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## JUSTICE AND COST-CONTAINMENT IN END-STAGE RENAL DISEASE

Brian V. Johnstone\*

The End-Stage Renal Disease Program ("ESRD"), launched by the Federal Government in 1972, has been evaluated both positively and negatively. There is significant research on the subject.<sup>1</sup> But a final verdict cannot yet be reached. There are at least three major criticisms which could be made of the program: 1) the decision-making process by which the program was established was seriously faulty;<sup>2</sup> 2) the program is too expensive; 3) the therapy for renal failure, in terms of the benefits to patients, is not worth this cost.<sup>3</sup> This article addresses the first of these two criticisms.

The negative assessments have influenced policies in other areas. For example, it has been reported that the experience with renal dialysis has con-

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1. See Eggers, Connerton & McMullan, *The Medicare Experience with End-Stage Renal Disease: Trends in Incidence, Prevalence, and Survival*, 5 HEALTH CARE FINANCING REV. 69 (1983-84) [hereinafter Eggers]; Evans, Manninen, Garrison, Hart, Blagg, Gutman, Hull & Lowrie, *The Quality of Life of Patients with End-Stage Renal Disease*, 312 NEW ENG. J. MED. 553 (1985); Evans, Manninen, Hart & Garrison, *Part I. The National Kidney Dialysis and Kidney Transplantation Study: A Summary of Results*, 1985 CONTEMP. DIALYSIS & NEPHROLOGY 41; Evans, Manninen, Hart & Garrison, *Part II. The National Kidney Dialysis and Kidney Transplantation Study: A Summary of Results*, 1985 CONTEMP. DIALYSIS & NEPHROLOGY 42; Evans, Manninen, Hart & Garrison, *Part III. The National Kidney Dialysis and Kidney Transplantation Study: Selected Findings*, 1985 CONTEMP. DIALYSIS & NEPHROLOGY 41. The decision-making by patients, families and physicians regarding dialysis and transplantation is the subject of a NIH funded research program at the Catholic University of America entitled: Therapeutic Options in End-Stage Renal Disease, principal researcher Dr. Mary Elizabeth O'Brien.

2. For example, in a recent work, Joseph Califano stated that, "The end-stage renal disease program is a classic example of effective lobbying by financially interested providers, human interest appeal and generous-to-the-point-of-waste social policy." J. CALIFANO, JR., *AMERICA'S HEALTH CARE REVOLUTION: WHO LIVES? WHO DIES? WHO PAYS?* 146 (1986).

3. See Dessner, *Stopping Long-Term Dialysis*, 314 NEW ENG. J. MED. 1449 (1986) (The author claims that this was the impression given to the public by the article by Neu & Kjellstrand, *Stopping Long-Term Dialysis: An Empirical Study of Withdrawal of Life-Supporting Treatment*, 314 NEW ENG. J. MED. 14 (1986)). A response to this criticism would require further research. The issue will not be addressed in this paper.

tributed significantly to the caution that has accompanied the development of liver and heart transplantations.<sup>4</sup> While technology will no doubt continue to produce life-saving treatments, it has been plausibly argued that, in view of the unexpectedly high costs of the ESRD program, not all such technologies are likely to be so funded.<sup>5</sup> On the other hand, it could be argued that the program has brought great benefits to many. On the basis of the positive outcomes, a case could be made for extending government support for health care. Thus, proponents of national health insurance have argued that the ESRD program provides necessary services to persons who could not pay for them from their own resources, and that government intervention in this case has had the direct result of saving thousands of lives.<sup>6</sup>

#### HOW WAS THE DECISION MADE TO FUND ESRD?

There are, of course, two basic treatments available to persons with end-stage renal disease — transplantation and dialysis. Transplantation was first successfully performed on identical twins in 1956. Successful transplants of kidneys from cadavers were first performed in the early sixties.<sup>7</sup> The artificial kidney was developed by the physician Willem Kolff in the Netherlands in the early 1940's. In the 1960's, the Seattle Artificial Kidney Center, the first major clinical center to apply a machine to replace kidney function, was opened.<sup>8</sup> However, during the next five years only 800 people were receiving hemodialysis even though those in need of it were estimated to number tens of thousands.<sup>9</sup> During the late 1960's and early 1970's renal dialysis and kidney transplants had an ambiguous status in the minds of many health professionals, somewhere between experiment and therapy.<sup>10</sup> The concerns which gave rise to hesitation were not simply the costs but questions as to whether the procedures offered genuine therapeutic benefits for patients. In this period, prior to government funding, a great scarcity of resources pre-

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4. Engelhardt, *Allocating Scarce Medical Resources and the Availability of Organ Transplantation: Some Moral Presuppositions*, 311 NEW ENG. J. MED. 67 (1984).

5. Kilner, *Who Receives Scarce Medical Resources? An Empirical and Ethical Study*, 1985 THE ANN. SOC'Y CHRISTIAN ETHICS 159.

6. Caplan, *Kidneys, Ethics and Politics: Policy Lessons of the ESRD Experience*, 6 J. HEALTH POL., POL'Y & L. 488, 489 (1981-82).

7. Eggers, *supra* note 1, at 69.

8. S. REISER & M. ANBAR, *THE MACHINE AT THE BEDSIDE: STRATEGIES FOR USING TECHNOLOGY IN PATIENT CARE* 14 (1984).

9. Sanders & Dukeminier, Jr., *Medical Advance and Legal Lag: Hemodialysis and Kidney Transplantation*, 15 UCLA L. REV. 366, 367 (1968).

10. Caplan, *supra* note 6, at 490. According to Caplan, if this conceptual and empirical ambiguity which surrounded the evolution of renal therapies and the ESRD program for reimbursement is ignored, we risk missing the point in seeking to frame the moral issues related to those suffering from renal failures.

vailed. In this situation, acutely difficult decisions on selecting patients, with all the attendant moral ambiguity, were unavoidable.<sup>11</sup> It has been proposed that one of the reasons for the decision to provide funding was to avoid having to make these difficult moral decisions.<sup>12</sup>

In 1966 and 1967, two reports were put together which were an integral part of the ESRD policy formulation process: 1) Report of the Committee on Chronic Kidney Disease to the U.S. Bureau of the Budget ("Gottschalk Report") and 2) Kidney Disease Program Analysis: Report to the Surgeon General ("Burton Report"). The Gottschalk Report, which was more influential, judged that the two forms of therapy were "sufficiently well advanced today to warrant launching a national program."<sup>13</sup> One important effect of this report was to support a general acceptance of dialysis and transplantation as therapy.<sup>14</sup> After the Gottschalk Committee's report, several bills incorporating the report's recommendations were proposed in Congress, but none were enacted.<sup>15</sup>

In 1965, the Kidney Disease Control Program ("KDCP") funded a number of treatment centers around the country to demonstrate the organizational feasibility of dialysis in various settings. Many of these centers became nationally prominent provider institutions. In 1969, the KDCP became part of the Regional Medical Programs; emphasis was then placed

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11. The criteria for selection of patients in the 1960's included biomedical criteria. "[O]nly half the dialysis centers in the United States [in 1967] had explicit medical criteria for selecting or rejecting a patient. Recurrently used contraindications were: . . . age and existence of other major disease states, such as diabetes, severe cardiovascular disease, and [cancer]." Fox, *The Medical Profession's Changing Outlook on Hemodialysis (1950-1976)*, in *ESSAYS IN MEDICAL SOCIOLOGY: JOURNEYS INTO THE FIELD* 122, 123 (1979). There were also psychological and social criteria. These tended to blur into social background, social status, and social worth considerations. Other selection bases such as first-come, first-serve, random lottery, and ability to pay were also used. Selection committees made up of medical professionals were organized but the predominant role in voting on patient selection was played by physicians, who were the primary gatekeepers. *Id.* Prior to 1973, patient selection for dialysis was by physicians or committee or first-come, first-serve basis or selection criteria including age, medical suitability, mental acuity, family environment, criminal record, economic status, employment record, availability of transportation, compliance with renal dialysis procedure, rehabilitation potential, psychiatric evaluation, marital status, educational background, occupation and future potential. See Evans, Blagg & Bryan, *A Social and Demographic Profile of Hemodialysis Patients in the United States*, 245 *J. A.M.A.* 487 (1981).

12. See Childress, *Allocating Health Care Resources*, in *PRIORITIES IN BIOMEDICAL ETHICS* 77, 89-90 (1981); Kilner, *supra* note 5, at 158.

13. Rettig, *Background Paper 2: Case Studies of Medical Technologies Case Study 1: Formal Analysis, Policy Formulation, and End-Stage Renal Disease*, in *THE IMPLICATIONS OF COST-EFFECTIVENESS ANALYSIS OF MEDICAL TECHNOLOGY* (U.S. Congress, Office of Technology Assessment Apr. 1981).

14. *Id.* at 21; Caplan, *supra* note 6, at 493.

15. Rettig, *supra* note 13, at 21.

on building dialysis facility capacity in this country. In 1963, the Veterans Administration ("VA") announced its intention to establish dialysis centers for eligible veterans in thirty VA hospitals. At the time of the passage of the 1972 amendments, VA hospitals were dialyzing one-fourth of the nation's dialysis patients.<sup>16</sup> The VA's submission of a budget request to the Bureau of the Budget ("BOB") for construction funds to set up dialysis units in several VA hospitals, and for the funds to staff these hospitals, was one factor which led to the establishment of the Gottschalk Committee.<sup>17</sup>

There are indications of a popular mind-set, expressed in loose, but rhetorically effective "distributive justice" arguments which may have influenced the climate in which the 1972 legislation was passed. Thus, Reiser proposes that "the historical coincidence of the clinical use of artificial kidneys and the emergence of a modern right to health care made the idea of limiting access to a lifesaving procedure through an allocation process difficult to bear."<sup>18</sup> In this context, it was not surprising, he says, that the U.S. Congress passed the 1972 legislation. One popular expression of this climate was an NBC News documentary aired on November 28, 1965, entitled "Who Shall Live?" The program, narrated by Edwin Newman, highlighted the contrast between the lack of funds for individuals who were in need of life-saving dialysis treatment and the hundreds of millions of dollars which were being spent on space exploration and weapons. Representative Melvin Laird (R. Wis.), then ranking Republican member of the House Appropriations Committee for Health, Education and Welfare ("HEW"), was quoted as stating: "We're spending billions of dollars to get to the moon, and it seems to me that these human problems which we have right here on earth, need to be solved."<sup>19</sup>

This type of argument is reflected again in the remarks of some of the supporters of the 1972 legislation. For example, during the debate on funding for dialysis, Senator Lawton Chiles argued:

In this country with so much affluence, to think that there are people who will die this year merely because we do not have enough of these machines and . . . dollars, so that we do have to make the choice of who will live and who will die, when we already know we have a good treatment . . . . This should not happen in this

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16. Rettig, *End-Stage Renal Disease and the "Cost" of Medical Technology*, in *MEDICAL TECHNOLOGY: THE CULPRIT BEHIND HEALTH CARE COSTS?* 88, 94-95 (S. Altman & R. Blender eds. 1979).

17. Rettig, *supra* note 13, at 7.

18. S. REISER & M. ANBAR, *supra* note 8, at 15.

19. Rettig, *supra* note 13, at 7. Rettig cites here the NBC News program, "Who Shall Live?" presented Nov. 28, 1965.

country.<sup>20</sup>

It may be assumed that this "rescue imperative" was a powerful factor in the decision-making process.

In summary, the following elements can be identified as significant in influencing the decision to fund — the medical acceptance of dialysis and transplantation as beyond the stage of experimentation, a moral unease with patient selection processes, a factual assumption that funds were available to cover the expected costs, and a moral conviction that to withhold funds from persons who would otherwise die was unacceptable.

The first legislation to deal with ESRD was Public Law 92-603. The process by which it was introduced and passed is quite remarkable. The legislative context was the discussion of a bill related to amending the current Social Security law in the 92nd Congress. During this process, the Senate Finance Committee conducted twenty days of public hearings on many aspects of Social Security and Welfare. No single group addressed the ESRD patient, although the Senate Finance Committee filled 3,700 pages and seven volumes with testimony. However, there was no discussion of the problems associated with kidney disease until they were introduced onto the floor of the Senate by Senator Hartke of Indiana on September 30, 1972, as amendment 555 (among a total number of 583 amendments).<sup>21</sup> According to Rettig, the decision-making process that led to Public Law 92-603 involved a short circuit of the normal procedure of hearings on proposed legislation.<sup>22</sup> The total amount of time initially allocated for discussion of amendment 555 was thirty minutes in the Senate. Ten minutes were added for further discussion.<sup>23</sup> As Caplan remarks, the need for therapy seemed clear to the legislators. All that stood between some 24,000 untreated persons and life was money. Renal patients and physicians wanted the bill passed and lobbied for it.<sup>24</sup>

With the enactment of Public Law 92-603, individuals with ESRD were provided this assistance through Section 2991 of the Social Security Amendments of 1972. The law extended Medicare coverage to individuals under 65

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20. Quoted in Rettig, *The Policy Debate on Patient Care Financing for Victims of End-Stage Renal Disease*, 40 *LAW. & CONTEMP. PROBS.* 196, 224 (1976-77).

21. 118 *CONG. REC.* 33,003 (1972). Senator Hartke used the following argument for distribution:

We spend billions of dollars each year to go from home to work, from coast to coast, from one continent to another and from earth to space. Tens of billions of dollars are spent on weapons to kill, on cosmetics . . . to make our lives easier. We do all of this, but when it comes to maintaining our health, we revert to primitive values.

22. Rettig, *supra* note 13, at 107.

23. 118 *CONG. REC.* 33,007 (1972).

24. Caplan, *supra* note 6, at 495.

who have permanent kidney failure, and require either dialysis or transplantation.<sup>25</sup> The ESRD program is an entitlement program, a term utilized by Congress which is defined as a "federal program that guarantees a certain level of benefits to persons who meet the requirements set by law."<sup>26</sup> This means that whatever amount of money is necessary to meet the needs of ESRD patients will be provided by the government. Congress and/or the administration may attempt to make the program more efficient and cost-effective, but they cannot change the federal budget so as to prevent a citizen from receiving care unless they amend the original legislation.<sup>27</sup> The ESRD program is the only such specific disease program. In the context of this law, the United States has essentially no restrictions for access based on age or medical criteria.<sup>28</sup>

#### COSTS AND COST CONTAINMENT

Cost has been a very important consideration throughout the history of the ESRD program in the United States. For example, Joseph Califano records that it was decided not to extend coverage for all kidney dialysis in the 1967 legislation "because we feared setting an expensive precedent and because of incipient concerns about becoming hostage to medical technology."<sup>29</sup> In 1967, BOB, although it had set up the Gottschalk Committee, distanced itself from the report, seeking to minimize public pressure for an expanded ESRD program. At that time BOB was increasingly feeling the effect of the Vietnam War demands on funds for the "Great Society."<sup>30</sup>

Senator Hartke estimated an annual cost of \$250 million at the end of four years, with the first full year cost at about \$75 million. He argued that "[t]he 90 to 110 million that this amendment will cost each year is a minor cost to

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25. In general, to qualify for ESRD benefits, a person must be undergoing a regular course of renal dialysis or have had a kidney transplant, and must be either insured under Social Security at the onset of the disease, a monthly Social Security beneficiary, or the spouse or dependent child of an eligible person. See Ney, *The ESRD Medicare Program: A Clarification*, 10 DIALYSIS & TRANSPLANTATION 227-30 (1981); Ruchlin, *The Public Cost of Kidney Disease*, 9 SOC. WORK HEALTH CARE 1 (1984). At present, eligibility for Medicare coverage begins with the third month in which a course of dialysis begins. Coverage may begin sooner if the patient participates in a self-care dialysis training program provided by an approved facility or receives a kidney transplant without starting or receiving dialysis.

26. Ney, *supra* note 25, at 227.

27. Ruchlin, *supra* note 25, at 3-5.

28. Eggers, *supra* note 1, at 70. However, while this may be the case in theory, it is not so in practice. Kilner has carried out a study in which questionnaires were sent to the medical directors of every kidney dialysis and transplantation facility in the United States. He found that the supposition that no one is turned away from any dialysis facility today, and that no one dies for lack of access to dialysis, is not correct. See Kilner, *supra* note 5, at 161.

29. J. CALIFANO, JR., *supra* note 2, at 146.

30. Rettig, *supra* note 13, at 19.

maintain life.”<sup>31</sup> The actual cost was, however, double that amount. The cost estimates were inaccurate for the first year, got worse in successive years, and failed to consider total Medicare and total national costs.<sup>32</sup> However, the incorrectness of these estimates were not the only factor which had a bearing on the decision. A reading of the discussion of the amendments (including amendment 555, the ESRD amendment) indicates that legislators anticipated some form of national health insurance as possible and likely in the near future. The political climate in which amendment 555 was framed and passed did not emphasize a dominant concern with cost-containment. Later, this became a crucial element in policy making.<sup>33</sup>

Subsequently, the ESRD Program Amendment of 1978 (Public Law 95-292) sought to promote more efficiency and economy in the provision of services by encouraging home dialysis and transplantation for the maximum number of suitable patients.<sup>34</sup> However, efforts to put the force of law behind the attainment of a significant increase in the proportion of home dialysis and self-care were notably restricted as the result of lobbying efforts by representatives of profit-making dialysis centers.<sup>35</sup> The next action by Congress in regard to ESRD was in the Omnibus Budget Reconciliation Act of 1981 (Public Law 97-35). The Act directed the Department of Health and Human Services (“HHS”) to set up a new dual reimbursement rate differentiating between hospital-based and free-standing dialysis facilities.<sup>36</sup> The reason for insisting on holding to the dual rate was a conviction that a single rate would thwart the intent of Congress to foster home dialysis. The fear was that hospital-based dialysis facilities which supported home patients would be driven from the market.<sup>37</sup> This again met with intense opposition from profit-making dialysis facilities. However, the dual rate was set up by Congress.<sup>38</sup> Title VI of Public Law 98-21 dealt with prospective payment.<sup>39</sup> The most recent legislative act to have a direct bearing on ESRD was Public

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31. 118 CONG. REC. 33,004 (1972).

32. Rettig, *supra* note 16, at 97.

33. Ruchlin, *supra* note 25, at 1.

34. Eggers, *supra* note 1, at 70.

35. Greenberg, *Washington Report*, 298 NEW ENG. J. MED. 1427 (1978).

36. Iglehart, *Funding the End-Stage Renal-Disease Program*, 306 NEW ENG. J. MED. 493 (1982).

37. *Id.* at 493.

38. Pristave & Riley, *HCFAs Publishes Final ESRD Prospective Reimbursement Regulations*, 12 DIALYSIS & TRANSPLANTATION 452 (1983). The composite rates went into effect on August 1, 1983, at \$131 per dialysis treatment for hospital-based facilities and \$127 per dialysis treatment for free-standing facilities.

39. See S. REP. NO. 23, 98th Cong., 1st Sess., reprinted in 1983 U.S. CODE CONG. & ADMIN. NEWS 351.



Law 99-272.<sup>40</sup>

The reimbursements for ESRD Medicare beneficiaries for Fiscal Year ("FY") 1983 was \$1,893.6 million, for FY 1984, \$1,953.5 million, and for FY 1985, \$1,941.9 million.<sup>41</sup> Total dialysis patients in 1984 numbered 78,483, and in 1985 numbered 84,797; renal transplants in 1984 numbered 6,968, and in 1985 numbered 7,695.<sup>42</sup>

However, while the costs of the program rose considerably, the significance of the increase has to be analyzed carefully. An important incentive to containing costs per treatment has been the payment screens for dialysis which were established by Medicare.<sup>43</sup> It is argued that if the cost per facility treatment is adjusted for inflation, this cost has actually fallen.<sup>44</sup> The increase in the overall costs of the program is due to the increase in the number of participants (1974 — 15,993; 1984 — 78,483 dialysis patients, 6,968 transplants). The reason why the number of participants has increased to such an extent is that the program is an entitlement program.<sup>45</sup>

#### THE DECISION-MAKING PROCESS: CRITERIA FOR ASSESSMENT

If we consider the procedure by which resources were allocated to the ESRD program, can we form a judgment on rational grounds that the procedure was adequate for the requirements of justice and fairness? Is there an identifiable and defensible normative framework which applies to processes

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40. The Consolidated Omnibus Budget Reconciliation Act of 1985, Pub. L. No. 99-272, § 9214, 100 Stat. 82, 180 (to be codified at 42 U.S.C. § 1395rr) set limits to the merger of End-Stage Renal Disease Networks. HCFA published proposed rules, 51 Fed. Reg. 12,714 (1986) (to be codified at 42 C.F.R. § 405) (proposed Apr. 15, 1986). In a letter to Mr. Otis Bowen, Secretary, HHS, dated June 27, 1986, Congressman Charles B. Rangel and 53 other members of Congress stated that, the proposed regulations were seen as aiming "to restructure substantially the End-Stage Renal Disease Program ("ESRD") and to reduce reimbursement for dialysis services . . . ." The signers expressed their deep concern at the potential impact on the safety of kidney patients and the stability of the ESRD program. HCFA published the final rule on August 26, 1986, 51 Fed. Reg. 30,356 (1986) (to be codified at 42 C.F.R. § 405) (proposed Aug. 26, 1986). If there were a reduction in reimbursement, this would, of course, bear directly on the subject of this article. There is, however, no explicit requirement for such a reduction in the proposed or final rule.

41. Telephone interview with Cathy Sage, Health Care Financing Administration, Division of Information Analysis (Jan. 23, 1987) [hereinafter Sage Interview].

42. Health Care Financing Administration, End-Stage Renal Disease Program Highlights (1985) (available from the Health Care Financing Administration, Division of Information and Statistics, 6325 Security Boulevard, Baltimore, M.D. 21207).

43. R. RETTIG, IMPLEMENTING THE END STAGE RENAL DISEASE PROGRAM OF MEDICARE at ix (1980).

44. R. BOVBJERG, P. HELD & H. PAULY, MEDICARE'S END STAGE RENAL DISEASE PROGRAM: HOW A MORE COMPETITIVE APPROACH WOULD ADDRESS IMPORTANT POLICY ISSUES. A REPORT FOR THE FEDERAL TRADE COMMISSION 3 (Aug. 1983).

45. Ney, *supra* note 25, at 228.

of decision-making? One possibility would be to consider a political decision-making process as analogous to a trial by combat. In such a case, the outcome would be decided by whoever had the force and/or fortune to prevail. Against this it would be argued that it is basic to human society or to the social contract to forego force and seek a resolution of differences on the basis of morality.<sup>46</sup> A second possibility would be to accept that there are moral rules for such decision-making processes, but that the only kind of rules available are those which the participants accept by agreed-upon conventions. This is ultimately unsatisfactory since it would leave unsolved the question of establishing the rules by which the conventions themselves could be derived. The third possibility is that there are some rules for decision-making processes and that these can be discovered by rational analysis. This is the position which will be defended here under the rubric of justice as participation.

#### JUSTICE AS PARTICIPATION

The decision-makers are moral agents with commitments and duties to their constituents and to those who will be affected by their decisions. The ethic of agency requires that those decision makers act as rational agents in decision-making, respecting those commitments and duties. Similarly, the "ethic of agency"<sup>47</sup> requires that those affected by the decisions be able to act as moral agents. The total process of decision-making ought to reflect a genuine reciprocity between the persons involved. That is, the process ought to be the joint activity of a community of moral agents. The ethic of agency, when applied to decision-making processes, requires a particular form of justice which could be called justice as participation.<sup>48</sup>

Justice as participation would require, positively, that persons take their part as responsible agents in the processes of decision-making, and negatively that they not be prevented from so doing. These basic requirements are the foundation for the primary criterion of justice as participation, which we could call "community of agency."

Responsible agency takes particular forms according to the specific com-

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46. Engelhardt, *supra* note 4, at 67. Cf. R. VEATCH, A THEORY OF MEDICAL ETHICS 110 (1981).

47. I take the term "ethic of agency" from Daniels, *Why Saying No to Patients in the United States is so Hard — Cost Containment Justice and Provider Autonomy*, 314 NEW ENG. J. MED. 1380, 1382 (1986).

48. What I call "justice as participation" is grounded on the concept of the dignity of the human person. As explained in Roman Catholic Social Teaching, this dignity is founded on the person's being created "in the image of God," i.e., as a person, a subject, capable of acting in a planned and rational way, capable of deciding about himself and with a tendency to self-realization." See POPE JOHN-PAUL II, ON HUMAN WORK 13 (1981).

mitments assumed by agents. Some of these commitments arise from freely assumed roles which carry with them specific sets of duties. The responsible agency of a legislator is governed by specific commitments to constituents, to the Constitution and to the good of the nation. The responsible agency of the physician is structured according to the requirements of good medicine. Other commitments arise partly from conditions which come into being without free choice, and partly from the free response persons make to these conditions. Thus, the sick person's commitment to pursuing a life-project directed to personal fulfillment is significantly modified by his sickness. Community of agency requires that each agent in that community be acknowledged and respected as an agent with specific forms of commitment. Thus, for example, the commitment of the physician to responsible medicine must be respected. In other words, the physician has a role-specific autonomy within the community. Similarly, the special commitment of the sick person to pursue a full life under conditions of special need must be respected. Community of agency would thus require that the sick person be respected, in the first place as an agent, and then as an agent with particular needs. The fact of physical or mental restriction does not undermine the moral autonomy of the person. Thus, the criterion of community of agency gives rise to a second criterion which might be called "commitment-specific autonomy."

Autonomy is relevant not only to individual agents, but also to groups. There are many communities of moral agents, and each community has its own relatively autonomous set of relationships. However, the communities are interrelated. For example, the community of moral agents in the health care community ought to have a certain autonomy founded on the particular requirements of the moral agency of providers and participating recipients. This autonomy, however, is not absolute. The members of this community are also members of the wider community, and have duties of social justice corresponding to the legitimate claims upon them of that wider community. These members have benefited from the wider community and have reciprocal duties to it. Hence, agents in a community ought to respect the criterion of social justice.

Particular structures in the community, for example those which give a certain form to the relationships between society and individual persons, between government and citizens, between health care institutions and sick persons, are established by policy decisions. Such policy decisions are supported by reasons which provide them with legitimation in the community. Persons in the exercise of their moral agency are necessarily engaged with these structures. Thus, the reasons which legitimate the structures must be such that they can be integrated with the moral commitments of the persons

they affect. If the reasons are not available, or fundamentally irreconcilable with those commitments, then the community of agency is violated. Such policies must, therefore, be legitimated by reasons which are openly stated, accessible to all and open to critical review by all persons affected. To express this requirement we could use the term "communicable legitimation."

Once policies are established and appropriately legitimated, the community of agency would require that those who carry out the policies be accountable to the other members of the community. Thus, the fundamental criterion leads to a principle of accountability.<sup>49</sup>

Further, the requirements of moral agency call for a negative liberty right to freedom from coercion or manipulation, and a positive claim right to the information necessary to form responsible judgments. Community of agency would also require the support which might be necessary for all persons and groups to participate on an equal footing. This would mean that affected persons and groups ought to be provided with an opportunity to participate, equal to that available to other persons and groups who would otherwise have advantages in information, or economic and political power. We could call this simply the criterion of equality in participation.

In summary, responsible moral agency in decision-making ought to respect the criteria of justice as participation, community of agency, commitment-specific autonomy, social justice, legitimation, accountability and equality.

How would these criteria apply to the procedure by which the ESRD program was established? Could the process be faulted on the grounds that it was unduly influenced by the "rescue imperative"? Such a charge would imply that considerations of justice were swept aside by an emotional human interest appeal. However, the rescue imperative, although it was expressed in a somewhat rhetorical fashion, respected some of the required criteria.<sup>50</sup> It regarded U.S. society as a community of moral agents who would want to save the lives of ESRD sufferers. It respected the aspirations of sufferers to pursue the fullest life possible, thus honoring their autonomy in this respect. It did not entail any provision which would violate the autonomy of physicians. The social justice dimension was considered in that an assessment of the available resources was made, and the wider requirements of society considered. The case was argued openly in a way which was presumed to reflect a community consensus.

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49. Cf. HASTINGS CENTER, *THE ETHICS OF LEGISLATIVE LIFE* 34-42 (1985).

50. For example, the arguments of Senators Chiles and Hartke. See 118 CONG. REC. 33,003 (1972)

It could be argued that the problems were not in the form in which the case was presented, but in the content and the process. The haste precluded an adequate investigation.<sup>51</sup> If we consider the criterion of community of agency, there is little evidence of wide consultation of patients and their families, even though it is reported that kidney patients lobbied for the program. Iglehart, writing in 1982, remarked that "little has been heard from patients with renal disease" in the debates on the subject.<sup>52</sup> This seems to have been the case from the beginning. Insofar as the process, to date, has not taken adequate account of patients, it has failed to respect the requirements of justice.

In relation to the criterion of equality in participation, an important consideration would be the lack of involvement of other persons likely to be affected. Those persons who might benefit from alternative arrangements, e.g., patients who suffer from disabilities other than ESRD of comparable seriousness, but who did not receive the particular advantages conferred on ESRD patients, should have been able to participate in some way. Similarly, those who were, in effect, called on to support the program by their taxes should have been able to take some part. In practical terms, it could be argued that the provision of hearings would have provided an adequate opportunity for due participation by those concerned. But there were no hearings on ESRD prior to the initial decision to fund the program. Thus, persons significantly affected by the decision were excluded altogether. The process which led to the formulation of Public Law 92-603 would not meet the criteria of justice and fairness on this count.

The right to relevant information must also be considered. This requirement must be taken in conjunction with the right to immunity from manipulation or coercion. The fact that interest groups sought to influence the decision is not, in itself, a ground for declaring the process unjust or unfair. There would be a basis for objection, however, if special interest groups sought to manipulate the process so as to exclude other groups with a legitimate interest, and thus to deprive the decision-makers of relevant information. If the decision-makers were not provided with or precluded from obtaining information about costs and options, which were both necessary to a reasonable decision, and which could have been provided with reasonable effort, then we could argue that the process entailed injustice. Similarly, there would be violations of justice if some participants sought to pervert the

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51. Three documents were printed in the record, including an article from the *New York Times*, by Lawrence K. Altman and a brief statement from the National Kidney Foundation. There is no indication that even these were considered in the thirty-minute discussion. See 118 CONG. REC. 33,004 (1972).

52. Iglehart, *supra* note 36, at 496.

process, for example, by excluding or distorting information or rushing the procedure so that all available information could not be presented.

It is difficult to know whether the information in the public record adequately reflects the process of decision-making in this case. But a preliminary judgment, on the evidence available, would be that the process was notably deficient in some important respects. It is equally difficult to say whether a more satisfactory process would have produced more accurate cost assessments. But the cost question calls for a specific analysis.

#### DOES THE ESRD PROGRAM COST TOO MUCH?

There are two fundamental issues here. Nobody wants to condemn a fellow human being to death, especially when these fellow human beings are identifiable individuals.<sup>53</sup> The second is that resources are finite and that some kind of limit has to be set. It is clear that no plausible principles of justice will entitle an individual patient to claim every potentially beneficial treatment.<sup>54</sup> However, it is not at all clear where limits should be set. How much is too much? In the case of the ESRD program, this question is particularly troubling. Mr. Erwin Hytner, Staff Director of the House Ways and Means Subcommittee on Oversight, and a congressional architect of the program said in an interview:

The program continues to present a kind of quandary to public policymakers. Having gotten into it, there is no way to get out. No one wants to go back to the death committees, but the costs are very high and that is troubling to Congress in an era of tightening resources.<sup>55</sup>

There are three levels of limits. The first concerns the factor of health expenditures as a whole, in relation to national resources. In the United States, health costs in 1975 amounted to 8.6% of the Gross National Product ("GNP"), by 1984, they were 10.3%.<sup>56</sup> Currently, the figure is approximately eleven percent. Can it be conclusively established that this is too much? The second level concerns the relationship of ESRD costs to all other health costs. In 1982, renal patients represented only one quarter of one percent (.25%) of the Medicare beneficiaries, but they consumed about four percent of total Medicare benefit payments and nearly ten percent of the budget for Medicare part B, which pays for outpatient care for the elderly.<sup>57</sup>

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53. Ruchlin, *supra* note 25, at 8.

54. Daniels, *supra* note 47, at 1380.

55. Iglehart, *supra* note 36, at 493.

56. Telephone interview with Angela Smith, Health Care Financing Administration, Office of the Actuary (Feb. 11, 1987).

57. Ruchlin, *supra* note 25, at 2.

These data explicate the tension between that group of persons which has been granted a legal entitlement to the technology needed to save their lives (ESRD Program beneficiaries) and other groups of persons who have equally serious needs, but no such legally established claim. If we agree with many authors that health care needs are in some way special,<sup>58</sup> can we also argue that some health care needs are more special than others in such a way as to justify the provisions for ESRD sufferers? This raises the question of equality of access to health care and of equity of access.<sup>59</sup> Can we solve these questions by constructing a theory of justice and deriving from that specific answers?

Before we can form reasonable judgments in this matter, we need to have a framework within which to deal with the question. Daniels has argued that questions of justice and cost-containment in the United States are beset by a systemic problem. The problem here concerns questions of limiting allocation of health care resources. In the British system there is a form of rationing health care. However, when decisions are made about introducing new procedures in the British system, they are made by weighing the net benefits of alternatives within a closed system. That is, decisions are made to withhold funds for certain projects on the grounds that although a certain group of patients would benefit, this would be unfair to other patients. The British system itself is justified on the grounds that it provides equitable access to a full range of health services that are fairly allocated on the basis of professional judgments about which needs are most important.<sup>60</sup> One might dispute the validity of such a system on the grounds that it rests one-sidedly on professional judgments. However, the framework is established and reasonable judgments can be made within it. For example, if Britain were to dialyze on the same scale as the United States, it would have had to increase its total health expenditure by over one percent. But this would have equalled the real growth in all health expenditure for two years according to the Prime Minister's Budget Request for 1983-84. Such funding would be possible only if large sacrifices were made in other areas.<sup>61</sup> Since the system itself is deemed to be structured so as to provide fair allocation of resources, such a major upheaval could reasonably be judged to be contrary to justice. Daniels is at pains to point out that the existence of such a system does not necessarily mean that the British system is in fact, just, or that the arguments which defend it are necessarily beyond dispute. Rather, the point is

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58. N. DANIELS, *JUST HEALTH CARE* 17 (1985).

59. *Id.* at 59.

60. Daniels, *supra* note 47, at 1381.

61. H. AARON & W. SCHWARTZ, *THE PAINFUL PRESCRIPTION: RATIONING HOSPITAL CARE* 91 (1984).

that considerations of justice are explicit in the way it is designed and in the decisions made about allocations.<sup>62</sup> On the other hand, such a system is lacking in the United States. If a particular Medicare expenditure were to be reduced, there is no guarantee that the funds saved will be used for a better purpose within the health system. Rather, such reductions may merely serve to reduce the pressure on the public budget.<sup>63</sup> This would seem to be clearly reflected in the arguments about funding in this country, where the need to reduce costs is made in the name of "cost-containment" in a general sense rather than on the basis of the needs of other areas of health care.

It would be conceivable that the withholding of funds from health care for the sake of other non-health purposes could be justified in terms of a broader system. Thus, a limit on the allocation of monies to health care might be justified and required by fairness to other persons or groups with other kinds of claims on society.

The justification for restricting expenditures on health care sometimes takes the form that rising health costs will seriously compromise the availability and accessibility of other goods that society needs to thrive, for example: food, housing, jobs or national security. Clearly, if health care costs would lead to national bankruptcy, or to serious damage to the food supply, that would be "too much." Some form of rationing would be necessary and justifiable.<sup>64</sup> But the alternatives are seldom so starkly presented. It is most often a question of how much should be provided for some legitimate needs rather than others.

Limitations of resources also arise because the resources of society have been allocated in certain ways, or members of society want them to be allocated in certain ways. These may conflict with the ways in which the resources would have to be allocated to provide for health care.<sup>65</sup> How are such conflicts to be reasonably resolved? Such limits are examples of the structures which shape the ways in which moral agents pursue their projects. As has been argued above, such structures ought to be justifiable by reasons which can be construed in terms of the justice commitments of the persons concerned. Can such reasons be found?

In discussing changing conceptions of justice in the United States, Alasdair MacIntyre proposes two models or types of persons.<sup>66</sup> Type A is concerned with his deserts. This person has earned his moderate wealth over

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62. Daniels, *supra* note 47, at 1381.

63. *Id.* at 1382.

64. Pellegrino, *Rationing Health Care: The Ethics of Medical Gatekeeping*, 2 J. CONTEMP. HEALTH L. & POL'Y 23, 36 (1986).

65. Engelhardt, *supra* note 4, at 70.

66. A. MACINTYRE, *AFTER VIRTUE: A STUDY IN MORAL THEORY* (2d ed. 1984).



the years. He argues that he is entitled to what he has earned and regards the threat to his projects posed by taxes as unjust. He is thus unwilling to pay more taxes to support expensive medical programs. The theory which corresponds to the convictions of this type of person is that of Robert Nozick.<sup>67</sup> A type B person is disturbed by the arbitrariness of inequalities in the distribution of wealth. He regards these as unjust. He might argue for the needs of persons, *e.g.*, those afflicted with ESRD, that such persons have a right to the life-saving technology available. An example of this kind of theory is that proposed by Norman Daniels.<sup>68</sup> This author adapts the theory of John Rawls.<sup>69</sup> According to MacIntyre, there is no way available in our community of resolving disputes between these rival theories and claims by having recourse to a higher theory. MacIntyre argues that modern politics cannot be a matter of genuine moral consensus. Indeed, in his view, modern politics is civil war carried on by other means.<sup>70</sup> If this is indeed true, then persons have radically different perceptions of their justice commitments. It would be difficult then, if not impossible, for decision-makers to justify their policies by reasons which would appeal to all members of the community.

It would appear that there are basically three contending approaches to the question of deciding how much society should pay for health care. Since a detailed discussion of these issues would far exceed the scope of this article, I offer a summary outline. The first approach holds that there is a way of discovering a just pattern for distribution. That is, in principle, we can determine what society ought to pay. The second position holds that there is no way of discovering this, so that we can deal only with what society chooses to pay or "willingness to pay."<sup>71</sup> The third position holds that while we cannot discover any obligatory pattern for distribution, we can determine the criteria for a just procedure of decision-making.<sup>72</sup>

There are arguments which would seem to confirm the view that we can indeed discover what constitutes a just pattern of distribution, at least in some instances. Any attempt to deal with the justice issues in this matter must entail some kind of comparison or weighing of, on one side, the resources of those (persons, groups and societies) who may provide the funds and the needs, claims and/or rights of those who are to receive them. In the weighing process, in the case of the ESRD program, the need of the prospec-

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67. R. NOZICK, *ANARCHY, STATE AND UTOPIA* (1974).

68. N. DANIELS, *supra* note 58.

69. J. RAWLS, *A THEORY OF JUSTICE* (1974).

70. A. MACINTYRE, *supra* note 66, at 235.

71. P. MENZEL, *MEDICAL COSTS, MORAL CHOICES: A PHILOSOPHY OF HEALTH CARE ECONOMICS IN AMERICA* (1983).

72. Engelhardt, *supra* note 4, at 67; *see also* H. ENGELHARDT, *THE FOUNDATIONS OF BIO-ETHICS* 336-69 (1986).

tive recipients is of an ultimate kind. Without dialysis (or transplant) they will die. It would seem, then, that in this kind of case we can discover norms of justice which establish persons' claims on the basis of evident and ultimate need. This is not necessarily the case. If funding is provided for one group of persons (sufferers from ESRD), then at some point it may have to be withheld from others, and those others may die as a result.<sup>73</sup> In such a case we would be involved in weighing life against life and it is not at all clear how this could be done.

Another possibility of discovering norms for just distribution would be to put a value much less than life into the scales. The argument would then go as follows. The projected expenditure for ESRD beneficiaries and program expenditures for 1986 is \$2.6 billion, for an estimated 96,000 patients.<sup>74</sup> Is that too much to keep 96,000 people alive — many of them in active lives — when the U.S. spends forty billion dollars for alcohol, thirty billion for tobacco, sixty-five billion for cosmetics, sixty-five billion for advertising, and unspecified billions for illicit drugs, gambling and various types of luxuries?<sup>75</sup> If we compare a life, or lives, with the satisfaction to be received from smoking or drinking, it would seem to be perfectly clear what should weigh most. If the nation could agree to cut back its consumption of alcohol by five percent or its use of tobacco by 6.6% and contribute what was thus saved to the ESRD program it would be enough, and would save 96,000 lives. Many would accept that it would be virtuous to make such a sacrifice to save others lives. However, it is not clear why those whose lives are threatened have a claim in justice on particular citizens, nor is it clear on what basis the state might claim the moral authority to exact that payment through taxation.<sup>76</sup>

However, I believe it is correct that one cannot argue, simply from a theory of justice, that a particular investment in providing health care is morally obligatory. But there is more to be said. Let us suppose that there is in place a "system," in the sense used by Daniels, in which considerations of justice are explicit, and which embraces the whole of society (rather than a health care system only). If such existed, it would be possible to find the established norms of justice and appeal to them to solve questions of allocation. The system of justice in the United States may admirably protect the rights of the individual and promote justice in this sense. However, there is

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73. Ruchlin, *supra* note 25, at 8.

74. Sage Interview, *supra* note 41.

75. *Cf.* Pellegrino, *supra* note 64, at 37.

76. H. ENGELHARDT, *supra* note 72, at 366. However, as Engelhardt points out there may be very important reasons to create such a claim or right or to see the provision of such care as a duty of beneficence.

no such institutionalized system of justice as described here. Even if there is no institutionalized system, there could still be a widely accepted theory of justice, which most persons would agree upon and to which appeals could be made; but this is also lacking. Thus, however strongly one may advocate a particular system of justice and call for its institutionalization in society, one must accept that such a system does not (yet) exist in the United States.

In practical terms, this means that we cannot discover a pattern of justice from which we can draw particular conclusions, such as, for example, that a particular expenditure is justified or required for ESRD patients. On the other hand, it is impossible, on the same grounds, to prove that a particular expenditure on ESRD is not justified or unjust. It cannot be proved that it costs too much. Such a line of argument, as is evident in Califano's latest work, tends to assume that "cost-containment" is an absolute imperative, but provides no adequate rationale for such a conclusion.<sup>77</sup> It would appear that this conclusion is based on the supposition that the United States cannot pay so much or that Americans are not willing to pay so much. But neither point is demonstrated. When we seek to establish the criteria for a just and fair process of decision-making in this matter, we may not make "cost-containment" the fundamental and dominant norm.<sup>78</sup>

Does all this mean that we are compelled, nevertheless, to fall back on what people are willing to pay? Is what people happen to decide to pay the only available criteria? Are there no rational criteria available? I propose to argue that this is not the case.

What the approaches which have been discussed so far have in common is that they seek to derive answers to allocation questions from generalized theories of justice or from general economic or political assumptions. They fail to take adequate account of the requirements of the moral agency of persons. That is, they ignore what I have called justice as participation. The criteria of justice as participation do not specify any particular amount as morally required, nor do they dictate what proportion of funding ought to be given to the ESRD program. However, they do indicate how decisions in this matter ought to be made and/or carried out. In other words, they provide criteria for a fair and just procedure of decision-making. In conclusion, I will argue for some norms based on this notion.

#### JUSTICE AS PARTICIPATION: NORMS FOR DECISION-MAKING

Several scenarios could be envisioned and some relevant norms proposed.

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77. J. CALIFANO, JR., *supra* note 2.

78. Such a simplistic focus on cost-containment is challenged, for example, by health economist Victor R. Fuchs. See V.R. FUCHS, *THE HEALTH ECONOMY* 358 (1986).

1) Within some form of cost-containment policy, the physician strives to limit the use of health care services. Dr. Edmund Pellegrino, Director of the Kennedy Institute of Ethics, Georgetown University, Washington, D.C., would accept that such negative gatekeeping, under certain carefully defined conditions of economic necessity and moral monitoring, might be morally justifiable.<sup>79</sup> What might these conditions be? From what has been said above, society could be justified in limiting funding for health care, and for ESRD in particular. The decision must not be based on purely political considerations or a market approach to human needs.<sup>80</sup> Justice as participation would require that the reasons for such limits be openly stated and accessible, and that they reflect the social justice commitments of the persons affected to their wider community. The policy itself must be constructed so as to respect providers and patients as moral agents with their due autonomy. Physicians and other providers have claims to be able to pursue their moral projects, that is to provide quality care. Patients have claims to be able to pursue their projects, that is to seek quality care. The policy ought to respect these claims. Insofar as a physician carries out a policy of limitation which conforms to these criteria, he would be acting in accord with justice as participation.

2) An arbitrary limit is set by government agencies in the name of cost-containment so that some potential beneficiaries of dialysis must be excluded or provided with less than quality care. Such a policy decision seriously affects the structures necessary for these patients to pursue their moral projects. Further, it does so for reasons which cannot be appropriated by responsible moral agents, since there are, in effect, no moral reasons. The community of moral agents is thus radically violated. Such a procedure fails to meet the criteria of justice as participation.

3) A government agency constructs a policy with incentives towards certain forms of treatment (e.g., home-dialysis). The incentives are planned to influence patient choices and the recommendations by physicians. If such incentives were structured to induce persons to choose forms of treatment solely because they were less expensive, and without regard for the medical needs and legitimate preferences of patients, this would be morally objectionable. Such an inducement imposes extrinsic decisions on the physician-patient community. It would violate the specific autonomy of physicians as agents committed to quality care, and likewise violate the moral autonomy of patients as agents seeking quality care in fulfillment of their health needs.

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79. Pellegrino, *supra* note 64, at 44.

80. Plough, *Medical Technology and the Crisis of Experience: The Costs of Clinical Legitimation*, 15 Soc. Sci. & Med. 89, 100 (1981).

4) Physicians, acting as gatekeepers, exclude some patients on *a-priori* economic grounds based on government policies. Physicians might conceal the economic and political reasons for the policy behind statements that the patient is not suitable, or simply not mentioning the availability of the treatment. Such a process would violate justice in excluding the patient from being a participant in the decision. It would also be morally questionable in inducing the physician to violate the requirements of his moral agency, specifically to forego the role of advocate of the patient, and to fail to honor his trust relationship with the patient.

5) The physician engages in a form of "positive gatekeeping" in which he encourages the use of health care facilities and services, such as dialysis, for personal or corporate profit. Pellegrino holds that this is an indefensible form of gatekeeping because "No moral justification can be mustered in its favor."<sup>81</sup> Such a case might be where a physician induced a patient to undertake a certain form of dialysis or dialysis in a facility where another form or home dialysis would be in the patient's genuine best interest, and did so for motives of profit. In such a case, the structures of the relationship between responsible agents are distorted such that the patient is reduced to a means to the physician's gain. However, an interest in profit, in itself, would not necessarily distort the relationship. Such distortion would occur only where it diverted the physician from acting as an agent of responsible medicine.

6) The physician acts as gatekeeper in using only those diagnostic and therapeutic modalities beneficial and effective for the patient. Pellegrino argues that this form of gatekeeping is both morally imperative and economically sound.<sup>82</sup> There are circumstances where patients and/or families, in consultation with medical professionals, choose not to undertake dialysis or choose to have it stopped.<sup>83</sup> There are situations in which such further treatment could be judged unduly burdensome and/or productive of no significant benefit to the patient. Such decisions would be morally justifiable. In these cases the patients could be choosing as responsible agents, and the physicians exercising the ethic of agency in practicing responsible medicine. There would be no distortion of the structures of the relevant relationships through extrinsic considerations.

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81. Pellegrino, *supra* note 64, at 44.

82. *Id.* It is not, however, clear why this would necessarily be "economically sound."

83. Neu & Kjellstrand, *Stopping Long-Term Dialysis: An Empirical Study of Withdrawal of Life-Supporting Treatment*, 314 NEW ENG. J. MED. 1, 14-20 (1986). See Smith, *Triage: Endgame Realities*, 1 J. CONTEMP. HEALTH L. & POL'Y 143, 145 *passim* (1985).