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AGE-BASED RATIONING AND TECHNOLOGICAL DEVELOPMENT

MAXWELL J. MEHLMAN*

I. INTRODUCTION

In his book *Setting Limits*, Daniel Callahan asserts two main theses. First, he urges that society reevaluate its position on aging and death so that the appropriate goal of medicine shifts from prolonging life to "helping people to live out a full and natural life span."¹ This author has no quarrel with Dr. Callahan's suggestion. Evidently distrusting that the aged and their caregivers will embrace this goal voluntarily, Dr. Callahan proposes as his second major theme that his approach be imposed on them through limitations on public spending, chiefly under the Medicare program.² "Medicare benefits," he states, "would be denied to some elderly people . . ."³ In particular, he advocates that benefits be denied to those persons who had lived a "natural life span," which Dr. Callahan refuses to specify in years beyond saying that "it would normally be expected by the late 70s or early 80s."⁴

Dr. Callahan recognizes that hinging his rationing program on the denial of Medicare benefits creates a problem of unfairness: not all elderly persons would die for lack of life-extending treatment, but only those who could not afford to buy the treatments for themselves outside of the Medicare system.⁵ Life-extending care could be financed not

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1. D. CALLAHAN, *SETTING LIMITS: MEDICAL GOALS IN AN AGING SOCIETY* 223 (1987) [hereinafter *SETTING LIMITS*].

2. *See id.* at 115-58. Dr. Callahan does not explain why voluntary rationing—the process whereby the elderly simply renounce life-extending care—is insufficient to achieve his objectives of rationing medicine and restoring its social and fiscal responsibility. Perhaps he is concerned that his ideas will never be accepted by enough people to achieve these goals. Alternatively, he may be concerned about the free rider problem, whereby those individuals who wished to live longer did so at the expense of those who did not.

3. *Id.* at 198.

4. *Id.* at 171.

5. *See id.* at 156-57. "That such a priority system would invite some abuses and create some new problems should not be denied or minimized. A government policy of denying Medicare support for life-extending treatment beyond a certain age would favor those elderly who could afford personally to pay for such care." *Id.*

only out of personal resources, but also with family funds,⁶ charitable contributions,⁷ and private insurance. This replaces the public wealth-transfer system represented by Medicare with a system of private wealth transfers that favors: (1) those able to finance care themselves or purchase insurance; (2) those with supportive or guilt-ridden families or friends of substantial financial means; and (3) those who are sufficiently attractive, well-connected, or well-marketed to provoke an adequate philanthropic response by the public.

At first Dr. Callahan downplays the significance of this problem when he states:

[A] rigorous effort to enforce egalitarian solutions is a good prescription for an authoritarian society. The benefits of the unfairness (if such it is) of the system I propose would be limited to those beyond a certain age, and precisely because of that advanced age would for most be a limited benefit, to be terminated shortly by death. I do not believe a society would be made morally intolerable by that kind of imbalance.⁸

Eventually, however, he begins to appreciate that unequal treatment of the elderly on the basis of wealth could threaten his entire rationing scheme: "The negative symbolism of a society and a medicine that denied life-saving care to those too poor to pay for it need not be elaborated upon. It could be potentially troubling at the least, and scandalous if widespread."⁹ Indeed, society repeatedly has balked at rationing life-saving care on the basis of wealth.¹⁰ For example, con-

6. See *id.* at 157 ("A government policy of denying Medicare support for life-extending treatment beyond a certain age . . . could also severely tempt many middle-class families to sacrifice their less-than-ample resources to save the life of a loved one they are not yet ready to relinquish.").

7. See *id.* at 198-99. Dr. Callahan's concern with charitable contributions raises the prospect of public as well as private appeals for assistance. He writes:

To make life-extending care available only to those who could pay for it would not necessarily mean that only the rich or affluent would benefit. It could and no doubt would invite desperate efforts to raise the needed money among those of modest means; they could spend themselves into impoverishment.

Id.

8. *Id.* at 157.

9. *Id.* at 199.

10. Denying life-saving care on the basis of wealth is different than allowing wealthy patients to purchase a better quality of health care than poor patients. So long as health care resources are developed and sold at least in part in a market-like environment, disparities of the latter sort will persist. Arguably, society merely has an obligation to ensure that all of its members receive an adequate, but not an optimum or equal level of care. See 1 PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, SECURING ACCESS TO HEALTH CARE 4 (1983) ("[T]he Commission proposes a standard of 'an adequate level of care,' which should be thought of as a floor below which no one ought

cern over the inability of poor patients with end-stage renal disease to obtain kidney dialysis in the late 1960s was a major reason for the initiation of the Medicare End-Stage Renal Disease Program,¹¹ which Dr. Callahan criticizes for its expense.¹² More recently, the Oregon legislature reinstated Medicaid payment for certain organ transplants after a storm of protest.¹³

One alternative that Dr. Callahan considers to avoid this problem is to prohibit anyone from purchasing or delivering life-extending care for the elderly—"[t]o make such care explicitly unlawful."¹⁴ He prudently rejects the idea, however, fearing the creation of a "lucrative black market," which would be impossible to police and which would encourage crime.¹⁵ Not only would such a ban promote profiteering, but it would penalize those providers who felt duty-bound to deliver life-extending care regardless of the patient's ability to pay. In any event, there would be no practical way of preventing the rich from purchasing abroad the care that they desired, in much the same way that, in the past, abortions that were not available lawfully in the United States were obtainable in Mexico.¹⁶

Dr. Callahan seems to have a different solution in mind. The underlying problem, as he sees it, is that we presently develop and employ

to fall, not a ceiling above which no one may rise."). As Dr. Callahan seems to recognize, however, denying life-sustaining care for elderly patients who desire to live is likely to be regarded as a denial of adequate care, at least in some cases.

11. *National Health Insurance Proposals: Hearings Before the House Committee on Ways and Means*, 92d Cong., 1st Sess., at 1524-46 (1971) (testimony of Mr. Shep Glazer, Vice President, National Association of Patients on Hemodialysis, concerning unaffordability of dialysis).

12. See SETTING LIMITS, *supra* note 1, at 144. Dr. Callahan states: "It has surely saved lives, but not for long, and the more than 80,000 users now cost well over \$2 billion a year." *Id.*

13. See Lund, *Oregon to Reinstate Transplants for Medicaid Patients*, *Am. Med. News*, Apr. 1, 1988, at 8, col. 1.

14. SETTING LIMITS, *supra* note 1, at 199. This is one of three possible alternatives offered to implement the idea of limiting life-extending health care for the elderly. See *id.* at 198-99.

15. See *id.* at 199. Dr. Callahan writes:

To make such care explicitly unlawful would pose another set of problems. Efforts to outlaw those goods or items which many people eagerly want, and often feel morally entitled to, are usually beset with enforcement problems and usually breed additional crime as an offshoot (think of the efforts to prohibit the use of alcohol in the 1920s, abortion through the 1960s, or, more recently, pornography and drugs). A lucrative black market in the saving of life among the elderly is all too plausible a scenario under any outright prohibition scheme.

16. L. LADER, *ABORTION* 57 (1966); see *Dallis v. Aetna*, 574 F. Supp. 547, 549 (N.D. Ga. 1983) (dietary treatments for cancer obtainable in Bahamas); Note, *Lae-trile: Statutory and Constitutional Limitations on the Regulation of Ineffective Drugs*, 127 U. PA. L. REV. 233, 234 (1978) (laetrile treatments obtainable in other countries).

medical technologies in a determined effort to extend the life of the extreme elderly, without regard to the quality of their lives or to the resulting drain on societal resources.¹⁷ Unless we solve this problem, we cannot expect to restrain health care expenditures for the elderly.¹⁸ Thus, he proposes that the government discourage the development or use of new technologies to extend life: "[N]o new technologies should be developed or applied to the old that are likely to produce only chronic illness and a short life, to increase the present burden of chronic illness, or to extend the lives of the elderly but offer no significant improvement in their quality of life."¹⁹ The accomplishment of this goal would require "[f]orthright government declarations that Medicare reimbursement will not be available for technologies that do not achieve a high, very high, standard of efficacy."²⁰

Formulated in this fashion, it is not clear whether Dr. Callahan's proposal, assuming it could be effectuated, would solve the problem of unfairness. His proposal rests on the assumption that we can discourage either the development of a technology or its use. Yet a reimbursement policy that merely discourages the use of life-extending technologies for Medicare beneficiaries permits those with sufficient funds to purchase the technologies outside of the Medicare system. Instead, a reimbursement policy that prevents these technologies from being developed in the first place is needed.²¹ A non-existent technology would be unavailable to both the rich and the poor; no inequity problem would exist.²²

At times, Dr. Callahan seems to realize that, to avoid the unfairness problem, he must discourage the development, and not simply the use, of undesirable technologies. At one point, for example, he advocates a reimbursement approach that would "discourage development of marginally beneficial items."²³ Furthermore, he worries about

17. Dr. Callahan writes:

[We need] an antidote to the major cause of a mistaken moral emphasis in the care of the elderly and a likely source of growing high costs of their care in the years ahead. That cause is constant innovation in high-technology medicine relentlessly applied to life-extending care of the elderly; it is a blessing that too often turns into a curse.

SETTING LIMITS, *supra* note 1, at 142.

18. *See id.* ("Unless an antidote is effective, and can be found, no alternative to the present arrangement is likely to take hold.")

19. *Id.* at 143. This is to counter the present "powerful bias in favor of innovative medical technology, and a correspondingly insatiable appetite for more of it." *Id.*

20. *Id.* Setting a high standard for reimbursement would be for the purpose of discouraging "marginally beneficial items." *Id.*

21. The same policy would have to be adopted by other technologically advanced countries so that the technologies could not be obtained elsewhere.

22. There would also be no need to ration life-extending care in individual cases, which would greatly relieve the problems of those caregivers who found rationing immoral. *See supra* notes 14-16 and accompanying text.

23. SETTING LIMITS, *supra* note 1, at 143.

preventing the development of technologies that would benefit the young as well as the old: "If technological development is discouraged, will that not damage the health interests of the young, even their chances to avoid a premature death?"²⁴ At other times, however, he focuses only on the need to restrict the use of existing technologies.²⁵ Perhaps he intends the restrictions on use to be applied only to technologies that already exist when his rationing program goes into effect.²⁶ Alternatively, Dr. Callahan may anticipate that, once reimbursement limits cause manufacturers to lose money on existing technologies, the manufacturers will refrain from developing similar technologies in the future.

Giving Dr. Callahan the benefit of the doubt, this Article assumes that he is proposing a reimbursement policy to prevent the development of undesirable, new technologies. The question is whether such an approach is feasible.

II. THE FEASIBILITY OF PREVENTING THE DEVELOPMENT OF UNDESIRABLE TECHNOLOGIES

In determining the feasibility of this approach one must first question whether Medicare reimbursement policy is capable of controlling the selective development of technologies. Medicare reimbursement accounts for almost one-half of all hospital revenues;²⁷ therefore, we might expect hospitals to refrain from acquiring technologies that were not reimbursable by the government. This would certainly affect the spread or diffusion of expensive, new technologies,²⁸ but it is less clear

24. *Id.* at 145; see *infra* notes 84-92 and accompanying text.

25. Dr. Callahan writes:

The existence of medical technologies capable of extending the lives of the elderly who have lived out a natural life span creates no presumption whatever that the technologies must be used for that purpose. . . . Medicine should in particular resist the tendency to provide to the aged the life-extending capabilities of technologies developed primarily to help younger people avoid premature and untimely death.

SETTING LIMITS, *supra* note 1, at 173 (emphasis in original).

26. This is contradicted, however, by his position that pre-existing, life-extending technologies in widespread use should be grandfathered under his rationing scheme. Dr. Callahan writes: "[I]t would now be cruel to terminate federal kidney-dialysis support for the elderly" *Id.* at 143. "A grandfather clause would also be needed in some circumstances: life-extending treatment such as insulin for diabetics or dialysis, if begun in early old age, should not be withdrawn in later old age." *Id.* at 183.

27. See *Health Statistics, Research, and Technology Assessment: Hearings on H.R. 5496 before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 98th Cong., 2d Sess. 544 (1984) (statement of Raymond Dross, M.D., on behalf of Health Insurance Association of America).

28. See INSTITUTE OF MEDICINE, *ASSESSING MEDICAL TECHNOLOGIES* 177 (1985) ("Diffusion refers to the spread of innovation over time in a social system.") An example of the impact of Medicare reimbursement on the diffusion of new technologies

that it would discourage their development. There is no evidence that manufacturers have curtailed the development of technologies because of current cost-containment efforts.²⁹ For example, technologies may be developed by academics and health care professionals who may be less responsive than hospital administrators to cost-containment pressures. In particular, basic research is often conducted without future applications in mind, creating the prospect that new, life-extending technologies will be invented before reimbursement pressures can be felt.³⁰

Even if reimbursement constraints subsequently reduce their commercial attractiveness and therefore limit their widespread adoption by providers, objectionable technologies might survive long enough and attract enough attention to become known to the medical community. Physicians then might have a duty in the course of obtaining their patients' informed consent to treatment to advise them that the new technologies exist.³¹ Those patients who could afford the technologies could then purchase them. This would create the same inequality problem previously mentioned, unless the technologies were also made available to patients under Medicare.

Assuming that Medicare payment policy is able to constrain the development of new technologies, however, it would be necessary to identify which technologies are objectionable before the government could refuse to pay for them.

is provided by magnetic resonance imaging (MRI) devices. Medicare currently uses a prospective payment system, known as diagnosis-related groups, that pays hospitals a fixed amount for inpatient care based on the patient's diagnosis, generally without regard to the nature of the care that is actually rendered. Since hospitals do not receive greater payment if they employ expensive, new technologies for their Medicare patients, they have a disincentive to use these technologies and therefore a disincentive to acquire them. However, this payment system does not yet cover outpatient care. As a result, the proportion of magnetic resonance imagers located in outpatient settings was twice that of computerized tomography scanners when compared at an equivalent stage of development, prior to the adoption of the prospective payment system. See Steinberg, Sisk & Locke, *X-Ray CT and Magnetic Resonance Imagers: Diffusion Patterns and Policy Issues*, 313 NEW ENG. J. MED. 859, 869 (1985).

29. The Prospective Payment Assessment Commission, which oversees the Medicare cost-containment program, has found that this program has had no impact on the availability of new technologies. See PROSPECTIVE PAYMENT ASSESSMENT COMMISSION, *MEDICARE PROSPECTIVE PAYMENT AND THE AMERICAN HEALTH CARE SYSTEM: REPORT TO CONGRESS 20* (June 1988).

30. For a general discussion of the development of new medical technologies, see Mehlman, *Health Care Cost Containment and Medical Technology: A Critique of Waste Theory*, 36 CASE W. RES. 778, 840 (1986).

31. If a physician is aware that a technology exists that might benefit his patient, the doctrine of informed consent obliges him to notify the patient of its existence even if the technology is difficult or expensive to obtain. See Kapp, *Legal and Ethical Implications of Health Care Reimbursement by Diagnosis Related Groups*, 12 L. MED. & HEALTH CARE 245, 251 (1984); Mehlman, *supra* note 30, at 861.

III. THE PROBLEM OF IDENTIFYING OBJECTIONABLE TECHNOLOGIES

Unless undesirable technologies are accurately identified, the rationing scheme would be under- or over-inclusive.³² If the program is under-inclusive, we would continue to pay for and develop technologies that should not be provided to the elderly. If the program is over-inclusive, on the other hand, we would discourage the development of desirable technologies.

To identify undesirable technologies, we first must decide what characteristics make a technology undesirable. Then we must find some method of detecting technologies with these characteristics in order to discourage their development.

Dr. Callahan attempts to provide some guidance for the first task: "[N]o technology should be developed or applied to the elderly that does not promise great and inexpensive improvement in the quality of their lives, no matter how promising for life extension."³³ In other words, he states, "[i]ncremental gains, achieved at high cost, should be considered unacceptable."³⁴ Furthermore, government policy should discriminate against "technologies that do not achieve a high, very high, standard of efficacy" to preclude the development of "marginally beneficial items."³⁵ "Routine use" of "routine technologies" should also be discouraged "[u]nless they can promise a high efficacy."³⁶

The rules that Dr. Callahan proposes are confusing and problematic. Even if the technologies would extend life substantially, they are not to be developed unless they promise great improvement in the quality of life for the elderly. Thus, the meaning and assessment of "quality of life" becomes very important in terms of specifying which technologies to discourage. Dr. Callahan recognizes that the term is vague,³⁷ saying that it entails the possession of "certain potentialities for personhood," which in turn encompasses, at a minimum, "the capacity to

32. The task of identifying technologies for which Medicare will not pay is performed as part of Medicare's coverage program. In 1987, the Health Care Financing Administration published a notice in the *Federal Register* describing the Medicare coverage system and requesting public comments. See Health Care Financing Administration, Medicare Program; Procedures for Medical Services Coverage Decisions; Request for Comments, 52 Fed. Reg. 15,560 (1987).

33. SETTING LIMITS, *supra* note 1, at 143 (Dr. Callahan also discusses undesirable characteristics of various technologies that would influence a government policy of discouragement).

34. *Id.*

35. *Id.*

36. *Id.* at 145. Dr. Callahan does not give any examples of the routine technologies to which he refers. For further information regarding rationing the use of routine technologies for the elderly, see *infra* note 83 and accompanying text.

37. See SETTING LIMITS, *supra* note 1, at 178 ("The term itself is not felicitous, lacking clear cultural roots and a precise, well-understood meaning.").

reason, to have emotions, and to enter into relationships with others."³⁸ In other words, technologies for the elderly are not to be developed unless they significantly increase the patient's capacity to employ higher brain functions, regardless of the degree to which they extend life. This creates a problem for elderly patients who already possess a high quality of life; under Dr. Callahan's proposals, life-extending technologies for these patients should not be developed because they cannot promise great improvement in the patients' quality of life. Dr. Callahan's solution to this problem—making an exception for these patients—is fatal to a technology-based rationing approach.³⁹

Assuming that quality of life has something to do with the capacity for higher brain functioning, when does a technology improve this dimension sufficiently to merit development? The answer to this question differs from person to person and from one period of a person's life to another. A healthy young person contemplating a tax increase to pay for more technology for the elderly might have a different view than an elderly patient. Medicare officials ultimately make these decisions guided by political expediency; but whose perspective is to govern the reimbursement decision?⁴⁰

Even if a particular technology would improve the quality of life significantly, Dr. Callahan's rule forbids its development unless the improvement is "inexpensive."⁴¹ How are we to determine that a technology is inexpensive? Should we compare the cost of the technology to the cost of similar technologies (e.g., the cost of magnetic resonance imagers compared to the cost of CT scanners), or to the opportunity cost in terms of alternate uses for the money (e.g., defense spending or housing)? Does Dr. Callahan mean that, unless the technology is inexpensive, it should not be developed no matter how much it promised to improve quality of life? Or should the cost of the technology be compared to its benefit, so that even a relatively expensive technology should be developed if it improved the quality of life to a sufficient degree? And if we compare costs and benefits, how can we calculate the value of freedom from pain or increased mobility?⁴²

38. *Id.* at 179-80.

39. *See infra* notes 94-97 and accompanying text.

40. For a more thorough discussion of this issue, see Mehlman, *supra* note 30, at 794-99.

41. *See supra* notes 33-34 and accompanying text.

42. *See* Mehlman, *supra* note 30, at 826-32. Market theory suggests that the ultimate purchaser of a product should decide the value of its benefits; but is the ultimate purchaser the patient or the Medicare program? If it is the former, how can patient values be employed retroactively to discourage technology development? In any event, patient choices will be less cost-conscious than Dr. Callahan might be willing to accept in view of the insurance feature of Medicare benefits, which gives beneficiaries a reduced stake in the economic consequences of their choices. Their stake could be increased by increasing their out-of-pocket expenditures, e.g., by increasing Medicare de-

Problems such as these are further complicated by Dr. Callahan's intention to withhold reimbursement for technologies that do not achieve a high standard of efficacy. In the language of technology assessment,⁴³ the term "efficacy" means the likelihood that the application of a technology will improve a patient's health status under ideal conditions.⁴⁴ When we say that a technology is highly efficacious, however, we are comparing its efficaciousness to something else, such as to the risk that it entails for patients or to the relative efficacy of other technologies. Thus we might say that a technology that yields a large amount of patient benefit and that presents only a low probability of minor risk to patients is highly efficacious relative to its risks. Alternatively, we might say that a technology is highly efficacious if it yields a larger amount of net patient benefit than other technologies. Unfortunately, Dr. Callahan fails to tell us which meaning he has in mind; yet his reimbursement strategy leads us in different directions depending on which meaning we adopt. For example, we might discourage the development of a powerful new chemotherapy agent if we are primarily concerned that it produces too many serious adverse effects; but we would likely promote its development if our approach is based on whether or not it is superior to the alternatives.⁴⁵

ductibles and coinsurance, but only at the price of making the system more regressive.

43. Technology assessment is the field which evaluates technologies to determine their relative costs and benefits. See OFFICE OF TECHNOLOGY ASSESSMENT, STRATEGIES FOR MEDICAL TECHNOLOGY ASSESSMENT 201-02 (1982) (defining technology assessment as "[a] comprehensive form of policy research that examines the technical, economic, and social consequences of technological application.").

44. See BANTA, BEHNEY & WILLEMS, TOWARD RATIONAL TECHNOLOGY IN MEDICINE: CONSIDERATIONS FOR HEALTH POLICY 98 (1981), where efficacy is defined as "[t]he probability of benefit to individuals in a defined population from medical technology applied for a given medical problem under ideal conditions of use." "Ideal conditions" refer to the conditions that exist in a controlled clinical experiment, in which the patient/subjects are carefully chosen and the technology is applied by specially trained personnel in a prescribed manner. Ideal conditions can be contrasted with the typical clinical conditions under which the technology is applied; while the performance of the technology under ideal conditions is called its "efficacy" or "efficaciousness," the term "effectiveness" is used to describe its performance under average conditions.

45. It is not clear which approach to efficacy is taken under the present system for determining which technologies Medicare will pay for, known as its "coverage policy." See *supra* notes 43-44 and accompanying text. The Food and Drug Administration (FDA) determines whether or not a drug or medical device is marketable in interstate commerce, *inter alia*, on the basis of whether or not it is "safe and effective" (which in turn is a prerequisite to its being covered under Medicare). The FDA generally takes the approach of comparing it to other technologies used to treat or to diagnose the same condition. Conversation with William Vodra, former Associate Chief Counsel for Drugs, Food and Drug Administration (Sept. 16, 1985). For a general description of the regulatory provisions governing the activities of the FDA, see Mehlman, *supra* note 30, at 787-88 n.44, 844-45.

The problems raised by Dr. Callahan's reimbursement decision-making rules are reflected in his examples. His paradigm for the type of technology that should not be developed is kidney dialysis for chronic renal failure.⁴⁶ He objects to the limited increase in lifespan that it makes possible,⁴⁷ to the quality of life that it produces,⁴⁸ and to its cost.⁴⁹ Yet dialysis obviously yields a sufficient quality of life from the standpoint of most patients for whom it is prescribed, since they choose to be placed on dialysis and rarely discontinue treatment on their own initiative.⁵⁰ Furthermore, it is arguably efficacious for many patients—especially those for whom a kidney transplant is not a viable alternative—since it prevents them from dying of kidney failure for an average of at least five years.⁵¹ Moreover, unless we conclude that an extra year of life is worth less than twenty-five thousand dollars, the average annual cost to Medicare for a patient on dialysis,⁵² the technol-

46. See *SETTING LIMITS*, *supra* note 1, at 143 (“[D]ialysis represents precisely the kind of technology that should not be sought or developed in the future.”).

47. *Id.* (“It does not greatly increase the life expectancy of its users . . .”).

48. *Id.* Increased lifespan for most users “is at the price of a doubtful or poor quality of life and an inability to achieve earlier levels of functioning.” *Id.*

49. *Id.* at 143-44. Dr. Callahan notes:

The appeal to Congress that in 1972 underwrote the costs of dialysis was that it would save lives and at a relatively modest cost (the estimate was for a maximum expenditure of \$400 million). It has surely saved lives, but not for long, and the more than 80,000 users now cost well over \$2 billion a year.

Id.

50. See, e.g., OFFICE OF TECHNOLOGY ASSESSMENT, LIFE SUSTAINING TECHNOLOGIES AND THE ELDERLY 249-50 (1987) [hereinafter *LIFE-SUSTAINING TECHNOLOGIES*] (“[M]ost patients who accept chronic dialysis adjust successfully and are able to carry on their family and work roles.”). This report cites a 1985 study revealing that only 8.5% of patients age 65 to 74 and 12% of patients over age 75 died as a result of withdrawal from dialysis. Another study notes that some of these patients withdrew from treatment because it had ceased to yield any health benefit or were withdrawn by surrogate decision makers. *Id.* at 262.

51. See *id.* at 251-52. The report stated:

Unfortunately, while transplantation is an attractive solution in principle, there are many difficulties in its implementation, especially the severe shortage of appropriately matched donor kidneys. In addition, life-long immunosuppressive therapy, necessary to prevent rejection of the donor organ, has many deleterious effects. Because of these and other problems, kidney transplantation is not at present a realistic option for most ESRD [end-stage renal disease] patients.

Id. (citation omitted).

52. The \$25,000 figure is derived by dividing the total expenditure for Medicare's End Stage Renal Disease Program (two billion dollars) by the number of dialysis patients (80,000), using Dr. Callahan's figures. See *SETTING LIMITS*, *supra* note 1, at 144. The actual cost of dialysis per patient may be different since the program also covers some of the costs of kidney transplants. See *LIFE-SUSTAINING TECHNOLOGIES*, *supra* note 50, at 258 (average annual Medicare cost per patient for dialysis in 1984 was \$21,051). Costs for dialysis under Medicare in 1984 were no different than costs in

ogy is not too expensive.

In short, Dr. Callahan's conclusion that chronic dialysis is the type of technology that should not be developed is only correct if we share his arbitrary, personal opinions about what constitutes an efficacious and inexpensive technology and about what should be regarded as an acceptable quality of life. The same is true of the other technologies that he complains about: intravenous and implantable infusion administration of antibiotics;⁵³ nasogastric and total parenteral nutrition feeding;⁵⁴ and emerging technologies for mechanical ventilation.⁵⁵

1974, when corrected for inflation. *Id.* Moreover, data from 1974 to 1979 show that, although costs per patient for Medicare's End-Stage Renal Disease Program rose 30.8% between 1974 and 1979, national per capita health expenditures for the same period rose by 74.9%. *Id.*

53. In SETTING LIMITS, *supra* note 1, at 144, Dr. Callahan states:

Antibiotics that can, at relatively low cost, be taken orally or given by injection are at present joined by those which can be given intravenously, a more expensive procedure. Eventually they will also be joined by those which can be infused by an implantable pump, a far more expensive procedure still.

Cf. id. at 412 (delivery and monitoring systems such as implantable pumps may yield more precise blood levels of drugs, reducing toxicity, side effects and dosage errors); LIFE SUSTAINING TECHNOLOGIES, *supra* note 50, at 338 (intravenous antibiotics often needed in long term treatment of severe infections to achieve adequate blood levels of drug).

54. Compare SETTING LIMITS, *supra* note 1, at 144 ("The provision of food and water can now go from the spoon and fork to the nasogastric tube, and then to the relatively new and very costly total parenteral nutrition . . . , the last at a cost of \$50,000 to \$100,000 a year.") with LIFE-SUSTAINING TECHNOLOGIES, *supra* note 50, at 287 ("Tube and intravenous nutritional support and hydration are clearly effective in sustaining life for patients of all ages who are physically unable to swallow, digest, or absorb food and fluids taken by mouth and for patients who do not take in food or fluids for whatever reason.") and *id.* at 320 ("[T]he well-documented relationship between malnutrition and poor outcome suggests that critically ill and chronically ill elderly patients might benefit from increased use of these treatments and that Federal [test] policies that discourage their use may ultimately increase the overall cost of medical care for such patients.").

55. In SETTING LIMITS, *supra* note 1, at 144-45, Dr. Callahan states:

Mechanical ventilation, a mainstay in the care of many elderly dying suffering from pulmonary insufficiency, is no less an area of advancing technology, ever able to sustain more people by evermore-sophisticated means—high-frequency ventilation (HFV), extracorporeal-membrane oxygenation (ECMO), and—still in the theoretical stage—peritoneal oxygenation and carbon dioxide removal, and an implantable artificial lung.

In LIFE SUSTAINING TECHNOLOGIES, *supra* note 50, at 205, it is stated:

Experience with this technology [mechanical ventilation] provides clear evidence that, for a substantial and diagnostically diverse patient population, mechanical ventilation can effectively assist or replace normal spontaneous breathing. Its wide availability and usually safe application have enabled thousands of patients of all ages to survive life-threatening pulmonary, neuromuscular, and neurologic disorders, as well as high-risk surgical procedures.

See also *id.* at 406 ("Developments important for long-term mechanical ventilation

Thus far our consideration has been limited to a determination of which characteristics render a technology one that Dr. Callahan would want to discourage. Assuming arguendo that we agree on this, however, we still face the formidable task of determining which technologies possess those characteristics.

First, we must decide whether we want to evaluate all new technologies for purposes of determining whether or not to discourage their development or only some technologies. Developers of proprietary technologies such as new drugs or medical devices would have an incentive to evaluate all new products to avoid expending research and development money on technologies that eventually would be refused reimbursement. However, Medicare would still need some system for reviewing proprietary technologies that beneficiaries were furnished to determine if the technologies were ones that Medicare should pay for. Furthermore, this would require that Medicare review the many new technologies that are not proprietary, in other words, that are not sold or licensed by their developers.⁵⁶ This is particularly characteristic of a medical or surgical technology, such as a new technique for performing an operation, that does not entail the use of a new drug or medical device.⁵⁷

Since many new technologies provided to Medicare beneficiaries would not run afoul of Dr. Callahan's prohibitions (assuming we understood what they were), evaluating all new technologies might be a waste of resources. To reduce the number of technologies requiring evaluation, however, Medicare would need some screening system to identify the more likely candidates.⁵⁸

The problem with constructing a screening system lies not only in deciding what technology characteristics to screen for, but in deciding when the screening should take place.⁵⁹ Screening technology in its early stage of development makes it less likely that it will be accessible outside of Medicare and, therefore, reduces problems of inequity if

include improved reliability, portability, ease of use, and comfort.”).

56. One could exclude these technologies from Dr. Callahan's rationing program to avoid having to identify them, but development of many of the most expensive technologies would then be undeterred. Surgical procedures alone account for approximately 30% of U.S. health expenditures. See Moore, *Surgical Streams in the Flow of Health Care Financing: The Role of Surgery in National Expenditures: What Costs Are Controllable?*, 201 ANNALS OF SURGERY 132, 134 (1985).

57. See Mehlman, *supra* note 30, at 820-21. The developers of these technologies rarely restrict their spread, such as by patenting them. Instead, developers seem intent on encouraging their colleagues to adopt their new techniques, and to that end publicize their success in the medical literature, at conventions, and in the workplace.

58. Evaluating all technologies would not be a waste of resources, however, if it were cheaper than developing and applying screening criteria.

59. This problem besets whoever performs the screening, including the manufacturer.

Medicare does not pay for it.⁶⁰ The younger the technology, however, the less will be known about it, including its future uses and its costs and benefits. Early screening therefore runs a greater risk of mistakenly discouraging potentially valuable technologies.⁶¹

Screening at an early stage of technological development creates a special difficulty for Dr. Callahan's rationing program. Since his objective is to discourage inappropriate technologies for the elderly, his program must identify those technologies prescribed for this age group; otherwise, his plan prevents the development of technologies that, while inappropriate for the aged, would be suitable for younger populations.⁶² In their early stages, however, technologies are typically tested and intended for use in younger populations. As Dr. Callahan himself recognizes, "their use gradually spreads from the younger to the older patient."⁶³ As a result, it is unlikely that a technology at an early stage of development is identifiable as intended exclusively for use in Dr. Callahan's elderly population.⁶⁴

Assuming that a suitable screen could be developed and that a time in the life of an emerging technology could be chosen for the screen to be applied, it would still be necessary to screen all new technologies prior to Medicare reimbursement. This would require some sort of "gate" through which all new technologies must pass. No such mechanism currently exists and it is unlikely that one could be created. The Food and Drug Administration operates the only such gate in the form of the licensing requirements under the Federal Food, Drug, and Cosmetic Act.⁶⁵ This law, however, covers only new drugs and medical

60. In addition, the older the technology, the more likely that potential patients and their providers will oppose the loss of the technology.

61. See Mehlman, *supra* note 30, at 802-03, 821. As emphasized therein, many technologies are also constantly changing, and the results of screening at one point may not apply to a technology at a later stage.

62. Actually, there is no way that his approach can avoid this. See *infra* notes 85-93 and accompanying text.

63. SETTING LIMITS, *supra* note 1, at 144. An example of this is percutaneous transluminal coronary angioplasty, a technique that widens the arteries to reduce the symptoms of cardiovascular disease such as angina. This procedure was originally performed on five patients between the ages of thirty-eight and sixty-one. Gruntzig, *Transluminal Dilatation of Coronary-Artery Stenosis*, THE LANCET 263 (1978). Eventually it was used in patients over sixty-five. See Mock, Holmes, Vlietstra, Gersh, Detre, Kelsey, Orszulak, Schaff, Piehler, Van Raden, Passamani, Kent & Gruentzig, *Percutaneous Transluminal Coronary Angioplasty (PTCA) in the Elderly Patient: Experience in the National Heart, Lung, and Blood Institute PTCA Registry*, 53 AM. J. CARDIOLOGY 89C-91C (Supp. 1984). Its use in patients eighty years of age and older is now being reported. See Kern, Deligonul, Galan, Zelman, Gabliani, Bell, Bodet, Naunheim & Vandormael, *Percutaneous Transluminal Coronary Angioplasty in Octogenarians*, 61 AM. J. CARDIOLOGY 457 (1988).

64. For a discussion of the consequences, see *infra* notes 86-92 and accompanying text.

65. 21 U.S.C. § 331(a), (d) (1982); *id.* § 351(f); *id.* § 355 (1982 & Supp. IV

devices, and therefore, as noted earlier,⁶⁶ would only restrict the development of new medical and surgical technologies that employed new drugs or devices. Furthermore, these licensing requirements are imposed at a late stage of the development process.⁶⁷ If licensing were restricted because the technology failed to meet Dr. Callahan's objectives, there could be a significant waste of research and development resources and the restrictions might come so late that they might fail to discourage further development in the face of pressure from patients, their families, and providers.⁶⁸ Finally, the Food and Drug Administration currently has no authority to refuse to license a product because of its cost.⁶⁹ Therefore, under current law, one of Dr. Callahan's chief objectives, discouraging expensive technologies, fails. Furthermore, it would likely prove extremely difficult to create a cost standard for the agency to apply.⁷⁰

The Medicare system itself operates a coverage system for determining whether or not it should pay for a technology that is provided to a beneficiary.⁷¹ The system does not screen new technologies routinely; rather, the system selects the technologies to be evaluated in a fairly haphazard fashion.⁷² It therefore would not serve as an effective

1986).

66. See *supra* notes 56-57 and accompanying text.

67. The development process often continues even after the product is licensed. For example, the manufacturer may develop new dosage forms or uses for a drug entity. Furthermore, the FDA requires the manufacturer to continue to monitor the safety and effectiveness of its products once licensed. This can lead to changes in the product or in its marketing.

68. See Blumstein, *Constitutional Perspectives on Governmental Decisions Affecting Human Life and Health*, 40 LAW & CONTEMP. PROBS. 231, 252 (1976). Professor Blumstein calls this type of pressure "institutional blackmail." He is so concerned about its ability to make society spend more on health care resources than it should that he argues that rationing should be conducted by private entities rather than by the government. For a criticism of his position, see Mehlman, *Rationing Expensive Life-saving Medical Treatments*, 1985 WIS. L. REV. 239, 274-78.

69. See Geweke & Weisbrod, *Clinical Evaluation vs. Economic Evaluation: The Case of a New Drug*, 20 MED. CARE 821 (1982). See K. WARNER & B. LUCE, *COST-BENEFIT AND COST-EFFECTIVENESS ANALYSIS IN HEALTH CARE: PRINCIPLES, PRACTICE, AND POTENTIAL 198-99* (1982), for a discussion of FDA's authority to use economic criteria in evaluating drugs and devices.

70. See *supra* notes 68-69 and accompanying text.

71. See *supra* note 65 and accompanying text.

72. For a description of the Medicare coverage system, see Health Care Financing Administration, *Medicare Program: Procedures for Medical Services Coverage Decisions; Request for Comments*, 52 Fed. Reg. 15,560 (1987). As this publication reveals, technologies for evaluation are identified following inquiries from beneficiaries, physicians and other providers, manufacturers, government officials, and the organizations that administer Medicare's decentralized claims process (carriers, fiscal intermediaries, and Peer Review Organizations). See *id.* at 15,561. Most coverage questions are resolved at a local or regional level, resulting in variations in coverage from one part of the country to another. Only national coverage determinations made by the

gatekeeping mechanism for Dr. Callahan's purposes.

The present coverage system could screen all new technologies if approval by the Health Care Finance Administration⁷³ were required prior to reimbursement eligibility.⁷⁴ Obtaining approval would be the provider's responsibility, since it would be reimbursed only for a covered item.⁷⁵ In the case of a proprietary technology, the provider could insist that the manufacturer obtain approval before the provider agreed to purchase the technology.⁷⁶

The major problem with this approach is its administrative cost. The slightest change in a previously approved technology could require a new screening process and possibly a complete new evaluation. This would entail a huge number of screening and evaluation procedures.⁷⁷

central offices of the Health Care Financing Administration are generally published, and these are not subject to notice-and-comment rulemaking procedures. *See* 1 C.F.R. § 305.87-8 (1988) (recommendation by Administrative Conference of the United States that national coverage determinations be subject to rulemaking procedures).

73. This is the office within the Department of Health and Human Services that administers the Medicare program

74. National Institutes of Health voluntarily established a similar system in an attempt to control research on recombinant DNA. *See* Department of Health and Human Services, Guidelines for Research Involving Recombinant DNA Molecules, 49 Fed. Reg. 46,266, 46,272-73 (1984).

75. Medicare regulations currently permit a provider to charge the cost of non-covered care to the patient if the patient had reason to know that the care was not covered at the time it was prescribed. *See* 42 U.S.C. § 1395pp(b)-(c) (1982 & Supp. IV 1986) (Medicare waiver policy). Unless the charges were prohibited, providers could simply notify patients that Medicare had not approved a technology and thereby place the costs of the noncovered technology on the patient. This would also make patients aware of the existence of new technologies that they might wish to purchase outside the Medicare system.

76. A similar shifting of risk occurs under the Federal Food, Drug, and Cosmetic Act, which allows a purchaser to avoid criminal liability for receipt of an unlawful product by obtaining a guarantee from the supplier that the product meets the requirements of the Act. *See* 21 U.S.C. § 333(c) (1982).

77. The Food and Drug Administration ("FDA") confronted this issue in attempting to regulate new medical devices following enactment of the Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 540 (1976) (codified as amended in scattered sections of 21 U.S.C.). The law contains provisions that allow the agency to waive formal, premarket approval for devices that are "substantially equivalent" to devices already on the market. *See* 21 U.S.C. §§ 360c(f)(1)(A)(ii), 360e (1982). The manufacturer must merely notify the agency of its intent to market the device and wait 90 days. Marketing may begin at that time unless the FDA contacts the manufacturer and orders it to desist pending further review. This system has not operated smoothly. The responsibility is on the manufacturer to decide in the first instance whether or not its device is substantially equivalent to an existing device, and manufacturers routinely have taken the position that their devices were substantially equivalent in the hopes of avoiding the much more extensive and expensive full-scale approval process. As a result, the agency has been burdened with the job of deciding whether or not the device is in fact sufficiently similar to a pre-existing device. This has taxed agency resources severely and has slowed down the approval of devices that represent only trivial

The costs would remain high unless the proponents of the technology were denied a significant opportunity to participate in the screening and evaluation process and were denied the opportunity to obtain administrative and judicial review of unfavorable decisions.⁷⁸ Although review of administrative decisions under Medicare historically has been restricted,⁷⁹ the need to obtain information on the new technology from its developers makes it essential that they be involved in the process,⁸⁰ while pressure from manufacturers, patient groups, and providers may make it impossible to limit their right to challenge the outcome.⁸¹

Once the government decided which technologies to evaluate according to Dr. Callahan's criteria, the government would have to conduct expensive full-scale evaluations.⁸² As in the case of screening, information costs could be reduced by relying on manufacturers for the data, but only in the case of proprietary products. Even then, the government would need to expend substantial resources to verify the data that would have been submitted.

In the end, the number of technologies needing evaluation would

changes from other products. In response, Congress is considering major changes in the process. See Rovner, *Tougher Medical-Device Oversight Approved*, 46 CONG. Q. 1735 (1988).

78. Computerized screens, which may reduce the costs, are increasingly used to assess the composition of health care resources and the quality of care. See, e.g., 2 *Medicare & Medicaid Guide* (CCH) ¶ 12,872.03 (1987) (generic quality screens to be used by Peer Review Organization).

79. See, e.g., Kinney, *The Medicare Appeals System for Coverage and Payment Disputes: Achieving Fairness in a Time of Constraint*, 1 ADMIN. L.J. 1, 82-93, 100-03 (1987); see also Mehlman, *supra* note 30, at 862-71 (discussion of limitations on patient challenges to Medicare coverage determinations).

80. The FDA largely relies on the product manufacturer for information on safety and efficacy. Cf. 21 U.S.C. § 355(b) (Supp. IV 1986) (requiring submission of data).

81. Manufacturers would be concerned not only about the effect of a denial of coverage following a negative evaluation but also about the impact on a product of being selected for evaluation following screening. See Blumenthal, *Federal Policy Toward Health Care Technology: The Case of the National Center*, 61 MILBANK MEMORIAL FUND Q./HEALTH & SOC'Y 584, 601 (1983) (describing opposition from medical device manufacturers to establishing a list of priority health care technologies for federal assessment on the ground that it would slow the development of the technology at an early stage); see also Kinney, *supra* note 79, at 88 ("Questions have been raised among beneficiary groups and medical equipment manufacturers about the fairness of HHS procedures for making national coverage determinations and, particularly, the opportunities for public input in these determinations.").

82. The evaluations would be expensive because of the necessity to obtain and review information about the technology. A budget of \$200 to \$300 million a year has been suggested for a federal health care technology assessment effort. See Relman, *Assessment of Medical Practices: A Simple Proposal*, 303 NEW ENG. J. MED. 153, 153-54 (1980). This would be in addition to the approximate \$450 million budget for the Food and Drug Administration. See OFFICE OF MANAGEMENT AND BUDGET, BUDGET OF THE UNITED STATES GOVERNMENT: FISCAL YEAR 1989 (1988).

be enormous and the cost of obtaining data about them overwhelming. This is underscored by Dr. Callahan's recognition that he is not simply talking about targeting a few major, highly visible diagnostic and treatment modalities, such as artificial organs or magnetic resonance imagers. As he points out, "the larger problem lies not such much in what have been called the 'big ticket' items as in the high costs of much more routine diagnostic and therapeutic procedures."⁸³ The cost of implementing Dr. Callahan's technology program for routine as well as exceptional technologies might be so large, in fact, that it might seem wiser simply to devote the funds to providing technologies to the elderly, or to encouraging research aimed at developing more cost-effective alternatives.

IV. THE INABILITY TO MITIGATE UNDESIRABLE EFFECTS OF AGE-BASED RATIONING

Thus far the discussion has been limited to the practical problems with designing and implementing a rationing program to discourage the development of technologies for the elderly once they reached a certain age. More fundamental problems arise, however, with Dr. Callahan's efforts to mitigate the undesirable effects of his age-based rationing approach.

Creating a non-discriminatory age-based rationing system necessarily requires that certain life-saving technologies not be developed. Yet unless these technologies were prescribed exclusively for patients beyond the cutoff age, preventing their development also deprives those *below* the cutoff age of potential benefits.

Dr. Callahan recognizes the problem, describing it as a "hazard" of his position.⁸⁴ He proposes a solution: "a technology assessment that examined whether, if [the technology] were developed for the young, its primary or disproportionate use might be among the elderly, and whether alternative means could be found to meet the needs of the

83. SETTING LIMITS, *supra* note 1, at 145; see Moloney & Rogers, *Medical Technology—A Different View of the Contentious Debate Over Costs*, 301 NEW ENG. J. MED. 1413 (1979) (blaming low unit-cost technologies such as laboratory tests for high health care costs). Perhaps glimpsing the impossibility of discouraging the development of technologies that are already routinely employed, Dr. Callahan confines his efforts to preventing their use. Dr. Callahan writes: "Unless they can promise a high efficacy also, their routine employment should be discouraged." SETTING LIMITS, *supra* note 1, at 145 (emphasis added).

84. SETTING LIMITS, *supra* note 1, at 145. Dr. Callahan writes:

An obvious dilemma here is that most technologies will benefit the young as well [as the old] and are developed with them often primarily in mind. If technological development is discouraged, will that not damage the health interests of the young, even their chances to avoid a premature death? That is a hazard

Id.

young."⁸⁵

It is not clear what Dr. Callahan means by such a technology assessment or what he would do with its results.⁸⁶ Assuming we could anticipate the eventual uses of a technology before its development,⁸⁷ at what point would use for the elderly be "disproportionate" or "primary"? For example, Dr. Callahan states that the elderly will be the "primary candidates" for the use of several existing technologies, including mechanical ventilation and artificial resuscitation (or CPR, for "cardiopulmonary resuscitation").⁸⁸ Yet data shows that only twenty-three percent of patients receiving CPR are over age eighty—roughly at Dr. Callahan's age cutoff⁸⁹—and only approximately one-third of the patients dependent on mechanical ventilators are over age seventy.⁹⁰ Even if we agree that this shows that these technologies are likely to be used primarily by the extreme elderly, so long as not to be used *exclusively* by them, the prevention of technological development would deprive eligible, younger patients of their benefits.⁹¹ If somehow we could have prevented the development of CPR, seventy-seven percent of individuals receiving CPR, who are deemed worthy to receive treatment under Dr. Callahan's approach, would have died for lack of the technology.⁹²

85. *Id.*

86. *Id.* Dr. Callahan concedes that he "leave[s] these as difficult problems for the trajectory [he is] proposing." *Id.*

87. As discussed earlier, this is virtually impossible to do. *See supra* notes 60-61 and accompanying text. In fact, it is not even easy to determine whether or not an existing technology is used primarily in the elderly since data on technology utilization are scant. *See, e.g.,* LIFE-SUSTAINING TECHNOLOGIES, *supra* note 50, at 175 ("For several reasons, accurate information on the utilization of CPR [cardiopulmonary resuscitation] is difficult to obtain.")

88. SETTING LIMITS, *supra* note 1, at 144.

89. *See supra* notes 3-4 and accompanying text.

90. *See* LIFE-SUSTAINING TECHNOLOGIES, *supra* note 50, at 176-77 (CPR data from Boston hospital showing even higher percentage of use by elderly than most studies show). Dr. Callahan also mentions antibiotics and artificial nutrition and hydration as additional technologies that are primarily for the elderly, but the only utilization data available are for patients ages sixty-five and older, which includes a large number of persons who would be eligible to receive the technology even under Dr. Callahan's scheme. *See id.* at 293-95 (data on utilization of antibiotics).

91. *See* SETTING LIMITS, *supra* note 1, at 145. Dr. Callahan suggests that alternative means might be found to provide these benefits to younger patients. The young would still be deprived of some benefit unless the net benefits from the alternative were substantially the same as the net benefits from the technology for the elderly. If this were the case, however, it is likely that the alternative technology would be so readily adaptable for use by the elderly that it could be said to exist for purposes of being purchased by elderly patients who could afford it.

92. The 77% figure is the remainder of the estimated patient population once the 23% of patients over 80 are subtracted. *See supra* notes 69-89 and accompanying text. Even if utilization by those over age 80 were greater, some younger patients would be disadvantaged if the technology did not exist.

On the other hand, if a technology that met his criteria for being discouraged were *not* likely primarily to be used by the elderly, Dr. Callahan seems to be saying that we should allow it to be developed, but that Medicare should not pay for its use in those patients beyond the cutoff age. Since the technology would exist, however, it could be purchased by wealthy patients, giving rise to the inequity problem. This is likely to be a common phenomenon under his approach, since, as noted earlier, he describes many of the technologies that he is concerned about as "routine."⁹³

Dr. Callahan's scheme is plagued not only by the prospect of inadvertently denying medical technologies to the young, but also by what to do about the exceptional elderly patient. On the one hand, he suggests in several places that the denial of benefits ought to be categorical once a certain age is reached.⁹⁴ Elsewhere, however, he urges that an exception be made for the "physically vigorous elderly person," apparently regardless of chronological age: "It is the one category in which an exception to the cessation of Medicare-supported life-extending treatment to those who have lived a full life span would be justified."⁹⁵

Permitting exceptions for the vigorous elderly destroys Dr. Callahan's scheme. It replaces an irrebuttable presumption based on age with a rebuttable presumption based on a combination of age and quality of life.⁹⁶ Before treatment were denied to a patient who desires it, Medicare would have to reject the patient's own assessment of the quality of his life. This would entail vastly more subjective judgments by Medicare than an age-based criterion and would be enormously expensive to administer. Due process considerations alone suggest that any patient facing a denial of life-sustaining care by Medicare

93. SETTING LIMITS, *supra* note 1, at 145; see *supra* note 83 and accompanying text.

94. See, e.g., SETTING LIMITS, *supra* note 1, at 138 ("Beyond the point of a natural life span, government should provide only the means necessary for the relief of suffering, not life-extending technology."); *id.* at 172 ("*Provision of medical care for those who have lived out a natural life span will be limited to the relief of suffering.*" (emphasis in original)).

95. *Id.* at 184. Ultimately, he seems to be unable to decide which approach to take:

By limiting life-extending care to everyone, would we not indiscriminately sweep up many in otherwise fine shape who, with one or two timely medical interventions, might have remaining a number of years of good life? The answer is that we would indeed, in a sense, penalize the latter group; or more precisely, we would not benefit them, despite the fact that they would gain much more from life-extending treatment than those in poor condition. But I see no way to avoid, at some point, a choice that will cause anguish, shorten some lives, and possibly appear unjust.

Id. at 155.

96. For a discussion of the constitutionality of employing an irrebuttable presumption to ration life-saving resources, see Mehlman, *supra* note 68, at 260-62 n.110.

on grounds of poor quality of life must be given such expensive procedural rights as notice, an opportunity for a hearing, and the right to administrative and judicial review.⁹⁷

More importantly, however, a system that denied technologies to certain elderly patients but not to others could not aim to prevent the technologies from being developed in the first place, since this would deprive all patients of their benefits. Instead, it would attempt to control costs by denying reimbursement for existing technologies. In fact, to be sure that the benefits of the technology would be enjoyed by eligible patients it would hope that its reimbursement restrictions would *not* be so severe that they discourage the development of technologies.⁹⁸

V. CONCLUSION

In attempting to create an age-based rationing system, in short, Dr. Callahan faces a dilemma—either he can choose to let patients die before their natural lifespan by preventing life-saving technological development, or he can allow technological development, in which case the wealthy can purchase the technology and the inequity problem arises.

Dr. Callahan perhaps could avoid this dilemma by attacking technologies that did not provide enough net benefit to *any* patients, regardless of their age or of the quality of their lives. In fact, he seems to adopt such a position in his discussion of dialysis.⁹⁹ Under this approach, we could discourage the development of these technologies without being concerned about depriving eligible patients of their benefits. Without the technologies, no problem of unfairness to the poor and to the middle class arises.

This suggestion is hardly new, however. It resembles Lewis Thomas' objections to "half-way" technologies—technologies that neither cure nor prevent disease, but merely "make up for it" or postpone disease-related death.¹⁰⁰ It runs into many of the practical difficulties with discouraging technological development described ear-

97. See Mehlman, *supra* note 68, at 277 n.177.

98. In other words, the age-based reimbursement restrictions would have to be set at such a cutoff that the demand from eligible patients would sufficiently trigger technological development.

99. See SETTING LIMITS, *supra* note 1, at 143 ("[Dialysis] does not greatly increase the life expectancy of its users . . . , and for most, that gain is at the price of a doubtful or poor quality of life and an inability to achieve earlier levels of functioning.").

100. See L. THOMAS, THE LIVES OF A CELL: NOTES OF A BIOLOGY WATCHER 31-36 (1974). For a critical reaction to targeting technologies for scrutiny on the basis of whether or not they are "half-way," see Smits, *The Clinical Context of Technology Assessment*, 9 J. HEALTH POL. POL'Y & L. 31, 33-34 (1984).

lier.¹⁰¹ Most importantly for Dr. Callahan's purposes, finally, it has nothing to do with setting health care limits based on age.

101. See *supra* notes 19-21 and accompanying text.