare's cost. The prospective payment system appears to be the most politically acceptable so far. The new Medicare Prescription Drug, Improvement, and Modernization Act of 2003<sup>119</sup> has yet to be fully implemented. It remains to be seen how acceptable it will be to the vocal and active Medicare population. The law is lengthy and complex, making it difficult to gauge its societal impact in advance.

#### V. WHAT CMS WANTS: THE SPECIFIC ROLE OF COST

What does CMS want? In determining the proper role of cost in CMS coverage decisions, CMS's concerns and priorities in this area are relevant. This section examines CMS's proposed criteria for making coverage decisions and criticisms this process has generated. It also highlights some problems with concepts CMS has embraced in furtherance of its goals.

A good starting point is the published proposed criteria for making national coverage decisions. These were done in three different publications in the *Federal Register*. The first proposed rule was published in 1989. The stated issue was to establish criteria and procedures for CMS (then HCFA) decisions about which health care technologies could be considered reasonable and necessary.<sup>120</sup> The rule was published after implementation of the prospective payment system and makes it expressly clear that these decisions would determine coverage, as opposed to payment for services. Coverage comes first in the two-step process. The proposed rule puts cost up front by making cost-effectiveness the first explicitly listed criteria for coverage

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118. *Id.* at 112.

119. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

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

decisions. In fact, cost-effectiveness is the only criteria described in the first section of the publication.

In this publication, CMS gives cost as one of the three reasons for considering an issue for a possible national coverage decision. "Health and safety concerns" is another, and the third, possible over-utilization or abuse, is in some regards a combination of the first two. It certainly has a large cost-conscious component.<sup>121</sup> The regulation then lists eight criteria considered by HCFA in determining if a national coverage decision should be made. Any one of these eight is sufficient, by itself. Number four is "the service is likely to represent a significant expense to the Medicare program."<sup>122</sup>

It is noteworthy that in the proposed regulation, CMS's historical description of its national coverage decision-making process appears to be inaccurate. Part one of this paper describes a process regarding coverage of heart transplants that was motivated and shaped by cost concerns. These concerns were straightforward: that heart transplants could prove to be so expensive as to strain the resources of the Medicare program. Yet in this proposed regulation written years after this coverage decision had been made, CMS states that safety, efficacy, and common acceptance by the medical community have been the fundamental tests for coverage. In fact, it seeks to change the criteria to allow consideration of cost.<sup>123</sup> In a more detailed description later in the proposed regulation of the criteria then in use for national coverage decisions, neither cost nor cost-effectiveness is mentioned.<sup>124</sup>

The publication does propose to expressly add cost-effectiveness to the coverage criteria and gives detailed

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121. Medicare Program; Criteria and Procedures for Making Medical Services Coverage Decisions that Relate to Health Care Technology, 54 Fed. Reg. at 4305.

122. Medicare Program; Criteria and Procedures for Making Medical Services Coverage Decisions that Relate to Health Care Technology, 54 Fed. Reg. at 4305.

123. Medicare Program; Criteria and Procedures for Making Medical Services Coverage Decisions that Relate to Health Care Technology, 54 Fed. Reg. at 4305-06.

124. Medicare Program; Criteria and Procedures for Making Medical Services Coverage Decisions that Relate to Health Care Technology, 54 Fed. Reg. at 4307-08.

descriptions of both its meaning and proposed use. It also attempts to distinguish cost-effectiveness in the coverage area from the use of cost-effectiveness in the payment area. This distinction is critically important when analyzing this issue. Medicare has long directed the regional carriers to consider cost-effectiveness in payment decisions. If a new technology has the same effectiveness but at a greater cost, carriers have been told to approve reimbursement for both technologies at the less expensive one's rate. This is described in the proposed regulation.<sup>125</sup> The directions to the carriers can be found in the coverage manuals under the descriptive term "least costly alternative" and are most commonly considered with durable medical equipment.<sup>126</sup>

The use of the term cost-effectiveness as it is applied to carriers is an appropriate one. A standard definition of a cost-effective technology is "one that is as effective as an alternative but less expensive."<sup>127</sup> If no alternative technology exists, any effectiveness is cost-effective. There are two problems with the coverage cost-effective analysis as proposed in the publication. The criteria of the cost-effective analysis CMS was proposing to make as part of a coverage decision is very broad and might appear to be more of a "cost-benefit" analysis, which is quite different. CMS proposed to consider elements that are far beyond the standard scope of "effectiveness" of medical treatment. These include indirect costs or savings such as increased productivity of the disabled and various transportation costs. These would be given a monetary value for purposes of the coverage decision evaluation.

A cost-benefit analysis seeks to determine if the cost of paying for something is worth the benefit to society based on the society's valuation of both the benefit and the cost. It is often determined by aggregating individual preferences

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125. Medicare Program; Criteria and Procedures for Making Medical Services Coverage Decisions that Relate to Health Care Technology, 54 Fed. Reg. at 4308-09.

126. See Centers for Medicare & Medicaid Services, *Medicare Program Integrity Manual*, Pub. 24, ch. 13 § 5.4 (Apr. 5, 2002); Medicare Carrier's Manual, Pub. 1790, ch. II § 2100.2 A-C (Feb. 21, 2003).

127. Paul E. Kalb, M.D., *Controlling Health Care Costs by Controlling Technology: A Private Contractual Approach*, 99 YALE L.J. 1109, 1112 (1990) (citing Doubilet, Weinstein & McNeil, *Use and Misuse of the Term "Cost Effective" in Medicine*, 314 NEW ENG. J. MED. 253, 254 (1986)).

into a ranking or scale. It is very problematic and particularly so for health care, where people's preferences tend to change dramatically when they become ill.<sup>128</sup> It can end up working to entrench preferences that are prejudicial, ill considered, or irrational. It can also be based on mistaken assessments as to what is most beneficial to a society or a sub-group (such as the "disabled").

However, whether the criteria given in the proposed regulation for cost-effectiveness fully fit within a definition of a cost-benefit analysis or not, the problem remains essentially the same. CMS wanders onto thin ice when it seeks to broadly assess the societal worth of financing a medical technology. Instead of sticking to the focused task of assessing relative health benefits per unit of expended resources, including indirect non-health benefits fundamentally alters the nature of CMS's role in making health coverage decisions. The more it seeks to have cost-effectiveness accomplish, the more they risk confrontation over their decisions.

The second problem is completely different from the first. If CMS uses the standard meaning of cost-effectiveness, this consideration does not appear to accomplish anything in addition to what is already accomplished by considering cost-effectiveness in the payment step. A cost-effective, viciously expensive new technology would still threaten the financial security of Medicare. This problem is what needs to be addressed more directly by a system such as the one proposed in the introduction to this article. In terms of where the right to consider cost comes from, in section III.C. of the proposed regulation CMS explains that it believes cost is a part of the "reasonable" determination and should now be considered due to the "current explosion of high-cost medical technologies."<sup>129</sup> This proposed regulation generated tens of thousands of negative comments.<sup>130</sup> The majority of them

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128. See generally HENRY S. RICHARDSON, DEMOCRATIC AUTONOMY: PUBLIC REASONING ABOUT THE ENDS OF POLICY 119-29 (2002).

129. Medicare Program; Criteria and Procedures for Making Medical Services Coverage Decisions that Relate to Health Care Technology, 54 Fed. Reg. at 4308-09.

130. Milhorn Interview, *supra* note 17.

disagreed with CMS as to the permissibility of considering cost in coverage decisions.<sup>131</sup>

No further action was taken on this issue until April 27, 1999, ten years later, when CMS published a general notice. The notice announced the process to be used in making national coverage decisions and formally withdrew the 1989 proposed regulation.<sup>132</sup> The general notice described a new approach to national coverage decisions. Congress had recently passed a law allowing these decisions to be made without CMS engaging in notice and comment rulemaking procedures,<sup>133</sup> generally required for agencies under the Administrative Procedure Act (“APA”).<sup>134</sup> National coverage decisions are made under 42 U.S.C. 1395y(l) of the Medicare Act and are binding on the entire Medicare program. Congress also acted to make these decisions unreviewable by administrative law judges, who otherwise do review appeals of Medicare denials.<sup>135</sup> The notice drew attention to these rules.

The description of how national coverage decisions would be made did not mention cost. There were some terms, not further defined, that could have within them a role for cost, such as issues involving “broad health policy concerns”<sup>136</sup> or ones that have “the potential to have a major impact on the Medicare program,”<sup>137</sup> but any specific criteria for national coverage decisions was entirely absent.

On May 16, 2000, CMS published a “Notice of intent to publish a proposed rule” in the *Federal Register*.<sup>138</sup> The stated intent was to solicit comments in advance on criteria

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131. *Id.*

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

133. 42 U.S.C. § 1395hh(a)(2) (2005); § 1395ff(f)(1)(A) (2005).

134. Administrative Procedure Act, 5 U.S.C. § 553(b)(3)(A) (2005).

135. Federal Health Insurance for the Aged and Disabled, 42 C.F.R. §§ 405.732, 405.860 (2005).

136. Medicare Program; Procedures for Making National Coverage Decisions, 64 Fed. Reg. at 22,623.

137. Medicare Program; Procedures for Making National Coverage Decisions, 64 Fed. Reg. at 22,623.

138. Medicare Program; Criteria for Making Coverage Decisions, 65 Fed. Reg. 31,124 (May 16, 2000).

to be used in making Medicare coverage decisions. The publication quotes from the legislative history of the Medicare Act, saying one of the goals of Medicare from the beginning was to make "the best of modern medicine" available to the beneficiaries.<sup>139</sup> It then said that Congress had two strong interests it expected CMS to pursue. The first is providing access to necessary medical care for Medicare beneficiaries and the second is ensuring the sound financial basis of the Medicare program.<sup>140</sup> The publication then describes the specific scope of coverage created by Congress in the Medicare Act, including the reasonable and necessary language, in close proximity to their explication of the "sound financial basis" prong of CMS's duties under the Medicare Act.<sup>141</sup> It implies that the job of a reasonable and necessary determination is to protect Medicare's financial well-being. This analysis is not stated explicitly in the publication but it does offer some basis for CMS's opinion that cost would be allowable under the reasonable and necessary language.

The notice of intent proposed that national coverage decisions would allow coverage if the item or service showed demonstrable medical benefit and presented an "added value" to the Medicare population.<sup>142</sup> The "added value" analysis presented in the publication tracked a narrow cost-effectiveness analysis. The difference between this and the payment approach to cost-effectiveness is that if an item or service is not cost-effective and Medicare already covers a cost-effective alternative, the new item or service will be denied coverage rather than being covered at the other item or service's cost.<sup>143</sup>

There is always a worry about industry's role in this debate. Device and pharmaceutical manufacturers have

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139. Medicare Program; Criteria for Making Coverage Decisions, 65 Fed. Reg. at 31,126.

140. Medicare Program; Criteria for Making Coverage Decisions, 65 Fed. Reg. at 31,126.

141. Medicare Program; Criteria for Making Coverage Decisions, 65 Fed. Reg. at 31,126.

142. Medicare Program; Criteria for Making Coverage Decisions, 65 Fed. Reg. at 31,127.

143. Medicare Program; Criteria for Making Coverage Decisions, 65 Fed. Reg. at 31,127.

enormous financial risks when coverage decisions are being made. They have the ability to provoke patient responses to Medicare decisions. If Medicare decides coverage, this will often control the dissemination of the technology around the country. Some commentators see this and argue that the economic benefits of the medical device and pharmaceutical industries are sufficiently important to merit protection in the CMS coverage process.<sup>144</sup> Whether one agrees with the importance of protecting industry or not, the role of industry raises a concern that is common in agency law. The problem is explained in public choice theory. When powerful interests take over the process to ensure their own financial gain, according to this theory, it is a plundering of the democratic process.<sup>145</sup> With an industry as powerful as the pharmaceutical and device industry, that needs to be a concern in terms of CMS's ability to resist the pressures brought to bear on them. Susan Bartlett Foote believes that this type of industry capture of agency action has been behind the failure of CMS to promulgate cost-effectiveness regulations.<sup>146</sup>

The requirement of a proven medical benefit for coverage is actually problematic on its own. Critics of cost-effectiveness analysis and, more broadly, of other forms of outcomes research, are keenly aware of the risks to individuals inherent in both cost consideration and efficacy studies. Hilde Lindemann Nelson has pointed out the normative decision inherent in defining a "good outcome." She uses theories about what real knowledge consists of to show it reflects one's individual perspective and is often socially situated.<sup>147</sup> Patients tend to have lower status than physicians in terms of the authority acceded to their type of

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144. See Eleanor D. Kinney, *Medicare Coverage Decision: Making and Appeal Procedures: Can Process Meet the Challenge of New Medical Technology?*, 60 WASH. & LEE L. REV. 1461 (2003).

145. William N. Eskridge, Jr. & John Ferejohn, *Structuring Lawmaking to Reduce Cognitive Bias: A Critical View*, 87 CORNELL L. REV. 616, 616 (2002).

146. See generally Susan Bartlett Foote, *Why Medicare Cannot Promulgate a National Coverage Rule: A Case of Regula Mortis*, 27 J. HEALTH POL. POL'Y & L. 707 (2002).

147. Hilde Lindemann Nelson, *Knowledge at the Bedside: A Feminist View of What's Happening with This Patient*, in MEANING AND MEDICINE: A READER IN THE PHILOSOPHY OF HEALTH CARE 106, 110 (1999) (interpreting Wittgenstein's theory of knowledge).



knowing. Physicians tend to be considered "in a position to know."<sup>148</sup>

In the ideal physician/patient interaction, both parties work together to achieve a treatment plan that respects a patient's autonomy and moves towards an outcome that will be perceived by all participants as a cure. Some knowledge that can come from the patient includes which abilities are necessary for their daily lives, what experiences will respect their bodily experience and other intensely personal parts of the presenting condition of the patient and the patient's actual illness.<sup>149</sup> This role for the patient, and the respect it entails for what the patient knows, is difficult to promote and is not terribly vigorous.

One problem with outcomes research, including cost-efficiency analysis, is that it minimizes the role of the individual patient's input. To hold physicians to treatment plans developed without an individual patient's input has a cost for the physician-patient relationship and may not result in the optimal end-result from the patient's perspective. At its best, "the outcomes movement promises to make health care more effective by [basing clinical decisions on] statistical analysis of large data bases."<sup>150</sup> Impersonal knowledge of outcome probabilities is given greater weight than a physician's clinical experience.<sup>151</sup>

There are costs when physician choices are dictated by statistical generalities. For example, a study typically determines that a therapy works in X% of cases. If X is high enough, or if no alternative to the therapy exists, it is likely X will become the accepted treatment. If X is low, it may not be effective in a high enough percentage of cases to merit inclusion in treatment paradigms. The patients represented by the small value of X will not, in the future, get the therapy, even though it was effective in their cases. The greater the number of clinical decisions based on outcomes studies that contained an unacceptably low efficacy, the greater the number of patients who will be

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148. *Id.*

149. *See id.* at 114.

150. Sandra J. Tanenbaum, *What Physicians Know*, 329 NEW ENG. J. MED. 1268, 1268 (1993).

151. *See id.* at 1269.

predictably deprived of care that would have been effective in their individual cases.<sup>152</sup>

After publication of the 2000 notice, no subsequent rule has been published. However, as described earlier in this article, Congress has recently passed a law which directed the Secretary of Health and Human Services to “make available to the public the factors considered in making national coverage determinations of whether an item or service is reasonable and necessary.”<sup>153</sup> No guidance as to what those factors should be was included, a waste of an opportunity to clarify what role cost, cost-effectiveness, or cost-benefit analysis should play.

Were CMS to expressly use cost in any form as grounds for denying national coverage of a medical technology, it is likely that a court would eventually analyze both the Medicare Act and the regulations interpreting it to determine the propriety of CMS’s criteria.<sup>154</sup> The theory and the criteria would, presumably, have some impact on a court’s ruling. Sean Tunis, the current director of CMS’s Office of Clinical Standards and Quality, is effectively the head of national coverage decisions. In an editorial he recently wrote for the *New England Journal of Medicine* discussing the problems in developing criteria for coverage decisions, he singled out the role of cost-effectiveness analysis as one of the most difficult policy issues. To quote, “[T]he use of economic analyses will be challenging to defend whenever a specific patient is denied care as a result . . . [w]hether coverage decisions and other Medicare policy decisions should be influenced by economic factors remains an important and controversial issue.”<sup>155</sup>

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152. See also David M. Frankford, *Food Allergy and The Health Care Financing Administration: A Story of Rage*, 1 WIDENER L. SYMP. J. 159 (1996) (describing problems such as manipulation of data for political or financial goals and other risks with outcome studies).

153. See § 731, 117 Stat. at 2349.

154. Due to the complexity of the laws governing appeals and review of national coverage decisions, among other things, actually getting this issue before a federal judge requires running a legal obstacle course that is beyond the scope of this paper to analyze. For example, see *Heckler v. Ringer*, 466 U.S. 602 (1984) where exhaustion of internal appeals of a Medicare national coverage decision was required before a case was deemed ripe for judicial review. For purposes of this paper, it will be presumed that it can be done.

155. Sean R. Tunis, M.D., *Why Medicare Has Not Established Criteria for*

It seems fair to presume from the conclusion of this editorial that what Dr. Tunis wants is a “robust and acceptable approach to evaluating costs in decisions about coverage and payment [to] . . . increase the likelihood that patients will receive the greatest total healthcare benefit from . . . Medicare spending.”<sup>156</sup>

Perhaps the question before a judge would be as follows: Given the change in the cost of the Medicare program and in medical technology generally, has cost-effectiveness become an essential part of deciding what is reasonable and necessary for Medicare to cover? Medicare’s retreat from an expansive to a more traditional definition of cost-effectiveness in its various publications could, arguably, allow the most recent definition to stand as the one it would pursue.

However, what Dr. Tunis concludes in his editorial, coupled with other remarks made by earlier CMS decision makers, could imply that CMS wants, or believes it needs, more than cost-effectiveness can give. This question, supported by the heart transplant decision, is as follows: May CMS deny coverage of medical technology because it simply costs too much, even if the technology would be beneficial to individual patients?

#### VI. STATUTORY INTERPRETATION OF “REASONABLE AND NECESSARY”

This section looks at the role of cost in the “reasonable and necessary” language of the Medicare Act from the perspective of the court system. This is a three-part analysis. The first examines court opinions that address this specific language. The second examines the impact of the relationship between agencies and Congress in Supreme Court opinions and related literature, as well as considering traditional methods of statutory interpretation. The third section discusses whether CMS is qualified to make the choices that are inherent in cost considerations,

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*Coverage Decisions*, 350 NEW. ENG. J. MED. 2196, 2197 (2004).

156. *Id.* at 2198. Dr. Tunis was given access to the research conducted for this article and based his assertions that the reasonable and necessary language was taken from an Aetna policy on that research. *See id.* at 2197.

in terms of its status as an agency of the executive branch of the federal government, as compared to Congress.

There are no court opinions that have specifically addressed the issue of cost as a criterion for Medicare national coverage decisions. Some decisions have addressed the scope of “reasonable and necessary” decisions made by Medicare under the Medicare Act.<sup>157</sup> In *Goodman v. Sullivan*, the Second Circuit Court of Appeals held that the “reasonable and necessary” standard did not require Medicare to cover all necessary services for beneficiaries.<sup>158</sup> This holding was important to Medicare because it clarified that Medicare was not subject to a rule that found the opposite for Medicaid beneficiaries.<sup>159</sup> No specific definition of necessary was given in the case. The court seemed to base its reasoning on the existence of limits within the Medicare statute beyond the requirement that care be reasonable and necessary, such as the exclusion from coverage for experimental treatment.<sup>160</sup> Given these other limits that limited coverage prior to a reasonable and necessary determination, all necessary care could not be presumed covered.

Some of the strongest language about resource allocation is in *Lerum v. Heckler*, a case from 1985.<sup>161</sup> The Seventh Circuit Court of Appeals described a utilization review board as an instrument of Medicare that reconciles the dual goals of providing health care and encouraging efficiency in the allocation of resources. The central issue in the case was Medicare’s requirement that patients use a skilled nursing facility rather than an acute care facility if the appropriate level of care could be provided in either setting.<sup>162</sup>

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157. See 42 U.S.C. § 1395y(a)(1)(A) (2005).

158. 891 F.2d 449 (2d Cir. 1989).

159. See, e.g., *Rush v. Parham*, 625 F.2d 1150 (5th Cir. 1980) (requiring Medicaid to provide coverage for a transsexual to have transgender surgery. Medicaid is the program that provides medical coverage for qualified low-income Americans and is administered by the same federal agency as Medicare).

160. The *Goodman* decision also held that FDA approval of a technology did not mean Medicare had to cover it. See *Goodman*, 891 F.2d at 451.

161. *Lerum v. Heckler*, 774 F.2d 210, 213 (7th Cir. 1985).

162. *But see Hultzman v. Weinberger*, 495 F.2d 1276, 1282 (3rd Cir. 1974)

In the case of *New York v. Secretary of Health and Human Services*, a case from New York in 1990, the court there held that the Secretary of Health and Human Services' final decision regarding an individual's appeal of a reasonable and necessary denial must be accurate and supported by substantial evidence.<sup>163</sup> This standard of review of a Medicare coverage decision could, theoretically, make it more difficult to have implicit cost concerns guide a coverage decision unless there was enough scientific evidence to reasonably reach the same conclusion, independent of cost.

These and related cases provide little guidance as to how courts define "reasonable and necessary" for Medicare. It seems that some consideration of cost is allowed, but it is focused on the type of facility providing care. The concern over using the appropriate facility goes back to the original Medicare Act and was clearly envisioned by the drafters. In the absence of substantial judicial guidance, the next step is to analyze this issue according to theories of statutory interpretation and agency law.

The issue of whether cost is a valid criterion for Medicare to consider is, at one level, a question of an agency's construction of the statute it administers. In this case, the statute is the Medicare Act and the question concerns the language at 42 U.S.C. section 1395y(a)(1)(A), which prohibits Medicare from making payments for health care that is not reasonable and necessary. In general, this issue is analyzed with reference to the Supreme Court's decision in *Chevron USA Inc. v. Natural Resources Defense Council, Inc.*<sup>164</sup> and cases further interpreting that decision. In *Chevron*, the Court devised a method for analyzing agency action that gave broad deference to agency action. This broad deference has been consistently applied since 1984, when *Chevron* was decided.

This article does not apply *Chevron* to the issue discussed here, except as *Chevron* was interpreted by the Supreme Court in March of 2000 in the case of *FDA v.*

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(the court did not allow HCFA to overturn a utilization review board's decision as to the appropriate setting for patient care).

163. *New York v. Sec'y of Health & Human Servs.*, 903 F.2d 122, 126 (2d. Cir. 1990).

164. 467 U.S. 837 (1984).

*Brown and Williamson Tobacco Corp.*, where the Court considered the FDA's attempt to regulate tobacco as a drug.<sup>165</sup> In *FDA v. Brown*, the moral argument for agency action, attempting to limit the destruction caused by cigarette smoking, is strong and clearly understood by the Court. Tobacco kills and otherwise harms large numbers of Americans. The FDA attempted to control it for the purpose of saving lives. The Supreme Court struck down the regulation and refused to allow the FDA to regulate in this area. The Court decreed that Congress was the one to act on this issue, not the FDA.

While the impact of *FDA v. Brown* may not be dramatic for most agency actions, it appears to be highly relevant as to the issue of cost and Medicare. *FDA v. Brown* has presented a new analysis for agency action in certain circumstances described below. In *FDA v. Brown*, the Court describes the *Chevron* analysis. First, has Congress spoken directly to the precise question at issue? If yes, that Congressional language must be the answer and an agency cannot defy it. If Congress has not directly and precisely spoken to the question, the court has to respect an agency's construction of its statute as long as it is a permissible construction.<sup>166</sup> Agencies are given broad deference by courts for two main reasons. The first is that a court is not the proper place for assessing the wisdom of policy choices from among competing visions. The second is due to an agency's presumed expertise as to facts and circumstances related to the regulated subject.<sup>167</sup>

In *FDA v. Brown*, the Court had no language in front of it from Congress that specifically addressed whether the FDA could regulate tobacco or not. Yet it held that the FDA was prohibited from regulating tobacco on the grounds that "Congress [had] directly spoken to the issue here and precluded the FDA's jurisdiction to regulate tobacco products."<sup>168</sup> In order to figure out if Congress specifically addressed the question at issue, the Court did a broad historical examination of both Congressional and FDA behavior. It was not limited to legislative language that was

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165. 529 U.S. 120, 132-33 (2000).

166. *See id.* at 132.

167. *Id.*

168. *Id.* at 133.

passed, and was not limited to considering the FDA's enabling statute. Most impressively, the Court said "we must be guided to a degree by common sense as to the manner in which Congress is likely to delegate a policy decision of such economic and political magnitude to an administrative agency."<sup>169</sup> This reliance on "common sense" seemed to open the door to a vast array of information for the Court to consider.

This decision clearly has implications for whether Medicare's coverage criteria could withstand a judicial challenge. To put it simply, the implications depend on how one views the role of cost. Is cost-effectiveness merely a sensible consideration, one already promoted by Congress in the prospective payment system? Or is Medicare attempting to embark on an explicit program to ration health care for the elderly? The first formulation might very well survive a *Chevron* analysis. The second is more problematic.

There are different types of information the *FDA v. Brown* Court considered that have relevance here. One point was inconsistencies within what the FDA wished to do with the existing regulatory structure. The FDA has an obligation to determine if drugs are safe and effective. Tobacco is not either one, and has no beneficial purpose. Yet the FDA wished to create a regulatory structure for tobacco that did not involve an outright ban. Applied to Medicare, an inconsistency in considering cost in the coverage area is that Congress enacted legislation specifically addressing cost in the second step, payment, and even included a cost-effectiveness evaluation as part of this step. CMS would be making two separate cost determinations, which appears to be redundant and does not clearly fit within the scheme already created by Congress.

In *FDA v. Brown*, the Court said it was relevant that Congress considered and rejected bills that would have given the FDA the authority to regulate tobacco. In the case of Medicare, Congress has also considered and rejected bills that would have given CMS explicit authority to create a Medicare system that would work to ration health care. In Part five of this paper, the PSRO plan is described in some

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169. *Id.*

detail, as is the radically different plan that became law.<sup>170</sup> Furthermore, the Court considered Congressional action subsequent to the passage of the FDA Act on the issue of tobacco to be proof that Congress did not consider the power to regulate tobacco to be in the hands of the FDA.<sup>171</sup> If it had been, no further action on Congress' part would be required.

Congressional tobacco laws were passed after the problems with tobacco were well known. This relates to Medicare because of Congress passing the prospective payment system to address cost problems at Medicare. Congress held hearings, proposed legislation and created a payment structure clearly thinking about the cost of the Medicare program as something that needed to be fixed. Not to be repetitive, but Congress also put cost-effectiveness into a specific place in this plan.

The Court in this case also considered past statements by FDA senior officials who testified before Congress in 1965 that they did not have the power to regulate tobacco.<sup>172</sup> This is more complex when the same issue is considered as it applied to Medicare. Senior Medicare officials have said they do not have the power to explicitly consider cost<sup>173</sup> but many have also worried about cost and have said cost will be part of their analysis.<sup>174</sup> The most telling part of this analysis seems to be how the Court assesses the nature of the question presented. The greater the economic and political significance, the more likely the Court will demand some substance to a delegation claim by an agency.<sup>175</sup> The Court has made it clear in the next decision discussed here that rationing of health care is an area that needs to be guided by Congress.

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170. *See supra* Part V.

171. *See* FDA v. Brown, 529 U.S. at 137.

172. *Id.* at 145 (quoting FDA Deputy Commissioner Rankin, *Cigarette Labeling and Advertising: Hearings on H.R. 2248 Before the House Comm. On Interstate and Foreign Commerce*, 89th Cong. 193 (1965)).

173. *See supra* notes 12-13 and accompanying text.

174. *See supra* Part I.

175. *See* FDA v. Brown, 529 U.S. at 159.



In *Pegram v. Herdrich*,<sup>176</sup> the Court described the HMO Act as written to allow HMOs to ration health care. When asked to determine what are good or bad rationing choices, the Court said it could not do this. “[S]uch a debatable social judgment [is] not wisely required of courts unless for some reason resort cannot be had to the legislative process, with its preferable forum for comprehensive investigations and judgments of social value, such as optimum treatment levels and health care expenditure.”<sup>177</sup> *Pegram v. Herdrich* seems to describe a subject of political significance, the value judgment as to what are good and bad health care rationing decisions. This subject is perhaps as significant as tobacco was to the *FDA v. Brown* Court. It is not possible to “prevent unelected interpreters from making value choices” when agencies interpret statutes in difficult cases.<sup>178</sup> In our current legislative environment, statutes are often written for the purpose of creating regulatory agencies that need to devise regulations in politically contentious areas. There has to be some leeway given to these agencies to accomplish this. The job here is to determine where the Court will find a balance for Medicare coverage criteria.

*FDA v. Brown* appears to be a defense of Madisonian principles of government. Jonathan Turley writes about this in an article about *FDA v. Brown* and more generally about tobacco. He believes that “in a Madisonian democracy, it is more important how we resolve questions than what we resolve.”<sup>179</sup> The FDA appeared to be acting to fill a void left by Congressional inaction to address a terrible problem. However, to Turley, “the legislative process works to take diverse opinions and produce a common focal point that is acceptable to the majority.”<sup>180</sup> One point of our Madisonian system is to have a reliable way to address divisive issues. The design is to “neutralize division,” and to minimize the power of factions.<sup>181</sup>

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176. 530 U.S. 211 (2000).

177. *Id.* at 221-22.

178. WILLIAM N. ESKRIDGE, JR., DYNAMIC STATUTORY INTERPRETATION 174 (1994).

179. Jonathan Turley, *A Crisis of Faith: Tobacco and the Madisonian Democracy*, 37 HARV. J. ON LEGIS. 433, 435 (2000).

180. *Id.* at 436.

181. *Id.* at 452.

Congress is where the positions of the different factions are meant to be forged into compromises acceptable to the majority. The idea is to force “the debate and reconciliation of differing public values.”<sup>182</sup> Using this logic, if agencies are permitted to step into a void created when Congress cannot reach a majority decision on an issue, the act of allowing agencies to do this threatens to empower factions, which in turn threatens the underpinnings to the stability of a highly diverse culture. The more volatile or difficult a decision is, the more profoundly this concern applies.

However, at the same time the *FDA v. Brown* Court defended Madisonian government, it also gave a reading to the legislative history that is unusually expansive and contrary to many theories in this area. As the dissent pointed out, the Court is using the views of a later Congress to interpret a statute enacted in 1938.<sup>183</sup> But the Court has, in the past, been opposed to this. The most striking member of the majority in *FDA v. Brown* is Justice Scalia, who once said in a concurring opinion: “[A]rguments based on subsequent legislative history . . . should not be taken seriously, not even in a footnote.”<sup>184</sup>

Following the original intent of the original legislature that drafted a statute is a theory that is strongly held by many and has been around for centuries.<sup>185</sup> There are also many who have pointed out the numerous problems with this theory.<sup>186</sup> One main problem is that times and circumstances change. Often, original intent was formulated when current circumstances were not remotely imagined. Another problem is more complex. True legislative intent is very difficult to know. Legislators utilize game theory when promoting and negotiating statutes. What is said, or enacted, is often motivated by reasons that are unknowable by an observer. For example, someone could vote for a bill in order to get someone else to vote for another bill. The sheer number of issues being

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182. *Id.* at 453.

183. See 539 U.S. at 161 (Breyer, J. dissenting).

184. *FDA v. Brown*, 529 U.S. at 182 (Breyer, J., dissenting) (quoting Justice Scalia’s opinion in *Sullivan v. Finkelstein*, 496 U.S. 617, 632 (1990)).

185. See ESKRIDGE, *supra* note 178, at 14.

186. For example, see *supra* note 178.

negotiated at any one time makes it difficult to know who intends what, and when.

Because times change, an agency's job can be substantially different from what it once was. A certain degree of flexibility, of growth, in an agency's realm of power is essential to developing a dynamic agency. The dynamic agency is one that can best promote the more general, underlying goals it was set up to further.<sup>187</sup> In the case of Medicare, times have changed, but the changes came almost immediately after the passage of the bill. Medicare's costs soon skyrocketed. The original intent of the Medicare Statute appears to be unusually clear. The goal was to provide coverage. The scope of coverage was determined by how many votes were needed and which coverage plan would get those votes. There was also some fear of voters being angry if an empty promise of coverage was made. A very generous payment plan was enacted to quiet the medical establishment, primarily voiced through the AMA. As is often quoted, the goal was to bring "the best of American medicine" to the elderly.<sup>188</sup>

When a situation changes and Congress fails to act, that is when it might be crucial for agencies to be given leeway. Rather than seeing this Congressional failure as evidence of a robust Madisonian system at work, it could be evidence of special interest groups controlling Congress or of Congress lacking courage. In Medicare, it is the accusation of absence of Congressional fortitude that has the greatest resonance. As described earlier in this paper, it has long been considered political suicide for an elected official to try and limit health care.<sup>189</sup> While the government does not provide for all of the care people need, once the government does make a promise in this area it is almost impossible to back away from it.<sup>190</sup> The programs are considered "politically sacrosanct."<sup>191</sup>

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187. See generally ESKRIDGE, *supra* note 178.

188. See, for example, *supra* note 139.

189. See Milhorn Interview, *supra* note 17.

190. FEDERAL HEALTH PROGRAMS: PROBLEMS AND PROSPECTS x (Stuart H. Altman & Harvey M. Sapolsky eds., 1981).

191. *Id.*

In an area such as medical care, the problem of "tragic choices" makes it even more politically difficult for Congress to act to make explicit changes. In the book *Tragic Choices*, Guido Calabresi and Philip Bobbitt examine the way societies handle allocations of scarce resources. Certain choices society makes determine which guiltless person will suffer and which will not.<sup>192</sup> Sometimes these decisions are based on resource allocations that are difficult to defend, but often a policy maker must choose between competing justifiable notions of what is the best use of a resource. By not expressly acting, a tragic choice can often be made implicitly, a far less dangerous political act.<sup>193</sup> The implicit choice risks being less rational. In medicine, this irrationality can result in health programs spending limited dollars in ways not calculated to get the greatest health return.

By giving responsibility for a tragic choice to a federal agency, there is hope that the agency could be sufficiently shielded from political pressure to actually respond to the problem and generate the best utilitarian result. The experience with Medicare so far would not support an agency being the best to explicitly tackle the problem of cost of health care. CMS's attempts at proposing cost criteria have failed on two levels. The proposals have received negative responses that have prevented their enactment.<sup>194</sup> Worse, it is unclear if even the first regulation, proposed in 1989, would serve to protect Medicare from the greatest financial threats posed by new medical technology. As stated earlier, medicine can be both extremely effective and extremely expensive. It would appear that up to this point, it is the less overt cost considerations, such as the ones in the heart transplant case, that have proven to be capable of

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192. GUIDO CALABRESI & PHILIP BOBBITT, *TRAGIC CHOICES: THE CONFLICTS SOCIETY CONFRONTS IN THE ALLOCATION OF TRAGICALLY SCARCE RESOURCES* 17 (1978).

193. Implicit choices are often balanced by rescue impulses. These spring from the relationship between first order and second order allocation choices, those we make for society generally and those we make when confronted with an individual in need. An example of this tension in the book *Tragic Choices* involves a first order decision to not have a shore patrol along a beach but a concurrent second order willingness to spend a million dollars to save a single downed ballonist. CALABRESI & BOBBITT, *supra* note 192, at 21.

194. See Tunis, *supra* note 155.

protecting Medicare from unbearable financial strain. This phenomenon fits both the *Tragic Choices* analysis of what we can stand to decide as a society and the accepted notions as to the political impossibility of an explicit rationing decision surviving in this area.

The political danger in tampering with the coverage provided by the Medicare Program can be understood using the concept of the super-statute, discussed in an article by William Eskridge and John Ferejohn.<sup>195</sup> These statutes are the few that “penetrate public normative and institutional culture in a deep way.”<sup>196</sup> A super-statute (1) seeks to establish a new normative or institutional framework for state policy, (2) sticks in the public culture so that (3) the statute and its principles have a broad effect on the law, including beyond the law of the specific statute.<sup>197</sup> The law is usually enacted to fix a particularly “vexing” social or economic problem, and proves robust as a solution, standard or norm over time.<sup>198</sup> Then, its policy and principles become axiomatic to the culture.<sup>199</sup> The legitimacy of a super-statute comes from the feedback of the populace, experts, and government officials.<sup>200</sup>

The article lays out canons of statutory interpretation for super-statutes. More relevant here, however, is the quality of resonance to the public of these statutes that Eskridge and Ferejohn describe. If the Medicare Act is a super-statute and its promise to care for the elderly has sunk into the fabric of this culture, that promise is deserving of an elevated level of respect. It is almost impossible to know in advance if express rationing would be considered a violation of the promise. The implicit rationing that has occurred could, when exposed, provoke a powerful reaction.

Mark Hall has written on the role of trust in medical care. He asserts that trust is the glue that holds the doctor-

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195. William N. Eskridge, Jr. & John Ferejohn, *Super-Statutes*, 50 DUKE L.J. 1215 (2001).

196. *Id.* at 1215.

197. *Id.* at 1216.

198. *Id.*

199. *Id.*

200. *Id.* at 1217.

patient relationship together and makes it possible.<sup>201</sup> He also asserts that preserving, justifying, and enhancing trust is a critical project for health care law, public policy and medical ethics.<sup>202</sup> He posits that health care trust is different from other types of trust, such as the trust in commercial transactions, and is more important for the success of health care than for other arenas.<sup>203</sup> If he is right, the exposure of covert cost considerations and a shift to overt cost considerations could serve to fracture the trust of the public.

If Medicare is a super-statute, and if trust is an essential element of our health care system, it will be politically costly for whoever accomplishes a shift to overt cost considerations, be it an agency, Congress, or the courts, and will be subject to correction.<sup>204</sup> The proposed regulations never became actual regulations. Catastrophic coverage, perceived as a challenge to Medicare, was repealed by Congress. The courts have not yet had an opportunity to speak on this, but *FDA v. Brown* gives them ample ammunition should they need it.

The last major question is whether CMS is both qualified and capable of making the cost-based choices it wants to make. It needs to be clear that our efforts to create a just health care system take place “in the face of a force for whom justification is irrelevant.”<sup>205</sup> That force is illness. Health disparities are often beyond our control whereas access to health care often depends on societal choices. Illness can be grossly unfair. Medicare seems to have been an attempt to provide a limited scope of protection from the financial burden of the predictable gross unfairness of illness for the elderly.

Agency law requires an agency to have a rational claim or basis for its action. Congress does not have the same

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201. Mark A. Hall, *Law, Medicine, and Trust*, 55 STAN. L. REV. 463, 470 (2002).

202. *Id.* at 470-71.

203. *Id.* at 471.

204. See Eskridge & Ferejohn, *supra* note 195, at 1252.

205. Jerry L. Mashaw, *Small Things Like Reason Are Put In A Jar: Reason and Legitimacy in The Administrative State*, 70 FORDHAM L. REV. 17, 18 (2001) (summarizing Carl Jung on the relationship between God and Job).

obligation.<sup>206</sup> We know Congress made economically irrational promises in the original Medicare Act to convince physicians and hospitals to participate in the Medicare system.<sup>207</sup> The structure of the coverage decision, paying for care that is reasonable and necessary, may have the same flaw, that of economic irrationality. Because Congress' will shapes an agency's responsibilities, CMS might very well have been given an impossible task. This task would be to develop national coverage criteria that accomplish some form of savings without depriving anyone of the care they need. Presuming a complex, if not impossible task, CMS has to carefully legitimate what it does with these criteria on the basis of the rationality of the choices it makes.

Jerry Mashaw wrote on the different types of agency action and the different types of rationality that need to support them.<sup>208</sup> Relevant here is a concept called social rationality.<sup>209</sup> The justification called for in issues of social rationality is the rightness or justice-furthering quality of the decision being made. Medicare moves from fact-finding regarding efficacy of a medical technology, and moves towards making decisions about the social value of a technology when it considers cost. The form of the underlying rational needs to shift to match the change in the type of decision the agency is making.

Agencies generally shy away from acknowledging they are making value judgments, claiming that the values they apply are specified in their statutes.<sup>210</sup> Yet cost-benefit analysis is an attempt to increase social welfare by crafting a rule properly.<sup>211</sup> A broad cost-effectiveness analysis attempts to do much the same. A decision to limit the availability of medical technology because of its cost is

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206. *See id.* at 19.

207. One could say Congress either created a highly inflationary system that gave away the store or one could say that Congress created a structure that deprived it of the power to use Medicare's market power to negotiate lower costs. Either description may have been politically necessary but probably resulted in a more expensive Medicare program.

208. *See Mashaw, supra* note 205, at 30.

209. Mashaw uses this term and theory to build on the work of the philosopher Jurgen Habermas. *See id.* at 30.

210. *See id.* at 32.

211. *See id.* at 33.

clearly a value judgment. Somewhere in this specific decision is a more broad determination that at a certain point in medical care, the cost is more than the country should spend. If CMS fails to justify its coverage decisions with reference to social rationality, the decisions in this critical area will probably fail to appear legitimate. Leaving out crucial parts of the reasoning process in public communications delegitimizes the end result. However, to expressly acknowledge what they are really addressing is almost impossible in the current political and social environment.

### CONCLUSION

In conclusion, the Congressional directive to HHS to make available to the public the factors considered in making national coverage decisions for Medicare beneficiaries has brought to the forefront a number of problems for Medicare. Medicare has considered cost when making decisions about coverage of expensive medical technology. Cost has shaped coverage decisions. At different times, various HHS and CMS staff have called for the importance of considering cost.

One can consider cost in two broad ways. The first is to determine when something is too expensive to pay for, given its overall expense to the Medicare program and without considering its potential health benefits to Medicare beneficiaries. The second is to assess the cost-effectiveness of technology.<sup>212</sup> Cost-effectiveness has been proposed as a criterion but has never been officially adopted as Medicare policy in coverage decisions. However, it is used in determining how much to pay once coverage is approved.

If CMS includes cost in any manner in the factors for national coverage determinations, it faces a difficult process of justifying the consideration, given the potent political and social ramifications. Congress has not given CMS the explicit power to do this. Recent Supreme Court cases imply the Court could overturn a CMS action in this area, finding Congress to be the proper place for this type of decision to be made. Furthermore, CMS has never proposed

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212. Cost-benefit analysis has not been expressly proposed by Medicare.



considering cost considerations beyond cost-effectiveness. However, CMS may be unable to function properly as regards stewardship of the Medicare program if it doesn't consider the absolute cost of new technology as part of coverage decisions.

The ramifications of Medicare's coverage factors are immense. Coverage decisions tend to be followed by non-governmental payers as regards their own coverage. The factors that Medicare chooses have a strong likelihood of becoming the factors that govern all non-governmental United States coverage decisions. By compelling Medicare to explicitly state the factors that go into coverage decisions, Congress has brought this conflict to a head. Gregg Bloche has written on hidden rationing of health care.<sup>213</sup> He argues that making rationing less visible "lowers the profile of health care equity concerns on the political agenda."<sup>214</sup> If this is true, the corollary should apply. Making rationing more visible is likely to increase its political profile. This adds further support to the idea that Congress should brace itself for what is likely to follow its directive to HHS. Medicare does not have the capacity to resolve the political and social issues that it must in order to both protect the program's financial integrity and protect the beneficiaries. Given the social importance of Medicare, this failure will be powerfully felt.

This article's goal is to make clear the importance and complexity of this issue and to call for Congressional action. While the political costs are clear and it is hard not to both understand and have empathy for legislators facing this challenge, Congress has failed both HHS and the country by allowing this problem to go unaddressed. Some guidance must be given to Medicare as to how Congress expects it to grapple with extremely expensive, medically effective technology. The political risks, great as they are, do not excuse Congressional inaction, especially in light of their recent legislation. Furthermore, the issue of how much we are willing to pay for new and expensive medical technology needs to be addressed. It is far too easy to envision the appearance of technologies that we simply cannot afford to

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213. M. Gregg Bloche, *Trust and Betrayal in the Medical Marketplace*, 55 STAN. L. REV. 919 (2002).

214. *Id.* at 941.

provide to all who might benefit from them. A mechanism needs to be developed for handling this problem both pragmatically and ethically.

