

RATIONING ACCESS TO ADVANCED MEDICAL TECHNIQUES

Douglas J. Besharov, J.D., LL.M.*
Jessica Dunsay Silver, J.D.†

INTRODUCTION

Explicit rationing of medical care, that is, the deliberate denial of treatment for some individuals who might benefit therefrom, may seem totally alien to our expectations about access to health care. Until now, explicit rationing of medical care has been avoided, except when natural scarcity places an *unalterable* limit on availability. However, rising health care costs and the federal budget deficit have forced the government to consider rationing some health care because it costs too much.

While there is much informal or "hidden" rationing in health care, this article focuses on the explicit, formal methods of rationing that might be used to determine access to advanced medical techniques. It describes the various means by which such rationing might be accomplished, illustrating each by an actual example of its use, and then it examines the ethical and legal concerns that are raised.¹

* Resident Scholar at the American Enterprise Institute for Public Policy Research and Adjunct Professor of Law at Georgetown and American Universities. This article was prepared with the assistance of John Doris, Jr. and Harvetta Asamoah. The opinions expressed herein are solely those of the authors. Address correspondence and reprint requests to Mr. Besharov at the American Enterprise Institute, 1150 17th St. N.W., Washington, D.C. 20036.

† When this article was written, Ms. Silver was a Visiting Fellow at the American Enterprise Institute for Public Policy Research, on leave from the Department of Justice, Civil Rights Division.

¹ While this article touches on a number of legal issues, it is not intended to present a complete legal analysis. Of necessity, the authors have given only limited attention to the subtle questions of "federal financial assistance," "program or activity," and others associated with the statutes discussed. The consideration of legal issues has been limited to those which would arise in a nongovernmental system of rationing. Limitations of time and space precluded consideration of the constitutional issues presented by a governmental rationing scheme, including issues of Congressional authority to enact such a scheme, as well as the impact of equal protection and due process guarantees. The issue of "state action"—or the circumstances under which private action might be considered public action—is also beyond the scope of this article.

To illustrate the currency of these issues, this article concentrates on the example of rationing of heart transplants. This focus is chosen for several reasons. Heart transplantation is currently an area of explicit and severe rationing because of the natural scarcity of donor organs. In addition, patient selection criteria are publicly known, and, therefore, easier to identify and analyze. Moreover, the federal government seems to be deliberately rationing heart transplants. Finally, the rationing criteria established for heart transplants will set an important precedent for future decisions about access to advanced medical techniques.

I. RELUCTANCE TO RATION: THE KIDNEY DIALYSIS EXPERIENCE

Perhaps the best known recent example of explicit rationing involved kidney dialysis. In the 1960s and early 1970s, the high cost of kidney dialysis (approximately \$12-15,000 per year) placed the procedure out of the reach of many patients.² Demand, however, still outstripped the limited facilities and staff available, and hospitals were forced to ration. Many applied medical and/or social worth criteria, including age, medical suitability, mental acuity, family involvement, criminal record, economic status, employment record, availability of transportation, willingness to cooperate in the treatment regimen, likelihood of vocational rehabilitation, psychiatric status, marital status, educational background, occupation, and future potential.³

At the Seattle Artificial Kidney Center, an anonymous screening committee was set up to choose patients. The committee was composed of a physician, a lawyer, a housewife, a businessman, a labor leader, a state government official, and a minister.⁴ One lay member reported his experience:

The choices were hard . . . I remember voting against a young woman who was a known prostitute. I found I couldn't vote for her, rather than another candidate, a young wife and mother. I also voted against a young man who, until he learned he had renal failure, had been a ne'er-do-well, a real playboy. He promised he would reform his character, go back to school, and so on, if only he were selected for treatment. But I felt I'd lived long enough to know that a person like that won't really do what he was promising at the time.⁵

² Note, *Scarce Medical Resources*, 69 COLUM. L. REV. 620, 637 (1969).

³ Evans, *Health Care Technology and the Inevitability of Resource Allocation and Rationing Decisions*, 249 J.A.M.A. 2208, 2209 (1983).

⁴ Note, *supra* note 2, at 661.

⁵ R. FOX & J. SWAZEY, *THE COURAGE TO FAIL* 232 (1974).

One writer saw in its deliberations "a disturbing picture... of the Seattle committee measuring persons in accordance with its own middle-class suburban value system... The Pacific Northwest is no place for a Henry David Thoreau with bad kidneys."⁶ The committee came to be known as the "God squad."⁷

The Los Angeles County-USC Medical Center took a different approach. It used a lottery to select dialysis patients. Initial screening on the basis of medical and other criteria placed a prospective patient into either an optimal or an alternate group. Candidates were chosen at random from the optimal group. When that group was exhausted, patients were selected from the group of alternates.⁸

Congress turned its attention to the shortage of kidney dialysis during consideration of the Social Security Amendments of 1972. It found a medical technology that could save lives, but that was available to only a small percentage of those needing it.⁹ Senator Hartke articulated the fundamental question that faced our elected representatives: "How do we explain that the difference between life and death is a matter of dollars?"¹⁰

Not surprisingly, Congress rejected rationing. It chose to solve the shortage by simply expanding Medicare coverage to pay for kidney dialysis for virtually everyone in need.¹¹ The ease with which it did so was undoubtedly influenced by the then rapid growth in federal tax receipts.

Unrestricted access to kidney dialysis was assured at a high price.

⁶ Sanders & Dukeminier, *Medical Advance and Legal Lag: Hemodialysis and Kidney Transplantation*, 15 UCLA L. REV. 357, 378 (1968).

⁷ *Nightline: Medical Miracles: Can We Afford the Bill?* (ABC television broadcast, August 29, 1985) (transcript at 4).

⁸ Sanders & Dukeminier, *supra* note 6, at 372 n.45.

⁹ See, e.g., 118 Cong. Rec. 33003 (1972) (Remarks of Sen. Hartke).

¹⁰ *Id.*

¹¹ See Social Security Amendments of 1972, Pub. L. 92-603, Title II, §299 I, 86 Stat. 1329 (Oct. 30, 1972), as amended Social Security Act-End Stage Renal Disease Program-Improvements, Pub. L. 95-292, 99 Stat. 307 (codified as amended at 42 U.S.C.A. § 1395rr (1983 & West Supp. 1987)). The End Stage Renal Disease (ESRD) program provides Medicare Hospital Insurance (HI) benefits to individuals with end stage renal disease. 42 U.S.C.A. §1395c (1983 & West. Supp. 1987). This provides basic protection against the costs of hospital, related post-hospital, home health services, and hospice care. 42 U.S.C.A. §1395c (1983 & West Supp. 1987). The ESRD program also entitles individuals who pay monthly premiums to participate in the Supplemental Medical Insurance (SMI) program. This covers medical costs including physicians' services and surgical procedures. 42 U.S.C.A. §§ 1395i, 1395k (1983 and West Supp. 1987).

Individuals who are determined to have end stage renal disease do not have to meet the age and disability criteria required to be eligible for the HI and SMI programs, rather, they need only have irreversible renal disease. 42 U.S.C.A. § 1395c (1983); 42 C.F.R. § 402.2102 (1986) (definition of "end stage renal disease"). Kidney donors are also automatically eligible for these benefits. 42 U.S.C.A. § 1395rr (d) (1983).

Although original cost estimates ranged from \$100,000 to \$250,000 per year, they were overtaken by political and medical realities.¹² In 1965, there were only 300 dialysis patients; in 1969, the number was still under 1,000. But by 1972, the number grew to 10,000. The End-Stage Renal Disease dialysis program now covers 78,000 patients, at an annual cost of over \$1.5 billion.¹³

II. NO MORE "EASY" SOLUTIONS: CURRENT BUDGETARY REALITIES

The development of advanced medical techniques has been welcomed by society as a means of lengthening and improving the quality of life. As the kidney dialysis experience demonstrates, it has been assumed that costs alone should not bar access to needed medical care. The result has been to keep sicker people alive, for longer periods of time—at ever greater cost.

Americans currently spend \$458.2 billion per year—10.9% of the GNP—on medical care.¹⁴ From 1981 to 1986, health care prices rose 49% while overall consumer prices increased by only 23%.¹⁵ The high cost of medical care, combined with the aging of the population and the resultant increase in the prevalence of chronic disease and disability, has raised serious concerns about future health expenditures. Between 1950 and 1978, total annual health expenditures increased 1,500%. Since 1950, the percentage of the GNP attributable to medical care expenditures has doubled. It is estimated that 80% of health care resources are devoted to chronic disease. Over 45% of those 65 and older have some chronic disease and the incidence doubles between the 65-74 age group and the over 75 age group.¹⁶ In the next 10 years, the over 75 population is projected to increase four times as fast as the population under 65.¹⁷ The effect on medical costs is obvious.

¹² 118 Cong. Rec. 33003 (1972) (Remarks of Senator Hartke).

¹³ R. EVANS, D. MANNINEN, T. OVERCAST, L. GARRISON, J. YAGI, K. MERRIKIN, & A. JONSEN. *THE NATIONAL HEART TRANSPLANTATION STUDY: FINAL REPORT*, 44-11, 14 (Battelle Human Affairs Research Centers, Seattle, Washington (1984)), published in 1984 *END STAGE RENAL DISEASE RESEARCH REPORT* (May 1986) (hereinafter EVANS).

¹⁴ TELEPHONE INTERVIEW WITH ROSS H. ARNETT, III, Health Care Financing Administration, Office of the Chief Actuary (Aug. 12, 1987).

¹⁵ CONGRESSIONAL BUDGET OFFICE, *REDUCING THE DEFICIT: SPENDING AND REVENUE OPTIONS* 65 (1987).

¹⁶ Evans, *Health Care Technology and the Inevitability of Resource Allocation and Rationing Decisions*, 253 J.A.M.A. 2047, 2049, 2050 (1985).

¹⁷ Arnett, Cowell, Davidof, & Freeland, *Health Spending Trends in the 1980's: Adjusting to Financial Incentives*, 6 HEALTH CARE FINANCING REV. 1 (No. 3, 1985).

Respected commentators are beginning to suggest that limits be placed on the availability of health care. One observer dramatically asserted:

It is time for us to bite the bullet and begin debating explicitly how we are going to ration health care. I know that the topic is unpleasant, and we'd all prefer it to go away. But it won't vanish, and we have no good alternative. One reason is that the skyrocketing cost of health care is crowding out other essential societal services and functions. Medicaid alone is forcing virtually all our states to keep down spending on education, libraries, law enforcement, parks and other high priority needs because Medicaid's insatiable appetite must be fed. In Washington the need to pay for Medicaid and Medicare entitlements is forcing ruinous cuts in necessary programs from aid to the poor to scientific research.¹⁸

Gramm-Rudman-Hollings,¹⁹ the federal budget deficit reduction legislation, has made this an immediate concern for publicly financed health care. Although special rules spare Medicare from Gramm-Rudman's full force by limiting the across-the-board cut to one percent in Fiscal Year 1986, and two percent thereafter,²⁰ the latter still translates into a reduction of approximately \$1.5 billion.²¹ Under this legislation, maintaining current levels of medical care will be difficult enough, given the growth of our aging population, which has caused Medicare rolls to increase at an annual rate of approximately two percent.²² But it will be impossible to do so if Medicare attempts to fund the many new and enormously expensive, life saving medical treatments now on the horizon.

¹⁸ Schwartz, *We Need to Ration Medicine*, Newsweek, Feb. 8, 1982, at 13.

¹⁹ Balanced Budget and Emergency Deficit Reduction Act of 1985, Pub. L. No. 99-177, 99 Stat. 1037 (1985) (popularly known as "Gramm-Rudman-Hollings"). This legislation sets a maximum congressional budget deficit target for 1985 to 1990. *Id.* Title II, § 201(a)(7). Once that target is exceeded by more than \$10 billion dollars, the President is empowered to reduce the excess deficit by sequestering federal program funds. *Id.* § 252. Medicare budget cuts are subject to special sequestration rules. *Id.* § 256(d)(1).

²⁰ *Id.* § 256(d)(1).

²¹ Medicare outlays for 1987 are projected to be over \$71 billion. Executive Office of the President, Office of Management and Budget, *Historical Tables*, Table 3.1, at 3.1(6) (1987). Four other major laws have played a role in the slowdown in Medicare outlays. U.S. GENERAL ACCOUNTING OFFICE, *MEDICARE AND MEDICAID: EFFECT OF RECENT LEGISLATION ON PROGRAM AND BENEFICIARY COSTS*, REPORT NO. HRD-87-53 (1987), reprinted in 4 *MEDICARE AND MEDICAID GUIDE* (CCH) ¶ 36,243, at 13,749, 13,762 (Apr. 1987). See *id.* at 13,752-54, 13,759-60, 13,762 (discussing the impact of the Omnibus Budget Reconciliation Acts of 1981 and 1986, the Deficit Reduction Act of 1984, and the Consolidated Omnibus Budget Reconciliation Act of 1986). See also, e.g., U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH CARE FINANCING ADMINISTRATION, REVISION TO THE COMPOSITE RATE SYSTEM, PROCESSING RENAL EXCEPTION REQUESTS, AND FUNDING OF ESRD PROGRAMS BASED ON OBRA, PROGRAM MEMORANDUM (INTERMEDIARIES) NO. A-86-32 (Jan. 1987), reprinted in 4 *MEDICARE AND MEDICAID GUIDE* (CCH), ¶ 35,987, at 12,899-901 (Feb. 1987) (reduction in base payment rates for dialysis treatments and funding for ESRD network facilities).

²² Based on information obtained from the Health Care Financing Administration, HHS.

It has been estimated that each year hundreds, and perhaps thousands, of new technologies are developed.²³ Many are very expensive. For example, magnetic resonance imaging (MRI), the new imaging device, costs between \$800,000 and \$2 million per unit. A lithotriper, a device used to dissolve kidney stones without surgery, can cost between \$600,000 and \$1.5 million. The total price for coronary artery by-pass surgery, neo-natal intensive care, and kidney dialysis all number in the billions of dollars. Some of these new technologies save money in patient care costs, and so pay for themselves. Others do not. In any event, it has been estimated that new technology has accounted for a 50% increase in per diem costs of hospital care.²⁴

III. THE COST OF ONE NEW TECHNOLOGY: HEART TRANSPLANTS

The improved ability to transplant hearts illustrates the present dilemma over costs. Successful heart transplantation is a recent medical miracle. As recently as the early 1970s, less than 25% of all heart transplant patients survived more than five years. But the improvements in surgical techniques and the use of cyclosporine, the anti-rejection drug, have raised five year survival rates to over 40%.²⁵ In 1984, 346 heart transplants were performed.²⁶ In 1986, the last year for which data are available, 1,368 were performed.²⁷ Heart transplants cost between \$57,000 and \$110,000 each, and the average cost is \$95,000.²⁸

In November of 1979, the federal government authorized Medicare payment for heart transplants at Stanford University on a temporary basis pending the development of final criteria for establishing coverage. In June, 1980, just seven months later, Medicare coverage was discontinued in an apparent effort to avoid the massive costs involved. The Secretary of Health and Human Services (HHS) announced, at that time, that

²³ Evans, *supra* note 16, at 2049.

²⁴ *Id.* at 2049, 2050.

²⁵ R. EVANS, D. MANNINEN, T. OVERCAST, L. GARRISON, J. YAGI, K. MERRIKIN, & A. JONSEN, THE NATIONAL HEART TRANSPLANTATION STUDY: EXECUTIVE SUMMARY, Figure ES-3, at ES-48 (Battelle Human Affairs Research Centers, Seattle, Washington (1985)).

²⁶ U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH CARE FINANCING ADMINISTRATION, ORGAN TRANSPLANTATION QA 2 (1987).

²⁷ *Id.*

²⁸ *Organ Transplants: Hearing Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 99th Cong., 2d Sess. 71 (1987) (statement of Roger W. Evans, Ph.D.).

Medicare would evaluate not only the safety and efficacy of new technologies, but also their "social consequences," before "financing their wide distribution."²⁹ Thereafter, HHS contracted with the Battelle Institute to conduct a massive technology assessment, which was not completed until late 1984.

The Battelle study revealed how expensive a heart transplant program could become. According to the Battelle Institute study, each year, over 84,000 Medicare beneficiaries of all ages die of heart ailments when they might be kept alive by a transplant.³⁰ For the whole population, the number is about 272,000.³¹ Of course, not all these people would meet the applicable medical criteria. The Battelle study estimated that less than 14% of eligible patients would actually qualify for transplants under the prototypical Stanford criteria.³²

Until now, the availability of donor hearts suitable for transplantation has been a natural limitation on the number of transplants. But this is changing. The Battelle study estimated that, each year, there are about 16,000 suitable donor hearts. Although few of these are currently donated, the study estimated that, if more efforts were made to secure organs and, especially, to encourage heart donations from dying patients (or their families), the number could be increased dramatically. One estimate was that about 8,500 hearts could become available.³³

Already, such efforts have begun. In 1984, Congress passed the National Organ Transplant Act, which, when funded, will promote "systematic efforts" by organ procurement organizations to acquire all usable organs, including arrangements with hospitals to identify potential donors, professional education, and improved means of acquisition and preservation of organs. An organ sharing network is planned.³⁴

Even more aggressive steps are being taken to encourage organ donations. At least three states (California, New York, and Oregon) have passed laws *requiring* hospitals to ask families if they are willing to donate a dying patient's organs.³⁵ One proposal for increasing organ retrieval went so far as to suggest legislation to create a *presumption* that all dying persons consent to organ donations—unless they, or their next of kin, expressly refuse.³⁶

²⁹ R. EVANS, *supra* note 25, at ES-8-9.

³⁰ R. EVANS, *supra* note 13, at Table 13-28.

³¹ *Id.* Table 12-13.

³² R. EVANS, *supra* note 25, at ES-29.

³³ *Id.* ES-36, Table ES-13.

³⁴ Pub. L. No. 98-507 (1984).

³⁵ Washington Post, October 23, 1985, Health Section, at 5.

³⁶ Sanders & Dukeminier, *supra* note 6, at 410-13.

While legislation creating such a presumption seems unlikely, it is not hard to imagine that financial incentives could be offered to encourage organ donation. To quiet ethical concerns about "buying" organs, the incentive could take the form of an offer to pay uninsured medical and funeral costs.

Moreover, as recent news stories demonstrate, medical science is on its way to producing another miracle—the artificial heart. And as Baby Fae, the infant who received the baboon heart, showed us, animal organ transplants are also on the horizon. Once these procedures are perfected, there will be no natural limit to the supply of hearts. Medicare does not currently cover the expenses of artificial heart transplants, but Health Care Financing Administration (HCFA) officials have left open the possibility of extending coverage to experimental medical procedures once they are approved by the Federal Drug Administration.³⁷ Medicare already pays for various organ transplants—kidney, cornea, bone marrow, and liver (for children with end-stage liver disease).³⁸

It may take three years, or 10, but these efforts will inevitably increase the number of hearts available for transplantation far beyond anything currently anticipated. The increase in availability will make a heart transplantation program extremely expensive. Even if only the projected 8,500 transplants are performed for Medicare recipients each year, and each transplant costs a conservatively estimated \$80,000, the annual bill for heart transplants would be over \$680 million. For that limited population, this one medical procedure could result in an increase in total Medicare costs equal to almost half of the amount of the cut mandated by Gramm-Rudman-Hollings. This does not include annual follow-up costs of six to twelve thousand dollars for each patient, costs which increase geometrically each additional year of the program.³⁹

At a not too distant date, it will be possible to perform many more transplants, as more donor, artificial, and animal hearts become available. If only half of those needing a new heart were given one, the price would be over \$3 billion for Medicare beneficiaries alone. If the kidney

³⁷ U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH CARE FINANCING ADMINISTRATION, HCFA RULING NO. HCFAR 87-1, MEDICARE PROGRAM: CRITERIA FOR MEDICAL COVERAGE OF HEART TRANSPLANTS (Apr. 6, 1987), reprinted in 4 MEDICARE AND MEDICAID GUIDE (CCH) ¶ 36.216, at 13,616, 13,619 (Apr. 1987) (hereinafter HCFA RULING NO. HCFAR 87-1).

³⁸ Heckler, *Exciting New Era of Organ Transplantation Progress Poses Numerous Ethical Questions*, U.S. Government Printing Office (1985).

³⁹ R. EVANS, *supra* note 25, at ES-19.

dialysis experience were repeated, and coverage were extended to the whole population, the cost would be over \$10 billion annually.

These staggering numbers help explain why federal health officials were so hesitant to extend Medicare coverage to heart transplants. Medicare officials realized that once they began funding heart transplants, there would be immense pressure to extend coverage to everyone in need. The simple truth is that, in deciding who gets a new treatment, the line will be drawn where the money stops.

IV. EXPANDING MEDICARE TO COVER HEART TRANSPLANTS

In mid-1986, federal officials bowed to professional and political pressure. On October 17, 1986, they announced that Medicare would soon begin to cover heart transplants. On April 6, 1987, the HCFA issued a ruling that formally extended Medicare coverage to heart transplants.⁴⁰ Coverage was extended retroactively to October 17, 1986.

In its "summary and final expenditure estimate," HCFA projected that Medicare would cover 98 heart transplants in fiscal year 1988, with an increase in federal expenditures of \$10 million. By 1990, the cost would be an estimated \$20 million.⁴¹

How are these estimates to be reconciled with the results of the Battelle study? The answer is that in the ruling Medicare did not extend Medicare coverage to all potential transplant recipients.

First, a patient must receive disability benefits for 29 months before even qualifying for Medicare benefits.⁴² However, by statute, this is not a requirement for kidney dialysis and kidney transplant patients.⁴³ This limits the number of potential recipients in two ways: (1) many patients needing a new heart simply die before their 29-month waiting period ends, and, (2) those that have been on disability long enough tend to be older, and many of them will be disqualified because of their age.

Second, the HCFA ruling sharply limits coverage in two ways. Patient selection criteria were established that substantially shrank the pool of eligible patients. Some of the criteria are given more weight than

⁴⁰ HCFA RULING NO. HCFAR 87-1, *supra* note 37, at 13.616. Hospital Insurance payments will be made under DRG #103, "Heart Transplants," and SMI reimbursements will be made on the basis of reasonable charges. *Id.* at 13.637.

⁴¹ *Id.* at 13.643, 13.645.

⁴² *Id.* at 13.620.

⁴³ *Supra* note 11.

others, and, for present purposes, only the "seriously adverse factors" need be summarized:

1. Advancing Age—a patient beyond the age of 50 (and especially between 53 to 57 years of age) must be selected with "particular care to ensure an adequately young physiologic age," and physicians must ensure the absence or insignificance of coexisting disease.
2. Disease—the presence of pulmonary, renal, systemic, or cerebrovascular diseases in the patient which would reduce the likelihood of survival or pre-existing disease in the donor heart.
3. Behavior Pattern or Psychiatric Illness—a history of behavior or psychiatric illness that would "interfere significantly with compliance with a disciplined medical regimen."⁴⁴

The foregoing are only guidelines to indicate the "type of factors or areas" HCFA requires hospitals to consider in accepting patients.⁴⁵ Hospitals are responsible for establishing their own particular criteria. However, those that propose to accept patients falling "far outside" the guidelines will not be eligible for Medicare funding. HCFA reasoned that acceptance of such beneficiaries would place them at an "unnecessary risk" and would "waste scarce resources."⁴⁶

The HCFA ruling also rations heart transplants by restricting the number of hospitals that can qualify for Medicare reimbursement. It imposes minimum standards for experience, commitment of resources and professional expertise, success, and patient selection, which can be summarized as follows:

1. Experience—hospitals must have had a cardiac transplantation program since 1985; must have performed 36 heart transplants (including 12 in 1986, 12 in 1985, and 12 during 1982 to 1985); and must have performed 500 cardiac catheterizations, 500 coronary arteriograms, and 250 open-heart operations annually since 1982.⁴⁷
2. Success—hospitals must demonstrate that 24 of the 36 patients survived for one full year, and that 12 survived for two full years;

⁴⁴ HCFA RULING NO. HCFAR 87-1, *supra* note 37, at 13,641-13,642.

⁴⁵ *Id.* at 13,641.

⁴⁶ *Id.* at 13,625.

⁴⁷ *Id.* at 13,638-39, 13,627 (response to public comments).

and must show one- and two-year actuarial survival rates of 73% and 65% respectively.⁴⁸

3. Resources—hospitals must plan to perform at least 12 transplants annually; must organize comprehensive surgical, nursing, and anesthesia heart transplant teams; and must have or make available Medicare-approved laboratory facilities.⁴⁹
4. Patient Selection—hospitals must have adequate patient selection criteria that are substantially within the Medicare guidelines for patient selection (the facility remaining responsible for the ethical considerations of its selection decisions).⁵⁰

Under these strict criteria, Medicare officials have estimated that only 10 medical centers will qualify for heart transplant funding. The HCFA acknowledged that these criteria both limit the number of facilities approved for reimbursement and preclude some patients from receiving heart transplants. In fact, the cost saving was estimated to be about \$25 million in 1990, or half the program's total cost.⁵¹ HCFA stated that, in adopting the criteria, it "did not propose to assure an even geographic distribution"⁵² of facilities and stated that it recognized "the hardship that this may place on some transplant recipients and their families."⁵³ Despite this, HCFA maintained that the criteria would ensure a successful clinical outcome and that "the issue of geographic access will diminish over time as more centers gain the necessary experience to meet the criteria."⁵⁴ Thus, those patients whose financial status precludes them from traveling to a qualified facility must wait until their local hospital meets these criteria.

By adopting these limitations on eligibility, Medicare officials obtained an easily enforced limit on the number of transplants. Without acknowledging it, Medicare officials have opted for rationing—to limit costs of this advanced medical technology.

⁴⁸ *Id.*

⁴⁹ *Id.* at 13,638, 13,640.

⁵⁰ *Id.* at 13,638. Medicare also requires hospitals to participate in an organ procurement program: to have detailed plans for patient management; and, to maintain and submit survival and selection data on both Medicare and non-Medicare heart transplant patients. *Id.* at 13,638-40.

⁵¹ *Organ Transplants: Hearing Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce, supra* note 28, at 19 (Memorandum to The Secretary of Health and Human Services from the Acting Assistant Secretary for Health).

⁵² HCFA RULING NO. HCFAR 87-1, *supra* note 37, at 13,630.

⁵³ *Id.*

⁵⁴ *Id.*

V. RATIONING ADVANCED MEDICAL TECHNIQUES

In recent years, there have been intense efforts to contain health care costs. While rationing may be abhorrent or at least exceedingly difficult for most Americans to accept, many knowledgeable commentators believe that total medical expenditures should be limited. For example, Aaron and Schwartz argue in favor of curbing expenditures that generate "benefits worth less than costs."⁵⁵ They suggest that this be accomplished by setting limits on hospital budgets, thereby forcing physicians and hospital administrators to "develop rules of thumb for defining what care constitutes standard medical practice and what care is extravagant."⁵⁶ Of necessity, this means rationing. Evans defines rationing as "[t]he process by which criteria are applied to selectively discriminate among patients who are eligible for resources that have been previously allocated to various programs."⁵⁷

Heart transplants are only one of many new medical technologies that do not save money, only suffering or lives. Many more are on the horizon. Possibly, they will be provided without concern for their cost. But assuming that society wants to limit the costs involved by restricting access to them, what methods would be available? In other words, how could access to new technologies be rationed?

From now on, with each new medical technique that emerges, society must answer two related questions: (1) Will this technique be made available to all, regardless of cost? and, (2) If not, how will it be distributed?

The first question, of course, is one of the macroallocation of resources between health and other programs, and among health programs. In answering it, society must examine the effect of allocation on anonymous "statistical lives." The second inquiry is one of microallocation, or rationing. Here society is forced to examine the effect of its decisions—often matters of life and death—on identified individuals. Unfortunately, those who advocate rationing often underestimate the moral, practical, and legal obstacles.

A. Let the Market Do Its Work

A market system rations based on ability and willingness to pay. Ordinarily, the market determines access to most goods and services. If

⁵⁵ H.J. AARON & W. SCHWARTZ, *THE PAINFUL PRESCRIPTION* 119 (1984).

⁵⁶ *Id.* at 123.

⁵⁷ Evans, *supra* note 3, at 2211.

people want something enough, they will pay its market price. The advantages of a market economy, to all citizens, outweigh the fact that many cannot afford to pay the market price for some things and, therefore, must do without them, no matter how badly they are desired.

While financial ability is accepted as the means of distributing most goods, society has generally taken a different approach to medical care. There was public outrage in 1985 when the *Washington Post* reported that rich foreign nationals were receiving a disproportionate percentage of kidney transplants in the Washington, D.C. area. The foreign nationals' ability to pay more for a transplant than that provided by private insurance or public funds made them more valuable, and therefore more attractive, patients.⁵⁸

The report of the President's Commission for the Study of Ethical Problems in Medicine and Behavioral Research reflected a widely accepted belief that society has an ethical obligation to ensure equitable access to health care for all. It asserted: "[A]ll citizens should be able to secure an adequate level of care without excessive burdens."⁵⁹

With the enactment of Medicare and Medicaid, the federal government rejected a purely market approach to providing medical care. It decided that American society was rich enough and humane enough to make provision for the medical needs of the elderly and the poor.

But the federal government does not provide medical care to all regardless of ability to pay. As a result, some 10% of the population must pay for health care from their own pockets—the unemployed, those employed by small employers, and the self-employed.

Today, the market is rationing access to heart transplants. Except for the few individuals lucky enough to qualify under the Medicare criteria (and to be accepted by a hospital that also qualifies) or lucky enough to be on Medicaid in one of the states that funds transplants, the only way to get a transplant is to buy one or have one's health insurance pay for it (assuming that the policy covers transplants). Three-quarters of large private insurance companies pay for heart transplants.⁶⁰ This is rationing. The winners are those who can afford private medical insurance that pays for transplants or who work for employers who buy the insurance for them.

Thus, some people will die because they cannot afford a heart

⁵⁸ *Washington Post*, June 10, 1985, at C1, col. 1.

⁵⁹ PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BEHAVIORAL RESEARCH, SECURING ACCESS TO HEALTH CARE 4, 25 (1983).

⁶⁰ R. EVANS, *supra* note 25, at ES-85.

transplant. The media recently reported the story of a 19-year-old girl who needed a heart transplant. She was accepted into the Stanford program and told that she would be at the top of the list of candidates. All she needed was \$125,000 to pay for the transplant. Without health insurance that would cover the cost of the operation, her family was unable to raise the money. She died three months later.⁶¹

It is of course possible that the government will continue to exclude some heart transplants from full Medicare coverage, but that will require a substantial change in our social ethic. Transplantation can mean the difference between life and death, and the media can be counted on to bring into every home the names and faces of real people who are dying for lack of a transplant. As knowledge about the efficacy of these new technologies grows, it takes little imagination to predict that the political pressure to fund them could become irresistible. After all, the development of most advanced medical techniques is only possible because public funds are available.

Thus, even if routine medical care were distributed on the basis of ability to pay, society might well reject that method when the patient's life is at stake. Furthermore, it will be difficult to deny Medicare coverage of transplants for people who could return to healthy, productive lives while continuing to provide, for example, kidney dialysis treatments for elderly, comatose patients, as is now the case.

Assuming that society decides that ability to pay or the possession of private insurance should not alone decide who gets access to advanced medical techniques, what else is there that does not open the floodgates to additional and uncontrolled spending? This takes us to the next form of rationing—putative medical criteria.

B. Establish Strict Medical Criteria

Once it is concluded that rationing is necessary, reliance on medical criteria is, perhaps, the most acceptable approach. It is certainly the most rational—selecting patients for treatment by deciding who can benefit most therefrom. Moreover, it corresponds with public perceptions of how medical treatment decisions are made.

But the issue is more complicated if, as with heart transplants, there are more who can benefit than there are available hearts. Physicians are then asked to choose who has the greatest chance of survival.

Medical selection standards are currently being used to ration heart transplants. Generally, patients who can pay for a transplant (or who have

⁶¹ *Medical Miracles: Can We Afford The Bill?*, *supra* note 7, at 2.

insurance or Medicare or Medicaid that will pay) are deemed eligible if they have a critical medical need for a transplant, that is, they have less than a 25%⁶² likelihood of surviving more than six months. Most often, they are invalids for whom no other treatment is expected to be successful.⁶³ But since there are more who qualify even under these strict criteria, further screening is necessary.

When HHS invited transplant centers to participate in the Battelle study, it published suggested eligibility criteria developed by the National Heart, Lung, and Blood Institute.⁶⁴ The criteria illustrate the kinds of complex, subjective factors involved in an honest assessment of medical eligibility.

The guidelines are presented to demonstrate that there is no magic line that separates those whose condition justifies a transplant and those whose do not. Although the criteria vary somewhat, the six participating hospitals generally followed these criteria, which can be summarized as follows:

1. Advancing age, beyond the age (usually 50 or 55) at which the "individual begins to have diminished capacity to withstand postoperative complications."
2. Comorbid conditions, including severe pulmonary hypertension, severe liver or kidney dysfunction, active systemic infection, recent pulmonary infarction, insulin-requiring diabetes mellitus, significant peripheral or cerebrovascular disease, acute peptic ulcers, or any other systemic disease "likely to limit or preclude survival and rehabilitation after transplantation."
3. History of a behavior pattern (including drug or alcohol addiction) or psychiatric illness "likely to interfere significantly with compliance with a disciplined medical regimen."
4. "Absence of adequate external psychosocial supports for either short or long term."

Physicians undoubtedly would describe all of these criteria as medical. That is, they are designed to produce a successful clinical outcome. For example, some of the "comorbid conditions" are considered disqualifying because a patient who has one of these conditions may be unable to survive a transplant or the use of immunosuppressive drugs, which are necessary to avoid rejection of the transplant. Similarly,

⁶² HCFA RULING No. HCFAR 87-1, *supra* note 37, at 13.625.

⁶³ 46 Fed. Reg. 7072-73 (1981); HCFA RULING No. HCFAR 87-1, *supra* note 37, at 13.641.

⁶⁴ 46 Fed. Reg. 7073-74 (1981).

behavioral history and external psychosocial supports are considered relevant to the patient's ability to adapt to the necessary alterations of lifestyle, including adherence to a strict diet, medication regimen, and other restrictions.

But there are problems with the use of these medical criteria. It is not clear to what extent their predictive validity has been demonstrated empirically. Moreover, medicine is not an exact science. Relative judgments about anticipated clinical success are uncertain and highly intuitive.

Yet, physicians must assign each patient a place on the relative scale of survival. Does the patient have a 50% chance, or only 40%? At best, these percentages are only roughly accurate, based on aggregate averages of experience across many physicians and hospitals and patients.

Moreover, the vague and undefined nature of these criteria afford the decision maker wide discretion to act in accordance with personal values. That may be true even though facially valid criteria are being applied. For example, the transplant policy of one Washington, D.C. hospital, after outlining a set of explicit "clinical factors," goes on to state that such factors are "unique to each case" and that it is difficult to form and adhere to any set of explicit rules concerning them.⁶⁵

Some of these criteria may be valid as threshold qualifications. For example, an alcoholic derelict may have no prospect of adopting the necessary post-operative regimen. However, when the criteria are employed as relative qualifications (who has the optimum external supports), the result may be to favor the patient whose lifestyle reflects that of the decisionmaker.

Personal feelings also intrude in "medical" decision making. For example, in some kidney dialysis programs of the late 1960s, internists admitted that they had to like particular patients or get some psychological satisfaction from them to consider them suitable patients for treatment.⁶⁶

In 1985, physicians in Pittsburgh admitted another form of favoritism in the application of medical criteria. According to the *Pittsburgh Press*, Dr. Henry Behnson, director of surgery at Pittsburgh's esteemed Presbyterian University Hospital, admitted that doctors would select patients for transplants in violation of hospital criteria for "compassionate" reasons. "Compassionate" reasons seemed to apply in situations where the patient was running out of money to stay in Pittsburgh, was a

⁶⁵ WASHINGTON HOSPITAL CENTER, DONOR ORGAN ALLOCATION/RECIPIENT SELECTION (Wash., D.C. 1985).

⁶⁶ Sanders & Dukeminier, *supra* note 6, at 379.

doctor or a child of a doctor, or was a member of the Saudi Arabian royal family. Remarked Dr. Behnson, "I'd hope Tom [Starzl, preeminent transplant surgeon at Presbyterian] would take care of my daughter and vice-versa." One surgeon on the staff was quoted as saying that a call from the President could also qualify a patient for a "compassionate" transplant. Dr. Starzl was quoted as saying that transplants might be done for "diplomatic" reasons.⁶⁷

Another problem in trying to ration by purely medical criteria is that physicians are ill-equipped to serve as rationing agents. Their training, ethical standards, and social role prepare them to serve in the best interests of each patient, not to choose among patients. Writing in the *New England Journal of Medicine*, Dr. Norman Levinsky stated: "When practicing medicine, doctors cannot serve two masters. It is to the advantage of both our society and of the individuals it comprises that physicians retain their historic single-mindedness. The doctor's master must be the patient."⁶⁸

Although the present severe shortage of donor hearts has forced physicians to ration by criteria aimed generally at identifying those most likely to survive a transplant, when donor hearts and funding are more available, medical criteria would relax and physicians would be inclined to treat all for whom the likely benefit did not outweigh the risk.

The kidney dialysis experience demonstrates that medical criteria are not static, but respond to considerations of availability and funding. In 1972, there were 10,000 patients on kidney dialysis; over the years the number has risen to 78,000. In significant part, this is due to a relaxation of selection criteria, so that dialysis is provided to older and sicker patients. For example, before 1972, only seven percent of dialysis patients were over 55. By 1978, more than 45% were over 55.⁶⁹

Therefore, while it might be possible to establish criteria that avoid the obvious weaknesses of existing approaches, no honest medical criteria would provide a meaningful restriction on ultimate costs. All medical criteria are a function of available funding. This reality brings up the next two forms of rationing which, for purposes of discussion, can be divided into two categories—egalitarian and utilitarian.

C. The Egalitarian Approach—Use a Queue or a Lottery

Assuming that X dollars are available for a particular medical treatment and that basic medical suitability is established (recognizing

⁶⁷ Schneider & Flaherty, *Favoritism Shrouds Presby Transplants*. Pittsburgh Press, May 12, 1985.

⁶⁸ Levinsky, *The Doctor's Master*, 311 *NEW ENG. J. MED.* 1573, 1579 (1984).

⁶⁹ R. EVANS, *supra* note 25, at ES-103, Table ES-26.

that even this is an ambiguous concept), access could be determined by random selection. Under a lottery, after a pool of those needing treatment is developed, final selection is done by the luck of the draw. The draft lotteries of the not so distant past provide an apt picture of how a lottery might be approached. As need be, the names of winners could be pulled from the wicker basket or the bouncing ping-pong balls.

Lotteries expose the arbitrariness of random decision making processes, and it is not surprising that research uncovered only one example of a medical lottery, the Los Angeles procedures for determining access to kidney dialysis described earlier.

A queue has received more serious consideration. The Massachusetts Task Force on Organ Transplantation, for example, recommended a queue system because "it most closely approximates the randomness of a straight lottery, without having [the] obviousness of making equity the only value being promoted."⁷⁰ In the manner of a bread line, advanced medical techniques could be rationed on the basis of "first come, first served." A waiting list could be established, then published, so that people know where they stand in line, much as is done for many public housing projects.

Rationing by queue takes place in Britain, where many patients must wait considerable periods of time—even years—for many surgical procedures. After being referred for treatment, patients are added to a waiting list, and then must wait their turn in the queue for treatment, although exceptions are made for emergencies.⁷¹ A queue system was also used at several hospitals in the 1960s to ration kidney dialysis, including Georgetown University Hospital, Montefiore Hospital, Yale–New Haven Hospital, and the Veterans Administration hospitals in Portland, Oregon and Bronx, New York.⁷²

The Massachusetts Task Force on Organ Transplantation recommended a two-step selection process. Initial screening, by a medical committee, would be based on medical suitability. If there were insufficient resources to transplant all who could benefit, selection by a second committee from the medically-suitable group would be based "primarily" on a first-come, first-served basis.⁷³ The highest ranking candidate who is tissue and size "matched" to the donor will receive the heart. The proposal allows for "jumping" the queue if the second level

⁷⁰ DEPARTMENT OF PUBLIC HEALTH, COMMONWEALTH OF MASSACHUSETTS, REPORT OF THE MASSACHUSETTS TASK FORCE ON ORGAN TRANSPLANTATION 81 (1984) (hereinafter MASSACHUSETTS TASK FORCE REPORT).

⁷¹ H.J. AARON & W. SCHWARTZ, *supra* note 55, at 104.

⁷² Note, *supra* note 2, at 659-60.

⁷³ MASSACHUSETTS TASK FORCE REPORT, *supra* note 70, at 16.

selection committee believes an individual is "in immediate danger of death and the person who would otherwise get the organ can survive long enough to be reasonably assured that he or she will be able to get another organ."⁷⁴ Of course, this means that the first individual faces a marginally greater danger of dying before another suitable heart is found.

If queue jumping is permitted, differences in patient income, education, social access, and geographic location could result in inequalities of access. For example, in Britain, an aggressive physician can sometimes short-circuit the queue to get preferential treatment for a patient.⁷⁵

Most importantly, both lotteries and queues can produce results that are most charitably described as anomalous. They can award a new heart to a 65-year-old person but deny one to an individual who is 45 years old. At the extreme, they can award a new heart to a convicted murderer while letting the mother of five children or a research scientist die. Remember the mini-uproar when the first Swedish artificial heart was implanted in a tax dodger. Such results might well offend notions of fairness and efficiency,⁷⁶ and could be seen as a "capitulation to irrationality."⁷⁷

Certainly, a lottery or a queue system that would deny a new heart to the President of the United States would be unacceptable. It has been suggested that some "escape valve" from the queue be permitted for an individual expected to make a contribution that he or she alone can make and that is "related to a concern which society values more than the life of one man."⁷⁸

It is likely that an egalitarian approach would add utilitarian considerations to the process. For example, the Massachusetts Task Force, although proposing a queue to avoid using "conscious, value-laden, social worth selection criteria" of the sort employed by the Seattle Artificial Kidney Center,⁷⁹ nevertheless described the purpose of the initial medical screening as offering "transplantation to those who can benefit the most from it in terms of probability of living for a significant period of time with a reasonable prospect for rehabilitation."⁸⁰ Thus, it is clear that even a random system may employ social worth criteria.

⁷⁴ *Id.* at 81.

⁷⁵ H.J. AARON & W. SCHWARTZ, *supra* note 55, at 54.

⁷⁶ Annas, *The Prostitute, the Playboy, and the Poet: Rationing Schemes for Organ Transplantation*, 75 AM. J. PUB. HEALTH 187, 188 (1985).

⁷⁷ Bayer, *Justice and Health Care in an Era of Cost Containment*, 9 SOC. RESPONSIBILITY 37, 39 (1983).

⁷⁸ Note, *supra* note 2, at 663-64.

⁷⁹ MASSACHUSETTS TASK FORCE REPORT, *supra* note 70, at 80.

⁸⁰ *Id.* at 16.

The problem lies in deciding who, besides the President, should get a new heart. What, then, can be said about such explicitly utilitarian rationing?

D. The Utilitarian Approach—Determine the Social Worth of Providing Treatment

A utilitarian rationing scheme would explicitly employ the kinds of social worth criteria that are an implicit element in many medical criteria. Social worth criteria could be used to measure the value to society of saving an individual's life. Considerations could include the patient's occupation, marital status and family size, religious/moral attributes, intelligence, economic status, and educational background.

It seems highly unlikely that evaluation of social worth by any of these criteria would be considered an acceptable basis for rationing. Principles of equality reject the notion of evaluating the relative worth of individuals. Even if such evaluations were acceptable, consensus would be achieved only at the extremes—preferring a research scientist over a mass-murderer. Otherwise, there would be no general agreement on the importance of any of these criteria. Such an approach would be reminiscent of the workings of the Seattle "God squad."

It is also possible that social worth criteria will be adopted in the guise of medical criteria. Consider the National Heart, Lung, and Blood Institute patient selection criteria for heart transplants described above. Although these are medical criteria in the sense that they are designed to maximize the chances of achieving a successful clinical outcome, they also seem to reflect social worth considerations.

Purely medical criteria evaluate prospects of successful clinical outcome by answering the threshold question: Will this patient benefit from the procedure? With patients who are estimated to live no longer than six months without a transplant, the answer would seem to be that anyone whose life can be extended would benefit. Of course, if a life is prolonged for only one day we would conclude that such *de minimis* benefit does not constitute clinical success. It is hard, however, to conclude that the patient who lives an additional year does not represent a clinical success.

The criteria, moreover, are not designed simply to identify those who are most likely to benefit. They appear also to be aimed at singling out those who can survive longer and be more productive. The most obvious example is the criterion of "advancing age," that is, over 50 or 55. Chronological age may be a general indicator of physiological condition, but a cut-off of 50 or 55 seems arbitrary. Although the Battelle study

reports a statistical correlation between age and ability to survive a heart transplant, it does not define survival (such as, one month or one year). Moreover, the statistics do not fully justify the 50-55 cut-off. The study examined the numbers of transplant patients in each age category who were alive, compared to the number who had died. Of those 30-39, 50% were still alive at the time of the study, of those 40-49, 39% were still alive and of those over 50, 21% were still alive.⁸¹

Medical condition is easily evaluated on an individual basis. Patient-selection criteria include a litany of comorbid conditions which would be contraindications to treatment. It is not clear what age adds to these more specific criteria. Hence, it is reasonable to ask whether age is being employed, at least to some extent, as a social worth criterion to measure future contribution in terms of life expectancy and anticipated productivity. An unstable behavioral or psychological history (including alcoholism and drug addiction) and the absence of external psychosocial supports could be seen to reflect nonmedical considerations, as well.

Age and rehabilitative potential may be more acceptable measures of social worth than other criteria. Surely they are easier to apply than more general notions of value to society. Age is completely objective. Rehabilitative potential, while more subjective, can be measured by objective factors. If our purpose is to maximize the benefit derived from a heart transplant, the use of age and rehabilitative potential may be justified.

At the same time, these criteria adversely affect members of certain groups—the aged and the handicapped—who, in the past, have been the victims of discrimination. A national policy against such discrimination is embodied in the Federal Age Discrimination Act⁸² and the Rehabilitation Act.⁸³

VI. POSSIBLE LEGAL CHALLENGES TO SOCIAL WORTH CONSIDERATIONS

Current rationing criteria for hearts have so far gone unchallenged because of the great scarcity of donor hearts and the absence of artificial or animal substitutes. As has been seen, this scarcity is sure to lessen, if

⁸¹ R. EVANS, *supra* note 25, at ES-47, Table ES-15.

⁸² Federal Age Discrimination Act of 1975 (codified at 42 U.S.C.A. § 6101 (1985)) (purpose of the Act is to prohibit discrimination on the basis of age in programs or activities receiving federal financial assistance).

⁸³ Rehabilitation Act of 1973 (codified at 29 U.S.C.A. § 701 (1985 & West Supp. 1987)) (purpose of the Act is to maximize employability, independence, and integration of handicapped individuals into the community through research, training, services, and the guarantee of equal opportunity).

not disappear. As availability increases, the standards of purely medical suitability would be expected to relax.⁸⁴ When that happens, the social worth character of existing selection criteria will become more apparent.

These criteria are vulnerable to legal attack from several different directions. Most likely to be challenged first is the age cut-off. The Federal Age Discrimination Act, passed in 1973 and amended in 1978,⁸⁵ prohibits discrimination on the basis of age in all federally financed programs, which includes all hospital and other facilities which receive Medicaid and/or Medicare Part A funding for hospital costs. An age qualification for participation clearly violates the terms of the basic prohibition, although there are a number of statutory exceptions which may permit the use of age if it is a valid and necessary predictor of clinical success. If, however, age is used as a measure of social worth, its validity would be highly questionable. The enactment of this legislation must be seen as a rejection by Congress of the notion that the elderly are less worthy than others.

This Act, as well as section 504 of the Rehabilitation Act and Title VI of the Civil Rights Act of 1964, reaches the activities of private and public recipients of federal financial assistance. If HCFA guidelines are read to authorize exclusion of potential transplant patients on the basis of age, handicap, or other prohibited criteria, an additional issue is presented. Can the federal government, by regulation, authorize a selection process by a recipient of federal funds that would otherwise violate these statutes? Under Section 504 and Title VI, the answer is that it probably cannot. But under current case law, it remains an open question. Under section 90.3 (b)(1) of Title 45 of the Code of Federal Regulations, which exempts age-related criteria established by statute from the prohibition contained in the Federal Age Discrimination Act, it appears that only a statute, not a regulation, can provide such authorization.

The consideration of rehabilitative potential raises legal issues under section 504 of the Rehabilitation Act.⁸⁶ That section prohibits discrimination in federally financed programs against "otherwise qualified" handicapped individuals.⁸⁷ Handicapped individuals protected by the Act

⁸⁴ R. EVANS, *supra* note 25, at ES-102.

⁸⁵ 42 U.S.C.A. § 6101 (1983), as amended by Comprehensive Older Americans Act Amendments of 1978, Pub. L. No. 95-478, 92 Stat. 1513 (1978).

⁸⁶ 29 U.S.C.A. § 794 (West, Supp. 1987).

⁸⁷ Section 504, codified as amended at 29 U.S.C.A. § 794 (West Supp. 1987) provides:

No otherwise qualified individual with handicaps in the United States . . . shall, solely by reason of his handicap, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance or under any program or activity conducted by any Executive agency . . .

include those who have a physical or mental impairment which substantially limits a major life activity, have a record of such an impairment, or are regarded as having such an impairment.⁸⁸ In addition to physical disorders, the Act applies to mental or emotional illness, alcoholism, and drug addiction as handicapping conditions.⁸⁹ In the area of health care, handicapped individuals would not be considered "otherwise qualified" if they fail to meet eligibility criteria,⁹⁰ so long as those criteria are legitimate and necessary to accomplish the purpose of the program. In other words, if the heart transplant program has, as one of its eligibility criteria, a requirement that recipients be sighted, it would certainly discriminate against blind patients in violation of the Rehabilitation Act. A good argument can be made that anyone who can benefit from a heart transplant under purely medical criteria is otherwise qualified.

Of course, those with conditions such as severe pulmonary hypertension or severe kidney dysfunction may be handicapped but they nevertheless may be excluded if their condition makes it unlikely that they would survive a heart transplant. On the other hand, if they are excluded because it is thought that, even after a transplant, they will be unable to return to an active life, the exclusion would probably violate the law. If rehabilitation means achieving some minimal level of functioning, it may exclude those with other physical and mental disabilities. Decisions based upon expected "quality of life" would probably not be upheld under the Rehabilitation Act. Of course, the Act probably would not require hospitals to give a transplant to a patient who cannot be expected to return to consciousness.

The criteria involving mental and emotional condition, including alcoholism and drug addiction, are also suspect. The Rehabilitation Act was enacted largely to prevent the use of untested generalizations about the handicapped which deny them access to government funded programs.⁹¹ At the very least, any disqualifying criterion which explicitly incorporates a handicapping condition will be subject to close scrutiny to determine whether it is necessary to achieve the program's goals. Government regulations specifically prohibit a health care facility from discriminating in admission or treatment against a drug or alcohol abuser who seeks treatment for a medical condition.⁹²

The more difficult question is how section 504 should be interpreted

⁸⁸ 29 U.S.C.A. § 706(8)(B) (West Supp. 1987).

⁸⁹ 45 C.F.R. §§ 84.3(j)(2)(i), 84.53 (1986).

⁹⁰ *Southeast Community College v. Davis*, 442 U.S. 397 (1979).

⁹¹ *School Bd. of Nassau County, Fla. v. Arline*, 107 S.Ct. 1123, 1126 (1987).

⁹² 45 C.F.R. § 84.53 (1986).

in light of a scarcity of resources. The language of the provision is absolute barring discrimination against those persons who are "otherwise qualified." It does not appear to contemplate relative judgments of qualification. If a handicapped person is considered qualified, but less qualified than others because of the handicapping condition, may the individual be rejected in favor of the more qualified? It would seem that if a heart transplant program is truly choosing patients most likely to survive a transplant and a handicapped patient is rejected because the likelihood of survival is somewhat less, this may nevertheless be consistent with the Act.⁹³ It is much easier to accept this interpretation when choices are forced upon us by natural scarcity than when the scarcity is artificially created. At the same time, relative judgments based on expected level of functioning probably would be unacceptable.

Other criteria, like external psychosocial supports, may have a statistically significant adverse impact on identifiable groups, including blacks and the handicapped. That is, proportionately fewer blacks and handicapped will be able to satisfy that criterion. Although this is not a criterion explicitly using race or handicap, it may still be subject to challenge for its disproportionate effect under Title VI of the 1964 Civil Rights Act⁹⁴ or section 504.⁹⁵ Again, such a criterion would have to be closely scrutinized to determine whether it is necessary to accomplishing the objectives of the heart transplant program.

Many of the patient selection criteria for heart transplants are vague and undefined, thereby vesting broad discretion in the decisionmaker. Such discretion permits the exercise of existing biases. Purposeful discrimination on the basis of race, age, or handicap is certainly barred by the statutes discussed above.

There also may be potential medical malpractice liability for physicians and hospitals. Generally, physicians are obligated to inform patients of all possible treatments.⁹⁶ Once a patient is in the care of a physician the physician has a duty to provide all appropriate treatment.⁹⁷ Even if the physician withdraws from the physician-patient relationship,

⁹³ See *Doe v. New York University*, 666 F.2d 761 (2d Cir. 1981).

⁹⁴ 42 U.S.C.A. § 2000d (1981). Section 601 of Title VI provides: "No person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance." *Id.*

⁹⁵ *Guardians Ass'n v. Civil Service Comm'n of New York*, 463 U.S. 582 (1983) (Title VI); *Alexander v. Choate*, 469 U.S. 287, 292-99, & n.17 (1985) (section 504 and 45 C.F.R. § 84.4(b)(4) (1986)).

⁹⁶ See, e.g., *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir.), cert. denied, 409 U.S. 1064 (1972); *Truman v. Thomas*, 27 Cal. 3d 285, 611 P.2d 902 (1980).

⁹⁷ See W. PROSSER, *HANDBOOK OF THE LAW OF TORTS* 162-64 (4th ed. 1971).

the patient must be referred to another physician who could provide the treatment.⁹⁸ In some states, a physician must obtain the informed consent of the patient before the patient declines treatment.

The hospital has a more general obligation to ensure that adequate care is delivered. While the hospital is not responsible for individual treatment decisions, it may not prevent an eligible patient from receiving an appropriate treatment available in the hospital.

Of course, physicians are generally held to a standard of care measured by the practice of other physicians.⁹⁹ If the eligibility criteria are generally accepted among transplant specialists, adherence to those criteria would provide a defense to most malpractice actions. While there is still a severe scarcity of donor organs, these strict criteria will continue to be applied by most physicians. But when availability is increased, some physicians will begin treating patients who do not meet the strict criteria and may thereby establish a standard of care which takes in a wider group of patients. At that point, narrower rationing schemes could expose physicians and hospitals to possible liability, especially if the selection standards can be challenged as unreasonable.

Social worth criteria are rarely explicitly labeled as such, and this consideration, combined with the fact that most people are either ignorant that the patient's social worth is being considered or are in agreement with the decision to withhold treatment, has prevented a major challenge to them. But unless newly developing technologies are made as widely available as they were in the past, it seems likely that this kind of rationing will become more visible—and more subject to challenge.

Therefore, if medical criteria are to survive legal attack, it must be clear that they are not social worth criteria in disguise. Medical criteria which exclude individuals based on age or handicap will be upheld only if they are legitimate and necessary in predicting clinical success. In addition, using age and rehabilitative potential as social worth criteria will probably require statutory authorization by Congress. One must question how likely Congress is to do this in light of its past inability to deny life saving medical treatments to voters and their families.

CONCLUSION

Society has not yet been forced to adopt widespread rationing of medical care. The climate, however, is changing. With federal budget

⁹⁸ See, e.g., *Spendlove v. Georges*, 4 Utah 2d 392, 295 P.2d 336 (1956); *Hall v. Nagel*, 139 Ohio St. 265, 39 N.E.2d 612 (1942).

⁹⁹ See W. PROSSER, *supra* note 97.

reductions, programs which, in the past, have been allowed to grow indiscriminately, will be faced with the need to cut expenditures. Assuming, for the purposes of discussion, that existing benefits will not be reduced sufficiently to pay for the provision of advanced medical technologies, this article has described the various ways in which access to them might be rationed.

Before adopting such ethically troubling schemes to decide who should live and who should die, society should sharply reconsider the open-ended and largely unquestioning way in which other medical services are provided—a practice that creates the financial pressure to ration advanced technology. The overuse of heart bypass operations has led them to be called the hysterectomies of the 1980s. Similarly, it seems impossible to justify denying heart transplants for people who could return to healthy, productive lives while continuing to use limited Medicare funds, for example, to pay for dialysis treatments of elderly, comatose patients, as is now the case. That Medicare coverage for even minor medical procedures, like bunion removals, is not based on the patient's ability to pay only magnifies the inequities of current reimbursement policies.¹⁰⁰

Asking such questions about the relative merit of different health care benefits is not for the faint of heart. It is many times more difficult to take away benefits from current recipients—and the industry groups that serve them—than it is to refuse to give a new benefit, however needed, to an amorphous group of potential beneficiaries. Entering this political and ethical thicket will require government leaders to show common sense and courage, two commodities in short supply these days. But it is worth a try. After all, heart transplants are only one of the many expensive new medical techniques that do not save money—only lives.

¹⁰⁰ See generally Meyer, *Imbalance, Inequity, and Inefficiency in Health Care Financing*, 2 BELL ATL. Q. 7 (Summer 1985).